

**From:** [Advertising Compliance](#)  
**To:** s22  
**Cc:** s22  
**Subject:** IMPORTANT: Letter from the Therapeutic Goods Administration for Naturally Elevated Pty Ltd ( TGA ref: AC-000000014762) [SEC=OFFICIAL]  
**Date:** Thursday, 10 August 2023 4:56:42 PM  
**Attachments:** [image005.png](#)  
[2023.10.08 - TGA letter - Opportunity to provide submissions prior to commencing enforcement action.pdf](#)  
**Importance:** High

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Dear s22,

Please find attached correspondence from the Therapeutic Goods Administration.

Please carefully read the letter and provide receipt of this email by **Monday 14 August 2023**.

You are welcome to make submissions as to why regulatory action **should not** be taken and can do so by **12 noon** on **Thursday 31 August 2023**.

Please do not hesitate to contact me should you have any further queries.

Kind Regards,

s22  
s22 – Advertising and Product Investigation Section  
**Regulatory Compliance Branch**

Australian Government, Department of Health and Aged Care  
PO Box 100, Woden ACT 2606, Australia

P: s22 | e: s22@health.gov.au

***Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

*This response contains general information given to you without prejudice, it is not binding on the TGA, and it does not constitute legal advice. You may need to get your own independent advice to ensure that all of the legislative requirements are met.*



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22

Naturally Elevated Pty Ltd  
ACN 636 315 109  
Unit 19 67 Bancroft Road  
PINKENBA QLD 4008

Email and express post: s22@elevatedextracts.com.au

Our Reference: AC-000000014762

10 August 2023

Dear s22

**Opportunity to provide submissions as to why regulatory action should not be taken in relation to the alleged unlawful advertising of therapeutic goods**

1. The Therapeutic Goods Administration (TGA) has previously written to your business, Naturally Elevated Pty Ltd (Naturally Elevated) in relation to the alleged unlawful advertising of therapeutic goods, specifically medicinal cannabis products.
2. Our previous correspondence provided you with notice of the TGA's concerns about the advertising of medicinal cannabis products and provided education on some of the relevant regulatory requirements in relation to the advertising of therapeutic goods with reference to the civil penalty and criminal offence provisions and relevant legislation.
3. Consistent with [how we manage advertising compliance](#) and the information found at [compliance actions and outcomes](#), an escalation of regulatory action is being considered, relevantly because 'the alleged breach is such that there is a likely impact on the consumers' ability to use therapeutic goods safely or appropriately'.
4. The TGA's previous correspondence concerned the advertising of therapeutic goods, so an escalation of regulatory action in relation to your advertising of medicinal cannabis products is now appropriate.
5. The purpose of this letter is to provide Naturally Elevated with an opportunity to make submissions before a decision is made about whether escalated enforcement action should be taken in relation to alleged unlawful advertising which appeared on online platforms for which Naturally Elevated appears to be responsible.

6. You are welcome to make submissions as to why regulatory action should not be taken and can do so by **12 noon on Thursday, 31 August 2023**.

#### Action required

- Confirm receipt of this letter by **Monday 14 August 2023**.
- Carefully consider the information provided below.
- Provide your submission to the TGA by **12 noon on Thursday 31 August 2023** as to why regulatory action should not be taken in relation to the non-compliant advertising on the online platforms set out below.

#### Notice of intention to take enforcement action

7. The TGA is considering whether escalated enforcement action should be taken in relation to alleged unlawful advertising which appeared on the Naturally Elevated, Canwell Pty Ltd and/or Farma Group online platforms (including websites and social media pages), for which Naturally Elevated appears to be responsible.
8. The websites of concern include:
  - a. the website at <https://elevatedextracts.com.au/>
  - b. the website at <https://farmagroup.com.au/>
  - c. the website at <https://canwell.com.au/>(collectively, the Websites).
9. The social media pages of concern include:
  - a. the Instagram account on <https://www.instagram.com/canwellaustralia/>, and
  - b. the Facebook account on <https://www.facebook.com/canwellaustralia/>(collectively, the Social Media pages).
10. The enforcement action being considered by the TGA may include:
  - a. giving you infringement notices under section 42YK of the *Therapeutic Goods Act 1989* (the Act) as an alternative to court action, or
  - b. preparing the matter for court either under section 42Y of the Act, or by preparing a brief to the Commonwealth Director of Public Prosecutions.
11. The enforcement action being considered may not be limited to the examples provided in this letter, and may extend to any other unlawful advertising of any kind.
12. Naturally Elevated's submissions will be taken into account by a delegate of the Secretary of the Australian Government Department of Health and Aged Care before a decision is made.
13. Please note that information about any compliance action taken against Naturally Elevated may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

#### Advertising therapeutic goods

14. Under the Act, a person who advertises or causes the advertising of therapeutic goods on certain circumstances may be liable for criminal sanctions (s 42DL of the Act)

and/or civil penalties (s 42DLB(1) of the Act). These circumstances include where the advertisement:

- a. contains a [prohibited representation](#), being a reference to a particular condition like mental illnesses, such as depression and anxiety, and no TGA approval has been given.<sup>1</sup>
- b. contains a [restricted representation](#), being a reference to a to a serious form of a disease, condition, ailment or defect, such as Multiple Sclerosis and epilepsy, and no TGA approval has been given.<sup>2</sup>
- c. refers to substances, or therapeutic goods containing substances, included in Schedule 3, 4 or 8 to the [current Poisons Standard](#), such as cannabis or cannabidiol, and no exception applies.
- d. contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by a government, such as 'TGA approved'.<sup>3</sup>

### Summary of alleged contraventions

15. We identified prohibited representations, restricted representations, references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard, and representations about government approvals, on the Websites and the Social Media pages which we allege contravene the advertising provisions in the Act.
16. Specifically, we allege that the Websites contained:
  - ***prohibited and/or restricted representations*** - statements which refer to specific serious medical conditions such as Chron's Disease, Parkinson's Disease, Restless Leg Syndrome, Epilepsy, Multiple Sclerosis, Anorexia, Autism, Cerebral Palsy, and Endometriosis.
  - ***representations about government approvals*** - statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government or government authority, such as the statement made that Naturally Elevated trading as Elevated Extract products "[...] conform with the Therapeutic Goods 'Standard for Medicinal Cannabis' (TGO 93) Order 2017'.
  - ***references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard*** - statements which promote the supply of medicinal cannabis products by stating "World-Class Medicinal Cannabis oils, isolates and tinctures that are ethically sourced and fairly priced."
17. In addition, we allege that the advertisements on the Social Media pages referred to serious medical conditions, such as Anxiety, PTSD and Cancer (***prohibited representations***).

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<sup>1</sup> See subsection 42DLB(1) of the Act, where subsection 42DLB(2) applies; and subsection 42DL(1) of the Act where subsection 42DL(5) applies.

<sup>2</sup> See subsection 42DLB(1) of the Act, where subsection 42DLB(4) applies; and subsection 42DL(1) of the Act, where subsection 42DL(7) applies.

<sup>3</sup> See subsection 42DLB(1) of the Act where subsection 42DLB(6) applies; and subsection 42DL(1) of the Act where subsection 42DL(9) applies.

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## Important Information

18. The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. Please read the [TGA guidance](#) on therapeutic goods advertising.
19. Contraventions of the advertising requirements under the Act and the Advertising Code can result in criminal penalties of up to \$1.1 million or imprisonment for individuals, or \$5.5 million for corporations, or civil penalties of up to \$1.375 million for individuals or \$13.75 million for corporations. An entity who aids, abets, counsels, procures or induces another person (i.e. by providing incentives) to contravene the Act may also be liable under the Act.<sup>4</sup>
20. A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
21. It is strongly recommended that you seek independent legal advice or the assistance of a regulatory affairs consultant to help you to comply with your regulatory obligations while you operate in the therapeutic goods space, and to respond to this letter. Please refer to the TGA's website at <http://www.tga.gov.au/regulatory-affairs-consultants> for information about regulatory consultants.
22. Naturally Elevated may also wish to refer to the following guidance provided by the TGA for [Advertising guidance for businesses involved in medicinal cannabis products](#)

Please contact **s22** by email at [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au) or phone **s22** if you wish to discuss this matter further.

Yours sincerely

**s22**

**s22**

**s22**, Advertising and Product Investigations Section  
Regulatory Compliance Branch  
Therapeutic Goods Administration

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<sup>4</sup> Section 42YC of the Act.

**From:** s22  
**To:** [Advertising Compliance](#)  
**Cc:** s22; s22; s22  
**Subject:** RE: IMPORTANT: Letter from the Therapeutic Goods Administration for Naturally Elevated Pty Ltd ( TGA ref: AC-000000014762) [SEC=OFFICIAL]  
**Date:** Thursday, 31 August 2023 1:27:09 PM  
**Attachments:** [image001.png](#)  
[TGA\\_REP\\_23-001 - part 1.pdf](#)  
[TGA\\_REP\\_23-001 - part 2.pdf](#)

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**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good afternoon,

Please find attached our official response and request for subsequent action.

Please Note: Due to size, it is spread across two attachments.

We appreciate the support during this time.

Further, we look forward to working with you closer to ensure future compliance.

With thanks,

s22 | s22  
Elevated Extracts  
Phone: s22  
Web: [www.elevatedextracts.com.au](http://www.elevatedextracts.com.au)  
LinkedIn: s22  
Mission: #EqualAccess

*P.S. Please accept our apologies, acknowledging this is now 90 minutes past deadline (I had a typo in your email address).*

---

**From:** Advertising Compliance <advertising.compliance@tga.gov.au>  
**Sent:** Thursday, August 10, 2023 4:57 PM  
**To:** s22 <s22@elevatedextracts.com.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** IMPORTANT: Letter from the Therapeutic Goods Administration for Naturally Elevated Pty Ltd ( TGA ref: AC-000000014762) [SEC=OFFICIAL]  
**Importance:** High

Dear s22,

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Please carefully read the letter and provide receipt of this email by **Monday 14 August 2023**.

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Please do not hesitate to contact me should you have any further queries.

Kind Regards,

s22  
s22 – Advertising and Product Investigation Section  
Regulatory Compliance Branch

Australian Government, Department of Health and Aged Care  
PO Box 100, Woden ACT 2606, Australia

P: s22 | e: s22@health.gov.au

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Naturally Elevated Pty Ltd  
67 Bancroft Rd  
Pinkenba, QLD 4008  
AUSTRALIA  
ABN: 91 636 315 109

To: **s22**  
Advertising and Product Investigations Section Regulatory Compliance Branch  
Therapeutic Goods Administration

Cc: **s22**  
[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

Via: email and registered express post

TGA Reference: AC-000000014762  
Naturally Elevated Reference: TGA/REP/23-001

30 August 2023

Dear **s22**

Naturally Elevated response to TGA letter. *TGA Reference: AC-000000014762*  
***Opportunity to provide submissions as to why regulatory action should not be taken in relation to the alleged unlawful advertising of therapeutic goods***

Thank you for your letter and supporting information, dated 10 August 2023.

#### **BACKGROUND**

Naturally Elevated takes the TGA allegations seriously relating to breaches in advertising of medicinal cannabis products.

Naturally Elevated genuinely appreciates the TGA providing supportive information and giving opportunity for Naturally Elevated to provide a submission as to why regulatory action should not be taken in relation to the alleged unlawful advertising of therapeutic goods.

Naturally Elevated content writers have attended TGA advertising seminars and education sessions.

#### **SYSTEMATIC REVIEW**

Naturally Elevated has performed a comprehensive systematic review of business operational systems and processes relating to advertising of therapeutic goods and services. This has included legal advice and engaging an external regulatory affairs consulting firm – **s47E(d)** – registered with the Australian Medicinal Cannabis Association.

Naturally Elevated throughout the systematic review has referenced the TGA document [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)

#### **CHANGE CONTROLS**

Appendices A-I details the documents and records used by Naturally Elevated to investigate and make controlled changes to the content in words and pictures across all websites and social media – to make good any breaches in compliance with advertising legislation, as administered by the TGA, including:

- prohibited and/or restricted representations;





**Naturally Elevated Pty Ltd**  
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 AUSTRALIA  
 ABN: 91 636 315 109

- representations about Government approvals; and
- references to substances included in Schedule 2, 3, 4 or 8 of the current Poisons Standard.

The Appendices included at the end of this letter are intended to provide a transparent dossier of documents, as evidence of the systematic review and controlled changes made to the Naturally Elevated websites and social media pages – to make good the deficiencies – as listed in the TGA letter in Appendix J.

### **OUR PLEA and OUR PLEDGE**

It is with respect and deep humility that we request the TGA does not enforce any infringement notices, nor penalties, nor public communications about the historic breaches of advertising by Naturally Elevated, as alerted by the TGA in points *i.* and *ii.* below:

- infringement notices under section 42YK of the Therapeutic Goods Act 1989 (the Act) as an alternative to court action; or*
- preparing the matter for court either under section 42Y of the Act, or by preparing a brief to the Commonwealth Director of Public Prosecutions.*

### **Our plea**

The reasons that Naturally Elevated requests that the TGA does not enforce penalties are listed in our plea and our pledge, as follows:

1. Naturally Elevated has worked with the TGA to make good the alleged advertising breaches;
2. Naturally Elevated wishes to engage the TGA for guidance and clarification on an ongoing basis;
3. Naturally Elevated has already had significant negative financial impact and lost productivity making good the deficiencies identified by the TGA, with support from the TGA, legal advisors, and regulatory affairs consultancy firm;
4. Naturally Elevated – if we were to receive an infringement notice and public notification – will likely feel the negative financial impact on the business to the extent that cost cuts by redundancies would likely need to occur. This would result in adverse impact on the livelihoods of individuals, their families and communities; and
5. Naturally Elevated – as demonstrated in Appendices A-I have made systematic changes to the business operations resulting in changes to websites and social media sites, to fully comply with the TGA Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019 .

### **Our pledge**

6. Naturally Elevated pledges to continue to implement periodic cycles of continuous quality improvement to its business operations – including advertising compliance – to always ensure product quality, clinical efficacy and patient safety along the supply chain;
7. Naturally Elevated has provided education and training to its executives, managers on staff on compliance with the TGA Advertising guidance for businesses involved in medicinal cannabis



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products; v1.0 Oct 2019 to avoid prohibited representations and restricted representations;  
and

8. Naturally Elevated has added this incident and subsequent activities to our '*Lessons Learnt Log*', which is a project management tool.

In addition to that, a request has been put through to the developers for changes and a commitment to have it done via the 16<sup>th</sup> of September. We also have the brand new site launching in 4-5weeks time whereby content management will be done in-house and more streamlined to cater for these scenarios.... which will never happen again.

Notwithstanding the above and, to ensure our ongoing compliance, I would like to request an audience with you and/or any relevant team members.

The objective of said meeting would be to align on any remaining "grey" areas and confirm best practice in navigating said topics.

We would be willing to travel to you, host you at our office or execute a simple video call.

Please contact us for further information or clarification as needed.

With kind regards,

Yours Faithfully,

**s22**

Naturally Elevated Pty Ltd  
Unit 19 67 Bancroft Road PINKENBA QLD 4008

ACN 636 315 109

**\*\* APPENDICES follow on next pages \*\***



Naturally Elevated Pty Ltd  
 67 Bancroft Rd  
 Pinkenba, QLD 4008  
 AUSTRALIA  
 ABN: 91 636 315 109

Appendix A  
 DR – Deviation Report DR/QC/23-001

### Form – Deviation Report

Source document: SOP-038-00 Deviations  
 Document copyright

#### Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
s22	s22	s22	21-Aug-2023
Document Owner – Confirming the technical content of this document			
s22	s22	s22	21-Aug-2023
Quality – Confirming compliance of this document with the Pharmaceutical Management System and/or Regulatory Compliance			
s22	s22	s22	21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

SECTION 1: Deviation Description			
Initiated by: s22			
Dev ID: DR/QC/23-001			
Deviation description: TGA alerted Elevated Extracts and Carwell by letter of non-compliance of website and social media with Advertising and Promotion of non-approved medicines, medical cannabis.			
SECTION 2: Deviation Type			
Investigator's name:	s22	Department:	Quality & Compliance
Deviation type: Medicinal cannabis advertising or promotion non-compliance with Therapeutic Goods Act 1989 on website and social media.			
<input type="checkbox"/> Deviation from procedure	<input type="checkbox"/> Non-conforming material/ product/result/data	<input type="checkbox"/> Planned deviation	
<input type="checkbox"/> Deviation within facility/ services/environment	<input checked="" type="checkbox"/> Deviation from regulations	<input type="checkbox"/> Adverse trend detected	
Impacted product/material/equipment: Written online material by Carwell and Elevated Extracts about medicinal cannabis.			
Batch numbers/codes: n/a			
Is product quarantine required? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes – Location:			
List other immediate/containment actions taken:			
1. Full review of TGA communications and allegations of corporate non-compliance.			
2. Full review with website developers of online content.			
3. s22 authorised immediate shut down of websites, social media.			
4. s22 authorised full review and edit to remove of online content.			
5. s22 authorised website developers to remove approximately 60% of content from website pages, to ensure compliance with TGA Advertising and Promotion rules.			
6. s47E(0) consultancy firm engaged for investigation, review and recommendations for changes to website content – to ensure full TGA compliance with Advertising and Promotion.			
Initial impact assessment: Does the deviation have impact on product/material:			
<input type="checkbox"/> Safety <input type="checkbox"/> Quality <input type="checkbox"/> Identity <input type="checkbox"/> Potency <input type="checkbox"/> Purity <input checked="" type="checkbox"/> No SQI/PP impact			



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## Form – Deviation Report

Source document: SOP-038-00 Deviations

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Justification: no physical products affected. This deviation report relates to regulatory non-compliance.			
Risk assessment number: <i>(Mandatory for any deviation with SQuIPP Impact)</i>		RA/QC/23-001	
Completed by (Name)	Position	Signature	Date
s22	s22	s22	22-Aug-2023

<b>SECTION 3: Deviation Level</b>			
Has a risk assessment been completed for the deviation?			
<input checked="" type="checkbox"/> Yes – see attached record number: 001 <input type="checkbox"/> No – justification: <input type="checkbox"/> No SQuIPP impact (product Safety, Quality, Identity, Potency, and Purity) or <input type="checkbox"/> Other (specify):			
<input type="checkbox"/> Linked deviations – Dev IDs: n/a			
Deviation level:	<input type="checkbox"/> Minor <i>Escalation to senior management optional</i>	<input type="checkbox"/> Major <i>Escalation to senior management optional</i>	<input checked="" type="checkbox"/> Critical <i>Escalation to senior management mandatory</i>
<input checked="" type="checkbox"/> Escalated to executive – date: 14/08/2023		Escalated to s22 Naturally Elevated	
Quality Representative (Name)	Position	Signature	Date
s22	s22	s22	25-Aug-2023

<b>SECTION 4: Deviation Investigation</b>		
Investigation plan	<input type="checkbox"/> Not required	
Investigation action	Resp. person	Due date
1. Full review TGA communications and allegations	s22	21-Aug-2023
2. DR – process deviation report		25-Aug-2023
3. CAPA – corrective action & preventative action		25-Aug-2023
4. RCA – root cause analysis		25-Aug-2023
5. Develop summary of TGA medicinal advertising rules CAN do & CANT do		21-Aug-2023
6. Develop procedure for periodic CY Q review of Naturally Elevated online materials to demonstrate compliance with TGA advertising rules		25-Aug-2023
7. TR – update training records for staff involved in 1-6		25-Aug-2023
8. Write response to TGA with Appendices 1-7		28-Aug-2023
1. Effectiveness check 1-8 (mandatory)		29-Aug-2023



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 67 Bancroft Rd  
 Pinkenba, QLD 4008  
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## Form – Deviation Report

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Sources of information to review:			
<ul style="list-style-type: none"> <li>TGA letters and other communications.</li> <li>All websites and social media by Naturally Elevated, Carwell, On-Schedule, Farma.</li> <li>References listed in the in-house checklist of advertising and promotion "CANT do &amp; CAN do"               <ol style="list-style-type: none"> <li>ss 42DL(10); Therapeutic Goods Act 1989</li> <li>ss 42DL(12); Therapeutic Goods Act 1989</li> <li>Australian Regulatory Guidelines for Advertising Therapeutic Goods, ARGATG</li> <li>Advertising guidance for businesses involved with medicinal cannabis products - Complying with therapeutic goods advertising requirements; Therapeutic Goods Administration, Version 1.0, October 2019.</li> <li>Part 8, Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021</li> <li>Part 1, Schedule 2, Therapeutic Goods Regulations 1990</li> <li>ss 42DLB(6); Therapeutic Goods Act 1989</li> </ol> </li> </ul>			
Detailed investigation plan attached?		<input checked="" type="checkbox"/> Yes; section 4	<input type="checkbox"/> Not required
Copies of relevant records attached?		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not required
Trend analysis and historical assessment			
Date range of historical review:			
<ol style="list-style-type: none"> <li>Attended previous seminars run by the TGA on advertising.</li> <li>Attended seminars run by the MClA clinic sessions.</li> <li>Review and edits of websites material aligned with regulatory compliance knowledge and insights gained from 1 and 2.</li> </ol>			
List any previous events related to this deviation (include frequency and impact):			
NIL			
List any trends related to this deviation:			
NIL			
Other comments:			
NIL			
Completed by (Name)	Position	Signature	Date
s22	s22	s22	24-Aug-2023
SECTION 5: Finalise the investigation			
Determine root cause		<input type="checkbox"/> Not required	
Root cause analysis record: 001			
Root cause category:		<input type="checkbox"/> Method	<input type="checkbox"/> Materials
		<input type="checkbox"/> Measurement	<input type="checkbox"/> Machines
		<input checked="" type="checkbox"/> People	<input type="checkbox"/> Environment



**Form – Deviation Report**

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<p><b>Summary of root cause:</b>                  The following root cause analysis (RCA) methodology was applied with subsequent findings:</p> <ol style="list-style-type: none"> <li>1. Identify and clarify the problem. TGA allegations of non-compliance.</li> <li>2. Breakdown and analyse the problem by visiting the websites and cross-referencing to the TGA allegations.</li> <li>3. "5 Whys" investigation of the overall system and individual processes to determine why, the problems – listed as TGA allegations – had occurred</li> <li>4. RCA findings by s47 Consultant                         <ol style="list-style-type: none"> <li>a. Naturally Elevated website content author and authorizer is the same person.</li> <li>b. Naturally Elevated – at the time of online publication – did not have access to a person to review websites content for full regulatory compliance.</li> <li>c. Naturally Elevated – with best intentions – based on review of TGA Advertising and Promotion guidelines and after attending TGA and MCIA educational seminars, thought that their website content was compliant with the TGA requirements.</li> </ol> </li> </ol>			
<p><b>Corrections and Corrective actions</b></p>			<input type="checkbox"/> Not required
<p>Are corrections required to address to the result of the deviation?</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Yes – list corrections required, including responsible person and due date:</p> <ol style="list-style-type: none"> <li>1. s22 to review website material content and recommend edits and deletions.</li> <li>2. s22 to review and edit recommended edits for regulatory compliance.</li> <li>3. s22 to review 1 and 2, and approve changes for web developers to make final changes</li> <li>4. s22 and s22 to re-check for final review of pre-live website contents.</li> <li>5. s22 to review 4 and approve changes for web developers to make final changes for updated websites 'go-live'.</li> </ol>			
<p>Are corrective actions required to permanently address the root cause of the deviation?</p> <p><input checked="" type="checkbox"/> Yes – CAPA number: CAPA/QC/23-001</p> <p><input type="checkbox"/> No – justification:</p>			
<p>Completed by (Name)</p> <p>s22</p>	<p>Position</p> <p>s22</p>	<p>Signature</p> <p>s22</p>	<p>Date</p> <p>25-Aug-2023</p>
<p>Quality Representative (Name)</p> <p>s22</p>	<p>Position</p> <p>s22</p>	<p>Signature</p> <p>s22</p>	<p>Date</p> <p>25-Aug-2023</p>
<p><b>SECTION 6: Closeout</b></p>			
<p><b>Final impact assessment</b></p> <p>List any impacts of the deviation on related batches or products (including those in the marketplace), results, locations or systems not already included:</p> <ol style="list-style-type: none"> <li>1. Quality of products unaffected.</li> <li>2. Websites shutdown resulted in significant loss of revenue.</li> <li>3. Added financial costs for external stakeholders engagement to fix root cause of process failure by process re-design.</li> <li>4. Loss in business productivity by diverting resources to fix websites content for compliance.</li> </ol>			
<p>List supplier(s) of suspect raw materials:</p> <p>n/a</p>			



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 ABN: 91 636 315 109

## Form – Deviation Report

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Residual impact on:			
<input type="checkbox"/> Safety <input type="checkbox"/> Quality <input type="checkbox"/> Identity <input type="checkbox"/> Potency <input type="checkbox"/> Purity <input checked="" type="checkbox"/> No SQulPP impact			
Justification:			
1. Not applicable. Product quality unaffected. 2. Non-conformance with advertising and promotion as enforced by the TGA.			
Detailed impact assessment report attached:		<input checked="" type="checkbox"/> Yes; see section 6 <input type="checkbox"/> Not required	
Were the corrective actions effective?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
If no, describe the outcome and proposed further actions to eliminate the deviation:			
n/a			
Final batch disposition status:			
1. Not applicable. Product quality unaffected. 2. Non-conformance with advertising and promotion as enforced by the TGA.			
Quality Representative (Name)	Position	Signature	Date
s22	s22	s22	25-Aug-2023

<b>SECTION 7: Cancellation or Extension</b>			
Type of action: n/a <input type="checkbox"/> Cancellation <input type="checkbox"/> Extension			
<input type="checkbox"/> Approved <input type="checkbox"/> Rejected. Reason for rejection: n/a			
Quality Representative (Name)	Position	Signature	Date
n/a	n/a	n/a	n/a

DOCUMENT END



**Naturally Elevated Pty Ltd**  
67 Bancroft Rd  
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## Form – Deviation Report

Source document: SOP-038-00 Deviations

Document copyright

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### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar-2023	N/a	Initial document

Template reference: TMP-003-04\_Form Template (Portrait)\_r01





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## Appendix B

## CAPA – Corrective Actions &amp; Preventative Actions CAPA/QC/23-001

## Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-06 Corrective and Preventive Actions

Document copyright

## Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
s22	s22	s22	21-Aug-2023
Document Owner – Confirming the technical content of this document			
s22	s22	s22	21-Aug-2023
Quality – Confirming compliance of this document with the Pharmaceutical Quality System and/or Regulatory Compliance			
s22	s22	s22	21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

## SECTION 1: CAPA details

CAPA ID: CAPA/QC/23/001		Date initiated: 23-Aug-2023	
Initiator's name: s22		Department: Quality & Compliance	
Description of the CAPA:			
<ol style="list-style-type: none"> <li>s22 to review website material content and recommend edits and deletions.</li> <li>s22 to review and edit recommended edits for regulatory compliance.</li> <li>s22 to review 1 and 2, and approve changes for web developers to make final changes.</li> <li>s22 and s22 to re-check for final review of pre-live website contents.</li> <li>s22 to review 4 and approve changes for web developers to make final changes for updated websites 'go-live'.</li> </ol>			
Is this CAPA linked to a Quality System record?		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes – Ref number: CAPA/QC/23/001	
Are there other open related CAPAs?		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes – CAPA number: n/a	
Have batches been impacted?		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Does this CAPA affect product registration?		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
CAPA criticality: <input checked="" type="checkbox"/> Critical <input type="checkbox"/> Major <input type="checkbox"/> Minor		Proposed date of closure: 28-Aug-2023	
Completed by (Name)	Position	Signature	Date
s22	s22	s22	23-Aug-2023
Quality Approval (Name)	Position	Signature	Date
s22	s22	s22	23-Aug-2023

## SECTION 2: CAPA team members

Name	Title	CAPA Responsibility
s22		Investigation and legal compliance
		System review with web developers
		Staff awareness and training updates
		Quality and regulatory compliance
Comments: n/a		



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## Form – Corrective and Preventative Action (CAPA)

Source document: SOP-038-00 Corrective and Preventive Actions

Document copyright

SECTION 3: Implementation plan		
Root cause analysis record: See Deviation Report (30-Aug-2023) See Root Cause Analysis Report (30-Aug-2023)		
Probable root cause: The following root cause analysis (RCA) methodology was applied with subsequent findings: <ol style="list-style-type: none"> <li>1. Identify and clarify the problem. TGA allegations of non-compliance.</li> <li>2. Breakdown and analyse the problem by visiting the websites and cross-referencing to the TGA allegations.</li> <li>3. "5 Why's" investigation of the overall system and individual processes to determine why, the problems – listed as TGA allegations – had occurred.</li> <li>4. RCA findings by S47E Consultant:               <ol style="list-style-type: none"> <li>a. Naturally Elevated website content author and authorizer is the same person.</li> <li>b. Naturally Elevated – at the time of online publication – did not have access to a person to review websites content for full regulatory compliance.</li> <li>c. Naturally Elevated – with best intentions – based on review of TGA Advertising and Promotion guidelines and after attending TGA and MCIA educational seminars, thought that their website content was compliant with the TGA requirements.</li> </ol> </li> </ol>		
Implementation tasks		
Tasks	Resp.	Due Date
1. to review website material content and recommend edits and deletions	S22	25-Aug-2023
2. to review website material content and recommend edits and deletions		28-Aug-2023
3. to review 1 and 2, and approve changes for web developers to make final changes.		28-Aug-2023
4. to re-check for final review of pre-live website contents and report to S22	S22 and	28-Aug-2023
5. to review 4 and approve changes for web developers to make final changes for updated websites 'go-live'.	S22	30-Aug-2023
Describe what the CAPA will address: CAPA will address websites for contents complaint with the requirements outlined by the TGA letter 10-Aug-2023 listing allegations of non-compliance. Excerpt of letter as a screenshot below:		



### Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-00 Corrective and Preventive Actions

Document copyright

<p><b>SECTION 3: Implementation plan</b></p> <p>Summary of alleged contraventions</p> <p>15. We identified prohibited representations, restricted representations, references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard, and representations about government approvals, on the Websites and the Social Media pages which we allege contravene the advertising provisions in the Act.</p> <p>16. Specifically, we allege that the Websites contained:</p> <ul style="list-style-type: none"><li>• <b>prohibited and/or restricted representations</b> - statements which refer to specific serious medical conditions such as Chron's Disease, Parkinson's Disease, Restless Leg Syndrome, Epilepsy, Multiple Sclerosis, Anorexia, Autism, Cerebral Palsy, and Endometriosis.</li><li>• <b>representations about government approvals</b> - statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government or government authority, such as the statement made that Naturally Elevated trading as Elevated Extract products "[...] conform with the Therapeutic Goods 'Standard for Medicinal Cannabis' (TGO 93) Order 2017'.</li><li>• <b>references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard</b> - statements which promote the supply of medicinal cannabis products by stating "World-Class Medicinal Cannabis oils, isolates and tinctures that are ethically sourced and fairly priced."</li></ul> <p>17. In addition, we allege that the advertisements on the Social Media pages referred to serious medical conditions, such as Anxiety, PTSD and Cancer (<b>prohibited representations</b>).</p>
<p>Describe how the CAPA addresses root cause:</p> <ol style="list-style-type: none"><li>1. The CAPA will drive a systematic review of systems, process and webpages content, including edits and deletions and authorisations – before website go-live before close of business 30-Aug-2023.</li><li>2. Full review of TGA communications and allegations of corporate non-compliance.</li><li>3. Full review with website developers of online content.</li><li>4. s22 authorised immediate shut down of websites, social media.</li><li>5. authorised full review and edit to remove of online content.</li><li>6. authorised website developers to remove approximately 60% of content from website pages. to ensure compliance with TGA Advertising and Promotion rules.</li><li>7. s47E(d) consultancy firm engaged for investigation, review and recommendations for changes to website content – to ensure full TGA compliance with Advertising and Promotion.</li></ol>
<p>List any limitations of the CAPA or areas out of scope:</p> <p>Out of scope – not included in TGA allegations of non-compliance.</p>
<p>List appropriate acceptance criteria:</p> <ol style="list-style-type: none"><li>1. Website changes.</li><li>2. Second author review and edit of website material.</li><li>3. Executive review, edit and authorization for website 'go-live'.</li></ol>



## Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-06 Corrective and Preventive Actions

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<b>SECTION 3: Implementation plan</b>	
4. Systems and process changes for website edits, review and authorisations to publish website 'go-live'.	
5. Periodic review every 3 months of websites content compliance.	
List regulatory causes the CAPA addresses:	
The <u>Advertising guidance for businesses involved with medicinal cannabis products - Complying with therapeutic goods advertising requirements; Therapeutic Goods Administration, Version 1.0, October 2019</u> as specified in the <u>Therapeutic Goods Act 1989 (22 January 2019) - SUPERSEDED</u> but current at the time of publishing the Guidance document by the TGA (Oct 2019).	
1. <u>ss 42DL(10); Therapeutic Goods Act 1989 (22 January 2019)</u> 1.1. <i>"This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority)."</i>	
2. <u>ss 42DL(12); Therapeutic Goods Act 1989 (22 January 2019)</u> 2.1. <i>"This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority)."</i>	
3. <u>Australian Regulatory Guidelines for Advertising Therapeutic Goods, ARGATG</u>	
4. <u>Advertising guidance for businesses involved with medicinal cannabis products - Complying with therapeutic goods advertising requirements; Therapeutic Goods Administration, Version 1.0, October 2019.</u>	
5. <u>Part 8, Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021;</u>	
6. <u>Part 1, Schedule 2, Therapeutic Goods Regulations 1990; and</u>	
7. <u>ss 42DLB(6); Therapeutic Goods Act 1989 (22 January 2019)</u> 7.1. <i>"This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:</i> (a) <i>a statement of the availability of the goods as a pharmaceutical benefit; or</i> (b) <i>a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or</i> (c) <i>a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph."</i>	
Copies of relevant records attached?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not required
Attach the risk assessment to this form - RA ID: RA/QC/23-001	
Risk controls are required?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
1. <b>s22</b> to review website material content and recommend edits and deletions.	
2. <b>s22</b> to review and edit recommended edits for regulatory compliance.	



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## Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-00 Corrective and Preventive Actions

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SECTION 3: Implementation plan		
3. s22	to review 1 and 2	and approve changes for web developers to make final changes.
4. s22	and s22	to re-check for final review of pre-live website contents.
5. s22	to review 4	and approve changes for web developers to make final changes for updated websites 'go-live'.
Effectiveness measures		
Effectiveness measures are required:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Effectiveness to be managed with a CAPA:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Raising effectiveness CAPAs included in implementation tasks?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Effectiveness measure	Resp.	Due Date
Check implementation plan steps actioned	s22	28-Aug-2023
Check approved website edits changed	s22	28-Aug-2023
Check execs updated on all steps in CAPA execution	s22	30-Aug-2023
Communication plan		
List all areas/staff (stakeholders) who are impacted by the CAPA actions: Company executives, middle managers and staff.		
Communications plan to execute changes:		
1. Changes review and stress test to TGA Advertising in-house document 'CAN'T do & CAN do'.		
2. Training updates & awareness to staff on advertising, promotion and education.		
3. No changes without regulatory compliance officer review and approval.		
4. Director to approve all website edits, additions and deletions before website 'go-live'.		
Notify all stakeholders of the proposed CAPA:	<input checked="" type="checkbox"/> Yes	date: 21-Aug-2023

SECTION 4: Pre-implementation approval			
CAPA is approved to commence:		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Comments: Executive approval to execute as above Sections.			
Completed by (Name)	Position	Signature	Date
s22			21-Aug-2023
Quality Approval (Name)	Position	Signature	Date
s22			21-Aug-2023
SECTION 5: Implement Actions			
All documentation is complete and appropriate:		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
CAPA evidence is present and correct:		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Quality System reference (CC, training, CAPA) All updated and completed.	Initiated 21-Aug-2023	Closed (Yes/No)	



### Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-00 Corrective and Preventive Actions

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SECTION 5: Implement Actions			
1. review website material content and recommend edits and deletions	25-Aug-2023	YES	
2. re-check 1.	28-Aug-2023	YES	
3. review 1 and 2, and approve changes for web developers to make final change	25-Aug-2023	YES	
4. re-check for final review of pre-live website contents	28-Aug-2023	YES	
5. executive review 4 and approve changes for web developers to make final changes for updated websites 'go-live'	29-Aug-2023	YES	
Summarise the outcome of the CAPA: 1. Full systematic review of problems 2. Controlled changes 3. Controlled checks of content 4. Controlled cross-checks of content 5. Staff training implemented 6. Reported to executive			
<b>Effectiveness check</b>			
Is CAPA effectiveness during implementation effective? <input checked="" type="checkbox"/> Effective <input type="checkbox"/> Passable <input type="checkbox"/> Ineffective			
If no, describe the outcome and proposed further actions to eliminate the root cause: n/a			
<b>The CAPA implementation is complete and ready for approval and closeout</b>			
Completed by (Name)	Position	Signature	Date
s22			25-Aug-2023

SECTION 6: Closeout			
CAPA outcome acceptable?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Implementation plan was followed?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
All evidence is attached (reports, data or records etc.) DR, RCA, CAPA	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Were the corrective actions effective?	<input checked="" type="checkbox"/> Ongoing monitoring	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
All quality system records are complete (CAPA, CC, training etc.)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
All quality system records meet requirements of the CAPA plan?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
All implementation risks were appropriately managed?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Final batch disposition: Not applicable. Products quality unaffected.			
Closed by (Name)	Position	Signature	Date
s22			29-Aug-2023



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### Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-00 Corrective and Preventive Actions

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<b>SECTION 7: Cancellation or Extension</b>			
Type of action: <input type="checkbox"/> Cancellation <input type="checkbox"/> Extension			
Reason: n/a		Date notified: n/a	
Requested by: n/a		Date: n/a	
<input type="checkbox"/> Approved <input type="checkbox"/> Rejected. Reason for rejection:			
Quality Representative (Name)	Position	Signature	Date
n/a	n/a	n/a	n/a

DOCUMENT END



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## Form – Corrective and Preventative Action (CAPA)

Source document: SOP-039-00 Corrective and Preventive Actions

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### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	Initial document

Template reference: TMP-003-04\_Form Template (Portrait)\_r01





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## Appendix C

## RCA – Root Cause Analysis RCA/QC/23-001

## Form – Root Cause Analysis

Source document: SOP-085-00 Root Cause Analysis

Document copyright

## Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
s22	[Redacted]		21-Aug-2023
Document Owner – Confirming the technical content of this document			
s22	[Redacted]		21-Aug-2023
Quality – Confirming compliance of this document with the Pharmaceutical Quality System and/or Regulatory Compliance			
s22	[Redacted]		21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

SECTION 1: Approach		
Investigator:	s22	
Team member(s):	s22	<input type="checkbox"/> N/A
RCA number:	RCA/QC/23-001	
Parent quality record:	n/a. All details in this form and attached forms listed below section, 'Supporting Information'	
Date of problem:	01/08/2021 to 31/08/2022 As per TGA letter from 26/05/2023 - TGA ref# AC-000000014762	
Date RCA conducted:	21-Aug-2023	
Supporting information		
Document reference	Title	Copy attached?
FRM-038-01	Form – Deviation Report	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
FRM-039-01	Form – Corrective and Preventative Action (CAPA)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
FRM-043-01	Form – Quality & Compliance Risk Assessment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
AC-000000014762	TGA Letter: 10 August 2023 s22 Advertising and Product Investigations Section Regulatory Compliance Branch	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No



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## Form – Root Cause Analysis

Source document: SOP-065-00 Root Cause Analysis

Document copyright

Problem Details
<p><b>Problem description:</b>            Advertising and promotion non-compliance allegations received from TGA. Excerpt of letter below:</p> <div style="border: 1px solid black; padding: 5px;"> <p><b>Summary of alleged contraventions</b></p> <p>15. We identified prohibited representations, restricted representations, references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard, and representations about government approvals, on the Websites and the Social Media pages which we allege contravene the advertising provisions in the Act.</p> <p>16. Specifically, we allege that the Websites contained:</p> <ul style="list-style-type: none"> <li>• <b>prohibited and/or restricted representations</b> - statements which refer to specific serious medical conditions such as Chron's Disease, Parkinson's Disease, Restless Leg Syndrome, Epilepsy, Multiple Sclerosis, Anorexia, Autism, Cerebral Palsy, and Endometriosis.</li> <li>• <b>representations about government approvals</b> - statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government or government authority, such as the statement made that Naturally Elevated trading as Elevated Extract products "[...] conform with the Therapeutic Goods 'Standard for Medicinal Cannabis' (TGO 93) Order 2017'.</li> <li>• <b>references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard</b> - statements which promote the supply of medicinal cannabis products by stating "World-Class Medicinal Cannabis oils, isolates and tinctures that are ethically sourced and fairly priced."</li> </ul> <p>17. In addition, we allege that the advertisements on the Social Media pages referred to serious medical conditions, such as Anxiety, PTSD and Cancer (<b>prohibited representations</b>).</p> </div>
<p><b>Background information:</b> (include sequence of events, any deviations to the approved procedures; its existing policy, procedures, guidelines that if followed may have had prevented the quality issue/problem encountered or that may require review)</p> <p><b>Probable root cause:</b>            The following root cause analysis (RCA) methodology was applied with subsequent findings:</p> <ol style="list-style-type: none"> <li>1. Identify and clarify the problem. TGA allegations of non-compliance.</li> <li>2. Breakdown and analyse the problem by visiting the websites and cross-referencing to the TGA allegations.</li> <li>3. "5 Why's" investigation of the overall system and individual processes to determine why the problems – listed as TGA allegations – had occurred.</li> <li>4. RCA findings by <b>SAFE</b> Consultant:             <ol style="list-style-type: none"> <li>a. Naturally Elevated website content author and authorizer is the same person.</li> <li>b. Naturally Elevated – at the time of online publication – did not have access to a person to review websites content for full regulatory compliance.</li> </ol> </li> <li>5. Naturally Elevated – with best intentions – based on review of TGA Advertising and Promotion guidelines and after attending TGA and MCIA educational seminars, thought that their website content was compliant with the TGA requirements.</li> </ol>



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## Form – Root Cause Analysis

Source document: SOP-065-00 Root Cause Analysis

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SECTION 2: RCA details	
RCA tool used:	Yes
Analysis attached?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No See documents listed in section 1.
Most probable root cause (including justification for findings)	<p>The following root cause analysis (RCA) methodology was applied with subsequent findings:</p> <ol style="list-style-type: none"> <li>1. Identify and clarify the problem. TGA allegations of non-compliance.</li> <li>2. Breakdown and analyse the problem by visiting the websites and cross-referencing to the TGA allegations.</li> <li>3. "5 Why's" investigation of the overall system and individual processes to determine why, the problems – listed as TGA allegations – had occurred</li> <li>4. RCA findings by <b>S47E</b> Consultant:             <ol style="list-style-type: none"> <li>a. Naturally Elevated website content author and authorizer is the same person.</li> <li>b. Naturally Elevated – at the time of online publication – did not have access to a person to review websites content for full regulatory compliance.</li> <li>c. Naturally Elevated – with best intentions – based on review of TGA Advertising and Promotion guidelines and after attending TGA and MCIA educational seminars, thought that their website content was compliant with the TGA requirements.</li> </ol> </li> </ol>
CAPA ID:	CAPA/QC/23-001 <input type="checkbox"/> N/A



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### Form – Root Cause Analysis

Source document: SOP-065-00 Root Cause Analysis

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SECTION 3: Approvals			
Completed by (Name)	Position	Signature	Date
s22			25-Aug-2023
RCA Quality Lead (Name)	Position	Signature	Date
s22			29-Aug-2023
Executive review (Name)	Position	Signature	Date
s22		s22	29-Aug-2023
Executive approval (Name)	Position	Signature	Date
s22			29-Aug-2023

DOCUMENT END



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## Form – Root Cause Analysis

Source document: SOP-065-00 Root Cause Analysis

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### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar-2023	N/A	Initial document

Template reference: TMP-003-04\_Form Template (Portrait)\_r01



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## Appendix D

## RA – Risk Assessment RA/QC/23-001

## Form – Quality &amp; Compliance Risk Assessment

Source document: SOP-043-00 Quality Risk Management

Document copyright:

## Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
s22	[REDACTED]		21-Aug-2023
Equipment Owner – Confirming the technical content of this document			
s22	[REDACTED]		21-Aug-2023
Quality – Confirming compliance of this document with the Pharmaceutical Quality System and/or Regulatory Compliance			
s22	[REDACTED]		21-Aug-2023
			01-Aug-2025

<b>Risk Description</b>	
Risk Assessment ID No. RA/QC/23-001	Date: 24-Aug-2023
Risk assessment team s22 [REDACTED]	
<b>Areas impacted:</b>	
<ol style="list-style-type: none"> <li>1. Company websites and SEO to generate business.</li> <li>2. Business performance by revenue, reputation.</li> <li>3. Reduced prescriber and patient access.</li> <li>4. Business operations by lack of clarity on how to proceed to ensure regulatory compliance.</li> </ol>	
<b>Associate document (CC, CAPA, audit, etc.):</b>	
See attached	
<ol style="list-style-type: none"> <li>1. Deviation Report</li> <li>2. Corrective Action and Preventive Actions</li> <li>3. Root Cause Analysis</li> <li>4. TGA Letter 10-Aug-2023</li> </ol>	



## Form – Quality & Compliance Risk Assessment

Source document: SOP-043-00 Quality Risk Management

Document copyright

### Describe the hazard or event:

Issue, remedy, assessment

#### Issue

TGA letter 10-Aug-2023 highlights non-compliance with advertising and promotion rules. Excerpt below.

#### Summary of alleged contraventions

15. We identified prohibited representations, restricted representations, references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard, and representations about government approvals, on the Websites and the Social Media pages which we allege contravene the advertising provisions in the Act.
16. Specifically, we allege that the Websites contained:
  - **prohibited and/or restricted representations** - statements which refer to specific serious medical conditions such as Chron's Disease, Parkinson's Disease, Restless Leg Syndrome, Epilepsy, Multiple Sclerosis, Anorexia, Autism, Cerebral Palsy, and Endometriosis.
  - **representations about government approvals** - statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government or government authority, such as the statement made that Naturally Elevated trading as Elevated Extract products "[...] conform with the Therapeutic Goods 'Standard for Medicinal Cannabis' (TGO 93) Order 2017'.
  - **references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard** - statements which promote the supply of medicinal cannabis products by stating "World-Class Medicinal Cannabis oils, isolates and tinctures that are ethically sourced and fairly priced."
17. In addition, we allege that the advertisements on the Social Media pages referred to serious medical conditions, such as Anxiety, PTSD and Cancer (**prohibited representations**).

#### Remedy

##### Probable root cause:

The following root cause analysis (RCA) methodology was applied with subsequent findings:

1. Identify and clarify the problem. TGA allegations of non-compliance.
2. Breakdown and analyse the problem by visiting the websites and cross-referencing to the TGA allegations.
3. "5 Why's" investigation of the overall system and individual processes to determine why, the problems – listed as TGA allegations – had occurred.
4. RCA findings by **PA7E** Consultant:
  - a. Naturally Elevated website content author and authorizer is the same person.
  - b. Naturally Elevated – at the time of online publication – did not have access to a person to review websites content for full regulatory compliance.

Naturally Elevated – with best intentions – based on review of TGA Advertising and Promotion guidelines and after attending TGA and MCIA educational seminars, thought that their website content was compliant with the TGA requirements.



Naturally Elevated Pty Ltd  
 67 Bancroft Rd  
 Pinkenba, QLD 4008  
 AUSTRALIA  
 ABN: 91 636 315 109

## Form – Quality & Compliance Risk Assessment

Source document: SOP-043-00 Quality Risk Management

Document copyright

### How the CAPA addresses root cause:

1. The CAPA will drive a systematic review of systems, process and webpages content, including edits and deletions and authorisations – before website go-live before close of business 30-Aug-2023.
2. Full review of TGA communications and allegations of corporate non-compliance.
3. Full review with website developers of online content.
4. s22 authorised immediate shut down of websites, social media.
5. s22 authorised full review and edit to remove of online content.
6. s22 authorised website developers to remove approximately 60% of content from website pages, to ensure compliance with TGA Advertising and Promotion rules.
7. s47E(d) consultancy firm engaged for investigation, review and recommendations for changes to website content – to ensure full TGA compliance with Advertising and Promotion.

### Assessment

#### Systems

1. s22 to review website material content and recommend edits and deletions.
2. s22 to review and edit recommended edits for regulatory compliance.
3. s22 to review 1 and 2, and approve changes for web developers to make final changes.
4. s22 and s22 to re-check for final review of pre-live website contents.
5. s22 to review 4 and approve changes for web developers to make final changes for updated websites 'go-live'.

#### Business

1. Quality, safety and efficacy of products unaffected.
2. Websites shutdown resulted in significant loss of revenue to Naturally Elevated.
3. Added financial costs for external stakeholders engagement to fix root cause of process failure by process re-design.
4. Loss in business productivity by diverting resources to fix websites content for compliance.
5. Drop in morale of all personnel in the business by associated mental stress of the identified incident and actions required to resolve.
6. Potential threat of job losses affecting individuals, family and community livelihoods.





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## Form – Quality & Compliance Risk Assessment

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Risk Assessment	
What are the risks associated with the hazard/event described above?	
Severity	Is there an impact on final product quality?
	<input type="checkbox"/> Direct Impact <input type="checkbox"/> Indirect Impact <input checked="" type="checkbox"/> No impact
	Is there an impact on the patient safety?
	<input type="checkbox"/> Direct Impact <input type="checkbox"/> Indirect Impact <input checked="" type="checkbox"/> No impact
	Is there an impact on manufacturing or process efficiency?
	<input type="checkbox"/> Direct Impact <input type="checkbox"/> Indirect Impact <input checked="" type="checkbox"/> No impact
Is there an impact on the validated state?	
<input type="checkbox"/> Direct Impact <input type="checkbox"/> Indirect Impact <input checked="" type="checkbox"/> No impact	
Provide further details for direct impacts:	
<ol style="list-style-type: none"> <li>1. Advertising non-conformance as allegations imposed by the TGA.</li> <li>2. Threat to business of financial penalty imposed by TGA, which may lead to:               <ol style="list-style-type: none"> <li>2.1. job losses affecting livelihoods of individuals, families and community.</li> <li>2.2. bad reputation of company if information reported publicly by TGA.</li> </ol> </li> </ol>	

Probability of occurrence	Does the hazard/event impact 1 or more batches? Batch#:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	Does the hazard/event impact batches already released? Batch#:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	Does the hazard/event impact 1 or more products? Products:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	Does the hazard/event cause a systemic problem? Describe: Advertising non-conformance as alleged by the TGA, may be the result of the company's misinterpretation of the Therapeutic Goods Act advertising rules.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	Has the hazard/event occurred before? If yes, how frequently? n/a	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No



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<b>Detection</b>	Are risk controls already in place that will detect the hazard/event? If yes, describe the existing controls:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	Are risk controls already in place to detect the consequences caused by the hazard/event? If yes, describe the existing controls:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Evaluation</b>	Classify the risk: <input type="checkbox"/> Low <input type="checkbox"/> Medium <input checked="" type="checkbox"/> High	
	(If the answer to any question in Severity was 'Direct Impact' or Occurrence was 'Yes' or Detection was 'No' the risk cannot be Low.)	
	<b>Justify the risk classification:</b> 1. TGA has reported alleged non-conformance with advertising as specified in the Therapeutic Goods Act of medicinal cannabis as unapproved medicines not registered on the TGA ARTG. 2. The risk if the TGA enforces penalties may be: 2.1. \$100's fines to the business up to \$1.1M 2.2. imprisonment of the company executive up to 5 years. 2.3. implementation of cost savings by making redundant staff at short notice, adversely affected their livelihood, families and communities. 2.4. adverse reputation of the business as perceived by the public. 2.5. adverse reputation of the TGA as perceived by the public.	



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<b>Risk Control</b>			
<b>What additional controls are recommended?</b>			
<ol style="list-style-type: none"> <li>1. Implementation of in-house checklist of advertising and promotion compliance</li> <li>2. Review of all websites and social media site for advertising compliance</li> <li>3. Review and approval of all websites and social media by a nominated company representative</li> </ol>			
<b>How will effectiveness of control be measured?</b>			
<ol style="list-style-type: none"> <li>1. Nominated company representative to control all content relating to advertising and promotion on all company websites and social media.</li> <li>2. Write and update company procedures relating to the advertising and promotion content of all company websites and social media.</li> <li>3. Review of compliance audit of all websites and social media by a nominated company representative every 4 months, followed up by report to the company Executive.</li> <li>4. Engagement with TGA to guide compliance with advertising and promotion rules.</li> </ol>			
<b>What residual risk remains after control measures are implemented?</b>			
		<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Medium <input type="checkbox"/> High
<b>Justification:</b>			
<ol style="list-style-type: none"> <li>1. Robust systems will have been implemented with monitoring and reporting to ensure systems are controlled, relating the advertising and promotion on all company websites and social media.</li> <li>2. The company representative will engage with the TGA Advertising and Product Investigations Section Regulatory Compliance Branch for clarification of website and social media, that content conforms with the requirements, as specified in the <i>Therapeutic Goods Act 1989</i>.</li> </ol>			
<b>Approval</b>			
<b>Approved by (name)</b>	<b>Signature</b>	<b>Position</b>	<b>Date</b>
Department Manager or Executive			
s22			29-Aug-2023
Quality & Regulatory Compliance – initial review			
s22			29-Aug-2023

DOCUMENT END



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## Form – Quality & Compliance Risk Assessment

Source document: SOP-043-00 Quality Risk Management

Document copyright

### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	

Template reference: TMP-QA-0103 Form Template (Portrait) v001



## Logbook – Deviation Report

Document copyright

### Document Approvals

Approved by	Signature	Position	Date
<i>Author – Confirming the technical content of this document</i>			
S22	[Redacted]		21-Aug-2023
S22	[Redacted]		21-Aug-2023
<i>Quality – Confirming compliance of this document with the Quality System and/or Regulatory compliance</i>			
S22	[Redacted]		21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

### Logbook cover sheet

Equipment/Item description:	n/a	Equipment ID:	n/a
Equipment location:	n/a	Department:	Quality & Compliance
Logbook No:	DR-001	Date of Issue:	21-Aug-2023
Issued by (name)	Signature	Position	Date
S22	[Redacted]		21-Aug-2023
Reviewed by (name)	Signature	Position	Date
S22	[Redacted]		21-Aug-2023

DR log – Deviation Report

Appendix E

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### Logbook – CAPA – Corrective Actions & Preventative Actions

Document copyright

#### Document Approvals

Approved by	Signature	Position	Date
<small>Author – Confirms the technical content of this document</small>			
			S22 21-Aug-2023
<small>Management Director – Confirms the technical content of this document</small>			
			S22 21-Aug-2023
<small>Quality &amp; Compliance Manager – Confirms the technical content of this document</small>			
			S22 21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

#### Logbook cover sheet

Equipment/Item description:	n/a	Equipment ID:	n/a
Equipment location:	n/a	Department:	Quality & Compliance
Logbook No:	CAPA-001	Date of issue:	21-Aug-2023
Issued by (name)	Signature	Position	Date
			S22 21-Aug-2023
Reviewed by (name)	Signature	Position	Date
			S22 21-Aug-2023

CAPA log – Corrective Actions & Preventative Actions

Appendix F







## Logbook – RCA – Root Cause Analysis

Document copyright

### Document Approvals

Approved by	Signature	Position	Date
<small>Author – Confirms the technical content of this document</small>			
S22	[Redacted]		21-Aug-2023
<small>Manager's Approval – Confirms the technical content of this document</small>			
S22	[Redacted]		21-Aug-2023
<small>Approval of the RCA process</small>			
S22	[Redacted]		21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

### Logbook cover sheet

Equipment/Item description:	n/a	Equipment ID:	n/a
Equipment location:	n/a	Department:	Quality & Compliance
Logbook No:	RCA-001	Date of Issue:	21-Aug-2023
Issued by (name)	Signature	Position	Date
[Redacted]	[Redacted]	[Redacted]	21-Aug-2023
Reviewed by (name)	Signature	Position	Date
[Redacted]	[Redacted]	[Redacted]	21-Aug-2023

RCA log – Root Cause Analysis

Appendix G

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# Logbook – RA – Quality & Compliance Risk Assessment

Document copyright

## Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document	[Redacted]		21-Aug-2023
Reviewed by – Confirming the technical content of this document	[Redacted]		21-Aug-2023
Quality – Confirming compliance of this document with the Quality System and the Regulatory requirements	[Redacted]		21-Aug-2023
Effective Date	21-Aug-2023	Review Date	01-Aug-2025

## Logbook cover sheet

Equipment/Item description:	n/a	Equipment ID:	n/a
Equipment location:	n/a	Department:	Quality & Compliance
Logbook No:	RA-001	Date of issue:	21-Aug-2023

Issued by (name)	Signature	Position	Date
[Redacted]	[Redacted]		21-Aug-2023
Reviewed by (name)	Signature	Position	Date
[Redacted]	[Redacted]		21-Aug-2023

RA log – Risk Assessment

Appendix H

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ABN: 91 636 315 109

## Appendix I

### Training records

#### Elevated Extracts Education & Training Quiz

Topic: Advertising guidance for businesses involved in medicinal cannabis products, v1.0 Oct 2019

Document owner: s22  
Date effective: 23-Aug-2023  
Version: v1.0

Resources:

1. Advertising guidance for businesses involved in medicinal cannabis products, v1.0 Oct 2019
2. Elevated Extracts in-house summary guide to 'CAN'T' do & CAN do' for advertising and promotion.
3. This document – education & training quiz

Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



## QUIZ QUESTIONS

STAFF NAME:

s22

DATE:

29/08/23

1. Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian Law does not allow distributors to talk to patients.
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care.
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

\*\* ANSWERS on next page \*\*



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AUSTRALIA  
ABN: 91 636 315 109

---

#### ANSWERS

**1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.

**2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.

**3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.

**4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.

**5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

NOTE – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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**Form – Training Form**

Source document: SOP-005-00 Training  
 Document copyright:

Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv/2019 v1.0	1. Advertising guidance for businesses to advertise medicinal cannabis products v1.0 (Oct 2019) 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 29/08/23	s22 29-Aug - 2023	Pass

Quality review by	Name: s22	Signature: s22	Date: 23-Aug-2023
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ABN: 91 636 315 109

### Form – Training Form

Source document: SOP-005-00 Training

Document copyright

#### Document Approvals

Approved by	Signature	Position	Date
<small>Author – Confirming the technical content of this document</small>			
s22			23-Aug-2023
<small>Deputy Director – Confirming the technical content of this document</small>			
s22			23-Aug-2023
<small>Quality – Confirming compliance of this document with the Quality System and/or Regulatory Compliance</small>			
s22			23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025



## Form – Training Form

Source document: SOP-005-00 Training

Document copyright

DOCUMENT END

### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-03\_Form Template (Landscape)\_r01



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ABN: 91 636 315 109

## Elevated Extracts Education & Training Quiz

Topic: Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019

Document owner: s22  
Date effective: 23 Aug 2023  
Version: v1.0

### Resources:

1. Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



## QUIZ QUESTIONS

STAFF NAME:

s22

DATE: 30-8-23

1. Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian law does not allow distributors to talk to patients.
  
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
  
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
  
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
  
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care.
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

\*\* ANSWERS on next page \*\*



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Pinkenba, QLD 4008  
AUSTRALIA  
ABN: 91 636 315 109

---

#### **ANSWERS**

- 1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
- 2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
- 3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
- 4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
- 5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

**NOTE** – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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**Form – Training Form**

Source document: SOP-005-00 Training  
 Document copyright

**Document Approvals**

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document	<b>s22</b>		23-Aug-2023
Document Owner – Confirming the technical content of this document	<b>s22</b>		23-Aug-2023
Quality – Confirming compliance of this document with the Quality System and/or Regulatory Compliance	<b>s22</b>		23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025

**Form – Training Form**

Source document: SOP-005-00 Training  
 Document copyright

Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv2019 v1.0	1. Advertising guidance for businesses involved in medicinal products, v1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	<b>s22</b>	<b>s22</b> 30-08-2023	Pass

Quality review by	Name: <b>s22</b>	Signature: <b>s22</b>	Date: 23-Aug-2023
-------------------	------------------	-----------------------	-------------------



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AUSTRALIA  
ABN: 91 636 315 109

**Form – Training Form**

Source document: SOP-005-00 Training

Document copyright

---

DOCUMENT END

**Change History**

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-05\_Form Template (Landscape)\_01



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AUSTRALIA  
ABN: 91 636 315 109

## Elevated Extracts Education & Training Quiz

Topic: [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)

Document owner: s22  
Date effective: 23-Aug-2023  
Version: v1.0

### Resources:

1. [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***





## QUIZ QUESTIONS

STAFF NAME:

s22

DATE:

30/8/23

1. Naturally Elevated (NE) and its companies can talk to ~~the~~ general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian Law does not allow distributors to talk to patients.
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care.
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

\*\* ANSWERS on next page \*\*



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Pinkenba, QLD 4008  
AUSTRALIA  
ABN: 91 636 315 109

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#### **ANSWERS**

- 1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
- 2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
- 3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
- 4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
- 5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

NOTE – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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### Form – Training Form

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Approved by	Signature	Position	Date
<small>Author – Confirms the technical content of this document</small>			
s22			23-Aug-2023
<small>Approved/Checked – Confirms the technical content of this document</small>			
s22			23-Aug-2023
<small>Valid – Confirms accordance of this document with the Health, Safety and/or Regulatory Legislation</small>			
s22			23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025



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Source document: SOP-005-00 Training  
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Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv2019 v1.0	1. Advertising guidance for businesses involved in medical cannabis products v1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules. 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 30/8/23	s22 30-08-2023	Pass

Quality review by	Name: s22	Signature: s22	Date: 23-Aug-2023
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#### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-05\_Form Template (Landscape)\_r01



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## Elevated Extracts Education & Training Quiz

Topic: [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)

Document owner: s22  
Date effective: 23-Aug-2023  
Version: v1.0

### Resources:

1. [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



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 ABN: 91 636 315 109

## QUIZ QUESTIONS

STAFF NAME: **s22** DATE: 28-AUG-2023

1. Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian Law does not allow distributors to talk to patients.
  
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
  
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
  
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
  
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care.
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

•• ANSWERS on next page ••



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---

#### ANSWERS

1. **b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
2. **d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
3. **c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
4. **b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
5. **c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

NOTE – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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Approved by	Signature	Position	Date
	<b>s22</b>		23-Aug-2023
	<b>s22</b>		23-Aug-2023
	<b>s22</b>		23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025



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Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv2019 v1.0	1. Advertising guidance for businesses involved in medicinal cannabis products, v1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 28-AUG-2023	s22 28-AUG-2023	Pass

Quality review by	Name: s22	Signature: s22	Date: 23-Aug-2023
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Source document: SOP-005-00 Training

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**Change History**

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-05\_Form Template (Landscape)\_01



## Elevated Extracts Education & Training Quiz

Topic: [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)

Document owner: **s22**  
Date effective: 23-Aug-2023  
Version: v1.0

### Resources:

1. [Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019](#)
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



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## QUIZ QUESTIONS

STAFF NAME

s22

DATE: 20/9/23

1. Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian Law does not allow distributors to talk to patients.
  
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
  
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
  
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
  
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

\*\* ANSWERS on next page \*\*



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---

#### **ANSWERS**

- 1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
- 2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
- 3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
- 4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
- 5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

**NOTE** – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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**Form – Training Form**

Source document: SOP-005-00 Training

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Approved by	Signature	Position	Date
Author – Confirms the technical content of this document			
s22	[Redacted]		23-Aug-2023
Document Owner – Confirms the technical content of this document			
s22	[Redacted]		23-Aug-2023
Quality – Confirms compliance of this document with the Quality System and/or Regulatory Conditions			
s22	[Redacted]		23-Aug-2023
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Source document: SOP005-00 Training  
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Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (eg. PASS)
TGA-adv2019 v1.0	1. Advertising guidance for businesses involved in medicinal cannabis products, v1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 30-8-23	s22 30-08-2023	Pass

Quality review by Name: s22 Signature: s22 Date: 23-Aug-2023





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**Change History**

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-05\_Form Template (Landscape)\_r01



## Elevated Extracts Education & Training Quiz

Topic: Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019

Document owner: **S22**  
Date effective: 23-Aug-2023  
Version: v1.0

### Resources:

1. Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



## QUIZ QUESTIONS

STAFF NAME:

s22

DATE:

29/8/23

- Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - No – because the Australian Law does not allow distributors to talk to patients.
- If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - \$100 + no jail
  - \$1,000 + 1 month jail
  - \$10,000 + 1 year jail
  - \$1,000,000 + 5 years jail
- The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
- A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - TRUE – because all ON-SCHEDULE staff are ANPRA registered healthcare professionals.
  - FALSE – because distributors cannot talk to patients about their medicines.
- The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - TRUE – because EE has a duty of care to provide the best possible care.
  - TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

\*\* ANSWERS on next page \*\*



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---

#### **ANSWERS**

- 1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
  - 2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
  - 3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
  - 4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
  - 5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.
- NOTE – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

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**Form – Training Form**

Source document: SOP-005-00 Training

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Approved by	Signature	Position	Date
Author – Confirms the technical content of this document	s22		23-Aug-2023
Local/Plant Manager – Confirms the technical content of this document	s22		23-Aug-2023
Health & Compliance representative of this equipment with the Quality System and the Business Processes	s22		23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025

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Source document: SOP-005-00 Training

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Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv2019 v1.0	1. Advertising guidance for businesses involved in medical cannabis products v 1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 21/2/23	s22 21/2/23	Pass

Quality review by	Name: s22	Signature: s22	Date: 23-Aug-2023
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#### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-05\_Form Template (Landscape)\_01



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## Elevated Extracts Education & Training Quiz

Topic: Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019

Document owner: s22  
Date effective: 23-Aug-2023  
Version: v1.0

### Resources:

1. Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019
2. Elevated Extracts in-house summary guide to 'CAN'T do & CAN do' for advertising and promotion.
3. This document – education & training quiz

### Instructions:

1. Resources to be read as part of education and training.
2. Trainee to complete quiz.
3. Trainee to complete training record – available from Quality & Regulatory Compliance Officer.
4. Trainer to complete training record.

**\*\* Quiz questions follow on next page \*\***



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## QUIZ QUESTIONS

STAFF NAME: **s22**DATE: 29/2/23

1. Naturally Elevated (NE) and its companies can talk to the general public about medicinal cannabis for the purposes of general education?
  - a. Yes – because NE is qualified to talk about its stocked medicinal cannabis brand products in detail to anyone.
  - b. Yes – because NE can provide supportive education, as long as they don't talk about any specific products that may influence patient choice by advertising or promotion.
  - c. No – because they are not registered doctors and only doctors can talk to patients about medicinal cannabis.
  - d. No – because the Australian Law does not allow distributors to talk to patients.
2. If NE is alleged to be in breach of TGA advertising rules, the penalty can be in the region of approximately:
  - a. \$100 + no jail
  - b. \$1,000 + 1 month jail
  - c. \$10,000 + 1 year jail
  - d. \$1,000,000 + 5 years jail
3. The TGA does not welcome distributors of medicines to ask for guidance on medicinal cannabis advertising and promotion.
  - a. TRUE – because the TGA is a Government organisation whose role it is to collect money from fines.
  - b. TRUE – because the TGA is busy focussing on helping pharmaceutical companies with high risk medicines management like chemotherapy and antibiotics.
  - c. FALSE – because the TGA role is to ensure all companies working in the medicinal cannabis industry has support to ensure medicines product quality, clinical efficacy and patient safety.
  - d. FALSE – because the TGA does not see the importance of distributors in the medicinal cannabis supply chain.
4. A patient who has a prescription for a medicinal cannabis product calls ON-SCHEDULE for advice on how to get the prescription filled and the expiry date of stock in the warehouse. The ON-SCHEDULE staff can talk to the patient and answer the questions about that specific product.
  - a. TRUE – because the TGA sees ON-SCHEDULE staff as experts in medicinal cannabis therapy.
  - b. TRUE – because the TGA allows ON-SCHEDULE staff to talk to patients that have been prescribed a product stocked by ON-SCHEDULE.
  - c. TRUE – because all ON-SCHEDULE staff are AHPRA registered healthcare professionals.
  - d. FALSE – because distributors cannot talk to patients about their medicines.
5. The Elevated Extracts (EE) website can include information on stocked products by brand name, form (e.g. flower, oil, vapes), price, quality statement of "TGA approved" and pricing to help the patient make the best informed decision.
  - a. TRUE – because EE has a duty of care to provide the best possible care.
  - b. TRUE – because the TGA welcomes help in educating the public about medicinal cannabis.
  - c. FALSE – because the Therapeutic Goods Act 1989 does not allow unapproved medicines to be advertised or promoted to the public.
  - d. FALSE – because only doctors, nurses and pharmacists websites can advertise and promote unapproved medicines directly to the public.

**\*\* ANSWERS on next page \*\***





**Naturally Elevated Pty Ltd**  
67 Bancroft Rd  
Pinkenba, QLD 4008  
AUSTRALIA  
ABN: 91 636 315 109

---

#### **ANSWERS**

- 1. b** – because it’s OK to talk in general without specifically mentioning branded products for advertising or promoting.
- 2. d** – fines can be close to \$1,000,000 or higher and may include a 5 year jail sentence.
- 3. c** – because the TGA role is to ensure product quality, clinical efficacy and patient safety across the supply chain for all medicines, including medicinal cannabis.
- 4. b** – because the (i) patient has been already prescribed the product, (ii) the questions don’t influence the patient’s choice of therapy through illegal advertising and promotion, and (iii) the questions won’t affect the clinical outcome for the patient.
- 5. c** – because no Schedule 4 Prescription Only Medicines and no Schedule 8 Controlled Drugs – including unapproved medicines – cannot be advertised or promoted to the public by law. This will influence the patients choice. The choice of therapy is a decision for the prescribing doctor and patient to decide together. However, if an AHPRA registered healthcare professional (e.g. doctor, nurse, pharmacist) asks questions about specific products stocked by the group of Naturally Elevated (NE) companies – then the NE staff can talk openly about stocked products with the healthcare professional – including products by brand name, form (e.g. flower, oil, vapes), price, and quality.

**NOTE** – the TGA does not “approve” medicines for use. Medicines are either “Registered on the ARTG” or are “unapproved”. Never use the term “TGA approved”.

DOCUMENT END

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Naturally Elevated Pty Ltd  
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 Pinkenba, QLD 4008  
 AUSTRALIA  
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**Form – Training Form**

Source document: SOP-005-00 Training

Document copyright

**Document Approvals**

Approved by	Signature	Position	Date
Author – Confirms the technical content of this document	s22		23-Aug-2023
Document Owner – Verifies the technical content of this document	s22		23-Aug-2023
Director – Confirms compliance of this document with the Health System public regulatory standards	s22		23-Aug-2023
Effective Date	23-Aug-2023	Review Date	01-Aug-2025

**Form – Training Form**

Source document: SOP-005-00 Training

Document copyright

Document ID & version	Document Title / Subject of Training	Type of Training (tick boxes)	Trainee (sign & date)	Trainer (sign & date)	Comments (e.g. PASS)
TGA-adv/2019 v1.0	1. Advertising guidance for businesses involved in medicinal cannabis products; v1.0 Oct 2019 2. In-house summary TGA advertising & promotion rules 3. In-house quiz to assess learning	<input checked="" type="checkbox"/> Read & understand <input checked="" type="checkbox"/> On the job <input checked="" type="checkbox"/> Quiz completed	s22 21/8/23	s22 21/8/23	Pass

Quality review by	Name: s22	Signature: s22	Date: 23-Aug-2023
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### Form – Training Form

Source document: SOP-005-00 Training

Document copyright

DOCUMENT END

#### Change History

Version Number	Date	Change Number	Description of Changes
01	Mar 2023	N/A	New document.

Template reference: TMP-003-03\_Form Template (Landscape)\_r01



**Naturally Elevated Pty Ltd**  
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AUSTRALIA  
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Appendix J

Letter from TGA Reference: AC-000000014762



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22

Naturally Elevated Pty Ltd  
ACN 636 315 109  
Unit 19 67 Bancroft Road  
PINKENBA QLD 4008

Email and express post: [s22@elevatedextracts.com.au](mailto:s22@elevatedextracts.com.au)

Our Reference: AC-000000014762

10 August 2023

Dear s22

Opportunity to provide submissions as to why regulatory action should not be taken in relation to the alleged unlawful advertising of therapeutic goods

1. The Therapeutic Goods Administration (TGA) has previously written to your business, Naturally Elevated Pty Ltd (Naturally Elevated) in relation to the alleged unlawful advertising of therapeutic goods, specifically medicinal cannabis products.
2. Our previous correspondence provided you with notice of the TGA's concerns about the advertising of medicinal cannabis products and provided education on some of the relevant regulatory requirements in relation to the advertising of therapeutic goods with reference to the civil penalty and criminal offence provisions and relevant legislation.
3. Consistent with [how we manage advertising compliance](#) and the information found at [compliance actions and outcomes](#), an escalation of regulatory action is being considered, relevantly because 'the alleged breach is such that there is a likely impact on the consumers' ability to use therapeutic goods safely or appropriately'.
4. The TGA's previous correspondence concerned the advertising of therapeutic goods, so an escalation of regulatory action in relation to your advertising of medicinal cannabis products is now appropriate.
5. The purpose of this letter is to provide Naturally Elevated with an opportunity to make submissions before a decision is made about whether escalated enforcement action should be taken in relation to alleged unlawful advertising which appeared on online platforms for which Naturally Elevated appears to be responsible.



**Naturally Elevated Pty Ltd**  
 67 Bancroft Rd  
 Pinkenba, QLD 4008  
 AUSTRALIA  
 ABN: 91 636 315 109

6. You are welcome to make submissions as to why regulatory action should not be taken and can do so by 12 noon on Thursday, 31 August 2023.

#### Action required

- Confirm receipt of this letter by Monday 14 August 2023.
- Carefully consider the information provided below.
- Provide your submission to the TGA by 12 noon on Thursday 31 August 2023 as to why regulatory action should not be taken in relation to the non-compliant advertising on the online platforms set out below.

#### Notice of intention to take enforcement action

7. The TGA is considering whether escalated enforcement action should be taken in relation to alleged unlawful advertising which appeared on the Naturally Elevated, Canwell Pty Ltd and/or Farma Group online platforms (including websites and social media pages), for which Naturally Elevated appears to be responsible.
8. The websites of concern include:
  - a. the website at <https://elevatedextracts.com.au/>
  - b. the website at <https://farmagroup.com.au/>
  - c. the website at <https://canwell.com.au/>
 (collectively, the Websites).
9. The social media pages of concern include:
  - a. the Instagram account on <https://www.instagram.com/canwellaustralia/>, and
  - b. the Facebook account on <https://www.facebook.com/canwellaustralia/>
 (collectively, the Social Media pages).
10. The enforcement action being considered by the TGA may include:
  - a. giving you infringement notices under section 42YK of the *Therapeutic Goods Act 1989* (the Act) as an alternative to court action, or
  - b. preparing the matter for court either under section 42Y of the Act, or by preparing a brief to the Commonwealth Director of Public Prosecutions.
11. The enforcement action being considered may not be limited to the examples provided in this letter, and may extend to any other unlawful advertising of any kind.
12. Naturally Elevated's submissions will be taken into account by a delegate of the Secretary of the Australian Government Department of Health and Aged Care before a decision is made.
13. Please note that information about any compliance action taken against Naturally Elevated may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

#### Advertising therapeutic goods

14. Under the Act, a person who advertises or causes the advertising of therapeutic goods on certain circumstances may be liable for criminal sanctions (s 42DL of the Act)



and/or civil penalties (s 42DLB(1) of the Act). These circumstances include where the advertisement:

- a. contains a prohibited representation, being a reference to a particular condition like mental illnesses, such as depression and anxiety, and no TGA approval has been given.<sup>1</sup>
- b. contains a restricted representation, being a reference to a to a serious form of a disease, condition, ailment or defect, such as Multiple Sclerosis and epilepsy, and no TGA approval has been given.<sup>2</sup>
- c. refers to substances, or therapeutic goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabis or cannabidiol, and no exception applies.
- d. contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by a government, such as 'TGA approved'.<sup>3</sup>

#### Summary of alleged contraventions

15. We identified prohibited representations, restricted representations, references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard, and representations about government approvals, on the Websites and the Social Media pages which we allege contravene the advertising provisions in the Act.
16. Specifically, we allege that the Websites contained:
  - *prohibited and/or restricted representations* - statements which refer to specific serious medical conditions such as Chron's Disease, Parkinson's Disease, Restless Leg Syndrome, Epilepsy, Multiple Sclerosis, Anorexia, Autism, Cerebral Palsy, and Endometriosis.
  - *representations about government approvals* - statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government or government authority, such as the statement made that Naturally Elevated trading as Elevated Extract products "[...] conform with the Therapeutic Goods 'Standard for Medicinal Cannabis' (TGO 93) Order 2017'.
  - *references to substances included in Schedule 3, 4 or 8 of the current Poisons Standard* - statements which promote the supply of medicinal cannabis products by stating "World-Class Medicinal Cannabis oils, isolates and tinctures that are ethically sourced and fairly priced."
17. In addition, we allege that the advertisements on the Social Media pages referred to serious medical conditions, such as Anxiety, PTSD and Cancer (*prohibited representations*).

---

<sup>1</sup> See subsection 42DLB(1) of the Act, where subsection 42DLB(2) applies; and subsection 42DL(1) of the Act where subsection 42DL(5) applies.

<sup>2</sup> See subsection 42DLB(1) of the Act, where subsection 42DLB(4) applies; and subsection 42DL(1) of the Act, where subsection 42DL(7) applies.

<sup>3</sup> See subsection 42DLB(1) of the Act where subsection 42DLB(6) applies; and subsection 42DL(1) of the Act where subsection 42DL(9) applies.



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AUSTRALIA  
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#### Important Information

18. The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. Please read the [TGA guidance](#) on therapeutic goods advertising.
19. Contraventions of the advertising requirements under the Act and the Advertising Code can result in criminal penalties of up to \$1.1 million or imprisonment for individuals, or \$5.5 million for corporations, or civil penalties of up to \$1.375 million for individuals or \$13.75 million for corporations. An entity who aids, abets, counsels, procures or induces another person (i.e. by providing incentives) to contravene the Act may also be liable under the Act.<sup>4</sup>
20. A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
21. It is strongly recommended that you seek independent legal advice or the assistance of a regulatory affairs consultant to help you to comply with your regulatory obligations while you operate in the therapeutic goods space, and to respond to this letter. Please refer to the TGA's website at <http://www.tga.gov.au/regulatory-affairs-consultants> for information about regulatory consultants.
22. Naturally Elevated may also wish to refer to the following guidance provided by the TGA for [Advertising guidance for businesses involved in medicinal cannabis products](#)

Please contact **s22** by email at [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au) or phone **s22** if you wish to discuss this matter further.

Yours sincerely

**s22**

**s22**

**s22**

Advertising and Product Investigations Section  
Regulatory Compliance Branch  
Therapeutic Goods Administration

---

<sup>4</sup> Section 42YC of the Act.



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Appendix K
Draft edits of web pages

Table with 2 columns: Draft edits of web pages and a right-hand column containing redaction codes (s47G(1)(a), s22) and formatting instructions (Formatted: Font: 14 pt, Bold). The main text includes a review date of 26-Aug-2023, a review by section, and a table of contents.





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s47G(1)(a)

s47G(1)(a)

#EqualAccess Roadmap

In our mission to provide equal access to all Australians in need of medicinal cannabis, we have subscribed to three guiding principles:

- 1. "Affordable" Products: The first step to true #EqualAccess is more affordable pricing.
2. Quality: Medicinal cannabis products must meet strict quality standards enforced under Australian law. This gives product quality assurance to doctors, patients, regulators and the industry.
3. Education and Support: Through a growing amount of evidence-based literature, the world is quickly understanding the potential benefits of medicinal cannabis for patients with unmet clinical needs. Contact us at Elevated Extracts for education resources about medicinal cannabis. We can help guide you through the process to access medicinal cannabis from a prescribing doctor and dispensing pharmacy.

\*\*DELETE IMAGE\*\* ILLEGAL

No images of oil, leaf, flower, plant, seeds allowed. TGA sees as advertising and promotion.



s47G(1)(a)

s22

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s22

Deleted: = partly between the black market and the Australian medical/pharmaceutical industry.

s22

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s22

Deleted: Price is NOT an indication of quality when it comes to Plant Medicine. The good news is that the highly regulated Australian market ensures all domestic products are of sound quality. Being Australian owned and operated, Elevated Extracts

s22

Deleted: is able to offer unrivalled prices on flowers, oils & APs that are GMP(TG 5) compliant (highest global standard) and derived from the most popular, resin and cannabinoid/terpene rich strains available.

s22

Deleted: Support Culture

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Deleted: both medically and recreationally

s22

Deleted: ushering in a mainstream acceptable of the responsible use of the products.

s22

Deleted: That said, Australia still has some way to go in educating everyday citizens as to the benefits of the Plant Medicine, thus breaking down any stigmas associated to the plant. Elevated Extracts is working with leading politicians, athletes, artists and researchers assist in bringing the domestic industry into the 21st century.

Comment threads on the right side of the page, including text like 'Use words to make your claims vague. Don't be specific.' and 'Edit as needed + add weblink'.



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s47G(1)(a)

s47G(1)(a)

### How to access Plant Based Medicines



#### Confirm Eligibility

Your prescribing doctor will discuss treatment options with you to help decide if medicinal cannabis is right for you. Your doctor may need to apply for regulatory approval. This is a quick process. Check if you're eligible here.



#### Book With A Doctor

If approved, your doctor will write a prescription for your treatment. Your doctor will then be able to send your approval and prescription to a pharmacy or can order your prescribed product.



#### Monitor Your treatment

It is important to check in regularly with your doctor to discuss whether medicinal cannabis is working for you, or if you are experiencing any side effects. Your doctor with your support, can manage dosing and choice of medicines.

END of WEBPAGE

s47G(1)(a)

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s22

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s47G(1)(a)

s47G(1)(a)

<https://on-schedule.au/>



### Plant Based Medicines

Medicinal Cannabis made easy. We work exclusively with Licensed Producers to ensure regulatory compliance, delivered on time, and without any hidden costs.

[View Range](#)

### Over-the-Counter

From [cannabis hardware] such as vapes, grinders and the innovative Zenco range, through to consumables including FijiKava and Hemp Oz, our Over-The-Counter range may support beneficial outcomes.

[Explore OTC](#)

### Nicotine

We've partnered with Hoosh to provide the safest, child-resistant, and reusable aluminium nicotine vaporizers and their accompanying pods. Help your patients move off cigarettes, ethically.

[Learn More](#)

s47G(1)(a)

s22

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Deleted: is sure to surprise and delight your customers.

s22

Considerations:  
1. Avoid nicotine vapes - unless TGA registered??  
2. TGA will check if hardware is TGA ARTG included medical device. Big fines apply if non-compliant.

Reply

s22

This page looks OK

Reply

s22

Check hardware is TGA ARTG included as a medical device. Big fines apply for non-compliance. Avoid promotion to save TGA fines.

Reply

s22

This page looks OK



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s47G(1)(a)

s47G(1)(a)

https://naturallyelevated.com.au/register/

Register

Thank you for registering interest in our site. We will contact you shortly and update you shortly.

© 2020-2021 Naturally Elevated. All rights reserved.

Register

Registration form fields including Name, Email, and Phone.



Hmmm... can't reach this page

It seems like you're having trouble reaching this page.

By:

- Checking the connection
Checking the proxy and firewall
Refreshing the browser page

Still having trouble?

Close

Register

Thank you for registering interest in our site. We will contact you shortly and update you shortly.

© 2020-2021 Naturally Elevated. All rights reserved.

END of WEBPAGE

s47G(1)(a)

Unknown Field Code Changed

s22

Patients register worked. Make sure controls in place to 100% assure that patient is prescribed an EE product. EE can talk openly to patients who have been prescribed an EE product. EE must have evidence that patient has been prescribed an EE product.

Reply

s22

Pharmacist registration page didn't work 26-Aug-2023

Reply

s22

EE only used by EE ONLY

Reply

s22

Terminated: Header Top (No border)



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s47G(1)(a)

s47G(1)(a)

https://elevatedextracts.com.au/international-export/

Elevated Exports

PROVIDING GLOBAL ACCESS TO ETHICALLY SOURCED AND FAIRLY PRICED PLANT BASED MEDICINES

Elevated Extracts have secured preferential partnerships with the longest standing, most technically advanced manufacturers of medicinal cannabis in Australia and around the world.

As such, we have the ability to offer medical cannabis products and excellent customer service with passion and support for patients, carers, doctors, nurses, pharmacists and other healthcare professionals.

If you are a patient, please speak to your doctor about medicinal cannabis options.

We welcome your doctor to contact us to discuss our range of medicinal cannabis products.

Elevated Extracts will work with your healthcare providers to deliver your medicinal cannabis products to you. Please forward all enquiries to hello@elevatedextracts.com.au

\*\*DELETE IMAGE\*\* ILLEGAL

No images of oil, leaf, flower, plant, seeds allowed. TGA sees as advertising and promotion.



END of WEBSITE

s22

Deleted: HIGH QUALITY

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White Labeled Bulk Whole Flower, Oil, Capsules & Tinctures.-)

s22

The Elevated Extract Range with localised labeling/ Regional Exclusivity Available

s22

Deleted: The Elevated Extract Range with localised labeling/ Regional Exclusivity Available

s22

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s22

Re-enforce this 'call to action' throughout the website

Reply

s22

Re-enforce this 'call to action' throughout the website

Reply

s47G(1)(a)



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s47G(1)(a)

s47G(1)(a)

https://elevatedextracts.com.au/

What We're All About

We are on a mission to provide affordable plant based medicines, such as medicinal cannabis for Australian patients. Patients are encouraged to speak to their doctor to check if medicinal cannabis is a suitable choice. Elevated Extracts is leveraging unparalleled partnerships and a global network to provide more affordable medicinal cannabis products to patients in need.

What is Plant Medicine?

Plant Based Medicine, includes medicinal cannabis and is prescribed by a doctor to relieve the symptoms of a medical condition, where other therapies have been insufficient. Medicinal cannabis can be used for a range of medical conditions. Speak to your doctor to check if medicinal cannabis is the right choice for you.

It is essential that medicinal cannabis is obtained via a doctor's prescription and dispensed from a pharmacy.

s22

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s22

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s22

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Deleted: such as anxiety, insomnia, nausea, chronic pain or epilepsy.

s22

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s22

Deleted: or via a reputable

s22

Deleted: to avoid unknown concentrations of cannabinoids and potentially harmful impurities (such as bacteria and mould) that can be found in black market products.

s22

OK to mention medicinal cannabis, if not in the heading. Talk in general terms about MC. Don't talk about EE products.

Reply

s22

Avoid word, implies some pharmacies are not reputable.

Reply

s47G(1)(a)



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s47G(1)(a)

s47G(1)(a)



**Our clients benefit from:**

- A fully licensed warehouse network that exceeds all state regulatory standards to store Schedule 4 & 8 medicines.
- A reliable logistics company that will ensure your corporate clients will receive your goods on time and to your specifications.
- A fulfillment centre for your high-volume direct-to-consumer business.

Our On-Schedule team are on hand to make every process more streamlined and affordable, all while amplifying your sales message with tailored marketing.

s47G(1)(a)

s22

Deleted: [redacted]

s22  
This is OK

Reply



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s47G(1)(a)

s47G(1)(a)

[Get Started](#)

### Services

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[Market Insights](#)  
[Logistics](#)

### Products

[Medicinal Cannabis](#)  
[Nicotine Vapes](#)  
[Full Catalogue](#)

### Company

[About](#)  
[Contact](#)



END of WEBPAGE

<https://farmagroup.com.au/>



Hmmm... can't reach this page

[farmagroup.com.au](https://farmagroup.com.au/) failed to connect.

Try:

- Check the connection
- Check the address for errors

or contact your provider

[Refresh](#)

[Cancel](#)

END of WEBPAGE

s47G(1)(a)





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## Appendix L.

### Elevated Extracts in-house checklist of advertising "CAN'T do and CAN do"

#### Medicinal Cannabis Advertising & Promotion in Australia

##### What a business or advocate CAN'T do & CAN do

*"Advertising medicinal cannabis to the public is prohibited" by law <sup>1,2</sup>*

#### DEFINITIONS

**advertising** is any statement, picture design, product label or package or any other material including media published that is intended to promote the use or supply of medicinal cannabis. Advertising is based on how the 'reasonable consumer' views the content being promoted – it is not the subjective intention of the publisher. This is how the TGA decides and fines advertising breaches.

**media** includes, TV radio, posters, displays, websites, emails, blogs, discussion forum, social media, workshops and education sessions to the public.

#### ROLES & RESPONSIBILITIES

TGA controls who can advertise to the public and AHPRA registered healthcare professionals.

ODC controls security under licence and permit for cultivation, manufacture, research, imports & exports.

State & Territory Department of Health controls health & safety by supplying licences to operate.

AHPRA & State Health Ombudsman regulates health services including the advertising of health services under s133 of the Health Practitioner Regulation National Law.

Business must comply with the TGA advertising code or risk heavy fines in \$100k's.

#### CAN'T do

✗ to public - no advertising allowed in any way of any substances contained in Schedule 3, 4 or 8 of the Poisons Standards<sup>1,2,3,4</sup> including pictures or pictorial representations of finished products, bulk flower or the cannabis plant.

✗ to public - no promotion of medicinal cannabis, and medicinal cannabis brands or products, including any statements that may promote the use or supply of an unapproved therapeutic good.

Broadly, the TGA considers the use of the phrase "medicinal cannabis" displayed prominently in published material to constitute the promotion of unapproved therapeutic goods, as well as statements that direct the reader to a means of accessing medicinal cannabis or material that contains testimonials about the benefits of using medicinal cannabis to treat serious medical conditions.

✗ to public – company or business name, trading name, product name, abbreviation, acronyms, colloquial names or any other reference that will make the public think of medicinal cannabis in any way will likely be considered a breach.

✗ to public – a business name or product name must not make people think of medicinal cannabis, including abbreviation, acronym, colloquial name, images or any other way that will make the public think of medicinal cannabis.

✗ to public – no website content, including link to external site that promotes the use or supply of medicinal cannabis.

✗ to public – a patient support group can't promote or encourage members to seek medicinal cannabis.

✗ to public – cannot make any superlative statements with respect to the quality of an unapproved therapeutic good (i.e. highest quality, finest grown, etc.).

✗ to public - cannot make any representations in relation to the use of medicinal cannabis to treat any specific indication or condition.<sup>5,6</sup>

✗ to public – cannot make any representation implying that the therapeutic goods have been recommended or approved by or on behalf of any Government Agency.<sup>7</sup> (e.g. TGA, or TGA approved prescribers).

✗ to public – cannot provide any specific details about a medicinal cannabis product, including educational materials, until such time as the individual receiving the materials is qualified as a patient accessing that specific product.

original: 14-Aug-2023  
 review: 01-Aug-2026



CAN do

- ✓ OK to promote health services involving medicinal cannabis e.g. "talk to your doctor about plant based medicines".
- ✓ OK to advertise exclusively to AHPRA registered health professionals after those AHPRA professionals have registered via your website or alternative registration method e.g. doctor, nurse, pharmacist, physio, subject to the material being educational material with respect to the medicine.
- ✓ OK if factual and balanced statement about medicinal cannabis that does not promote the use or supply<sup>1</sup>. 'Factual' information is published in medical journal articles, or genuine news.
- ✓ OK to refer to medicinal cannabis products in general terms in the context of general information about a range of other treatments.
- ✓ OK if information does not emphasise benefits of medicinal cannabis over other treatments.
- ✓ OK if patient support group circulates full 'factual' information about medicinal cannabis to its members, about 'possible' benefits and 'possible' side effects – and told 'talk to your doctor about the treatment options'.

REFERENCES

1. ss 42DL(10); Therapeutic Goods Act 1989
2. ss 42DL(12); Therapeutic Goods Act 1989
3. Australian Regulatory Guidelines for Advertising Therapeutic Goods, ARGATG
4. Advertising guidance for businesses involved with medicinal cannabis products - Complying with therapeutic goods advertising requirements, Therapeutic Goods Administration, Version 1.0, October 2019.
5. Part 8, Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021
6. Part 1, Schedule 2, Therapeutic Goods Regulations 1990
7. ss 42DLB(6); Therapeutic Goods Act 1989

DOCUMENT END

DOCUMENT END

**From:** [Advertising Compliance](#)  
**To:** s22 @naturallyelevated.com.au  
**Bcc:** s22  
**Subject:** IMPORTANT: Letter and infringement notices from the Therapeutic Goods Administration to s22  
- AC-000000014762  
**Date:** Monday, 18 September 2023 3:23:00 PM  
**Attachments:** [image001.png](#)  
[Letter and Infringement notices from the Therapeutic Goods Administration to s22 dated 18 September 2023.pdf](#)  
**Importance:** High

---

Dear s22

Please find attached a letter and 2 infringement notices to s22 dated 18 September 2023.

We ask that you confirm receipt of our correspondence by **19 September 2023**.

Yours sincerely

s22

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Advertising and Product Investigation Section | Regulatory Compliance Branch  
Australian Government, Department of Health and Aged Care  
Therapeutic Goods Administration

Location: Level 2 North 27 Scherger Drive, Fairbairn 2600

Phone: s22

PO Box 100, Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au)

*The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error, please notify the author immediately and delete all copies of this transmission.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22

s22

Our Reference: AC-000000014762

By Express Post and by e-mail:

s22@naturallyelevated.com.au

18 September 2023

Dear s22

Infringement notices given to s22

Infringement notice	Amount	Payment due by
TGAIN- AC-000000014762/2023-9	\$3,300	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-10	\$3,300	<b>16 October 2023</b>

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**Total                    \$6,600**

1. I refer to our previous correspondence in this matter, including our letters to Naturally Elevated Pty Ltd (Naturally Elevated) dated 16 March 2023, 26 May 2023 and 10 August 2023, and Naturally Elevated's submissions dated 31 August 2023.
2. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
3. I have decided to give 2 infringement notices to s22 (you) under Part 5A-2 of the Act on the basis that I reasonably believe that you contravened subsection 42DLB(1) of the Act, where subsections (2) and (7) applied. The infringement notices are enclosed with this letter. It is important that you carefully read the infringement notices and the information contained in them.
4. Infringement notices are an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in each notice. If you decide not to pay the infringement notices, court proceedings may be brought against you.
5. You should be aware that the maximum civil penalty that a court can impose on an individual for a single contravention of subsection 42DLB(1) of the Act is 5,000 penalty units. For the alleged contraventions described in the notices, this amounts to \$1,375,000.
6. **Part D** of each of the infringement notices includes information on how to pay the penalty amount, how to request an extension of the compliance period for payment of the infringement notices, or how to request that the infringement notices be withdrawn. If you wish to make any such request I recommend that you provide supporting documentation, which may include financial records.
7. For more information about infringement notices, please see the following resources on the Therapeutic Goods Administration's (TGA) website:
  - a. [Information about infringement notices](#)

- b. [Infringement notices issued by the Therapeutic Goods Administration](#).<sup>1</sup>

**Delegate comments**

8. While I am not required to provide reasons for giving you infringement notices under the Act, I offer the following comments to assist you to understand why I have decided to take this action.
9. The TGA is taking strong regulatory action to ensure compliance with the advertising requirements of the Act across the medicinal cannabis industry. In 2022-23, the TGA issued over 100 infringement notices (totalling over \$1 million) to medicinal cannabis entities, including clinics and individuals, for the alleged unlawful advertising of medicinal cannabis.<sup>2</sup>
10. The Court has stated that ignorance of, or inexperience with the requirements of the Act, is not an excuse for non-compliance.<sup>3</sup> It is your responsibility as someone who engages in a business involving the use of therapeutic goods and the provision of health services to be aware of and ensure that you comply with the Act.<sup>4</sup>
11. Naturally Elevated and you were first made aware of the advertising requirements under the Act on 16 March 2023. In our letter, Naturally Elevated was asked to review the advertising, and address any compliance issues, on all platforms for which Naturally Elevated is responsible, noting that the TGA reserved our rights in relation to any further non-compliance that we identified. I note that on 17 March 2023 you confirmed receipt of our letter.
12. Despite our guidance provided to Naturally Elevated, we have obtained evidence that the below Canwell platforms continued to advertise medicinal cannabis unlawfully from at least 16 March 2023 until mid-June 2023:
- a. <https://www.canwell.com.au/>
  - b. <https://www.instagram.com/canwellaustralia/>; and
  - c. <https://www.facebook.com/Canwell-Australia-109055414757594>.
13. Each day that a non-compliant advertisement remains visible may be a further contravention of the Act. More information about the alleged contraventions is outlined in the infringement notices.
14. We consider that you advertised medicinal cannabis or caused the advertisements described in the infringement notices for the following reasons:
- a. You are a director of Naturally Elevated.
  - b. In its response to a section 45AB notice issued to it on 26 May 2023, Naturally Elevated stated that you instructed all online publication and digital content on the Canwell platforms and you are responsible for the decision-making process relating to the approval of the publication on the Canwell platforms.
15. We identified over 40 contraventions of the advertising provisions across the Naturally Elevated platforms, including the above Canwell platforms. These potentially unlawful advertisements remained online for an extended period of time between March and June 2023, after we wrote to Naturally Elevated. In particular, we consider that the Canwell platforms promoted the use or

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<sup>1</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/non-compliance/compliance-and-enforcement-hub/compliance-actions-and-outcomes/information-about-infringement-notices> and <https://www.tga.gov.au/infringement-notices>.

<sup>2</sup> <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-news-and-updates>.

<sup>3</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865](#) at paragraph 76.

<sup>4</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518](#) at paragraph 251.

supply of medicinal cannabis, which is an unapproved prescription medicine, and contained a large number of prohibited and restricted representations made about medicinal cannabis.

16. Taking into account the alleged contraventions, Naturally Elevated's submissions dated 31 August 2023 and changes made to Canwell platforms since June 2023, I have decided to give you 2 infringement notices. I consider that giving you 2 infringement notices is an appropriate and proportionate enforcement response given the above factors.
17. While it remains open to me, I have not given you infringement notices for all alleged contraventions of the Act that we identified. This includes alleged contraventions which:
  - a. were subject to an infringement notice given to Naturally Elevated
  - b. occurred on the Elevated Extracts website and the Farma Group website<sup>5</sup>
  - c. arose from the use of the same restricted or prohibited representation on another social media post or page of the Canwell website, and
  - d. occurred on each day for which a non-compliant advertisement remained visible from 16 March to 19 June 2023.

**Additional steps you should take**

18. You should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter and accompanying notices are identified and resolved.
19. The TGA reserves its rights to take enforcement action in relation to any future non-compliance we identify, without further notice to you. As stated in our previous correspondence, we strongly recommend that you review all platforms for which you are responsible, including Naturally Elevated's Google Business Profile page, to ensure they do not promote a class of therapeutic good (such as prescription medicines) to avoid being liable for further contraventions of the Act. We also recommended you seek independent legal advice or the assistance of a regulatory affairs consultant to help you to comply with your regulatory obligations.
20. If you have any questions, please contact s22 by email at [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au) or phone s22.

Yours sincerely

A large black rectangular redaction box covering the signature of the official.A small black rectangular redaction box covering the name of the official.

Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration

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<sup>5</sup> <https://elevatedextracts.com.au/>, and <https://farmagroup.com.au/>.



## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

s22  
s22

By Express Post and By Email:

s22@naturallyelevated.com.au

#### Infringement Notice Number:

TGAIN-AC-000000014762/2023-9

Date given: 18/09/2023

Penalty total: \$3,300

Payment due: 16/10/2023

Enquiries: s22

Telephone: s22

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

#### INFRINGEMENT NOTICE GIVEN TO

s22

#### PART A: Infringement Notice given by

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to s22 under Part 5A-2 of the Act on the basis that I reasonably believe that s22 has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 28 April 2023, s22 did advertise, or caused the advertising of a therapeutic good, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabis, but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on an individual for a single contravention of section 42DLB(1) is 5,000 penalty units. For the above alleged contravention, this amounts to \$1,375,000.<sup>6</sup>

The amount payable under this notice is \$3,300. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
 Box 9848, Canberra ACT 2601**  
 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
 your notice by calling the  
 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-9 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-9 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

canwell.com.au

Canwell AUSTRALIA

How it works About Learn Our pricing [Book an appointment](#) Login

# Australia's most **convenient** medicinal cannabis service.

Consult with one of our doctors when convenient for you. [Book now](#)

The **only** all-in-one medicinal cannabis platform, that let lets you consult with a leading doctor and buy direct.

- ### 1. Book an appointment

Create your Canwell account and book an online appointment at a time that suits you.
- ### 2. See a doctor

Attend your consultation virtually using video or audio. We'll even send you reminders.
- ### 3. Buy direct

Order your prescription from within the Canwell platform for quick, discreet delivery.

## Why Canwell?

Australia's most convenient medicinal cannabis service, providing flexible access to Australian-based, AHPRA registered, licenced general practitioners, who are specifically trained in plant-based medicines. We deliver high quality, ethically sourced, and fairly priced medicinal cannabis products from Australian pharmacy partners direct to your door.

- Convenient**  
 Access flexible online appointments from anywhere and at any time.
- Fast discreet delivery**  
 Quick and discreet delivery if you're prescribed medicinal cannabis.
- Trusted**  
 Top Australian doctors specifically trained in plant-based medication.
- Access**  
 Access to leading ethically sourced medicinal cannabis products.
- Affordable**  
 Expert advice and access to the best medicinal cannabis products.
- 100% online**  
 Meet with your doctor from anywhere using video or audio.

[Get started](#) [Learn more about Canwell](#)

## See what others have to say

Excellent ★★★★★ 4.6 based on 468 reviews

- Claudia** ★★★★★

I was really impressed with the whole process! Having anxiety I was worried about the whole process of booking an appointment, talking to the Dr and purchasing my CBD oil! I feel reassured...

2 months ago
- Jason** ★★★★★

Great service, and nice to have a doctor that actually wants to hear, and to help a patient. Something that is rare in today's GP's

2 months ago
- Tracey** ★★★★★

Very understanding Dr.

2 months ago
- Ross** ★★★★★

Very informative and helpful. Gave me lots of options and suggestions, quick and easy service. Looking forward to see where this health journey goes.

2 months ago

REVIEWS

## Why consider medical cannabis?

A growing number of Australians are turning to medicinal cannabis to complement or often replace 'conventional' medicines.

Studies report that medical cannabis provides possible benefits for several conditions and is used to treat many symptoms, including pain, nausea, anxiety, and insomnia.

In addition, by helping to maintain homeostasis within the body, the Endocannabinoid System (ESC) and cannabis play a critical role in regulating immune response, mood, appetite, metabolism and memory.

[See if you're eligible](#)



## Medicinal cannabis can help with

Chronic Pain and Medicinal Cannabis

Auto Immune Diseases and Medicinal Cannabis

Chron's Disease / Ulcerative Colitis and Medicinal Cannabis

Fibromyalgia and Medicinal Cannabis

Inflammation and medicinal cannabis

Parkinson's and Medicinal Cannabis

Restless Leg Syndrome and Medicinal Cannabis

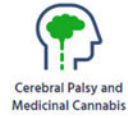
Epilepsy and Medicinal Cannabis

Depression and Medicinal Cannabis

Insomnia and Medicinal Cannabis

Post Traumatic Stress Disorder (PTSD) and Medicinal Cannabis

Stress and Medicinal Cannabis

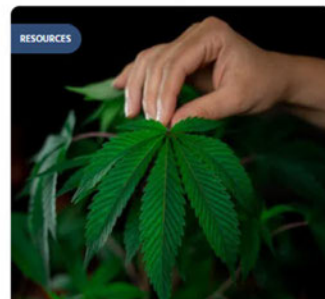


## Frequently Asked Questions

- > Is cannabis legal in Australia?
- > Who can sell cannabis in Australia?
- > How do I know if I'm eligible for medicinal marijuana?
- > Do I need a referral to apply for medicinal marijuana?
- > Can I register a family member or friend?
- > My child is under 18, are they still eligible for treatment?

[View all](#)

## Learn more about medical cannabis



April 20, 2023 | 2 minute read  
[Lifestyle](#)

### The History of 420


August 09, 2022 | 3 minute read  
[Lifestyle](#)

### A Tribute to the Sweetheart of the Medicinal Cannabis Industry

July 07, 2022 | 5 minute read  
[Genetic cannabis](#)

### Whole Flower: A Growing Industry

Read more in Cannabis resources News



s22

Speak with a top Australian doctor now.

Book an appointment

✔ Convenient
✔ Trusted
✔ Affordable
✔ Fast discreet delivery
✔ Access
✔ 100% online

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- [1300 273 824](tel:1300273824)
- [hello@canwell.com.au](mailto:hello@canwell.com.au)
- [Contact us](#)

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- [FAQs](#)
- [Our doctors](#)

**Learn**

- [Your guide to medicinal cannabis](#)
- [The benefits of cannabis](#)
- [Symptoms / Conditions](#)
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Canwell acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.

Windows Explorer

10.0.19041.2604

11:39:30 AM 28/04/2023

Windows 10 Enterprise 64-bit Build 19044 Taken by s22

11:39 AM  
28/04/2023



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

s22  
s22

By Express Post and By Email:  
s22@naturallyelevated.com.au

**Infringement Notice Number:**  
TGAIN-AC-000000014762/2023-10

**Date given:** 18/09/2023

**Penalty total:** \$3,300

**Payment due:** 16/10/2023

**Enquiries:** s22  
**Telephone:** s22  
**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

INFRINGEMENT NOTICE GIVEN TO

s22

**PART A: Infringement Notice given by**

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to s22 under Part 5A-2 of the Act on the basis that I reasonably believe that s22 has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 29 March 2023, s22 did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.instagram.com/p/ChBhnIM04is/>.

The advertisement contained a prohibited representation about the goods, being a reference to cancer. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on an individual for a single contravention of section 42DLB(1) is 5,000 penalty units. For the above alleged contravention, this amounts to \$1,375,000.<sup>7</sup>

The amount payable under this notice is \$3,300. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000014762/2023-10** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000014762/2023-10** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

The screenshot shows an Instagram post from the account 'canwellaustralia'. The post features a dark blue background with a person's hands holding a plant stem. The text 'Plant Medicine For' is in white, and 'CANCER PAIN' is in white on an orange rounded rectangle. The Canwell Australia logo is in the bottom right of the image. The caption reads: 'canwellaustralia Cancer pain differs from person to person and depends on a range of factors - including the type of cancer! We address the cancer to and individual pain tolerance. According to research, canwellaustralia have the capacity to ease pain and nausea - common side effects of both cancer itself as well as cancer treatment. More on the Canwell website under Symptoms & Conditions. Link in bio. #plantmedicine'. There are three comments from a user named '522': 'can't go with canwell! They don't care about patients at all and will send out outdated medicine to patients with the only to get a hold of canwell without being charged! (unacceptable) We took into making a formal complaint with TGA and ombudsman.', 'Being a patient for over 6 months my most recent equipment only provided me with 1 month of medicine at 100 dollars per month to spend thousands a year on equipment just to get the scripts.', and 'Hello Dads 🙏'. The post has 1 like and 2 replies. The browser address bar shows 'https://www.instagram.com/p/ChBhmMO4w/'. The Windows taskbar at the bottom shows the time as 2:45:34 PM on 29/03/2021, and the system tray shows 19°C Mostly cloudy and 3:40 PM on 29/03/2021. The text 'Captured by 522' is visible in the bottom right corner of the screenshot.

**From:** [Advertising Compliance](#)  
**To:** [s22@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)  
**Cc:** [s22@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)  
**Bcc:** s22  
**Subject:** IMPORTANT: Letter and infringement notices from the Therapeutic Goods Administration to Naturally Elevated Pty Ltd - AC-000000014762  
**Date:** Monday, 18 September 2023 3:23:00 PM  
**Attachments:** [image001.png](#)  
[Letter and Infringement notices from the Therapeutic Goods Administration to Naturally Elevated Pty Ltd dated 18 September 2023.pdf](#)  
**Importance:** High

---

Dear s22

Please find attached a letter and 8 infringement notices to Naturally Elevated Pty Ltd dated 18 September 2023.

We ask that you confirm receipt of our correspondence by **19 September 2023**.

Yours sincerely

s22

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Advertising and Product Investigation Section | Regulatory Compliance Branch  
Australian Government, Department of Health and Aged Care  
Therapeutic Goods Administration

Location: Level 2 North 27 Scherger Drive, Fairbairn 2600

Phone: s22

PO Box 100, Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au)

*The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

**Important:** *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error, please notify the author immediately and delete all copies of this transmission.*



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

Our Reference: AC-000000014762

**By Express Post and By Email:**

**s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

cc: **s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

18 September 2023

Dear **s22**

**Infringement notices given to Naturally Elevated Pty Ltd**

<b>Infringement notice</b>	<b>Amount</b>	<b>Payment due by</b>
TGAIN- AC-000000014762/2023-1	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-2	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-3	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-4	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-5	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-6	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-7	\$16,500	<b>16 October 2023</b>
TGAIN- AC-000000014762/2023-8	\$16,500	<b>16 October 2023</b>
<b>Total</b>	<b>\$132,000</b>	

1. I refer to our previous correspondence in this matter, including our letters to Naturally Elevated Pty Ltd (Naturally Elevated) dated 16 March 2023, 26 May 2023 and 10 August 2023, and Naturally Elevated's submissions dated 31 August 2023.
2. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
3. I have decided to give 8 infringement notices to Naturally Elevated under Part 5A-2 of the Act on the basis that I reasonably believe that it contravened subsection 42DLB(1) of the Act, where subsections (2), (4) and (7) applied. The infringement notices are enclosed with this letter. It is important that you carefully read the infringement notices and the information contained in them.
4. Infringement notices are an opportunity for Naturally Elevated to pay an amount as an alternative to having court proceedings brought against it in relation to the alleged contravention described in each notice. If Naturally Elevated decides not to pay the infringement notices, court proceedings may be brought against it.

5. Naturally Elevated should be aware that the maximum civil penalty that a court can impose on a corporation for a single contravention of subsection 42DLB(1) of the Act is 50,000 penalty units. For the alleged contraventions described in the notices, this amounts to \$13,750,000.
6. **Part D** of each of the infringement notices includes information on how to pay the penalty amount, how to request an extension of the compliance period for payment of the infringement notices, or how to request that the infringement notices be withdrawn. If Naturally Elevated wishes to make any such request I recommend that it provides supporting documentation, which may include financial records.
7. For more information about infringement notices, please see the following resources on the Therapeutic Goods Administration's (TGA) website:
  - a. [Information about infringement notices](#)
  - b. [Infringement notices issued by the Therapeutic Goods Administration](#).<sup>1</sup>

#### Delegate comments

8. While I am not required to provide reasons for giving you infringement notices under the Act, I offer the following comments to assist you to understand why I have decided to take this action.
9. The TGA is taking strong regulatory action to ensure compliance with the advertising requirements of the Act across the medicinal cannabis industry. In 2022-23, the TGA issued over 100 infringement notices (totalling over \$1 million) to medicinal cannabis entities, including clinics, for the alleged unlawful advertising of medicinal cannabis.<sup>2</sup>
10. The Court has stated that ignorance of, or inexperience with the requirements of the Act, is not an excuse for non-compliance.<sup>3</sup> It is Naturally Elevated's responsibility as a business involved with the use of therapeutic goods and the provision of health services to be aware of and comply with the Act.<sup>4</sup>
11. In deciding to give infringement notices, I have considered:
  - a. Naturally Elevated's compliance history including previous education and guidance provided to Naturally Elevated in relation to advertising requirements,
  - b. the seriousness and extent of the alleged contraventions, and
  - c. Naturally Elevated's financial position and written submissions received on 31 August 2023.
12. More information about the alleged contraventions is outlined in the infringement notices.
13. Naturally Elevated was first made aware of the advertising requirements under the Act on 16 March 2023. In that letter from the TGA, Naturally Elevated was asked to review the advertising, and address any compliance issues, on all platforms for which Naturally Elevated is responsible, noting that the TGA reserved our rights in relation to any further non-compliance that we identified.
14. Despite guidance provided to it, we have obtained evidence that Naturally Elevated allegedly continued to advertise medicinal cannabis unlawfully on platforms for which it is responsible from at least 16 March 2023 until mid-June 2023, including:

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<sup>1</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/non-compliance/compliance-and-enforcement-hub/compliance-actions-and-outcomes/information-about-infringement-notices> and <https://www.tga.gov.au/infringement-notices>.

<sup>2</sup> <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-news-and-updates>.

<sup>3</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865](#) at paragraph 76.

<sup>4</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518](#) at paragraph 251.

- a. <https://www.canwell.com.au/>
  - b. <https://www.instagram.com/canwellaustralia/>; and
  - c. <https://www.facebook.com/Canwell-Australia-109055414757594>.
15. Each day that a non-compliant advertisement remains visible may be a separate contravention of the Act.
  16. I am concerned about the extent and seriousness of the alleged unlawful advertising which appeared across the above Canwell platforms, and other Naturally Elevated websites, such as Elevated Extracts and Farma Group websites.<sup>5</sup>
  17. We identified over 40 contraventions of the advertising provisions across the Naturally Elevated and Canwell online platforms. These potentially unlawful advertisements remained online for an extended period of time between March and June 2023, after we wrote to Naturally Elevated. In particular, we consider that the Canwell platforms promoted the use or supply of medicinal cannabis, which is an unapproved prescription medicine, and contained a large number of prohibited and restricted representations made about medicinal cannabis.
  18. Having considered the above factors, the changes made to Naturally Elevated's platforms since June 2023 and its submissions, I have decided to give Naturally Elevated 8 infringement notices.
  19. While it remains open to me, I have not given Naturally Elevated infringement notices for all alleged contraventions of the Act that we identified. This includes alleged contraventions which:
    - a. occurred on the Elevated Extracts website and the Farma Group website,
    - b. arose from the use of the same restricted or prohibited representation across Canwell-branded platforms, and
    - c. occurred on each day for which a non-compliant advertisement remained visible between 16 March and 19 June 2023.
  20. I consider that 8 infringement notices are appropriate and proportionate in this case given the above factors and Naturally Elevated's financial position. In its response to the section 45AB notice issued to it on 26 May 2023, Naturally Elevated's Profit and Loss statement for 2022-23 indicates that it received a gross revenue of approximately **s11C(1)(b)** in that year.

**Additional steps you should take**

21. Naturally Elevated should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter and accompanying notices are identified and resolved.
22. The TGA reserves our right to take enforcement action in relation to any future non-compliance we identify, without further notice to you. As stated in our previous correspondence with you, we strongly recommend that Naturally Elevated review all of its platforms, including its Google Business Profile page, to ensure they do not promote a class of therapeutic good (such as prescription medicines) to avoid being liable for further contraventions of the Act. We also recommended you seek independent legal advice or the assistance of a regulatory affairs consultant to help you to comply with your regulatory obligations.

---

<sup>5</sup> <https://elevatedextracts.com.au/>, and <https://farmagroup.com.au/>.

23. If you have any questions, please contact s22 by email at [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au) or phone s22

Yours sincerely

s22

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

**s22** @[naturallyelevated.com.au](mailto:naturallyelevated.com.au)

cc: **s22** @[naturallyelevated.com.au](mailto:naturallyelevated.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-1

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of a therapeutic good, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/>.

The advertisement contained a prohibited representation about the good, being a reference to post traumatic stress disorder. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>6</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care.  
Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000014762/2023-1** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000014762/2023-1** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

18 September 2023

ANNEXURE A:

canwell.com.au

Canwell AUSTRALIA

How it works About Learn Our pricing [Book an appointment](#) Login

# Australia's most **convenient** medicinal cannabis service.

Consult with one of our doctors when convenient for you. [Book now](#)

The **only** all-in-one medicinal cannabis platform, that let lets you consult with a leading doctor and buy direct.

- ### 1. Book an appointment

Create your Canwell account and book an online appointment at a time that suits you.
- ### 2. See a doctor

Attend your consultation virtually using video or audio. We'll even send you reminders.
- ### 3. Buy direct

Order your prescription from within the Canwell platform for quick, discreet delivery.

## Why Canwell?

Australia's most convenient medicinal cannabis service, providing flexible access to Australian-based, AHPRA registered, licenced general practitioners, who are specifically trained in plant-based medicines. We deliver high quality, ethically sourced, and fairly priced medicinal cannabis products from Australian pharmacy partners direct to your door.

- Convenient**  
 Access flexible online appointments from anywhere and at any time.
- Trusted**  
 Top Australian doctors specifically trained in plant-based medication.
- Affordable**  
 Expert advice and access to the best medicinal cannabis products.
- Fast discreet delivery**  
 Quick and discreet delivery if you're prescribed medicinal cannabis.
- Access**  
 Access to leading ethically-sourced medicinal cannabis products.
- 100% online**  
 Meet with your doctor from anywhere using video or audio.

[Get started](#) [Learn more about Canwell](#)

## See what others have to say

Excellent ★★★★★ 4.6 based on 468 reviews

- Claudia** ★★★★★  
I was really impressed with the whole process! Having anxiety I was worried about the whole process of booking an appointment, talking to the Dr and purchasing my CBD oil! I feel reassured...  
2 months ago
- Jason** ★★★★★  
Great service, and nice to have a doctor that actually wants to hear, and to help a patient. Something that is rare in today's GP's  
2 months ago
- Tracey** ★★★★★  
Very understanding Dr.  
2 months ago
- Ross** ★★★★★  
Very informative and helpful. Gave me lots of options and suggestions, quick and easy service. Looking forward to see where this health journey goes.  
2 months ago

REVIEWS

## Why consider medical cannabis?

A growing number of Australians are turning to medicinal cannabis to complement or often replace 'conventional' medicines.

Studies report that medical cannabis provides possible benefits for several conditions and is used to treat many symptoms, including pain, nausea, anxiety, and insomnia.

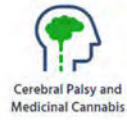
In addition, by helping to maintain homeostasis within the body, the Endocannabinoid System (ES) and cannabis play a critical role in regulating immune response, mood, appetite, metabolism and memory.



See if you're eligible

## Medicinal cannabis can help with

-   
Chronic Pain and Medicinal Cannabis
-   
Auto Immune Diseases and Medicinal Cannabis
-   
Chron's Disease / Ulcerative Colitis and Medicinal Cannabis
-   
Fibromyalgia and Medicinal Cannabis
-   
Inflammation and medicinal cannabis
-   
Parkinson's and Medicinal Cannabis
-   
Restless Leg Syndrome and Medicinal Cannabis
-   
Epilepsy and Medicinal Cannabis
-   
Depression and Medicinal Cannabis
-   
Insomnia and Medicinal Cannabis
-   
Post Traumatic Stress Disorder (PTSD) and Medicinal Cannabis
-   
Stress and Medicinal Cannabis

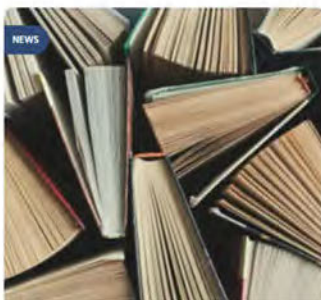


## Frequently Asked Questions

- > Is cannabis legal in Australia?
- > Who can sell cannabis in Australia?
- > How do I know if I'm eligible for medicinal marijuana?
- > Do I need a referral to apply for medicinal marijuana?
- > Can I register a family member or friend?
- > My child is under 18, are they still eligible for treatment?

[View all](#)

## Learn more about medical cannabis



April 20, 2023 | 2 minute read  
[Lifestyle](#)

### The History of 420

August 09, 2021 | 3 minute read  
[Lifestyle](#)

### A Tribute to the Sweetheart of the Medicinal Cannabis Industry

July 07, 2022 | 5 minute read  
[Generic cannabis](#)

### Whole Flower: A Growing Industry

Read more in

Cannabis resources

News

S22

Speak with a top Australian doctor now.

Book an appointment

- ✔ Convenient
- ✔ Trusted
- ✔ Affordable
- ✔ Fast discreet delivery
- ✔ Access
- ✔ 100% online

#### Be in the know with Canwell.

Subscribe for our latest articles and medicinal cannabis information.

Your email address

Subscribe

#### Keep in touch

- 1300 273 824
- [hello@canwell.com.au](mailto:hello@canwell.com.au)
- Contact us



#### About

- About Canwell
- FAQs
- Our doctors

#### Learn

- Your guide to medicinal cannabis
- The benefits of cannabis
- Symptoms / Conditions
- Cannabis resources
- News

#### How it works

- Process
- Pricing
- Register
- Eligibility test

#### Get started

- Login
- Register

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Canwell acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

**s22** @naturallyelevated.com.au

cc: **s22** @naturallyelevated.com.au

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-2

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/>.

The advertisement contained a prohibited representation about the good, being a reference to depression. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605

Email: [info@tga.gov.au](mailto:info@tga.gov.au)

<https://www.tga.gov.au>

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>7</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
 Box 9848, Canberra ACT 2601**  
 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
 your notice by calling the  
 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-2 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-2 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

canwell.com.au

Canwell AUSTRALIA

How it works About Learn Our pricing [Book an appointment](#) Login

# Australia's most **convenient** medicinal cannabis service.

Consult with one of our doctors when convenient for you. [Book now](#)

The **only** all-in-one medicinal cannabis platform, that let lets you consult with a leading doctor and buy direct.

- ### 1. Book an appointment

Create your Canwell account and book an online appointment at a time that suits you.
- ### 2. See a doctor

Attend your consultation virtually using video or audio. We'll even send you reminders.
- ### 3. Buy direct

Order your prescription from within the Canwell platform for quick, discreet delivery.

## Why Canwell?

Australia's most convenient medicinal cannabis service, providing flexible access to Australian-based, AHPRA registered, licenced general practitioners, who are specifically trained in plant-based medicines. We deliver high quality, ethically sourced, and fairly priced medicinal cannabis products from Australian pharmacy partners direct to your door.

- Convenient**  
 Access flexible online appointments from anywhere and at any time.
- Trusted**  
 Top Australian doctors specifically trained in plant-based medication.
- Affordable**  
 Expert advice and access to the best medicinal cannabis products.
- Fast discreet delivery**  
 Quick and discreet delivery if you're prescribed medicinal cannabis.
- Access**  
 Access to leading ethically-sourced medicinal cannabis products.
- 100% online**  
 Meet with your doctor from anywhere using video or audio.

[Get started](#) [Learn more about Canwell](#)

## See what others have to say

Excellent ★★★★★ 4.6 based on 468 reviews

- Claudia** ★★★★★  
I was really impressed with the whole process! Having anxiety I was worried about the whole process of booking an appointment, talking to the Dr and purchasing my CBD oil! I feel reassured...  
1 month ago
- Jason** ★★★★★  
Great service, and nice to have a doctor that actually wants to hear, and to help a patient - Something that is rare in today's GP's  
2 months ago
- Tracey** ★★★★★  
Very understanding Dr.  
2 months ago
- Ross** ★★★★★  
Very informative and helpful. Gave me lots of options and suggestions, quick and easy service. Looking forward to see where this health journey goes.  
2 months ago



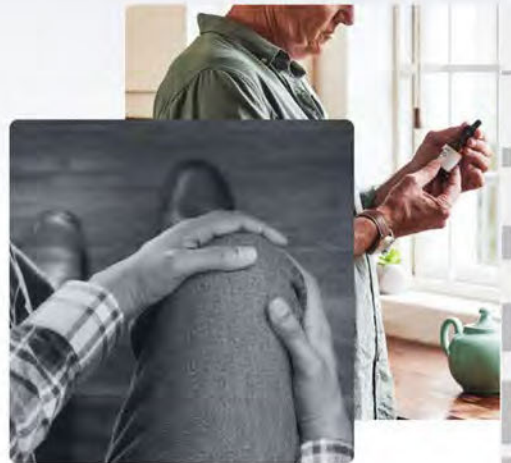
## Why consider medical cannabis?

A growing number of Australians are turning to medicinal cannabis to complement or often replace 'conventional' medicines.

Studies report that medical cannabis provides possible benefits for several conditions and is used to treat many symptoms, including pain, nausea, anxiety, and insomnia.

In addition, by helping to maintain homeostasis within the body, the Endocannabinoid System (ES) and cannabis play a critical role in regulating immune response, mood, appetite, metabolism and memory.

[See if you're eligible](#)



## Medicinal cannabis can help with

Chronic Pain and Medicinal Cannabis

Auto Immune Diseases and Medicinal Cannabis

Chronic Disease / Ulcerative Colitis and Medicinal Cannabis

Fibromyalgia and Medicinal Cannabis

Inflammation and medicinal cannabis

Parkinson's and Medicinal Cannabis

Restless Leg Syndrome and Medicinal Cannabis

Epilepsy and Medicinal Cannabis

Depression and Medicinal Cannabis

Insomnia and Medicinal Cannabis

Post Traumatic Stress Disorder (PTSD) and Medicinal Cannabis

Stress and Medicinal Cannabis



### Frequently Asked Questions

- > Is cannabis legal in Australia?
- > Who can sell cannabis in Australia?
- > How do I know if I'm eligible for medicinal marijuana?
- > Do I need a referral to apply for medicinal marijuana?
- > Can I register a family member or friend?
- > My child is under 18, are they still eligible for treatment?

[View all](#)

### Learn more about medical cannabis



April 20, 2023 | 2 minute read  
Lifestyle

### The History of 420

August 09, 2021 | 3 minute read  
Lifestyle

### A Tribute to the Sweetheart of the Medicinal Cannabis Industry

July 07, 2022 | 5 minute read  
Genetic cannabis

### Whole Flower: A Growing Industry

Read more in [Cannabis resources](#) [News](#)

Speak with a top Australian doctor now.

[Book an appointment](#)

✔ Convenient
✔ Trusted
✔ Affordable
✔ Fast discreet delivery
✔ Access
✔ 100% online

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 ✉ [hello@canwell.com.au](mailto:hello@canwell.com.au)  
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[Our doctors](#)

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[Your guide to medicinal cannabis](#)  
[The benefits of cannabis](#)  
[Symptoms / Conditions](#)  
[Cannabis resources](#)  
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[Pricing](#)  
[Register](#)  
[Eligibility test](#)

Get started

[Login](#)  
[Register](#)

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Canwell acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.

Windows Explorer | 10.0.19041.2604 | 11:39:30 AM 28/04/2023 | Windows 10 Enterprise 64-bit Build 19044 | Taken by s22 | 11:39 AM 28/04/2023





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

s22 @naturallyelevated.com.au

cc: s22 @naturallyelevated.com.au

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-3

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

s22

Telephone: s22

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/>.

The advertisement contained a restricted representation, being a reference to multiple sclerosis. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605

Email: [info@tga.gov.au](mailto:info@tga.gov.au)

<https://www.tga.gov.au>

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>8</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
 Box 9848, Canberra ACT 2601**  
 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
 your notice by calling the  
 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-3 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-3 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>8</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

canwell.com.au

Canwell AUSTRALIA

How it works About Learn Our pricing [Book an appointment](#) Login

# Australia's most **convenient** medicinal cannabis service.

Consult with one of our doctors when convenient for you. [Book now](#)

The **only** all-in-one medicinal cannabis platform, that let lets you consult with a leading doctor and buy direct.

- 1. Book an appointment**  
Create your Canwell account and book an online appointment at a time that suits you.
- 2. See a doctor**  
Attend your consultation virtually using video or audio. We'll even send you reminders.
- 3. Buy direct**  
Order your prescription from within the Canwell platform for quick, discreet delivery.

## Why Canwell?

Australia's most convenient medicinal cannabis service, providing flexible access to Australian-based, AHPRA registered, licenced general practitioners, who are specifically trained in plant-based medicines. We deliver high quality, ethically sourced, and fairly priced medicinal cannabis products from Australian pharmacy partners direct to your door.

- Convenient**  
Access flexible online appointments from anywhere and at any time.
- Trusted**  
Top Australian doctors specifically trained in plant-based medication.
- Affordable**  
Expert advice and access to the best medicinal cannabis products.
- Fast discreet delivery**  
Quick and discreet delivery if you're prescribed medicinal cannabis.
- Access**  
Access to leading ethically-sourced medicinal cannabis products.
- 100% online**  
Meet with your doctor from anywhere using video or audio.

[Get started](#) [Learn more about Canwell](#)

## See what others have to say

Excellent ★★★★★ 4.6 based on 468 reviews

- Claudia** ★★★★★  
I was really impressed with the whole process! Having anxiety I was worried about the whole process of booking an appointment, talking to the Dr and purchasing my CBD oil! I feel reassured...  
2 months ago
- Jason** ★★★★★  
Great service, and nice to have a doctor that actually wants to hear, and to help a patient. Something that is rare in today's GP's.  
2 months ago
- Tracey** ★★★★★  
Very understanding Dr.  
2 months ago
- Ross** ★★★★★  
Very informative and helpful. Gave me lots of options and suggestions, quick and easy service. Looking forward to see where this health journey goes.  
2 months ago

REVIEWS

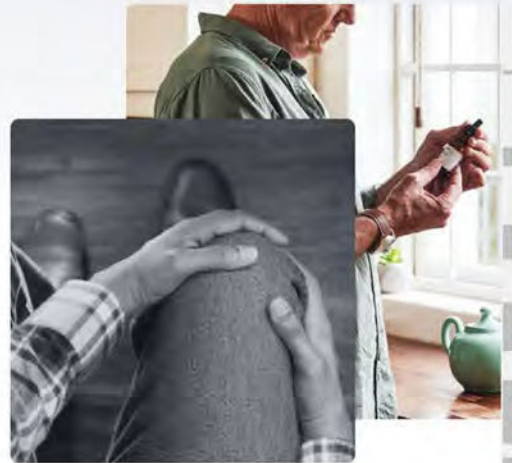
## Why consider medical cannabis?

A growing number of Australians are turning to medicinal cannabis to complement or often replace 'conventional' medicines.

Studies report that medical cannabis provides possible benefits for several conditions and is used to treat many symptoms, including pain, nausea, anxiety, and insomnia.

In addition, by helping to maintain homeostasis within the body, the Endocannabinoid System (ES) and cannabis play a critical role in regulating immune response, mood, appetite, metabolism and memory.

See if you're eligible



## Medicinal cannabis can help with

  
Chronic Pain and Medicinal Cannabis

  
Auto Immune Diseases and Medicinal Cannabis


  
Chron's Disease / Ulcerative Colitis and Medicinal Cannabis

  
Fibromyalgia and Medicinal Cannabis

  
Inflammation and medicinal cannabis

  
Parkinson's and Medicinal Cannabis

  
Restless Leg Syndrome and Medicinal Cannabis

  
Epilepsy and Medicinal Cannabis

  
Depression and Medicinal Cannabis

  
Insomnia and Medicinal Cannabis

  
Post Traumatic Stress Disorder (PTSD) and Medicinal Cannabis

  
Stress and Medicinal Cannabis



## Frequently Asked Questions

- > Is cannabis legal in Australia?
- > Who can sell cannabis in Australia?
- > How do I know if I'm eligible for medicinal marijuana?
- > Do I need a referral to apply for medicinal marijuana?
- > Can I register a family member or friend?
- > My child is under 18, are they still eligible for treatment?

[View all](#)

## Learn more about medical cannabis



NEWS



NEWS



RESOURCES

April 20, 2023 | 2 minute read  
Lifestyle

### The History of 420

August 09, 2021 | 3 minute read  
Lifestyle

### A Tribute to the Sweetheart of the Medicinal Cannabis Industry

July 07, 2022 | 5 minute read  
Genetic cannabis

### Whole Flower: A Growing Industry

Read more in [Cannabis resources](#) [News](#)

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Book an appointment

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✔ Fast discreet delivery
✔ Access
✔ 100% online

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Canwell acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.

Windows Explorer

10.0.19041.2604

11:39:30 AM 28/04/2023

Windows 10 Enterprise 64-bit Build 19044 Taken by s22

11:39 AM  
28/04/2023





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

**s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

cc: **s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-4

**Date given:** 18/09/2023

**Penalty total:** \$16,500.00

**Payment due:** 16/10/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/>.

The advertisement contained a restricted representation, being a reference to endometriosis. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605

Email: [info@tga.gov.au](mailto:info@tga.gov.au)

<https://www.tga.gov.au>

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>9</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
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 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
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 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-4 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-4 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>9</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

canwell.com.au

Canwell AUSTRALIA

How it works About Learn Our pricing [Book an appointment](#) Login

# Australia's most **convenient** medicinal cannabis service.

Consult with one of our doctors when convenient for you. [Book now](#)

The **only** all-in-one medicinal cannabis platform, that let lets you consult with a leading doctor and buy direct.

- ### 1. Book an appointment

Create your Canwell account and book an online appointment at a time that suits you.
- ### 2. See a doctor

Attend your consultation virtually using video or audio. We'll even send you reminders.
- ### 3. Buy direct

Order your prescription from within the Canwell platform for quick, discreet delivery.

## Why Canwell?

Australia's most convenient medicinal cannabis service, providing flexible access to Australian-based, AHPRA registered, licenced general practitioners, who are specifically trained in plant-based medicines. We deliver high quality, ethically sourced, and fairly priced medicinal cannabis products from Australian pharmacy partners direct to your door.

- Convenient**  
 Access flexible online appointments from anywhere and at any time.
- Trusted**  
 Top Australian doctors specifically trained in plant-based medication.
- Affordable**  
 Expert advice and access to the best medicinal cannabis products.
- Fast discreet delivery**  
 Quick and discreet delivery if you're prescribed medicinal cannabis.
- Access**  
 Access to leading ethically-sourced medicinal cannabis products.
- 100% online**  
 Meet with your doctor from anywhere using video or audio.

[Get started](#) [Learn more about Canwell](#)

## See what others have to say

Excellent ★★★★★ 4.6 based on 468 reviews

- Claudia** ★★★★★  
I was really impressed with the whole process! Having anxiety I was worried about the whole process of booking an appointment, talking to the Dr and purchasing my CBD oil! I feel reassured...  
1 month ago
- Jason** ★★★★★  
Great service, and nice to have a doctor that actually wants to hear, and to help a patient. Something that is rare in today's GP's.  
2 months ago
- Tracey** ★★★★★  
Very understanding Dr.  
2 months ago
- Ross** ★★★★★  
Very informative and helpful. Gave me lots of options and suggestions, quick and easy service. Looking forward to see where this health journey goes.  
2 months ago

REVIEWS.io

## Why consider medical cannabis?

A growing number of Australians are turning to medicinal cannabis to complement or often replace 'conventional' medicines.

Studies report that medical cannabis provides possible benefits for several conditions and is used to treat many symptoms, including pain, nausea, anxiety, and insomnia.

In addition, by helping to maintain homeostasis within the body, the Endocannabinoid System (ES) and cannabis play a critical role in regulating immune response, mood, appetite, metabolism and memory.

[See if you're eligible](#)



## Medicinal cannabis can help with

Chronic Pain and Medicinal Cannabis

Auto Immune Diseases and Medicinal Cannabis

Chronic Disease / Ulcerative Colitis and Medicinal Cannabis

Fibromyalgia and Medicinal Cannabis

Inflammation and medicinal cannabis

Parkinson's and Medicinal Cannabis

Restless Leg Syndrome and Medicinal Cannabis

Epilepsy and Medicinal Cannabis

Depression and Medicinal Cannabis

Insomnia and Medicinal Cannabis

Post Traumatic Stress Disorder (PTSD) and Medicinal Cannabis

Stress and Medicinal Cannabis



## Frequently Asked Questions

- > Is cannabis legal in Australia?
- > Who can sell cannabis in Australia?
- > How do I know if I'm eligible for medicinal marijuana?
- > Do I need a referral to apply for medicinal marijuana?
- > Can I register a family member or friend?
- > My child is under 18, are they still eligible for treatment?

[View all](#)

## Learn more about medical cannabis



April 20, 2023 | 2 minute read  
Lifestyle

### The History of 420

August 09, 2021 | 3 minute read  
Lifestyle

### A Tribute to the Sweetheart of the Medicinal Cannabis Industry

July 07, 2022 | 5 minute read  
Genetic cannabis

### Whole Flower: A Growing Industry

Read more in [Cannabis resources](#) [News](#)

Speak with a top Australian doctor now.

[Book an appointment](#)

[Convenient](#)
[Trusted](#)
[Affordable](#)
[Fast discreet delivery](#)
[Access](#)
[100% online](#)

**Be in the know with Canwell.**

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[AU](#) [CA](#)

Canwell acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.

Windows Explorer | 10.0.19041.2604 | 11:39:30 AM 28/04/2023 | Windows 10 Enterprise 64-bit Build 19044 | Taken by s22 | 11:39 AM 28/04/2023





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
ACN 636 315 109  
Unit 19 67 Bancroft Road  
PINKENBA QLD 4008

**By Express Post and By Email:**

s22 @naturallyelevated.com.au

cc: s22 @naturallyelevated.com.au

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-5

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

s22

Telephone: s22

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.canwell.com.au/about/about-canwell>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabis, but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at Annexure A to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>10</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care.  
 Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-AC-000000014762/2023-5 as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-AC-000000014762/2023-5 in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>10</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:

**Canwell**

Home & Terms About Us Contact Us Our Policy Sign Up/Account Login

## About Canwell.

Canwell is the first choice for Australians seeking high-quality, ethically sourced and fully dosed medical Cannabis. Our Australian-based doctors are specially trained in plant-based medicine and take a patient-first approach to every consultation.

### With Canwell, you can access the medicine you need when you need it most.

- Convenient** - Flexible, fast and online appointments with Australian and NZ doctors.
- Trusted** - The leading medical cannabis company in Australia, with a proven track record.
- Affordable** - Expert advice and medical cannabis prescriptions available.
- Fast discreet delivery** - Quick and secure delivery of your medical cannabis.
- Access** - Access to leading medical cannabis products.
- 100% online** - Medically supervised cannabis delivery.

**See what others have to say**

Excellent 5.0 (20/07/2024)

5.0 (20/07/2024) - "Very good service"

5.0 (20/07/2024) - "Great service"

5.0 (20/07/2024) - "Excellent service"

### Why consider medical cannabis?

A growing number of Australians are turning to medical cannabis for a complement or alternative to conventional medicine.

Quality medical cannabis services provide benefits for chronic conditions, such as pain, anxiety, and depression.

Prescription by leading medical professionals is the key. The 200+ medical doctors at Canwell can prescribe a critical new medical cannabis product, medical cannabis therapy.

[See if you qualify](#)

### Speak with a top Australian doctor now

[Sign up/Account](#)

Convenient Trusted Affordable Fast discreet delivery Access 100% online

### Be in the know with Canwell.

Subscribe for our latest news and medical cannabis information.

Keep in touch: 1300 773 888 | info@canwell.com.au | Contact Us

About: What is Canwell? FAQ: How it works

Learn: The benefits of cannabis | Canwell's Conditions | Cannabis resources | Home

How it works: Why you need medical cannabis | Why you need medical cannabis | Why you need medical cannabis | Why you need medical cannabis

Get started: Sign up | Register | Register

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

**s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

cc: **s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-6

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 29 March 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.facebook.com/Canwell-Australia-109055414757594>.

The advertisement contained a restricted representation, being a reference to chronic pain. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at Annexure A to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>11</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
 Box 9848, Canberra ACT 2601**  
 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
 your notice by calling the  
 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-6 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-6 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>11</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

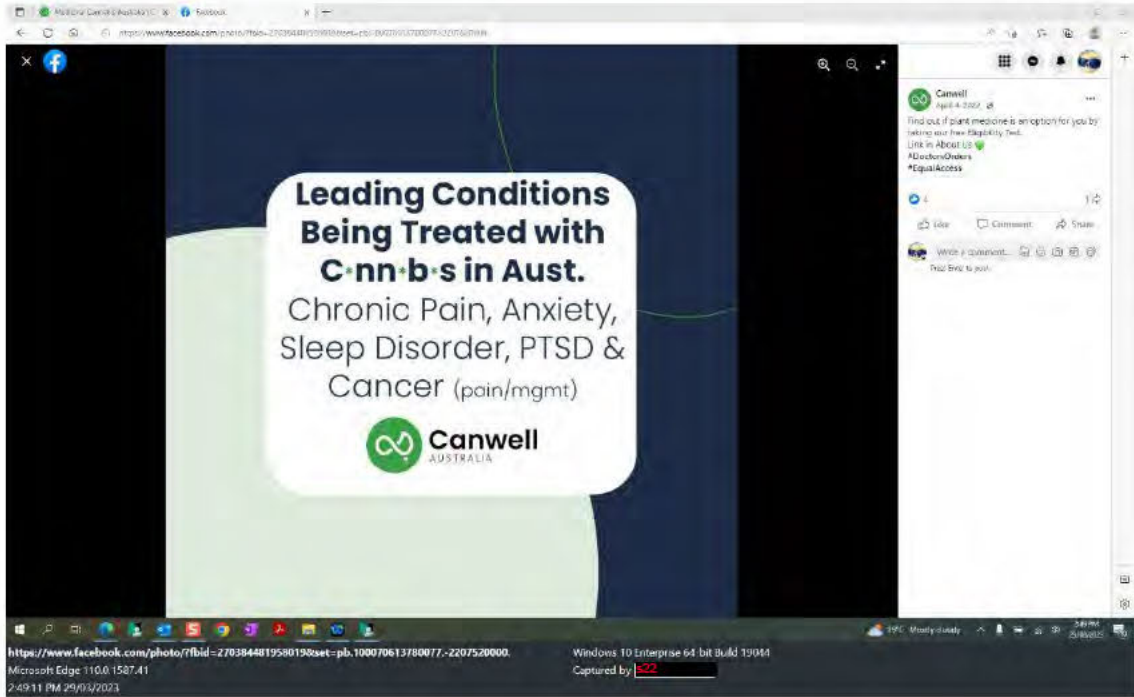
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 18 September 2023

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
ACN 636 315 109  
Unit 19 67 Bancroft Road  
PINKENBA QLD 4008

**By Express Post and By Email:**

s22 @naturallyelevated.com.au

cc: s22 @naturallyelevated.com.au

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-7

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

s22

Telephone: s22

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at <https://www.instagram.com/canwellaustralia/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabis, but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>12</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health and Aged  
 Care, Accounts Receivable, GPO  
 Box 9848, Canberra ACT 2601**  
 with your cheque made payable  
 to the Department of Health  
 and Aged Care.  
 Please allow 5 business days for  
 payment to be received.



#### CREDIT CARD

Use your credit card to pay  
 your notice by calling the  
 Collector of Relevant Monies  
 directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000014762/2023-7 as  
 reference to identify your  
 payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of  
 Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas  
 deposits are relevant). Please  
 include the infringement  
 notice number TGAIN-AC-  
 000000014762/2023-7 in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>12</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

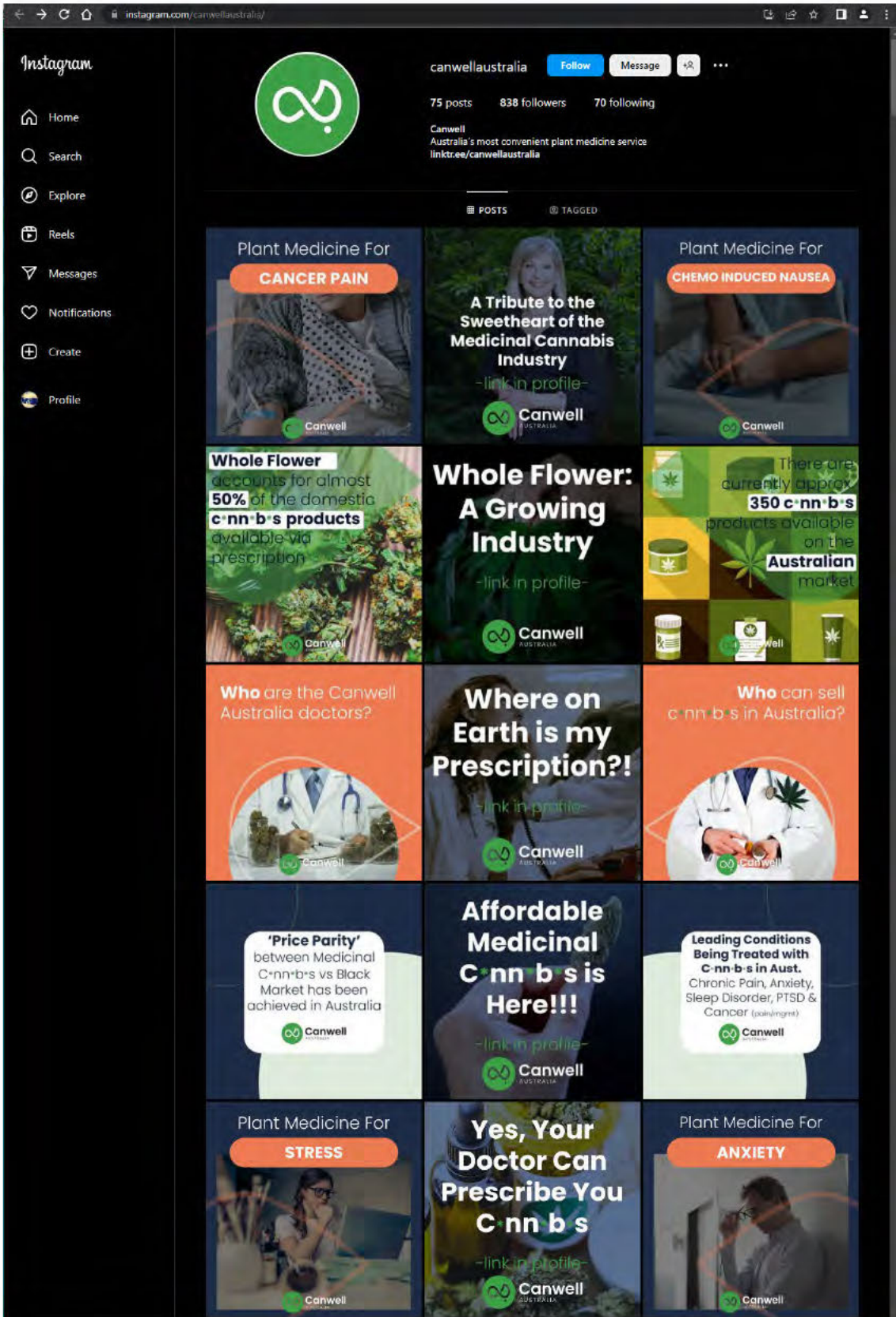
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

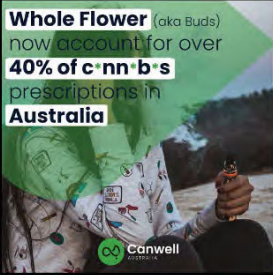



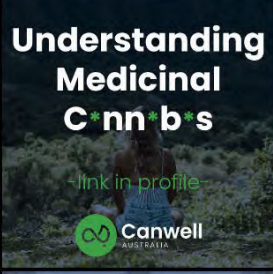
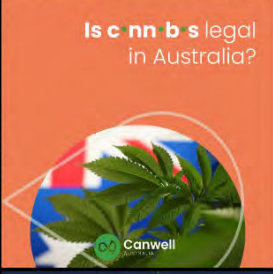

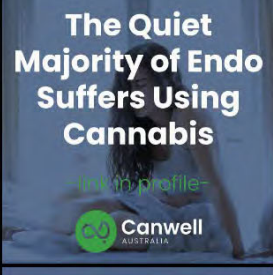




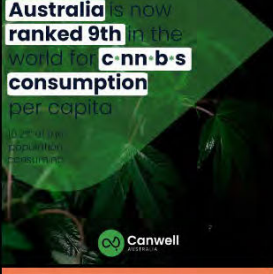


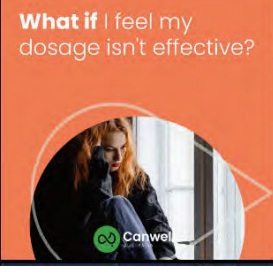
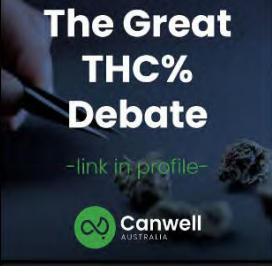
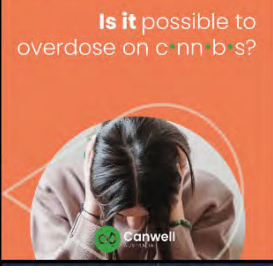


Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609






















Date: 18 September 2023









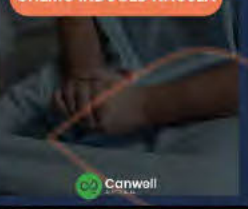






ANNEXURE A:



<p><b>Whole Flower</b> (aka Buds) now account for over <b>40% of c*nn*b*s</b> prescriptions in <b>Australia</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>20% Off All Appointments For Month of Feb</b> <small>(Taxes Apply)</small></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>There are now <b>more than 450</b> Authorised Prescribers (Doctors who can prescribe <b>c*nn*b*s</b> without seeking TGA preapproval) in <b>Australia</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>Who can sell c*nn*b*s</b> in Australia?</p>  <p>Canwell AUSTRALIA</p>	<p><b>Understanding Medicinal C*nn*b*s</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>Is c*nn*b*s</b> legal in Australia?</p>  <p>Canwell AUSTRALIA</p>
<p>It is estimated that one in nine Australian women has endometriosis</p>  <p>Canwell AUSTRALIA</p>	<p><b>The Quiet Majority of Endo Suffers Using Cannabis</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Almost 3/4 of Australian women with endometriosis are using illicitly cannabis</p>  <p>Canwell AUSTRALIA</p>
<p>Plant Medicine For <b>NEUROPATHY</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>TIPPING POINT</b> What to look forward to in 2022</p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Plant Medicine For <b>EPILEPSY</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>Australia</b> is now ranked <b>9th</b> in the world for <b>c*nn*b*s</b> consumption per capita</p>  <p>Canwell AUSTRALIA</p>	<p><b>Honahlee Launches 'Catalyst' Catalyst</b></p> <p>Australia's first independent industry supported cannabis medicines database.</p>  <p>Canwell AUSTRALIA</p>	<p>The <b>Aust. Therapeutic Goods Administration</b> approved <b>12,508</b> Medicinal <b>c*nn*b*s</b> applications in <b>Nov 2021</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>What if I feel my dosage isn't effective?</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>The Great THC% Debate</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>Is it possible to overdose on c*nn*b*s?</b></p>  <p>Canwell AUSTRALIA</p>



<p><b>Sativa Strains</b> Tend To Be Higher In THC &amp; Result In A Euphoric Head High</p> 	<p><b>Sativa or Indica: Does it Matter?</b></p> <p>-link in profile-</p> 	<p><b>Indica Strains</b> Generally Affects The Body More Than The Mind &amp; Are Higher in CBD</p> 
<p>Plant Medicine For <b>ARTHRITIS</b></p> 	<p><b>Dealing with Chronic Pain</b></p> <p>-link in profile-</p> 	<p>Plant Medicine For <b>FIBROMYALGIA</b></p> 
<p><b>Active Patients</b> set to reach nearly <b>100,000</b> by the end of <b>2021</b></p> 	<p><b>What's The Deal With Repeat Scripts?</b></p> <p>-link in profile-</p> 	<p><b>40%</b> of all <b>c*nn*b*s</b> <b>approvals</b> at the <b>federal</b> level are for <b>Whole Flower</b> (aka buds)</p> 
<p><b>What happens if I take too much THC?</b></p> 	<p><b>Can I Legally Get Edibles in Australia?</b></p> <p>-link in profile-</p> 	<p><b>What happens if I take too much CBD?</b></p> 
<p><b>The Earliest</b> Recorded Use Of C*nn*b*s Dates Back to China in 10,000 B.C.</p> 	<p><b>False Barriers to C*nn*b*s Access</b></p> 	<p><b>C*nn*b*s Boosts Mood Using The Same Mechanism As Chocolate</b></p> 
<p>Plant Medicine For <b>DEPRESSION</b></p> 	<p><b>How c*nn*b*s is being used to treat Parkinson's Disease</b></p> <p>-link in profile-</p> 	<p>Plant Medicine For <b>INSOMNIA</b></p> 
<p>The <b>Aust. Therapeutic Goods Administration</b> approved <b>10,791</b> Medicinal <b>C*nn*bi*s</b> applications in <b>Aug 2021</b></p> 	<p><b>Medicinal C*nn*b*s: The Federal Government 'Approves' Big Time!</b></p> <p>-link in profile-</p> 	<p>Over <b>150,000</b> <b>Australians</b> have been approved for medicinal <b>c*nn*b*s</b></p> 

<p>Is the product I receive quality controlled?</p>  <p>Canwell AUSTRALIA</p>	<p><b>CBD &amp; Anxiety</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Is c n n b s legal in Australia?</p>  <p>Canwell AUSTRALIA</p>
<p><b>CBD is WADA approved</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>What you need to know about CBD Oil</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>CBD can reduce inflammation</b></p>  <p>Canwell AUSTRALIA</p>
<p>Plant Medicine For <b>CANCER PAIN</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>Study: Medicinal C n n b s Has Potential To Treat Cancer</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Plant Medicine For <b>CHEMO INDUCED NAUSEA</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>76% of Australians</b> support legislation to allow c n n b s use for <b>medical</b> purposes</p>  <p>Canwell AUSTRALIA</p>	<p><b>Specialist Cannabis Doctors Provide Options for Chronic Pain Patients</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>61% of Australians</b> think personal c n n b s possession should <b>not</b> be a <b>criminal</b> offence</p>  <p>Canwell AUSTRALIA</p>
 <p><b>Canwell AUSTRALIA</b></p> <p>convenient plant medicine service.</p>		
<p>Access flexible online appointments from anywhere at any time, with discreet Australia-wide delivery.</p>		
<p> Canwell Australia acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.</p>		

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Naturally Elevated Pty Ltd  
 ACN 636 315 109  
 Unit 19 67 Bancroft Road  
 PINKENBA QLD 4008

**By Express Post and By Email:**

**s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

cc: **s22** [@naturallyelevated.com.au](mailto:s22@naturallyelevated.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000014762/2023-8

**Date given:** 18/09/2023

**Penalty total:** \$16,500

**Payment due:** 16/10/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

*Naturally Elevated Pty Ltd*

**PART A: Infringement Notice given by**

**s22**

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Naturally Elevated Pty Ltd (Naturally Elevated) under Part 5A-2 of the Act on the basis that I reasonably believe that Naturally Elevated has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 28 April 2023, Naturally Elevated did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis, on the web page located at

<https://www.instagram.com/canwellaustralia/>.

The advertisement contained a restricted representation, being a reference to epilepsy. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at Annexure A to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>13</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601 with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-AC-000000014762/2023-8 as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-AC-000000014762/2023-8 in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>13</sup> A penalty unit for a contravention alleged to have occurred on or after 1 January 2023 and on or before 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

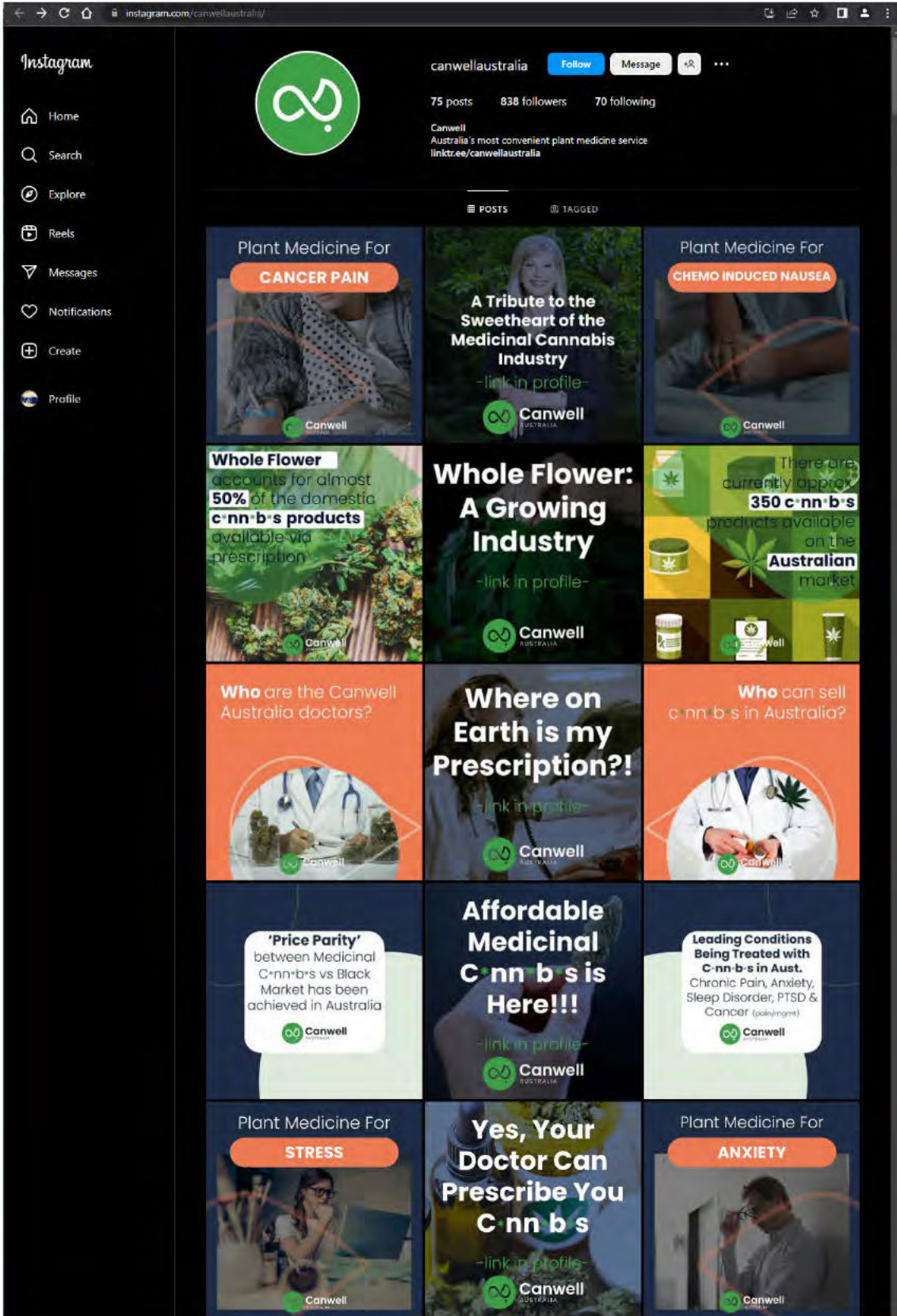
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.





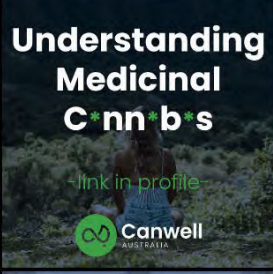
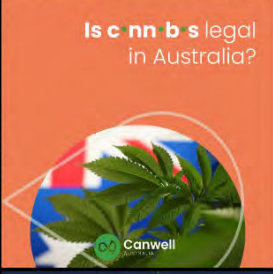

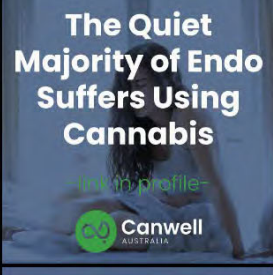




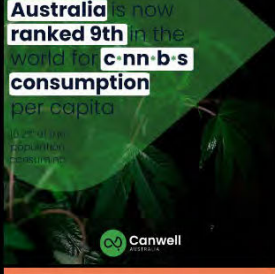


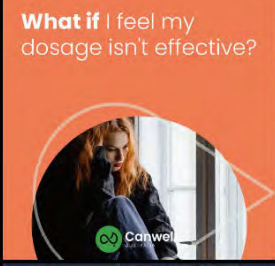
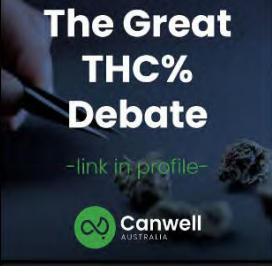
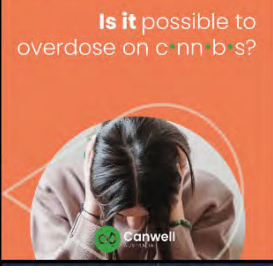


Delegate of the Secretary of the Australian Government Department of Health and Aged Care  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609






















Date: 18 September 2023









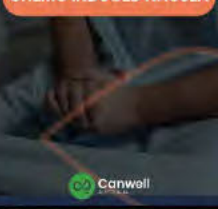






ANNEXURE A:



<p><b>Whole Flower</b> (aka Buds) now account for over <b>40% of c*nn*b*s</b> prescriptions in <b>Australia</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>20% Off All Appointments For Month of Feb</b> <small>(Taxes Apply)</small></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>There are now <b>more than 450</b> Authorised Prescribers (Doctors who can prescribe <b>c*nn*b*s</b> without seeking TGA preapproval) in <b>Australia</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>Who can sell c*nn*b*s</b> in Australia?</p>  <p>Canwell AUSTRALIA</p>	<p><b>Understanding Medicinal C*nn*b*s</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>Is c*nn*b*s</b> legal in Australia?</p>  <p>Canwell AUSTRALIA</p>
<p>It is estimated that one in nine Australian women has endometriosis</p>  <p>Canwell AUSTRALIA</p>	<p><b>The Quiet Majority of Endo Suffers Using Cannabis</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Almost 3/4 of Australian women with endometriosis are using illicitly cannabis</p>  <p>Canwell AUSTRALIA</p>
<p>Plant Medicine For <b>NEUROPATHY</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>TIPPING POINT</b> What to look forward to in 2022</p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Plant Medicine For <b>EPILEPSY</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>Australia</b> is now ranked <b>9th</b> in the world for <b>c*nn*b*s</b> consumption per capita</p>  <p>Canwell AUSTRALIA</p>	<p><b>Honahlee Launches 'Catalyst' Catalyst</b></p> <p>Australia's first independent industry supported cannabis medicines database.</p>  <p>Canwell AUSTRALIA</p>	<p>The <b>Aust. Therapeutic Goods Administration</b> approved <b>12,508</b> Medicinal <b>c*nn*b*s</b> applications in <b>Nov 2021</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>What if I feel my dosage isn't effective?</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>The Great THC% Debate</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>Is it possible to overdose on c*nn*b*s?</b></p>  <p>Canwell AUSTRALIA</p>



<p><b>Sativa Strains</b> Tend To Be Higher In THC &amp; Result In A Euphoric Head High</p> 	<p><b>Sativa or Indica: Does it Matter?</b></p> <p>-link in profile-</p> 	<p><b>Indica Strains</b> Generally Affects The Body More Than The Mind &amp; Are Higher in CBD</p> 
<p>Plant Medicine For</p> <p><b>ARTHRITIS</b></p> 	<p><b>Dealing with Chronic Pain</b></p> <p>-link in profile-</p> 	<p>Plant Medicine For</p> <p><b>FIBROMYALGIA</b></p> 
<p><b>Active Patients</b> set to reach nearly <b>100,000</b> by the end of <b>2021</b></p> 	<p><b>What's The Deal With Repeat Scripts?</b></p> <p>-link in profile-</p> 	<p><b>40%</b> of all <b>c*nn*b*s</b> approvals at the federal level are for <b>Whole Flower</b> (aka buds)</p> 
<p><b>What happens if I take too much THC?</b></p> 	<p><b>Can I Legally Get Edibles in Australia?</b></p> <p>-link in profile-</p> 	<p><b>What happens if I take too much CBD?</b></p> 
<p><b>The Earliest</b> Recorded Use Of C*nn*b*s Dates Back to China in 10,000 B.C.</p> 	<p><b>False Barriers to C*nn*b*s Access</b></p> 	<p><b>C*nn*b*s Boosts</b> Mood Using The Same Mechanism As Chocolate</p> 
<p>Plant Medicine For</p> <p><b>DEPRESSION</b></p> 	<p><b>How c*nn*b*s is being used to treat Parkinson's Disease</b></p> <p>-link in profile-</p> 	<p>Plant Medicine For</p> <p><b>INSOMNIA</b></p> 
<p>The <b>Aust. Therapeutic Goods Administration</b> approved <b>10,791</b> Medicinal <b>C*nn*b*s</b> applications in <b>Aug 2021</b></p> 	<p><b>Medicinal C*nn*b*s: The Federal Government 'Approves' Big Time!</b></p> <p>-link in profile-</p> 	<p>Over <b>150,000</b> <b>Australians</b> have been approved for medicinal <b>c*nn*b*s</b></p> 

<p>Is the product I receive quality controlled?</p>  <p>Canwell AUSTRALIA</p>	<p><b>CBD &amp; Anxiety</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Is c n n b s legal in Australia?</p>  <p>Canwell AUSTRALIA</p>
<p><b>CBD is WADA approved</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>What you need to know about CBD Oil</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>CBD can reduce inflammation</b></p>  <p>Canwell AUSTRALIA</p>
<p>Plant Medicine For <b>CANCER PAIN</b></p>  <p>Canwell AUSTRALIA</p>	<p><b>Study: Medicinal C n n b s Has Potential To Treat Cancer</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p>Plant Medicine For <b>CHEMO INDUCED NAUSEA</b></p>  <p>Canwell AUSTRALIA</p>
<p><b>76% of Australians</b> support legislation to allow c n n b s use for <b>medical</b> purposes</p>  <p>Canwell AUSTRALIA</p>	<p><b>Specialist Cannabis Doctors Provide Options for Chronic Pain Patients</b></p> <p>-link in profile-</p>  <p>Canwell AUSTRALIA</p>	<p><b>61% of Australians</b> think personal c n n b s possession should <b>not</b> be a <b>criminal</b> offence</p>  <p>Canwell AUSTRALIA</p>
 <p><b>Canwell AUSTRALIA</b></p> <p>plant medicine is <b>convenient</b> service.</p>		
<p>Access flexible online appointments from anywhere at any time, with discreet Australia-wide delivery.</p>		
<p> Canwell Australia acknowledge the Traditional Owners of the land where we work and live. We pay our respects to Elders past, present and emerging.</p>		

More

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**From:** [Advertising Compliance](#)  
**To:** s22  
**Cc:** s22  
**Bcc:** s22; s22  
**Subject:** RE: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-00000001715/AC-000000005995 [SEC=OFFICIAL]  
**Date:** Friday, 7 July 2023 9:28:00 AM  
**Attachments:** [Letter from Therapeutic Goods Administration to Trava Health Pty Ltd - 7 July 2023.pdf](#)  
[image003.gif](#)  
[image004.png](#)  
[image005.png](#)

---

Dear s22,

Please find attached a letter from the Therapeutic Goods Administration to Trava Health Pty Ltd dated 7 July 2023.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

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**From:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>  
**Sent:** Thursday, 6 July 2023 9:52 AM  
**To:** s22 <s22@travahealth.com.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** RE: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-00000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22,

Thank you for your email. We confirm receipt of your letter dated 3 July 2023.

We will respond to your letters of 25 and 27 June, and 3 July 2023 soon.

Kind regards,

s22  
[Redacted]

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Tuesday, 4 July 2023 11:17 AM  
**To:** Advertising Compliance <advertising.compliance@tga.gov.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22,

I received your correspondence this afternoon, Melbourne time, Monday 3rd of July. I am away and was travelling by plane for 36 hours starting Thursday, 29th of June. As I mentioned in my previous Letter, I am not an accountant, so I won't be able to provide the information to you, which may be less than accurate. I take it for granted that I should not, and I am not permitted to determine the costs hypothetically, and my accountant must carefully prepare those costs. Otherwise, I can provide you with misleading information that would be improper and in breach of my obligation as a permit holder. I have attached the Letter to support my reply.

Please be patient to help me get the correct information so that the information received is unimpeachable and not speculative, and I can then forward it to you.

In the meantime, if you have any more questions, please feel free to contact me.

Kind Regards,

s22 [Redacted] s22 [Redacted]

s22

s22@travahealth.com.au

<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria 3166



Trava Health Clinic respectfully acknowledges Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of the land, recognises their ongoing connection to land, waters and community and respects their past, present and emerging Elders.

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On 28/06/2023 2:25 pm, Advertising Compliance wrote:

Dear s22,

We confirm receipt of your letter dated 27 June 2023.

I am writing to you because we are concerned about the accuracy of the financial information that you have provided in response to question 4 of our notice issued under section 45AB of the Therapeutic Goods Act on 17 May 2023.

We will write to you separately to address the other matters raised in your letters of 25 and 27 June that do not relate to Trava's response to the notice.

### **Financial information**

Question 4 of our notice asked for revenue for the supply of medicinal cannabis and nicotine vaping products and services for the periods listed in the notice. From the description in your letter of 27 June, it appears that the amounts provided in your letter of 25 June were net profit, rather than revenue.

To comply with the notice, we ask that Trava confirm its revenue for the period of 1 July 2022 to 17 May 2023 with its accountant, and provide us this information by

12:00 pm on Friday 30 June 2023.

## Compliance with the notice

We note that you have told us you are not an accountant or legally trained. However, it is important that the information you provide in response to the notice is accurate. This is because there are serious penalties for providing false or misleading information in response to the notice (Part G of the notice).

As stated in our previous correspondence, if Trava requires assistance in complying with the Act, including its advertising and section 45AB obligations, it is open to Trava to engage a regulatory affairs consultant or legal practitioner.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 <s22@travahealth.com.au>

**Sent:** Tuesday, 27 June 2023 2:57 PM

**To:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>

**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL], reply

Dear Sir/Madam,

Thank you for your letter, the real,y is attached to your consideration

Kind Regards,

s22

s22

s22

s22 @travahealth.com.au



<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria 3166

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On 26/06/2023 1:34 pm, Advertising Compliance wrote:

Dear s22,

Thank you for your letter.

We are writing to you about the revenue provided at paragraph (l.)(i) on page 4 of your letter. We will write to you separately about the remaining matters raised in your letter.

Could you please confirm whether the amounts listed at paragraph (l.)(i) of the letter are gross profit, net profit or revenue by **5:00 pm tomorrow (Tuesday 27 June 2023)**?

To assist our assessment of this matter we ask that Trava provide, on a voluntary basis, any financial documents for the period from 1 July 2022 to 17 May 2023 which contain its revenue for the supply of medicinal cannabis and nicotine vaping products and associated services. This may include profit and loss, or income statements.

We ask that you provide any financial documents to us by **12:00 pm on Friday 30 June 2023**.

Please let me know if you have any questions.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Sunday, 25 June 2023 8:02 PM  
**To:** s22 <s22@Health.gov.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** [ATTACHMENT UNSCANNED]reply from Trava Health ref 00000001715

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/Madam,

The letter is attached to your consideration.



Kind Regards,

s22

s22

s22 @travahealth.com.au

s22

<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria 3166

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s22 @travahealth.com.au

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**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22  
Trava Health Pty Ltd  
ACN 651 466 616

Our References: AC-000000005995  
AC-000000001715

3 Portman Street  
Oakleigh VIC 3166

By Email:  
s22@travahealth.com.au

7 July 2023

Dear s22

We are writing to you about our ongoing correspondence in this matter. This includes your letters of 25 and 27 June, and 4 July 2023.

The purpose of our letter is to:

- provide Trava Health with an opportunity to provide any additional information (submissions) to be considered by a delegate of the Secretary of the Department of Health and Aged Care in deciding what enforcement action to take against it regarding alleged unlawful advertising, and
- respond to the matters raised in your letters of 25 and 27 June, and 4 July 2023.

#### **Action required**

We ask that you carefully consider our letter, and take the following actions:

- confirm receipt of our letter by **10 July 2023**.
- if Trava Health would like to make any submissions to the delegate it must provide its submissions in writing by email to [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au) by **9:00 am on 17 July 2023**.

#### **Intention to take enforcement action**

We are considering taking enforcement action against Trava Health in relation to the alleged unlawful advertising of therapeutic goods on its website and social media pages. The enforcement action being considered includes giving infringement notices to Trava Health for the types of contraventions described at paragraph 6 of our letter dated 2 March 2023 (our March letter).

Trava Health is welcome to make any submissions that it would like to be considered by a delegate of the Secretary in deciding what enforcement action to take against it.

Any submissions must be provided in writing by email to [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au) by **9:00 am** on **17 July 2023**. We note that submissions provided after this time may not be considered by the delegate.

We recommend that Trava Health immediately take steps to ensure that any non-compliant advertising is removed to avoid being liable for further contraventions. Each day that a non-compliant advertisement remains visible may be a further contravention of the *Therapeutic Goods Act 1989* (the Act). Any ongoing contraventions will be taken into account by the delegate in deciding what enforcement action to take against Trava Health.

### **Response to your letters**

We understand that you have raised several matters unrelated to our section 45AB notice in your letters of 24 June, 27 June and 4 July 2023. The matters were:

- the outcome of our assessment of this matter
- advertising and copyright guidance
- approval of advertisements.

Our response to each of these matters is below.

### **Our assessment**

You asked that we tell you whether the advertising issues outlined in our March letter have been addressed. We note that there were two aspects to our March letter:

- advertising of therapeutic goods on Trava Health's website and social media
- unauthorised use of copyright material.

Trava Health's website and social media pages continue to contain advertisements for medicinal cannabis and nicotine vaping products that appear non-compliant for the reasons outlined in our March letter. We have put Trava Health on notice of our concerns since March and have asked that it review and remove any unlawful advertising on multiple occasions. We are now considering enforcement action for the alleged unlawful advertising of therapeutic goods because no changes appear to have been made to the advertising.

We are not proposing to take enforcement action in relation to the unauthorised use of copyright material at this time because you have told us that Trava Health has ceased its unauthorised use of copyright material.

### **Guidance**

You asked for guidance to determine what is advertising, and what material produced by us may be used in Trava Health's advertising.

Representations that may amount to advertising were described at paragraph 5 of our March letter. More information can be found on our website, see for example the [advertising guidance for businesses involved with medicinal cannabis products](#).<sup>1</sup>

Information about when material on our website may be used was provided in our March letter. More information can be found in our [copyright statement](#).<sup>2</sup>

For more specific advice, you may wish to contact a [regulatory affairs consultant or advertising advisory service](#) or a legal practitioner.

### Approval of advertisements

You asked to submit advertisements to us for our approval.

We note that it is not the Therapeutic Goods Administration's role to approve or endorse advertisements for therapeutic goods. Our role is to monitor and enforce compliance with the Act, which includes educating entities about their advertising obligations to encourage voluntary compliance with the Act. In this case, we have provided Trava Health with sufficient guidance relating to its obligations under the Act.

Ultimately, it is Trava Health's responsibility as a business involving the use of therapeutic goods and the provision of health services to be aware of and comply with the regulatory requirements under the Act.<sup>3</sup>

As we have stated in our previous correspondence, it is open to you to seek assistance from a regulatory affairs consultant or legal practitioner.

Should you wish to discuss this letter with us, please contact s22 by email at [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au).

Yours sincerely

s22

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch  
Therapeutic Goods Administration

---

<sup>1</sup> <https://www.tga.gov.au/resources/resource/guidance/advertising-guidance-businesses-involved-medicinal-cannabis-products>.

<sup>2</sup> <https://www.tga.gov.au/copyright>.

<sup>3</sup> Secretary, Department of Health v Oxydmed Australia Pty Ltd [2021] FCA 1518 at paragraph [251].

**From:** s22  
**To:** [Advertising Compliance](#)  
**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]  
**Date:** Monday, 17 July 2023 1:02:36 PM  
**Attachments:** [image001.gif](#)  
[image002.png](#)  
[image003.png](#)  
[Reply to TGA , 170723.docx](#)

---

Dear s22 ,

I'm sending you the letter again.

Thank you for letting me know

Kind  
Regards,

s22

cc

s22

s22

s22 [@travahealth.com.au](mailto:s22@travahealth.com.au)

<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria  
3166



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s22 [@travahealth.com.au](mailto:s22@travahealth.com.au)

On 17/07/2023 10:30 am, Advertising Compliance wrote:

Dear s22 ,

I understand that Trava Health was planning to provide us with written submissions by 9 am

this morning, but I was unable to locate them our mailbox.

Could you confirm whether Trava Health has sent the written submissions to [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)?

Kind regards,

s22  
[Redacted]

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** Advertising Compliance  
**Sent:** Monday, 10 July 2023 3:03 PM  
**To:** s22 [Redacted], s22 [Redacted] <[Redacted]@travahealth.com.au>  
**Cc:** s22 [Redacted]  
**Subject:** RE: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22 [Redacted],

Thank you for confirming receipt of our correspondence.

Kind regards,

s22  
[Redacted]

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Sunday, 9 July 2023 10:25 PM  
**To:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>  
**Cc:** s22  
**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22,

Thank you for your correspondence dated 07 of July 2023.

I would like to confirm that I will be responding to the delegate in writing by email by 9.00am on 17 of July 2023.

Kind  
Regards,

s22



s22

s22

s22@travahealth.com.au

<https://www.travahealth.com.au>



3 Portman Street, Oakleigh, Victoria  
3166

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On 07/07/2023 9:28 am, Advertising Compliance wrote:

Dear s22,

Please find attached a letter from the Therapeutic Goods Administration to Trava Health Pty Ltd dated 7 July 2023.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>  
**Sent:** Thursday, 6 July 2023 9:52 AM  
**To:** s22 <s22@travahealth.com.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** RE: Letter from Trava Health Pty Ltd to the Therapeutic Goods



Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22 ,

Thank you for your email. We confirm receipt of your letter dated 3 July 2023.

We will respond to your letters of 25 and 27 June, and 3 July 2023 soon.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Tuesday, 4 July 2023 11:17 AM  
**To:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL]

Dear s22 ,

I received your correspondence this afternoon, Melbourne time, Monday 3rd of July. I am away and was travelling by plane for 36 hours starting Thursday, 29th of June. As I mentioned in my previous Letter, I am not an accountant, so I won't be able to provide the information to you, which may be less than accurate. I take it for granted that I should not, and I am not permitted to determine the costs hypothetically, and my accountant must carefully prepare those costs. Otherwise, I can provide you with misleading information that would be improper and in breach of my obligation as a permit holder. I have attached the Letter to support my reply.

Please be patient to help me get the correct information so that the information received is unimpeachable and not speculative, and I can then forward it to you.

In the meantime, if you have any more questions, please feel free to contact me.

Kind  
Regards,



s22



s22

s22

s22@travahealth.com.au

<https://www.travahealth.com.au>



3 Portman Street, Oakleigh, Victoria  
3166

Trava Health Clinic respectfully acknowledges Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of the land, recognises their ongoing connection to land, waters and community and respects their past, present and emerging Elders.

OFFICIAL: Sensitive

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On 28/06/2023 2:25 pm, Advertising Compliance wrote:

Dear s22,

We confirm receipt of your letter dated 27 June 2023.

I am writing to you because we are concerned about the accuracy of the financial information that you have provided in response to question 4 of our notice issued under section 45AB of the Therapeutic Goods Act on 17 May 2023.

We will write to you separately to address the other matters raised in your letters of 25 and 27 June that do not relate to Trava's response to the notice.

### **Financial information**

Question 4 of our notice asked for revenue for the supply of medicinal cannabis and nicotine vaping products and services for the periods listed in the notice. From the description in your letter of 27 June, it appears that the amounts provided in your letter of 25 June were net profit, rather than revenue.

To comply with the notice, we ask that Trava confirm its revenue for the period of 1 July 2022 to 17 May 2023 with its accountant, and provide us this information by **12:00 pm on Friday 30 June 2023**.

### **Compliance with the notice**

We note that you have told us you are not an accountant or legally trained. However, it is important that the information you provide in response to the notice is accurate. This is because there are serious penalties for providing false or misleading information in response to the notice (Part G of the notice).

As stated in our previous correspondence, if Trava requires assistance in complying with the Act, including its advertising and section 45AB obligations, it is open to Trava to engage a regulatory affairs consultant or legal practitioner.

Kind regards,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100

Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au)

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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Tuesday, 27 June 2023 2:57 PM  
**To:** Advertising Compliance <[advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)>  
**Subject:** Re: Letter from Trava Health Pty Ltd to the Therapeutic Goods Administration - AC-000000001715/AC-000000005995 [SEC=OFFICIAL], reply

Dear Sir/Madam,

Thank you for your letter, the reply is attached to your consideration

Kind  
Regards,

s22

s22

s22

[@travahealth.com.au](mailto:s22@travahealth.com.au)

Business  
Manager/CEO

<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria  
3166

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s22 [@travahealth.com.au](mailto:s22@travahealth.com.au)

On 26/06/2023 1:34 pm, Advertising Compliance wrote:

Dear **s22**,

Thank you for your letter.

We are writing to you about the revenue provided at paragraph (l.)(i) on page 4 of your letter. We will write to you separately about the remaining matters raised in your letter.

Could you please confirm whether the amounts listed at paragraph (l.)(i) of the letter are gross profit, net profit or revenue by **5:00 pm tomorrow (Tuesday 27 June 2023)**?

To assist our assessment of this matter we ask that Trava provide, on a voluntary basis, any financial documents for the period from 1 July 2022 to 17 May 2023 which contain its revenue for the supply of medicinal cannabis and nicotine vaping products and associated services. This may include profit and loss, or income statements.

We ask that you provide any financial documents to us by **12:00 pm on Friday 30 June 2023**.

Please let me know if you have any questions.

Kind regards,

**s22**

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

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**From:** s22 <s22@travahealth.com.au>  
**Sent:** Sunday, 25 June 2023 8:02 PM  
**To:** s22 <s22@Health.gov.au>  
**Cc:** s22 <s22@Health.gov.au>  
**Subject:** [ATTACHMENT UNSCANNED]reply from Trava Health ref 00000001715

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/Madam,

The letter is attached to your consideration.

Kind Regards,

s22

s22

s22@travahealth.com.au

s22

<https://www.travahealth.com.au>

3 Portman Street, Oakleigh, Victoria 3166

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s22@travahealth.com.au

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

To: TGA

Reference Number:

AC-000000005995

AC-000000001715

Date: 17<sup>th</sup> of July 2023

Dear **s22**,

Thank you for allowing me to send an additional letter to your Notice that we received on 17/05/2023.

The shortage of staff caused by the COVID pandemic has led to a need for innovative solutions to maintain patient care and medication supply. The introduction of texting services has allowed our business to efficiently manage patient medical care and ensure the timely delivery of medication. We had to support our patients during these challenging times proactively.

Communicating with patients for routine and critical matters is often complicated and, in some instances, verbally is not viable. Reaching out via text messaging is a fast and effective way to convey important patient information while creating a personal way to engage.

Some of those texts messaging were related to the following needs of the businesses:

1. Sending appointment reminders and accepting cancellations
2. Providing office location and business hours
3. Communicating about prescriptions issued, quantities prescribed and cost of medications by the Doctor to patient
4. Tracking numbers and postage inquiries
5. Tax invoices issued
6. Closure time for Holiday time or working hours of the clinic
7. Disruption of software issues etc.

Please be assured that we are committed to maintaining the highest standards of confidentiality and privacy in all our communications, and we take any concerns or inquiries from our patients very seriously.



The text was sent to inform our patients about the Christmas closure. We apologize for any confusion regarding this text or if we inadvertently caused any inconvenience.

After a thorough investigation, we concluded that on the 20<sup>th</sup> of December 2021 at 11:18 am, we had queries from a patient who had purchased one jar of T25 topaz and queried the price charged from the patient's account on the 20<sup>th</sup> of December 2022. We can confirm that the text message relied on the information to a patient who queried the price they paid for the product they ordered. Our reply was based on inserting part of the price in the text message related to Christmas break time, and the text was sent as follows:

'HoHoHo, Santa is knocking on your door, bringing you T25 topaz@\$145.00 per jar and wishing you a Merry X-mas and Happy New Year. Thank you for your continuing support this year. We will be closed from 22/12/22 and reopen on 2/01/23. See you in 2023!'

We want to clarify that we did not advertise the product in our text message to clients regarding our Christmas break business cluster.

Instead, we provided information on the cost of the product that a patient had ordered according to the prescribed medication by his Medicinal Cannabis doctor.

I assure you that we take accountability for any errors and are committed to continuously enhancing our processes to ensure accuracy in all communications.

The texting service we have introduced seems to be quite comprehensive. Patients can receive replies to queries related to review consults, ordering system, tracking numbers and prescription-related questions. It is a great way to streamline patient communication and ensure their medical needs are met on time.

After receiving the letter from TGA, an error was discovered in our texting service process. I want to assure you that this error has been rectified immediately, and steps have been taken to prevent similar issues from occurring in the future. It was determined that the software responsible for generating the phone number was not working correctly, and due to a glitch in the system, another patient's phone number appeared.

As a result, the software generated a phone number containing inaccurate information. In this instance, the phone number of another Patient of Trava Health was entered, and the text message was sent to the wrong patient.

As soon as this issue was identified, our team immediately began working to rectify the problem. We worked tirelessly to correct the error in updating the testing process to ensure that all the phones generated from that point forward were accurate and correct. We apologize for any inconvenience this may have caused and assure you that

we take this matter very seriously. We have implemented additional measures to ensure that our software and texting processes are continually working according to the required standards.

Nonetheless, we take compliance with regulations very seriously and are reviewing all of our materials to ensure that they meet all requirements.

We're sorry if this text message has caused any confusion regarding our advertising. We take compliance with regulations very seriously and are currently reviewing our materials to ensure that they meet all requirements

To add to it, I am writing to apologize to the Patient who has informed you about the text that he received, for any confusion or distress that he may have experienced due to the arrow of the system.

As a Business Manager of Trava Health Clinic, I understand that I am responsible for ensuring that the correct text messages are sent to particular patients safely and on time. I am deeply sorry that we fell short in this regard. I want to let you know that I take full responsibility for this error, and I will do everything in my power to ensure that it does not happen again.

Thank you for being so understanding, and please do not hesitate to advise this Patient that he can reach out to me for any further assistance or support.

Thank you for bringing this to our attention, and please let us know if you have any further concerns or questions.

Best regards,

s22

[REDACTED] of Trava Health

**From:** [Advertising Compliance](#)  
**To:** s22  
**Bcc:** s22  
**Subject:** Infringement notices from the Therapeutic Goods Administration to Trava Health Pty Ltd and s22 [SEC=OFFICIAL]  
**Date:** Wednesday, 26 July 2023 2:41:00 PM  
**Attachments:** [Infringement notices and letter from the Therapeutic Goods Administration to Trava Health Pty Ltd - 26 July 2023.pdf](#)  
[Infringement notices and letter from the Therapeutic Goods Administration to s22 - 26 July 2023.pdf](#)  
[image001.gif](#)

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Dear s22

Please find attached the following documents:

- letter and 5 infringement notices to Trava Health Pty Ltd dated 26 July 2023
- letter and 3 infringement notices to s22 dated 26 July 2023.

We ask that you confirm receipt of our correspondence by 27 July 2023.

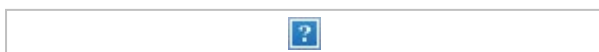
Yours sincerely

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Email: [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au)

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Trava Health Pty Ltd  
 ACN 651 466 616  
 3 Portman Street  
 Oakleigh VIC 3166

Our References: AC-000000005995

By Email:

s22 [REDACTED]@travahealth.com.au

26 July 2023

Dear s22 [REDACTED]

**Infringement notices given to Trava Health Pty Ltd**

<b>Infringement notice</b>	<b>Amount</b>	<b>Payment due by</b>
TGAIN-AC-000000005995/2023-1	\$16,500	24 August 2023
TGAIN-AC-000000005995/2023-2	\$16,500	24 August 2023
TGAIN-AC-000000005995/2023-3	\$16,500	24 August 2023
TGAIN-AC-000000005995/2023-4	\$16,500	24 August 2023
TGAIN-AC-000000005995/2023-5	\$16,500	24 August 2023
<b>Total \$ 82,500</b>		

- I refer to our previous correspondence in this matter, including our letters to Trava Health Pty Ltd (Trava Health) dated 2 March and 7 July 2023, and Trava Health's submissions dated 17 July 2023.
- I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
- I have decided to give 5 infringement notices to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act where subsections (2), (4) and (7) applied. The infringement notices are enclosed with this letter. It is important that you carefully read the infringement notices and the information contained in them.
- Infringement notices are an opportunity for Trava Health to pay an amount as an alternative to having court proceedings brought against it in relation to the alleged contraventions described in each notice. If Trava Health decides not to pay the infringement notices, court proceedings may be brought against it.
- Trava Health should be aware that the maximum civil penalty that a court can impose on a corporation for a single contravention of subsection 42DLB(1) of the Act is 50,000 penalty units. For the alleged contraventions described in the notices, this amounts to \$13,750,000.
- Part D of each infringement notices includes information on how to pay the penalty amount, how to request an extension of the compliance period for payment of the infringement notices or how to request that the infringement notices be withdrawn. If Trava Health wishes to make any such request I recommend that it provides supporting documentation, which may include financial records.

7. For more information about infringement notices, please see the following resources on the Therapeutic Goods Administration's website:
  - a. [Information about infringement notices](#)
  - b. [Infringement notices issued by the Therapeutic Goods Administration](#).<sup>1</sup>

#### Delegate comments

8. While I am not required to provide reasons for giving infringement notices under the Act, I offer the following comments to assist Trava Health to understand why I have decided to take this action.
9. The Therapeutic Goods Administration (TGA) is taking strong regulatory action to ensure compliance with the advertising requirements of the Act across the medicinal cannabis industry. In the last financial year, the TGA issued 101 infringement notices (totalling \$1,292,040) to medicinal cannabis entities, including clinics, for alleged unlawful advertising of medicinal cannabis.<sup>2</sup>
10. The Court has stated that ignorance of, or inexperience with the requirements of the Act, is not an excuse for non-compliance.<sup>3</sup> It is Trava Health's responsibility as a business involving the use of therapeutic goods and the provision of health services to be aware of and comply with the Act.<sup>4</sup>
11. Additionally, I note that Trava Health has been made aware of the advertising requirements under the Act since 2 March 2023, provided with ample opportunities to remove the alleged unlawful advertising and informed that failure to do so may result in escalated enforcement action being taken against it.
12. Despite our warnings and guidance provided to it, we have obtained evidence that Trava Health unlawfully advertised and continue to advertise medicinal cannabis on the below platforms for which it is responsible from at least 25 November 2022 until 28 June 2023:
  - a. <https://www.travahealth.com.au/>
  - b. <https://www.instagram.com/travahealthaus/>
  - c. <https://www.facebook.com/travahealthaus/>.Each day that a non-compliant advertisement remains visible may be a further contravention of the Act. More information about the alleged contraventions is outlined in the infringement notices.
13. Taking into account Trava Health's alleged contraventions, written submissions dated 17 July 2023 and financial information provided on 25 and 27 June, and 3 July 2023, I have decided to give Trava Health 5 infringement notices.
14. While it remains open to me, I have not given Trava Health infringement notices for all alleged contraventions of the Act that we identified. This includes alleged contraventions which:

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<sup>1</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/non-compliance/compliance-and-enforcement-hub/compliance-actions-and-outcomes/information-about-infringement-notices> and <https://www.tga.gov.au/infringement-notices>.

<sup>2</sup> <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-news-and-updates>.

<sup>3</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865](#) at paragraph [76].

<sup>4</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518](#) at paragraph [251].

- a. occurred in social media posts made prior to November 2022
- b. occurred in a text message sent to its customers in December 2022
- c. occurred in an identical or sufficiently similar advertisement on another social media post or page of the website
- d. arose from the use of the same restricted or prohibited representation on another social media post or page of the website
- e. occurred on each day for which a non-compliant advertisement remained visible between 25 November 2022 and 28 June 2023
- f. arose from the use of the TGA's logo by Trava Health on the website and at the Canberra Hemp, Health and Innovation Expo in November 2022.

#### **Additional steps Trava Health should take**

15. Trava Health should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter and accompanying notices are identified and resolved. In particular, we ask that Trava Health remove the TGA logo from its website. As stated in our letter of 2 March 2023, the unauthorised use of the Commonwealth Coat of Arms and our logo may raise concerns under the Act and other legislation including the *Criminal Code Act 1995* (Cth) and *Competition and Consumer Act 2010* (Cth).
16. The TGA reserves its rights to take enforcement action in relation to any future non-compliance we identify. As stated in our email on 15 June 2023, we strongly recommend that Trava Health take its platforms offline until its review is complete to avoid being liable for further contraventions of the Act.
17. We recommended Trava Health seek independent legal advice or the assistance of a regulatory affairs consultant to help it to comply with its regulatory obligations.
18. If Trava Health has any questions, please contact s22 [REDACTED] at [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au).

Yours sincerely



Nicole McLay  
Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Trava Health Pty Ltd  
ACN 651 466 616  
3 Portman Street  
Oakleigh VIC 3166

By Email:

s22 [REDACTED] [@travahealth.com.au](mailto:[REDACTED]@travahealth.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000005995/2023-1

**Date given:** 26/07/2023

**Penalty total:** \$16,500

**Payment due:** 24/08/2023

**Enquiries:**

s22 [REDACTED]

Telephone: s22 [REDACTED]

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Trava Health Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 16 March 2023, Trava Health did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.travahealth.com.au/>.

The advertisement referred to goods containing a substance (cannabis) being a Schedule 4 or 8 substance for which there was no authorisation or requirement by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>5</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-1** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-1** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>5</sup> A penalty unit for a contravention alleged to have occurred between 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

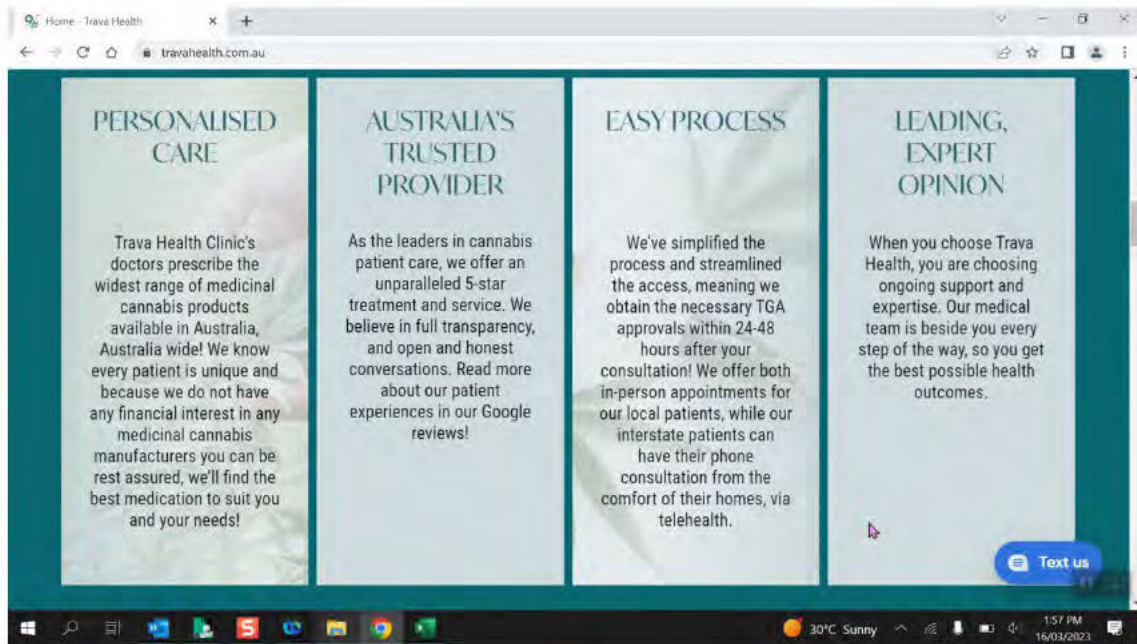
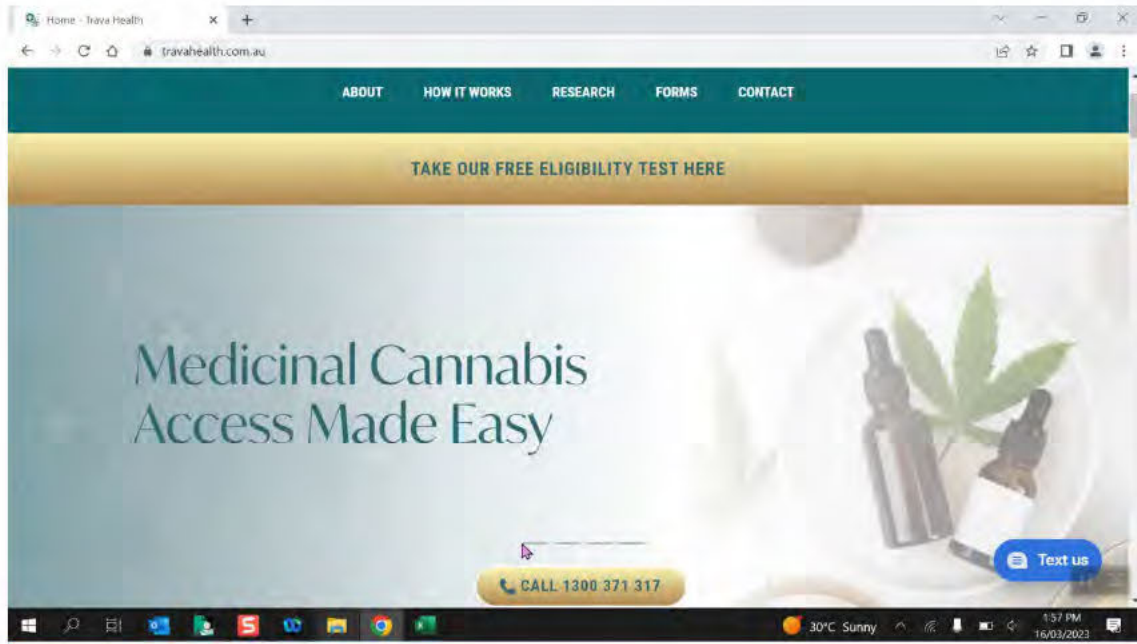
**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Trava Health Pty Ltd  
ACN 651 466 616  
3 Portman Street  
Oakleigh VIC 3166

By Email:

s22 [REDACTED] [@travahealth.com.au](mailto:s22@travahealth.com.au)

**Infringement Notice Number:**

TGAIN-AC-000000005995/2023-2

**Date given:** 26/07/2023

**Penalty total:** \$16,500

**Payment due:** 24/08/2023

**Enquiries:**

s22 [REDACTED]

Telephone: s22 [REDACTED]

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Trava Health Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, Trava Health did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.travahealth.com.au/about/>.

The advertisement contained a prohibited representation about the goods, being post-traumatic stress disorder. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>6</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-2** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-2** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit for a contravention alleged to have occurred between 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

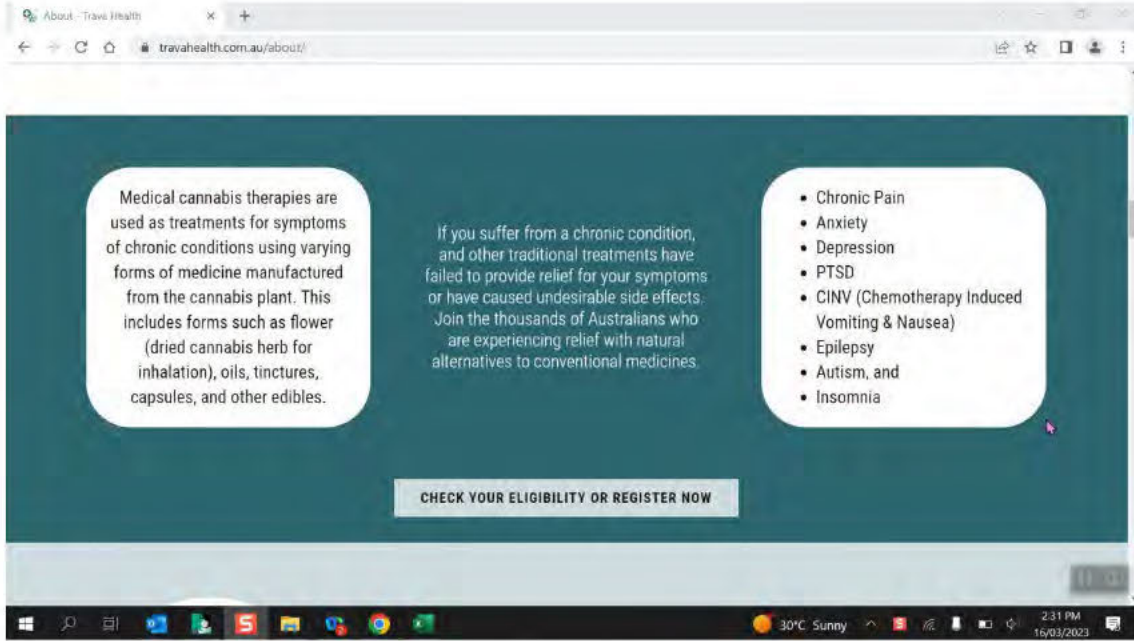
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

ANNEXURE A:







**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Trava Health Pty Ltd  
ACN 651 466 616  
3 Portman Street  
Oakleigh VIC 3166

By Email:  
s22 [REDACTED] [@travahealth.com.au](mailto:s22@travahealth.com.au)

**Infringement Notice Number:**  
TGAIN-AC-00000005995/2023-3

**Date given:** 26/07/2023

**Penalty total:** \$16,500

**Payment due:** 24/08/2023

**Enquiries:**

s22 [REDACTED]

Telephone: s22 [REDACTED]

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Trava Health Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, Trava Health did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.travahealth.com.au/about/>.

The advertisement contained a restricted representation, being chronic pain. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>7</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-3** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-3** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit for a contravention alleged to have occurred between 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

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If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

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- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

## ANNEXURE A:

About - Trava Health x +

travahealth.com.au/about/

Medical cannabis therapies are used as treatments for symptoms of chronic conditions using varying forms of medicine manufactured from the cannabis plant. This includes forms such as flower (dried cannabis herb for inhalation), oils, tinctures, capsules, and other edibles.

If you suffer from a chronic condition, and other traditional treatments have failed to provide relief for your symptoms or have caused undesirable side effects. Join the thousands of Australians who are experiencing relief with natural alternatives to conventional medicines.

- Chronic Pain
- Anxiety
- Depression
- PTSD
- CINV (Chemotherapy Induced Vomiting & Nausea)
- Epilepsy
- Autism, and
- Insomnia

[CHECK YOUR ELIGIBILITY OR REGISTER NOW](#)

30°C Sunny 2:31 PM 16/03/2023



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Trava Health Pty Ltd  
ACN 651 466 616  
3 Portman Street  
Oakleigh VIC 3166

By Email:  
s22 [REDACTED] @travahealth.com.au

**Infringement Notice Number:**  
TGAIN-AC-000000005995/2023-4

**Date given:** 26/07/2023

**Penalty total:** \$16,500

**Payment due:** 24/08/2023

**Enquiries:**  
s22 [REDACTED]  
Telephone: s22 [REDACTED]  
Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Trava Health Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, Trava Health did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CIfQBkTb4ZI/>.

The advertisement contained a restricted representation, being epilepsy. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>8</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-4** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-4** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>8</sup> A penalty unit for a contravention alleged to have occurred between 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
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- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

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Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

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- PO Box 100; WODEN ACT 2609

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**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

ANNEXURE A:

The screenshot shows a browser window displaying an Instagram post from the account 'travehealth'. The browser's address bar shows 'instagram.com/p/CHQ8Kt84ZI/'. The Instagram post features a green-themed graphic with the text 'MEDICINAL CANNABIS MADE EASY' and 'BETTER HEALTH STARTS HERE'. The graphic lists six benefits: 'THE QUALITY OF PRODUCTS', 'TREATMENT GUIDELINES', 'TYPICAL POTENTIALITY', 'SAFE DISPENSARY', 'SUPPORTS AND SUPPORTS', and 'EXPRESS DELIVERY'. Below the graphic, it says 'JOIN US TODAY & ENJOY OUR MULTIPLE BENEFITS' and provides contact information: '1300 371 317', '0482 084 945', and 'www.travehealth.com.au'. A QR code is also present. The post's caption reads: 'Are you suffering from - Anxiety - Cancer related symptoms for example pain (nausea & reduced appetite) - Spacing - Insomnia? Visit our website today for more information about our doctors and treatments and how we can get you started!'. The post includes several hashtags: #travehealth, #travehealthclinic, #travea6, #medicinalcannabisspecialist, #medicinalcannabisclinic, #medicinalherbs, #herbalmedications, #medicinal, #medicinalplants, #medicinalcannabiscolor, #anis, #medicinalweed, #travehealth, #travehealthcare, #cannabisdispensary, #medicinaldispensary, and #travea6clinic. A comment from user 's22' says: 'Nothing but love for this clinic. Thank you for being so kind, but supportive and understanding from the beginning!'. The reply from 'travehealth' says: 'We still haven't addressed our complaint about you threatening an epileptic patient to cancel his cannabis medication'. The screenshot also shows the Windows Explorer taskbar at the bottom with the text 'Windows Explorer 10.0.19041.2486', the system clock '3:24:55 PM 16/03/2023', and the text 'Taken by s22 Windows 10 Enterprise 64-bit Build 19044'.



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Trava Health Pty Ltd  
ACN 651 466 616  
3 Portman Street  
Oakleigh VIC 3166

By Email:  
s22 [REDACTED]@travahealth.com.au

**Infringement Notice Number:**  
TGAIN-AC-000000005995/2023-5

**Date given:** 26/07/2023

**Penalty total:** \$16,500

**Payment due:** 24/08/2023

**Enquiries:**  
s22 [REDACTED]  
Telephone: s22 [REDACTED]  
Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Trava Health Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to Trava Health Pty Ltd (Trava Health) under Part 5A-2 of the Act on the basis that I reasonably believe that Trava Health has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, Trava Health did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.facebook.com/TravaHealthAUS/posts/pfbid02G7AiXZtg2fmcyeFNsuM6xieTt6rHEyvWHT4awR4MNFsinj4FRcYX4edo6VZdfCrl>.

The advertisement contained a prohibited representation about the goods, being depression. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on a company for a single contravention of section 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$13,750,000.<sup>9</sup>

The amount payable under this notice is \$16,500. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-5** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-5** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>9</sup> A penalty unit for a contravention alleged to have occurred between 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

ANNEXURE A:

Trava Health Clinic  
November 9, 2022

THC & CBD are the two of the most prominent cannabinoids found in the cannabis plants.

Get in touch with us today and see how you can get started on your treatments, or head to our website and register online today!  
[www.travahealth.com.au](http://www.travahealth.com.au)

#travahealth #travahealthclinic #travataik #medicinalcannabisspecialist #medicinalcannabisclicnic #medicinalherbs #herbalnutrition #herbalfife #medicinalplants #medicinalchemistry #medicinalflowers #medicinalweed #telehealth #telehealthcare #dailycannabis #cannabiscommunity #cannabisresearch

THC	VS	CBD
<ul style="list-style-type: none"> <li>Psychoactive</li> <li>Anti-Anxiety</li> <li>Pain Relief</li> <li>Depressions</li> </ul>		<ul style="list-style-type: none"> <li>None-psychoactive</li> <li>Relaxation</li> <li>Pain Relief</li> <li>Appetite Stimulant</li> </ul>

www.travahealth.com.au  
1300 331 337

Like Comment Share

Write a comment...  
Press Enter to post.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Our References: AC-000000005995

s22  
s22

By Email:

s22 @travahealth.com.au

26 July 2023

Dear s22

Infringement notices given to s22

Infringement notice	Amount	Payment due by
TGAIN-AC-000000005995/2023-6	\$3,300	24 August 2023
TGAIN-AC-000000005995/2023-7	\$3,300	24 August 2023
TGAIN-AC-000000005995/2023-8	\$3,300	24 August 2023
<b>Total \$ 9,900</b>		

- I refer to our previous correspondence in this matter, including our letters to Trava Health Pty Ltd (Trava Health) dated 2 March and 7 July 2023, and Trava Health's submissions dated 17 July 2023.
- I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
- I have decided to give 3 infringement notices to you under Part 5A-2 of the Act on the basis that I reasonably believe that you have contravened section 42DLB(1) of the Act where subsections (2), (4) and (7) applied. The infringement notices are enclosed to this letter. It is important that you carefully read the infringement notices and the information contained in them.
- Infringement notices are an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contraventions described in each notice. If you decide not to pay the infringement notices, court proceedings may be brought against you.
- You should be aware that the maximum civil penalty that a court can impose on an individual for a single contravention of subsection 42DLB(1) of the Act is 5000 penalty units. For the alleged contraventions described in the notices, this amounts to \$1,375,000.
- Part D of each infringement notices includes information on how to pay the penalty amount, how to request an extension of the compliance period for payment of the infringement notices or how to request that the infringement notices be withdrawn. If you wish to make any such request I recommend that you provide supporting documentation, which may include financial records.



7. For more information about infringement notices, please see the following resources on the Therapeutic Goods Administration's (TGA) website:
  - a. [Information about infringement notices](#)
  - b. [Infringement notices issued by the Therapeutic Goods Administration](#).<sup>1</sup>

#### Delegate comments

8. While I am not required to provide reasons for giving you infringement notices under the Act, I offer you the following comments to assist you to understand why I have decided to take this action.
9. The Therapeutic Goods Administration is taking strong regulatory action to ensure compliance with the advertising requirements of the Act across the medicinal cannabis industry. In the last financial year, the TGA issued 101 infringement notices (totalling \$1,292,040) to medicinal cannabis entities, including clinics, for alleged unlawful advertising of medicinal cannabis.<sup>2</sup>
10. The Court has stated that ignorance of, or inexperience with the requirements of the Act, is not an excuse for non-compliance.<sup>3</sup> It is your responsibility as a director of a company involving the use of therapeutic goods and the provision of health services to be aware of and ensure that Trava Health complies with the Act.<sup>4</sup>
11. Additionally, I note that Trava Health and you have been made aware of the advertising requirements under the Act since 2 March 2023, provided with ample opportunities to remove the alleged unlawful advertising and informed that failure to do so may result in escalated enforcement action being taken.
12. Despite our warnings and guidance provided to it, we have obtained evidence that Trava Health unlawfully advertised and continue to advertise medicinal cannabis on the below platforms for which it is responsible from at least 25 November 2022 until 28 June 2023:
  - a. <https://www.travahealth.com.au/>
  - b. <https://www.instagram.com/travahealthaus/>
  - c. <https://www.facebook.com/travahealthaus/>.

Each day that a non-compliant advertisement remains visible may be a further contravention of the Act. More information about the alleged contraventions is outlined in the infringement notices.

13. We consider that you advertised medicinal cannabis or caused the advertisements described in the infringement notices for the following reasons:
  - a. You are Trava Health's Managing Director and Chief Executive Officer.
  - b. In Trava Health's letter of 25 June 2023 in response to our section 45AB notice dated 17 February 2023, you were named as the sole person who could change, post or

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<sup>1</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/non-compliance/compliance-and-enforcement-hub/compliance-actions-and-outcomes/information-about-infringement-notices> and <https://www.tga.gov.au/infringement-notices>.

<sup>2</sup> <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-news-and-updates>.

<sup>3</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865](#) at paragraph [76].

<sup>4</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518](#) at paragraph [251].

upload content to or who drafted or approved the content on the relevant Trava Health platforms from February 2023 until 17 May 2023.

14. Taking into account the alleged contraventions, Trava Health's written submissions dated 17 July 2023 and financial information provided on 25 and 27 June, and 3 July 2023, I have decided to give you 3 infringement notices.
15. While it remains open to me, I have not given you infringement notices for all alleged contraventions of the Act that we identified. This includes alleged contraventions which:
  - a. were subject to an infringement notice given to Trava Health
  - b. occurred in social media posts made prior to November 2022
  - c. occurred in a text message sent to Trava Health customers in December 2022
  - d. occurred in an identical or sufficiently similar advertisement on another social media post or page of the website
  - e. arose from the use of the same restricted or prohibited representation on another social media post or page of the website
  - f. occurred on each day for which a non-compliant advertisement remained visible between 25 November 2022 and 28 June 2023
  - g. arose from the use of the TGA's logo by Trava Health on the website and at the Canberra Hemp, Health and Innovation Expo in November 2022.

#### **Additional steps you should take**

16. You should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter and accompanying notices are identified and resolved. In particular, we ask that you remove the TGA logo from Trava Health's website. As stated in our letter of 2 March 2023, the unauthorised use of the Commonwealth Coat of Arms and our logo may raise concerns under the Act and other legislation including the *Criminal Code Act 1995 (Cth)* and *Competition and Consumer Act 2010 (Cth)*.
17. The TGA reserves its rights to take enforcement action in relation to any future non-compliance we identify. As stated in our email on 15 June 2023, we strongly recommend that Trava Health take its platforms offline until its review is complete to avoid being liable for further contraventions of the Act. We recommended you seek independent legal advice or the assistance of a regulatory affairs consultant to help you to comply with your regulatory obligations.
18. If you have any questions, please contact <sup>s22</sup> [REDACTED] at [Advertising.Compliance@tga.gov.au](mailto:Advertising.Compliance@tga.gov.au).

Yours sincerely



Nicole McLay  
Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22

3 Portman Street  
 Oakleigh VIC 3166

By Email:

s22 @travahealth.com.au

**Infringement Notice Number:**

TGAIN-AC-000000005995/2023-6

**Date given:** 26/07/2023**Penalty total:** \$3,300**Payment due:** 24/08/2023**Enquiries:**

s22

Telephone: s22

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)**INFRINGEMENT NOTICE GIVEN TO**

s22

**PART A: Infringement Notice given by**

Nicole McLay

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to s22 under Part 5A-2 of the Act on the basis that I reasonably believe that s22 has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, s22 did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.travahealth.com.au/about/>.

The advertisement contained a restricted representation, being autism spectrum disorder. Neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on an individual for a single contravention of section 42DLB(1) is 5,000 penalty units. For the above alleged contravention, this amounts to \$1,375,000.<sup>5</sup>

The amount payable under this notice is \$3,300. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-6** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-6** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>5</sup> A penalty unit for a contravention alleged to have occurred after 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

## ANNEXURE A:

Medical cannabis therapies are used as treatments for symptoms of chronic conditions using varying forms of medicine manufactured from the cannabis plant. This includes forms such as flower (dried cannabis herb for inhalation), oils, tinctures, capsules, and other edibles.

If you suffer from a chronic condition, and other traditional treatments have failed to provide relief for your symptoms or have caused undesirable side effects. Join the thousands of Australians who are experiencing relief with natural alternatives to conventional medicines.

- Chronic Pain
- Anxiety
- Depression
- PTSD
- CINV (Chemotherapy Induced Vomiting & Nausea)
- Epilepsy
- Autism, and
- Insomnia

[CHECK YOUR ELIGIBILITY OR REGISTER NOW](#)

30°C Sunny 2:31 PM 16/03/2023



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**s22**  
 3 Portman Street  
 Oakleigh VIC 3166

By Email:  
**s22** [@travahealth.com.au](mailto:@travahealth.com.au)

**Infringement Notice Number:**  
 TGAIN-AC-000000005995/2023-7

**Date given:** 26/07/2023

**Penalty total:** \$3,300

**Payment due:** 24/08/2023

**Enquiries:**

**s22**

Telephone: **s22**

Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

**s22**

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to **s22** under Part 5A-2 of the Act on the basis that I reasonably believe that **s22** has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 16 March 2023, **s22** did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CIfQBkTb4ZI/>.

The advertisement contained a prohibited representation, being cancer. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.



The maximum penalty that a court could impose on an individual for a single contravention of section 42DLB(1) is 5,000 penalty units. For the above alleged contravention, this amounts to \$1,375,000.<sup>6</sup>

The amount payable under this notice is \$3,300. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box 9848,  
Canberra ACT 2601** with  
your cheque made payable to  
the Department of Health and  
Aged Care.  
Please allow 5 business days  
for payment to be received.



#### CREDIT CARD

Use your credit card to pay  
your notice by calling the  
Collector of Relevant  
Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
TGAIN-AC-  
000000005995/2023-7 as  
reference to identify your  
payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
Department of Health and  
Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
TGAIN-AC-  
000000005995/2023-7 in  
the description of your  
transfer and allow two  
business days for payment  
to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit for a contravention alleged to have occurred after 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023

ANNEXURE A:

The screenshot shows a Windows Explorer window displaying an Instagram post. The browser address bar shows 'instagram.com/p/C1HQ8Kt18AZI/'. The Instagram post is from the account 'Medicinal Cannabis Clinic (@travehealth)'. The main image is a promotional graphic with a teal background and white text. The graphic reads 'MEDICINAL CANNABIS MADE EASY' and 'BETTER HEALTH STARTS HERE'. It features six icons representing services: 'APPOINTMENT SCHEDULING', 'TREATMENT GUIDELINES', 'MEDICAL ACCESSIBILITY', '24/7 DISPENSARY', 'ONLINE CONSULTATIONS', and 'EXPRESS DELIVERY'. Below the icons, it says 'JOIN US TODAY & ENJOY OUR MULTIPLE BENEFITS' and 'Our friendly & dedicated administration team are here to continuously help and support you along your medical cannabis journey.' Contact information includes the phone number '1300 371 317', the number '0482 064 845', and the website 'www.travehealth.com.au'. A QR code is also present. The Instagram interface shows a comment from user 's22' with the text: 'Nothing but love for this clinic! Thank you for being so kind but supportive and understanding from the beginning! 🙏🏻 🙏🏻 🙏🏻'. The comment is liked by 's22' and others. The Windows taskbar at the bottom shows the time as 3:24:55 PM on 16/03/2023, and the system version as Windows 10 Enterprise 64-bit Build 19044. The screenshot was taken by 's22'.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22  
 3 Portman Street  
 Oakleigh VIC 3166

By Email:  
 s22 @travahealth.com.au

**Infringement Notice Number:**  
 TGAIN- AC-000000005995/2023-8

**Date given:** 26/07/2023

**Penalty total:** \$3,300

**Payment due:** 24/08/2023

**Enquiries:**  
 s22  
 Telephone: s22  
 Email: [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**

s22

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice to s22 under Part 5A-2 of the Act on the basis that I reasonably believe that s22 has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 16 March 2023, s22 did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.facebook.com/TravaHealthAUS/posts/pfbid02G7AiXZtg2fmcyeFNsuM6xjeTtt6rHEyvWHT4awR4MNFsini4FRcYX4edo6VZdfCrI>.

The advertisement referred to a substance (cannabis) being a Schedule 4 or 8 substance for which there was no authorisation or requirement by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty that a court could impose on an individual for a single contravention of section 42DLB(1) is 5,000 penalty units. For the above alleged contravention, this amounts to \$1,375,000.<sup>7</sup>

The amount payable under this notice is \$3,300. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received.



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000005995/2023-8** as reference to identify your payment.



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000005995/2023-8** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit for a contravention alleged to have occurred after 1 January 2023 and 30 June 2023 is \$275 (section 4AA of the *Crimes Act 1914*). The value of a penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313.

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, civil penalty proceedings may be brought against you for the alleged contravention described in this notice.

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No further payment can be accepted for a lapsed notice, however the Secretary may at their discretion extend the compliance period to allow payment to be made. If you pay the penalty amount payable under this notice after the compliance period has lapsed (and the compliance period is not extended), you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 26/07/2023



ANNEXURE A:

The screenshot shows a Facebook post from Trava Health Clinic, dated November 3, 2022. The post text reads: "THC & CBD are the two of the most prominent cannabinoids found in the cannabis plants. Get in touch with us today and see how you can get started on your treatments, or head to our website and register online today! www.travahealth.com.au". Below the text is a list of hashtags including #travahealth, #travahealthclinic, #travataik, #medicinalcannabisspecialist, #medicinalcannabisclicnic, #medicinalherbs, #herbalifenutrition, #herbalife, #medicinalplants, #medicinalchemistry, #medicinalflowers, #medicinalweed, #telehealth, #telehealthcare, #dailycannabis, #cannabiscommunity, and #cannabisresearch. The main visual is a comparison chart titled "THC VS CBD" with the following details:

THC	VS	CBD
+ Psychoactive		+ None-psychoactive
+ Anti-Anxiety		+ Relaxation
+ Pain Relief		+ Pain Relief
+ Depressions		+ Appetite Stimulant

At the bottom of the chart, the website www.travahealth.com.au and phone number 1300 311 312 are listed. The post has 1 like and 1 share, and a comment box is visible at the bottom.

Windows Explorer  
10.0.19041.2486

2:48:52 PM 16/03/2023  
Windows 10 Enterprise 64-bit Build 19044

Taken by S22

**From:** [Advertising Compliance](#)  
**To:** "Embrace Wellness"; s22  
**Cc:** s22  
**Bcc:** s22  
**Subject:** IMPORTANT - Infringement Notices from the Therapeutic Goods Administration to Affinity Corp Australia Pty Ltd - CC-LQ4XPGY6/2021 [SEC=OFFICIAL]  
**Date:** Thursday, 8 June 2023 1:00:00 PM  
**Attachments:** [image001.gif](#)  
[Cover Letter and Infringement Notices to Affinity Corp Australia Pty Ltd.pdf](#)

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Dear the Proper Officer,

Please find attached a letter and 5 infringement notices from the Therapeutic Goods Administration to Affinity Corp Australia Pty Ltd.

We ask that you confirm receipt of our correspondence by **5:00 PM Friday 9 June 2023**.

Yours sincerely,

s22  
[Redacted]

Advertising & Product Investigation Section  
Regulatory Compliance Branch

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.



**Australian Government**  

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**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Affinity Corp Australia Pty Ltd  
ACN 632 051 408

Our Reference: CC-LQ4XPGY6/2021

s22

**By Express Post and By Email:**

[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com); and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

8 June 2023

The Proper Officer

**Infringement notices given to Affinity Corp Australia Pty Ltd**

<b>Infringement Notice</b>	<b>Amount</b>	<b>Payment Due by</b>
TGAIN- CC-LQ4XPGY6/2021-1	\$13,320.00	6 July 2023
TGAIN- CC-LQ4XPGY6/2021-2	\$13,320.00	6 July 2023
TGAIN- CC-LQ4XPGY6/2021-3	\$13,320.00	6 July 2023
TGAIN- CC-LQ4XPGY6/2021-4	\$13,320.00	6 July 2023
TGAIN- CC-LQ4XPGY6/2021-5	\$13,320.00	6 July 2023
<b>Total</b>	<b>\$66,600.00</b>	

1. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
2. I have decided to give five (5) infringement notices to Affinity Corp Australia Pty Ltd (Affinity Corp.) under Part 5A-2 of the Act, on the basis that I reasonably believe Affinity Corp Australia Pty Ltd contravened subsection 42DLB(1) of the Act, where subsections (2), (4) and (9) applied.
3. The infringement notices are enclosed to this letter and include information on how to pay the penalty amount, how to request an extension of the compliance period for payment, how to request that the infringement notices be withdrawn, and the actions that we may take in the event of non-payment of the infringement notices. It is important that Affinity Corp carefully read the infringement notices and the information contained within.
4. Infringement notices are an opportunity for Affinity Corp to pay an amount as an alternative to having court proceedings brought against them in relation to the alleged contraventions described in each of the notices.

5. If Affinity Corp chooses not to pay the penalty amount, proceedings may be brought against them for the alleged contraventions described in the infringement notices. We note that the maximum civil penalty that a court can impose on a company for a contravention of subsection 42DLB(1) of the Act is **\$11.1 million** per contravention.
6. There have been recent Federal Court decisions in which the court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.<sup>1</sup> Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those from the outset.<sup>2</sup>
7. You should be aware of the possible consequences for not paying an infringement notice. In a recent decision by the Federal Court, non-payment of a single infringement notice issued against a company resulted in the court ordering a total of \$96,000 in penalty against both the company and its executive directors.<sup>3</sup>
8. To avoid being liable for further contraventions of the Act, immediate steps should be taken to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting that we reserve our rights to take enforcement action in relation to any further non-compliance we may identify.
9. For more information about infringement notices, please see the following links to the refer TGA website:
  - a. [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#).
  - b. [Infringement notices | Therapeutic Goods Administration \(TGA\)](#).

#### **Delegate comments and concerns**

10. While I am not required to provide reasons for giving an infringement notice under the Act, I offer the following remarks to assist you to understand why I have decided to take this particular action.
11. I have reviewed the following platforms:
  - a. <https://www.embracewellnessoils.com.au/> (the Website)
  - b. <https://www.facebook.com/embracewellnessholistichub> and
  - c. <https://www.instagram.com/embracewellnessholistichub/> (collectively, the Social Media)
12. While not all information released to the public about therapeutic goods is advertising, I consider that the Website and Social Media unlawfully advertise medicinal cannabis products (therapeutic goods), as defined in section 3(1) of the Act, for the following reasons:
  - a. The Website and Social Media contain statements and pictorial representations which were intended, directly or indirectly, to promote the use or supply of medicinal cannabis products. For example:
    - i. The alleged advertisements directed the reader to a means of accessing medicinal cannabis products, such as direct links (access) to medicinal cannabis products available for purchase on the Website.

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<sup>1</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

<sup>2</sup> [Secretary, Department of Health v OxyMed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

<sup>3</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

- ii. The use of hashtags in Social Media posts, a function which is predominantly used to promote the content, that referred to medicinal cannabis such as #cbdoil #cbdproducts #cbdoilbenefits.
  - iii. The Social Media contains statements presented to be testimonials from other users who claim to have used products purchased from Affinity Corp.
  - iv. The Website and Social Media make unauthorised therapeutic claims regarding the efficacy of medicinal cannabis. For example, making references to serious forms of a disease, ailment, or condition, in circumstances which inferred (directly or indirectly) that medicinal cannabis may be, or is, a suitable treatment for the medical condition mentioned.
- b. The advertisements:
- i. Refer to goods that are not entered in the Australian Register of Therapeutic Goods, such as MCT Blend oil and Turmeric Infusion oil.
  - ii. Refer to substances which are included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, and
  - iii. Contain prohibited representations such as references to neoplastic disease or mental illness and/or restricted representations being references to serious forms of diseases, ailments, and conditions without TGA permission or approval.
13. Additionally, I note that Affinity Corp have previously been made aware of the advertising prohibitions under the Act, on at least two occasions:
- a. on 20 December 2021, you were warned regarding the alleged unlawful advertising of medicinal cannabis (the product) on the Website
  - b. on 28 January 2022 you were again warned about the alleged unlawful advertising of medicinal cannabis (the product) on the Website
  - c. you were provided with the opportunity to immediately remove and cease advertising in a way that contravenes the advertising requirements of the Act, and
  - d. you were informed that failure to do so may result in escalated enforcement action being taken including the issuing of directions or infringement notices or court proceedings.
14. Although some steps were taken to bring your advertising into compliance, the advertising remains non-compliant with the Act.
15. Each instance of non-compliant advertising on each day constitutes a separate contravention of the Act. We hold evidence that the contraventions as particularised in the infringement notices, occurred from at least late January 2022 to at least 12 April 2023.
16. I note that I have exercised my discretion to not give you infringement notices for all alleged contraventions of the Act identified at this time, including those:
- a. which occurred in Social Media posts made prior to July 2022
  - b. which appeared identical or sufficiently similar, to the advertising on another page of the Website or another Social Media post
  - c. arising from the same restricted or prohibited representation which was made multiple times on the Website and/or Social Media, and
  - d. which appeared on traditional media, such pamphlets, and banners.
17. Further, while it was open to me give an infringement notice to s22 as the Executive Officer of Affinity Corp within the meaning of subsection 54B(5) of the Act, I have

utilised my discretion to not give an infringement notice to s22 on this occasion. However, please be aware that if future contraventions of the Act are identified, and evidence is obtained to support that s22 knew the alleged contravention of the Act would be committed and failed to take all reasonable steps to prevent the commission of the contravention, escalated enforcement action may be taken, including court proceedings.

18. You should be aware the TGA laboratories completed an analysis of a product, '*Embrace Wellness Turmeric 1000 Black Seed and MCT Dietary Supplement*', which was purchased from the Website in January 2022.
19. The analysis of the product found it contained 'undeclared' substances, delta-9-tetrahydrocannabinoid (THC), low levels of the cannabinoids - Cannabidiol (CBDV), Cannabigerol (CBG) and Cannabinol (CBN). As such, the product is alleged to be counterfeit as defined in section 42E of the Act.
20. Importation, manufacture, and supply of counterfeit therapeutic goods is against the law and may be subject to criminal and civil penalty provision under the Act.
21. Please note, I have decided, at this stage, not to give you an infringement notice in relation to the counterfeit medicinal cannabis product. I consider, however, that you have been put on notice about advertising counterfeit products on your Website and Social Media, and request you immediately cease all advertising and supply of these products.
22. Please contact s22 by email at [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au) should Affinity Corp Australia Pty wish to discuss this matter further.

Yours sincerely



Nicole McLay

Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

The Proper Officer  
Affinity Corp Australia Pty Ltd  
ACN 632 051 408

§22

By Express Post and By Email:  
[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com), and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

**Infringement Notice Number:**  
TGAIN-CC-LQ4XPGY6/2021-1

**Date given:** 08/06/2023

**Penalty total:** \$13,320.00

**Payment due:** 6/07/2023

**Enquiries:** §22

**Telephone:** §22

**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

### INFRINGEMENT NOTICE GIVEN TO *Affinity Corp Australia Pty Ltd*

#### PART A: Infringement Notice given by

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Affinity Corp Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Affinity Corp Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 31 October 2022, Affinity Corp Australia Pty Ltd did advertise, or caused the advertising of therapeutic goods, being MCT Blend oil, on the web page located at <https://www.embracewellnessoils.com.au/product-page/cbd-oil-1000mg-30ml>, and

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being therapeutic goods that is neither the subject of an exemption, approval, or authority under the Act. The

reference to the prescribed good is not authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN-CC-  
 LQ4XPGY6/2021-1** as  
 reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN-CC-  
 LQ4XPGY6/2021-1** in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit for a contravention alleged to have occurred before 1 January 2023 is \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of failing to comply with this notice**

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 08/06/2023

# ANNEXURE A

MCT Blend 2000 | Embrace Well

embracewellnessoils.com.au/product-page/cbd-oil-1000mg-30ml

Home / Shop / MCT Blend 2000

← Prev | Next →

MCT Blend 2000

\$180.00

Size

Select ^

30ml

50ml

Add to Cart

Let's Chat!

https://www.embracewellnessoils.com.au/product-page/cbd-oil-1000mg-30ml  
Google Chrome 107.0.5304.63

10:02:49 AM 31/10/2022  
Windows 10 Enterprise 64-bit Build 19044

SNAGIT Capture taken by: s22



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

The Proper Officer  
 Affinity Corp Australia Pty Ltd  
 ACN 632 051 408

s22

**By Express Post and By Email:**  
[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com), and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

**Infringement Notice Number:**  
 TGAIN-CC-LQ4XPGY6/2021-2

**Date given:** 08/06/2023

**Penalty total:** \$13,320.00

**Payment due:** 6/07/2023

**Enquiries:** s22

**Telephone:** s22

**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Affinity Corp Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Affinity Corp Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Affinity Corp Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 31 October 2022, Affinity Corp Australia Pty Ltd did advertise, or caused the advertising of therapeutic goods, being Turmeric Infusion 2000, on the web page located at <https://www.embracewellnessoils.com.au/product-page/cbd-with-black-seed-mct-and-turmeric-1>, and

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being therapeutic goods that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box  
9848, Canberra ACT 2601**  
with your cheque made  
payable to the Department  
of Health and Aged Care.  
Please allow 5 business  
days for payment to be  
received



#### CREDIT CARD

Use your credit card  
to pay your notice by calling  
the Collector of Relevant  
Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-2** as  
reference to identify your  
payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-2** in the  
description of your transfer  
and allow two business days  
for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit for a contravention alleged to have occurred before 1 January 2023 is \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of failing to comply with this notice**

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 08/06/2023

ANNEXURE A

Turmeric Infusion 2000

Embrace Wellness  
TURMERIC 2000

\$200.00

Size

Select

30ml

50ml

Add to Cart

Let's Chat

http://www.embracewellnessoils.com.au/product-page/cbd-with-black-seed-mct-and-turmeric-1 10:00:23 AM 31/10/2022 SNAGIT Capture Taken by: s.22

Google Chrome 107.0.5304.63 Windows 10 Enterprise 64-bit Build 19044





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

The Proper Officer  
 Affinity Corp Australia Pty Ltd  
 ACN 632 051 408

s22

**By Express Post and By Email:**  
[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com), and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

**Infringement Notice Number:**  
 TGAIN-CC-LQ4XPGY6/2021-3

**Date given:** 08/06/2023

**Penalty total:** \$13,320.00

**Payment due:** 6/07/2023

**Enquiries:** s22

**Telephone:** s22

**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Affinity Corp Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Affinity Corp Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Affinity Corp Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 31 October 2022, Affinity Corp Australia Pty Ltd did advertise, or caused the advertising of therapeutic goods, being Embrace Canna Releaf Stick CBD 500mg, on the web page located at <https://www.embracewellnessoils.com.au/product-page/canna-leaf-stick-500mg>, and

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to arthritis. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box  
9848, Canberra ACT 2601**  
with your cheque made  
payable to the Department  
of Health and Aged Care.  
Please allow 5 business  
days for payment to be  
received



#### CREDIT CARD

Use your credit card  
to pay your notice by calling  
the Collector of Relevant  
Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-3** as  
reference to identify your  
payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-3** in the  
description of your transfer  
and allow two business days  
for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit for a contravention alleged to have occurred before 1 January 2023 is \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of failing to comply with this notice**

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 08/06/2023

ANNEXURE A

Canna Releaf Stick 500mg | Embrace Wellness Oils

Home / Shop / Canna Releaf Stick 500mg

Canna Releaf Stick 500mg

\$100.00

Quantity:

Add to Cart

An all natural, anti-inflammatory CBD infused Balm for Sore Muscles, Arthritis, Joint Pain, Aches, Spains, Inflammation, and more.

- 500mg CBD per stick
- Quick & Easy to apply
- Perfect to keep in the gym bag or handbag
- 100% stick

Contains: CBD Isolate, Rosemary, Camphor oil, Menthol, Benzoin, Coconut oil, Terpenes, MCT oil, Hemp oil

Let's Chat

https://www.embracewellnessoils.com.au/product-page/canna-leaf-stick-500mg 9:42:05 AM 31/10/2022 SNAGIT Capture Taken by: s22  
Google Chrome 107.0.5304.63 Windows 10 Enterprise 64-bit Build 19044



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

The Proper Officer  
 Affinity Corp Australia Pty Ltd  
 ACN 632 051 408

s22

**By Express Post and By Email:**  
[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com), and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

**Infringement Notice Number:**  
 TGAIN-CC-LQ4XPGY6/2021-4

**Date given:** 08/06/2023

**Penalty total:** \$13,320.00

**Payment due:** 6/07/2023

**Enquiries:** s22

**Telephone:** s22

**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Affinity Corp Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Affinity Corp Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Affinity Corp Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 1 November 2022, Affinity Corp Australia Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at

<https://www.facebook.com/photo/?fbid=461879035941309&set=a.454875703308309>,  
 and

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to auto-immune disease. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN-CC-  
 LQ4XPGY6/2021-4** as  
 reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN-CC-  
 LQ4XPGY6/2021-4** in the  
 description of your transfer  
 and allow two business days  
 for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit for a contravention alleged to have occurred before 1 January 2023 is \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.



**Effect of failing to comply with this notice**

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 08/06/2023

ANNEXURE A

**CBD & IMMUNE SYSTEM**

*Did You Know?*

CBD is known to be immune-modulating, which means it **can bring an over- or under-reacting immune system back into balance.**

- Calming a hyperactive immune system & strengthening a compromised one.
- Direct suppression of activation of various immune cell types, such as interfering with the release of cytokines.
- Induction of Apoptosis (cancer cell death)
- Promotion of healthy cells.
- Helps regulate stress response in the body, maintaining homeostasis as much as possible, naturally. This means our immune system can function properly.

Embrace Wellness

Embrace Wellness Holistic Hub  
August 28

This is incredible news for anyone suffering from autoimmune diseases!

Recent data from research in 2020 shows that cannabinoids have several benefits for our immune system such as...

02:43:11 9773  
00:44:9778  
1/ 26 The Entrance Rd, The Entrance NSW 2261  
2/ 11-13 Cochrane St, Kincumber NSW 2261

#endocannabinoidsystem #autoimmune #autoimmuneandcbd #immunesystem #antiinflammatoryfood #arthritis #psoriasis #parkinsons #embracewellness See less

Like Comment Share

Write a comment... Has this helped?

https://www.facebook.com/photo/?fbid=492187506243795&set=a.454875703308309 10:48:53 AM 1/11/2022 SNAGIT Capture taken by: s22  
Google Chrome 107.0.5304.63 Windows 10 Enterprise 64 bit Build 19044



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

The Proper Officer  
 Affinity Corp Australia Pty Ltd  
 ACN 632 051 408

§22

**By Express Post and By Email:**  
[info.embracewellness1@gmail.com](mailto:info.embracewellness1@gmail.com), and  
[revitalisedlife@outlook.com](mailto:revitalisedlife@outlook.com)

**Infringement Notice Number:**  
 TGAIN-CC-LQ4XPGY6/2021-5

**Date given:** 08/06/2023

**Penalty total:** \$13,320.00

**Payment due:** 6/07/2023

**Enquiries:** §22

**Telephone:** §22

**Email:** [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Affinity Corp Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Affinity Corp Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Affinity Corp Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 1 November 2022, Affinity Corp Australia Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at

<https://www.facebook.com/embracewellnessholisticclub/posts/pfbid0eSU1dQpKP26AnsJPpWz6MJCqFVwjHcEanGyh4ETqESqsoVsbcrlJ2AurRqS8fDESI>, and

The advertisement contained a prohibited representation about the goods, (whether in express terms or by necessary implication) being a reference to skin cancer and no permission under section 42DK of the Act was in force in relation to the prohibited representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box  
9848, Canberra ACT 2601**  
with your cheque made  
payable to the Department  
of Health and Aged Care.  
Please allow 5 business  
days for payment to be  
received



#### CREDIT CARD

Use your credit card  
to pay your notice by calling  
the Collector of Relevant  
Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-5** as  
reference to identify your  
payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
**TGAIN-CC-  
LQ4XPGY6/2021-5** in the  
description of your transfer  
and allow two business days  
for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit for a contravention alleged to have occurred before 1 January 2023 is \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

**Effect of failing to comply with this notice**

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit, and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [advertising.compliance@tga.gov.au](mailto:advertising.compliance@tga.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

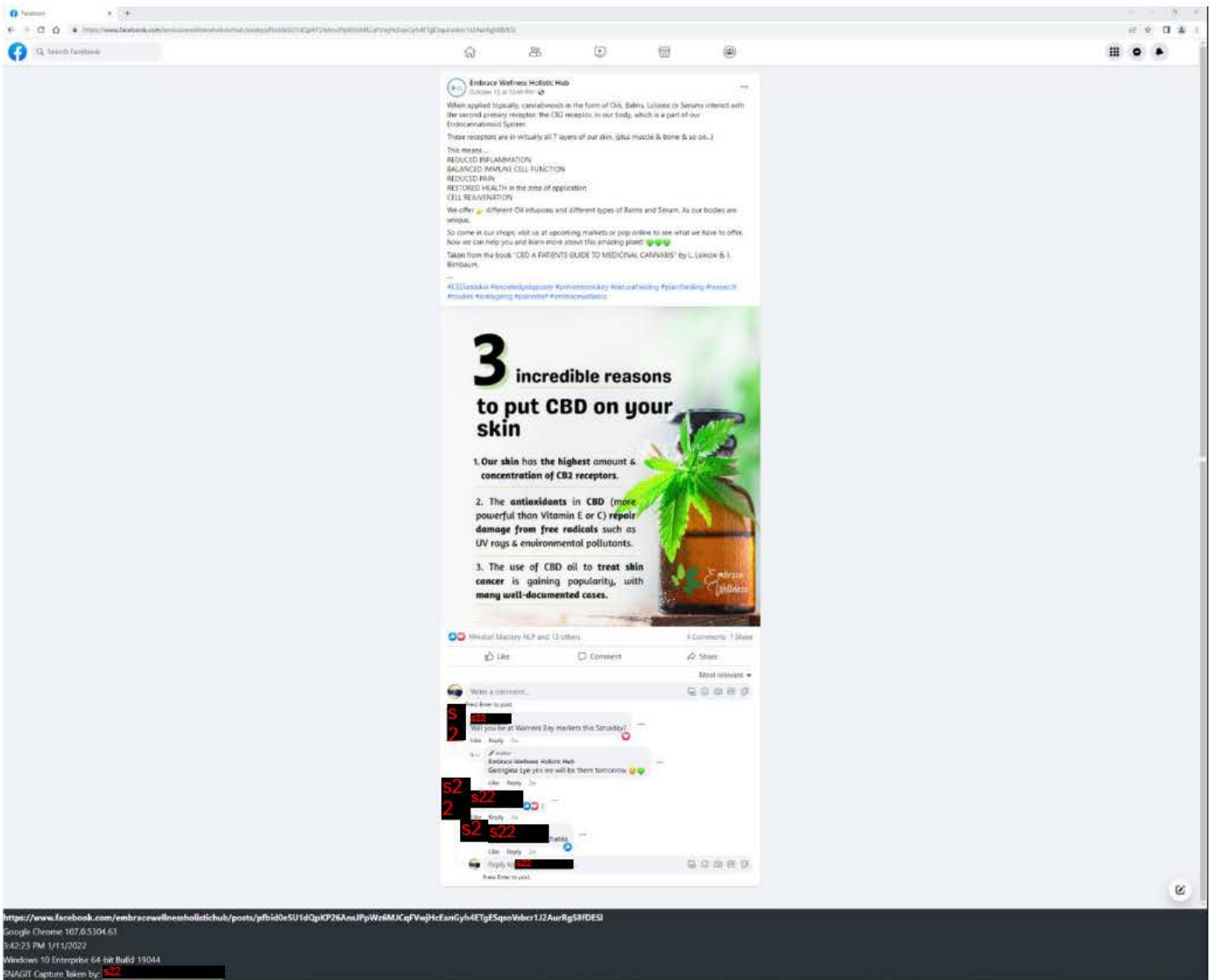
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 08/06/2023

ANNEXURE A



**From:** s22  
**To:** s22  
**Cc:** s22  
**Bcc:** s22  
**Subject:** Infringement Notices from the Therapeutic Goods Administration to Australian Institute of Medicinal Cannabis Pty Ltd (AIOMC) - CC-EJWB7UWD/2021 [SEC=OFFICIAL]  
**Date:** Monday, 31 October 2022 1:08:00 PM  
**Attachments:** [image001.gif](#)  
[Cover Letter and Infringement Notices to Australian Institute of Medicinal Cannabis Pty Ltd - 31 October 2022.pdf](#)

---

Dear The Proper Officer,

Please find attached a letter and 8 infringement notices from the Therapeutic Goods Administration to Australian Institute of Medicinal Cannabis Pty Ltd.

We ask that you confirm receipt of our correspondence by **5:00 PM** on **Tuesday 1 November 2022**.

Yours sincerely,

s22

Investigator  
Advertising & Product Investigation Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

Our Reference: CC-EJWB7UWD/2021

By express post and email at: [admin@midispensary.com.au](mailto:admin@midispensary.com.au); cc: \$22

31 October 2022

Dear The Proper Officer

**Infringement notices given to Australian Institute of Medicinal Cannabis Pty Ltd**

Infringement Notice	Amount	Payment Due by
TGAIN- CC-EJWB7UWD/2021-1	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-2	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-3	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-4	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-5	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-6	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-7	\$13,320.00	29 November 2022
TGAIN- CC-EJWB7UWD/2021-8	\$13,320.00	29 November 2022
<b>Total</b>	<b>\$106,560.00</b>	

1. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
2. I have decided to give 8 infringement notices (enclosed to this letter) to the Australian Institute of Medicinal Cannabis Pty Ltd (AIOMC) under Part 5A-2 of the Act, on the basis that I reasonably believe AIOMC has contravened subsection 42DLB(1) of the Act, where subsections (2), (4) and (7) applied.
3. The infringement notices are enclosed to this letter and include information on how to pay the penalty amount, how to request an extension of the compliance period for payment, how to request that the infringement notices be withdrawn, and the actions that we may take in the event of non-payment of the infringement notices. It is important that AIOMC carefully read the infringement notices and the information contained within.
4. Infringement notices are an opportunity for AIOMC to pay an amount as an alternative to having court proceedings brought against AIOMC in relation to the alleged contraventions described in each of the notices.
5. If AIOMC chooses not to pay the penalty amount, proceedings may be brought against AIOMC for the alleged contraventions described in the infringement notices. We note that the maximum civil penalty that a court can impose on a company for a contravention of subsection 42DLB(1) of the Act is **\$11.1 million** per contravention.

6. There have been recent Federal Court decisions in which the court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.<sup>1</sup> Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those from the outset.<sup>2</sup>
7. You should be aware of the possible consequences for not paying an infringement notice. In a recent decision by the Federal Court, non-payment of a single infringement notice issued against a company resulted in the court ordering a total of \$96,000 in penalty against both the company and its executive directors.<sup>3</sup>
8. To avoid being liable for further contraventions of the Act, AIOMC should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting that we reserve our rights to take enforcement action in relation to any further non-compliance we may identify.
9. For more information about infringement notices, I refer AIOMC to the following on the TGA website:
  - a. [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#).
  - b. [Infringement notices | Therapeutic Goods Administration \(TGA\)](#).

#### **Delegate comments and concerns**

10. While I am not required to provide reasons for giving an infringement notice under the Act, I offer the following remarks to assist AIOMC to understand why I have decided to take this particular action.
11. I have reviewed the following platforms for which AIOMC appear to be responsible:
  - a. <https://midispensary.com.au/>
  - b. <https://midispensary-cannabis-store.business.site/> (the Websites), and
  - c. <https://www.facebook.com/midispensary.com.au/> (Social Media)
12. While not all information released to the public about therapeutic goods is advertising, I consider that the Websites and Social Media unlawfully advertise medicinal cannabis products, as defined in section 3(1) of the Act, for the following reasons:
  - a. The Websites and Social Media contain statements and pictorial representations which were intended, directly or indirectly, to promote the use or supply of medicinal cannabis products. For example (but not limited to):
    - i. The alleged advertisements on the Websites directed the reader to a means of accessing medicinal cannabis products, such as direct links (access) to telehealth appointments with medical practitioners who may prescribe medicinal cannabis products.
    - ii. The Website and Social Media contain unapproved restricted representations regarding the efficacy of medicinal cannabis. For example, making references to serious forms of a disease, ailment or condition, in circumstances which inferred (directly or indirectly), without TGA permission or approval, that medicinal cannabis may be, or is, a suitable treatment for the medical condition mentioned.

---

<sup>1</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

<sup>2</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

<sup>3</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

- b. The advertisements:
- i. refer to substances which are included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, and
  - ii. contain prohibited representations such as references to neoplastic disease or mental illness and/or restricted representations being references to serious forms of diseases, ailments and conditions without TGA permission or approval.
13. Additionally, I note that AIOMC has previously been made aware of the advertising prohibitions under the Act, including (but not limited to):
- a. on 3 March 2022, you were warned regarding the alleged unlawful advertising of medicinal cannabis (the product) on your website <https://midispensary.com.au/>, and
  - b. you were provided with the opportunity to immediately remove and cease advertising the product in a way that contravenes the advertising requirements of the Act, and
  - c. informed that failure to act may result in escalated enforcement action being taken including the issuing of directions or infringement notices or court proceedings.
14. Although steps have been taken to bring your advertising in to compliance, the advertising is alleged to still unlawfully promote the use and/or supply of medicinal cannabis.
15. Each instance of non-compliant advertising on each day constitutes a separate contravention of the Act. We hold evidence that the contraventions as particularised in the infringement notices occurred from at least late May 2022 to at least 26 September 2022.
16. I note that I have utilised my discretion to not give you infringement notices for all alleged contraventions of the Act identified at this time, including those :
- a. which occurred in posts made on Facebook prior to January 2022
  - b. which appeared identical or sufficiently similar, to the advertising on another page of the Websites or another Social Media post, and
  - c. arising from the same restricted or prohibited representation which was made multiple times on the Website and/or Social Media.
17. Please contact s22 by email at s22 [s22@health.gov.au should AIOMC wish to discuss this matter further.](mailto:span style=)

Yours sincerely



Nicole McLay  
Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

By Express Post and Email at:  
[admin@midispensary.com.au](mailto:admin@midispensary.com.au)  
Cc: s22

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-1

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22

**Email:** s22@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at <https://midispensary.com.au/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-1**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-1**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A

**BREAKING NEWS!**  
The first MIDispensary clinic and pharmacy is opening in September 2022.  
**Location: 260 OXFORD STREET BONDJUNCTION**  
Come in, talk your doctor, see the MIDispensary and see your products online!

**Check your eligibility.**  
What is your current medical condition?  
Are you taking any drugs?  
Do you have any chronic health issues?  
Do you have any other conditions?  
Yes  
No

**The Plant-based Answer To Your Medical Condition is Now Available.**  
Start Your Journey With Us Today!

**Cost Effective**  
MIDispensary offers a range of products at a fraction of the cost of other medicinal cannabis products.

**Reliable Product**  
MIDispensary offers a range of products that are reliable and consistent in quality.

**Qualified Doctors**  
MIDispensary offers a range of products that are prescribed by qualified doctors.

**Our Medicinal Cannabis Qualified Team is here to help.**  
Our team of qualified doctors are trained in helping you understand the benefits of medicinal cannabis. We will help you understand the benefits of medicinal cannabis and how it can help you with your condition. We will also help you understand the benefits of medicinal cannabis and how it can help you with your condition.

**Check your eligibility today.**  
Take the first step towards your medicinal cannabis journey. See if you are eligible for our products.

**Understanding Plant-Based Therapy**  
The use of plant-based therapy has been shown to be effective in treating a range of conditions. It is a natural and safe way to improve your health and well-being. It is a natural and safe way to improve your health and well-being.

**Top 5 Frequently Asked Questions**

**1300 MITime (648 463)**

**Follow Us On**

Facebook | LinkedIn | Instagram | YouTube

**Follow Us**





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

By Express Post and Email at:

[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-2

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22, s22

**Email:** s22@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay

Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at <https://midispensary.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to gastrointestinal system disorders. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-2**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-2**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A

**mi** MiDispensary

**BREAKING NEWS!**  
The first MiDispensary clinic and pharmacy is opening in September 2022.  
**Location: 260 OXFORD STREET (BOND) JUNCTION**  
Come in, see your doctor's appointment, and pick up your prescription same day.

**Check your eligibility.**

The plant-based answer to your medical condition is now available.

**Start Your Journey With Us Today!**

**Cost effective**  
MiDispensary offers a range of products at a fraction of the cost of other medical cannabis providers. We have your best interests at heart.

**Medical products**  
Our highly qualified team can help you find the right product for your condition.

**Qualified doctors**  
Our doctors are highly qualified and experienced in the field of medicinal cannabis.

**Our Medicinal Cannabis Qualified Team is here to help.**

Our team of qualified doctors are here to help you find the right product for your condition. We have your best interests at heart.

**Check your eligibility today.**

Take the first step towards a new way of thinking about your health. Check your eligibility today.

**Understanding Plant-Based Therapy**

The plant-based therapy we offer is a natural way to help you manage your condition. It's a safe and effective way to improve your quality of life.

**Top 5 Frequently Asked Questions**

**1. How do I know if I'm eligible?**  
Complete a short questionnaire on our website. If you're eligible, we'll contact you to discuss your condition and how we can help.

**2. What's the cost?**  
Our products are highly affordable. We offer a range of payment options to suit your needs.

**3. How long does it take to see results?**  
The effects of our therapy can be felt within a few days. However, it may take a few weeks to see the full benefits.

**4. How safe is it?**  
Our therapy is completely safe and has no side effects. It's a natural way to improve your health.

**5. Can I stop taking it if I don't like it?**  
Yes, you can stop taking it at any time. There are no withdrawal symptoms.

**1300 MiTime (648 463)**

Facebook Instagram Twitter

**260 Oxford Street (Bond) Junction**  
Sydney NSW 2000  
Tel: 1300 648 463  
www.mi-dispensary.com.au



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

**By Express Post and Email at:**

[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-3

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22, s22

**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at [https://midispensary.com.au/eligibility-check/?pass\\_entry=4bny](https://midispensary.com.au/eligibility-check/?pass_entry=4bny).

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to mild osteoarthritis. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-3**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-3**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)



Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

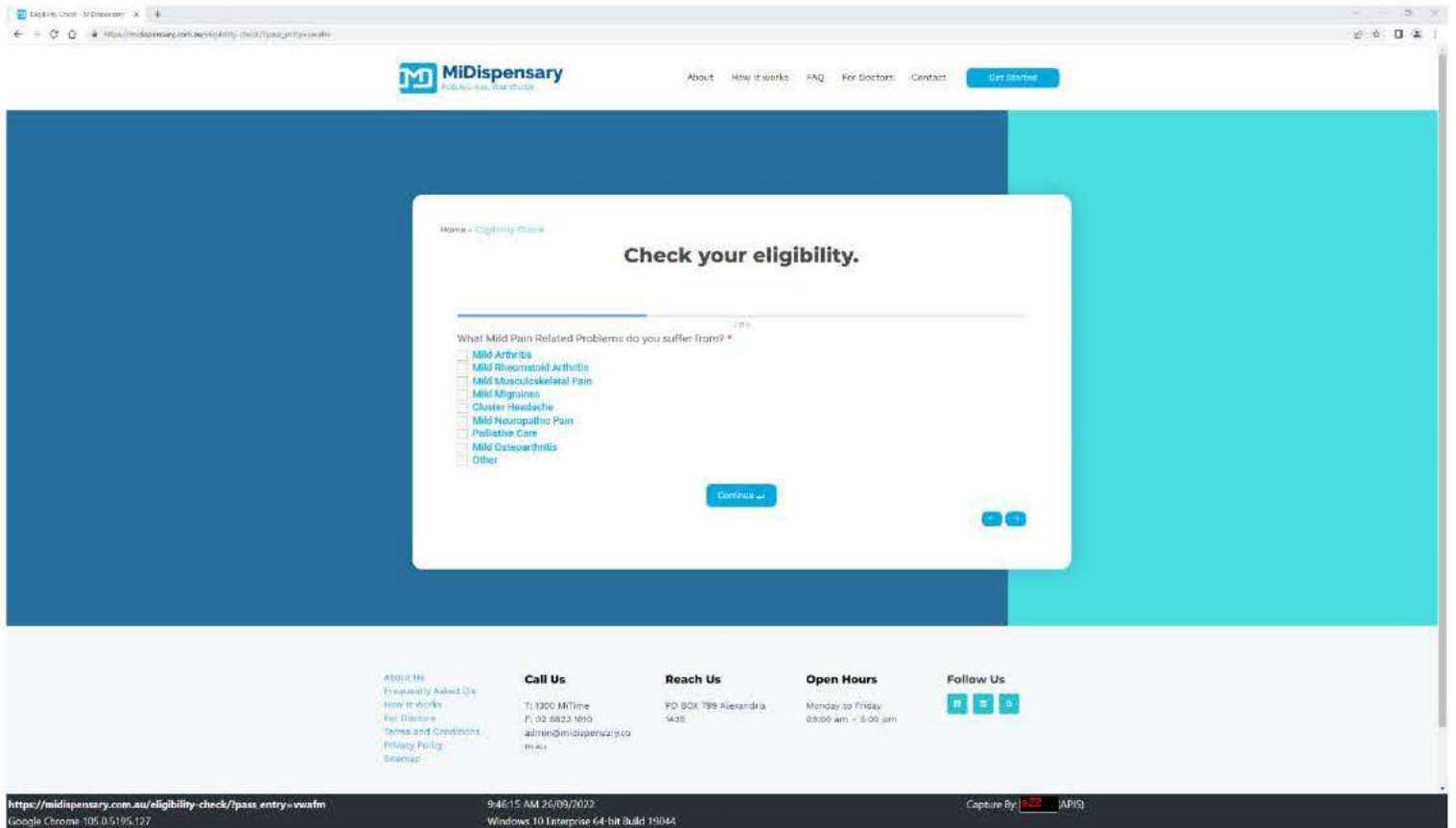
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

# ANNEXURE A





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

By Express Post and Email at:

[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-4

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 s22

**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at [https://midispensary.com.au/eligibility-check/?pass\\_entry=pdwiy](https://midispensary.com.au/eligibility-check/?pass_entry=pdwiy).

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to anxiety. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN-CC-  
 EJWB7UWD/2021-4**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN-CC-  
 EJWB7UWD/2021-4**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

---

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

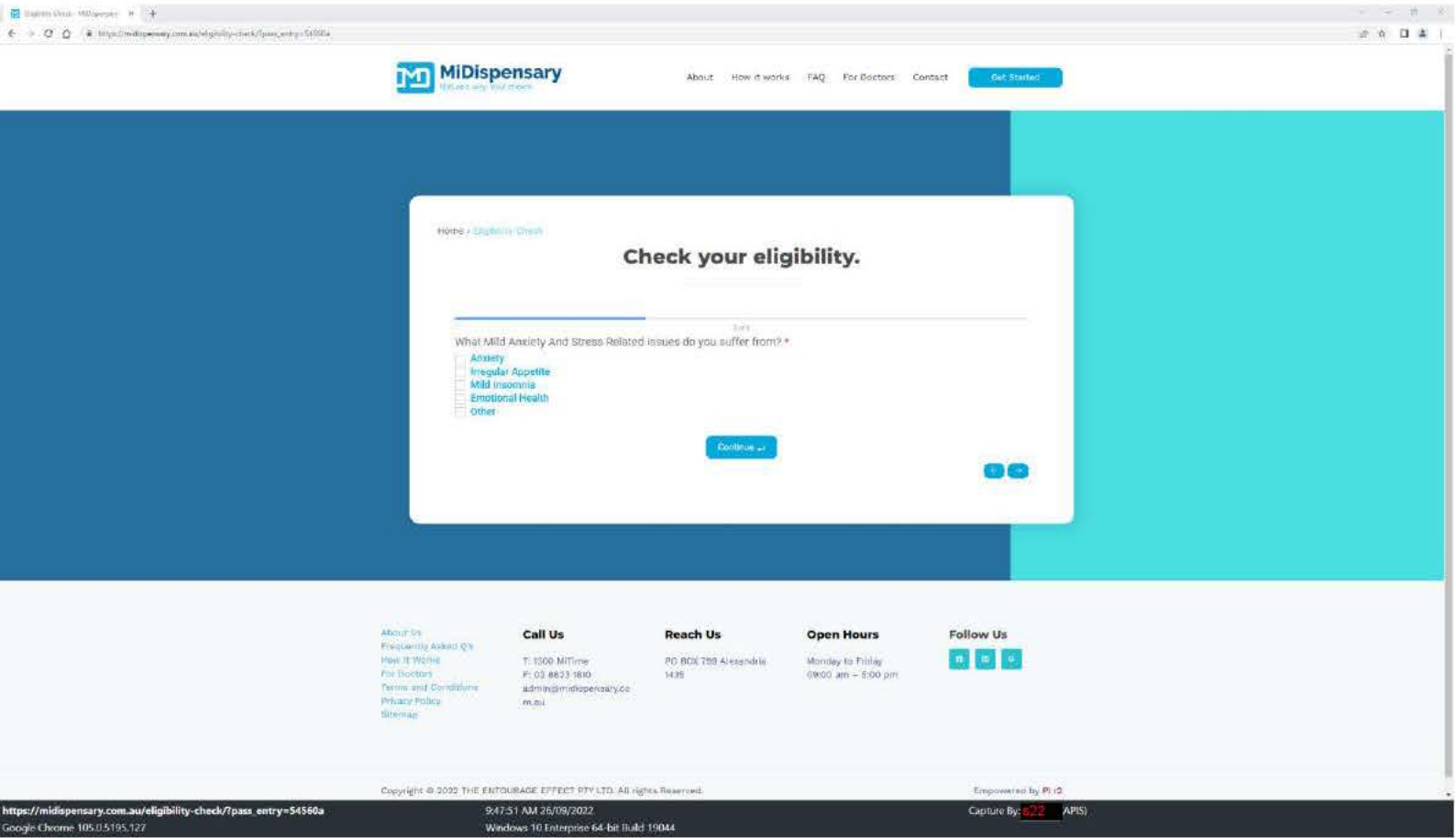
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

# ANNEXURE A





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

**By Express Post and Email at:**

[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-5

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22, s22

**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at [https://midispensary.com.au/eligibility-check/?pass\\_entry=5z2io](https://midispensary.com.au/eligibility-check/?pass_entry=5z2io).

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to medically diagnosed irritable bowel syndrome. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.



The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
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### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
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 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-5**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-5**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

---

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

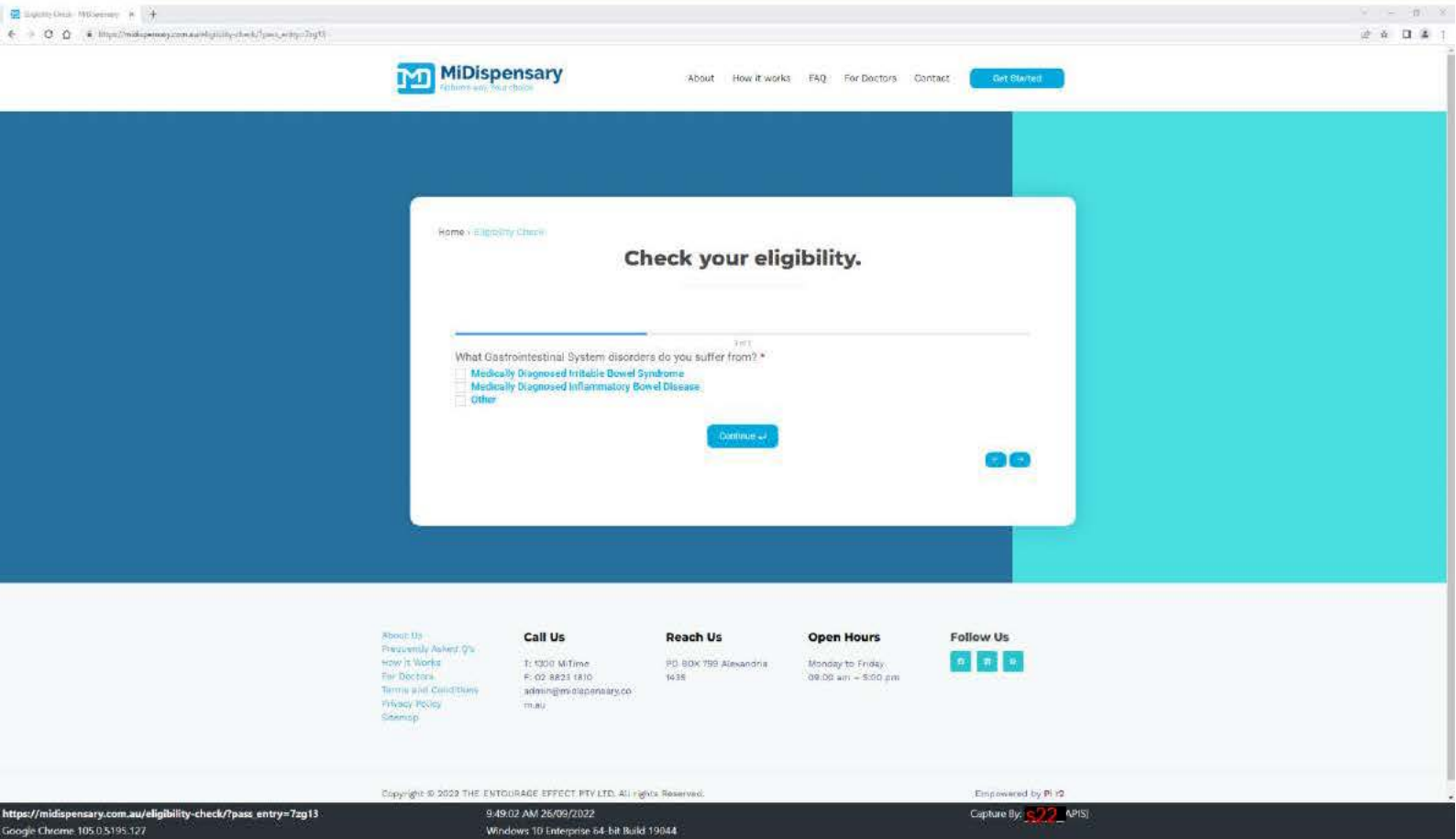
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

# ANNEXURE A





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

**By Express Post and Email at:**  
[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22 [REDACTED]

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-6

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 [REDACTED] s22 [REDACTED]

**Email:** s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at [https://midispensary.com.au/eligibility-check/?pass\\_entry=5z2io](https://midispensary.com.au/eligibility-check/?pass_entry=5z2io).

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to medically diagnosed inflammatory bowel disease. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-6**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-6**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

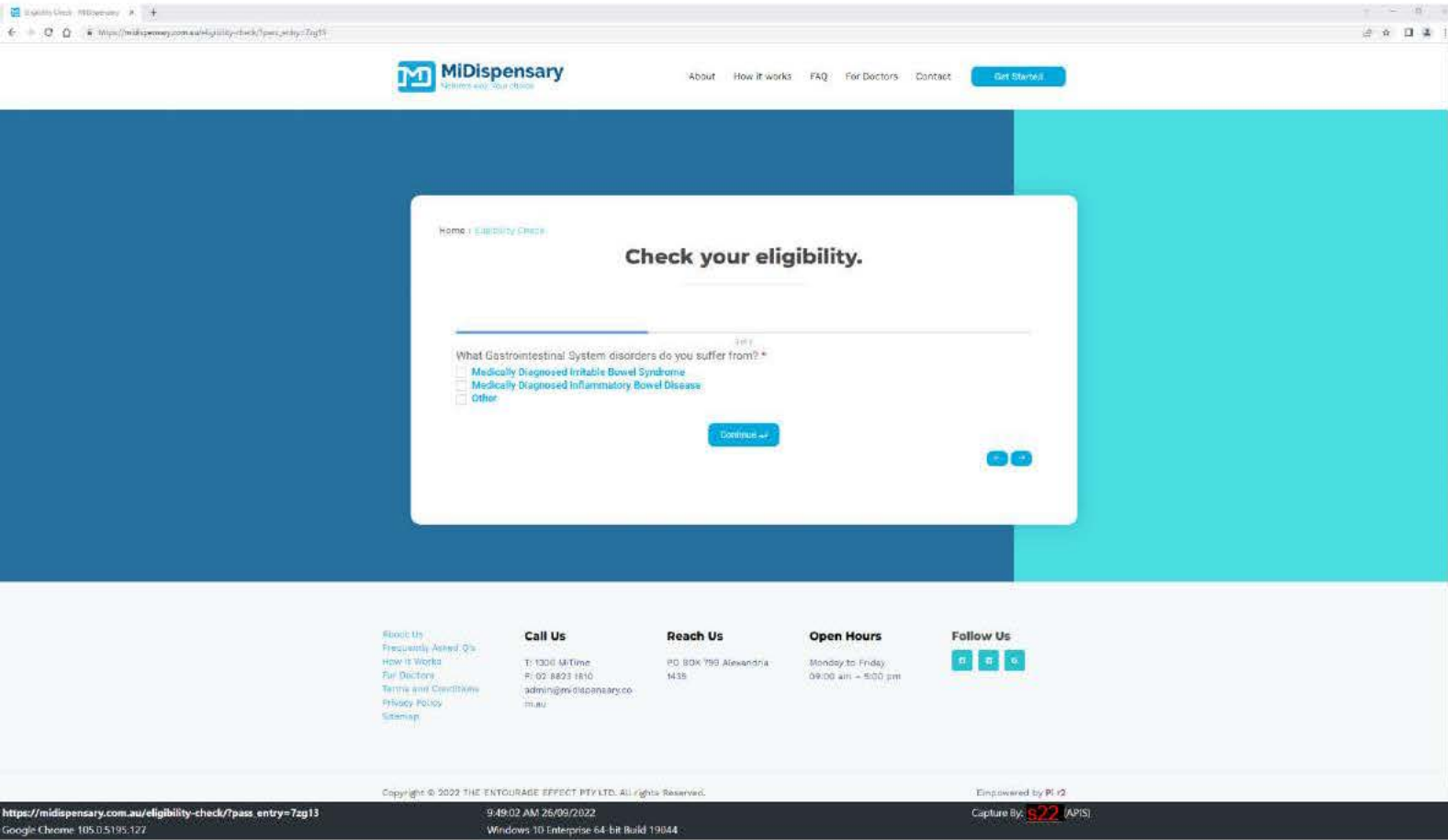


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022



# ANNEXURE A





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

**By Express Post and Email at:**  
[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

Cc: s22 [REDACTED]

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-7

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 [REDACTED], s22 [REDACTED]

**Email:** s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at <https://midispensary-cannabis-store.business.site/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-7**  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-7**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

---

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

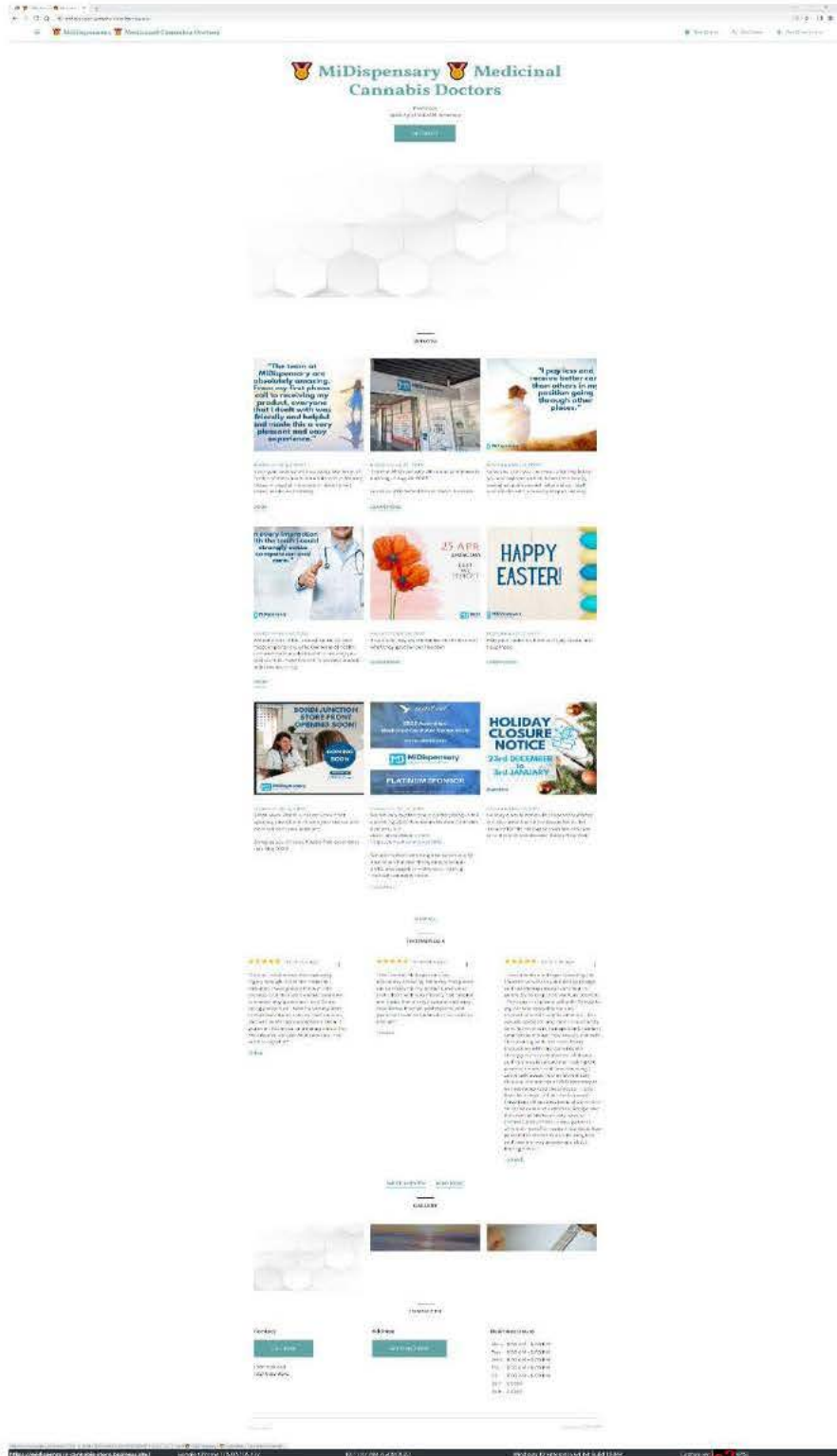
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A





**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

The Proper Officer  
Australian Institute of Medicinal Cannabis Pty Ltd  
ACN 650 003 133  
C/- Duly & Associate  
26 Ridge Street  
North Sydney NSW 2060

**By Express Post and Email at:**  
[admin@midispensary.com.au](mailto:admin@midispensary.com.au)

**Cc:** s22 [REDACTED]

**Infringement Notice Number:**  
TGAIN-CC-EJWB7UWD/2021-8

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 [REDACTED], s22 [REDACTED]

**Email:** s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Australian Institute of Medicinal Cannabis Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Australian Institute of Medicinal Cannabis Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Australian Institute of Medicinal Cannabis Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 26 September 2022, Australian Institute of Medicinal Cannabis Pty Ltd did advertise, or caused the advertising of therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.facebook.com/midispensary.com.au/posts/156402330050686>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health and  
 Aged Care, Accounts  
 Receivable, GPO Box  
 9848, Canberra ACT 2601**  
 with your cheque made  
 payable to the Department  
 of Health and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-8**  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
**TGAIN- CC-  
 EJWB7UWD/2021-8**  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice; and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A

The screenshot shows a Facebook post from the page 'MIDispensary'. The post text reads: 'American music artist Beyoncé is building a hemp farm. During an interview with Harper's BAZAAR, "Queen B" revealed how she discovered CBD, one of the main compounds of the cannabis plant. I discovered CBD on my last tour, and I've experienced its benefits for soreness and inflammation. It helps with my restless nights and the agitation that comes from not being able to fall asleep," she told Harper's BAZAAR. <https://www.foibles.com/cb.ampproject.org/.../b6...amp>

Below the text is a photograph of Beyoncé in a gold sequined dress. Underneath the photo is a link: 'WWW.FOIBLES.COM/EN/LAUNCH/PROJECT/096'. The post title is 'CBD Enthusiast Beyoncé Says She is Building A Hemp Farm' and the truncated text below it says 'American music artist Beyoncé is building a hemp farm. During an interview with Harper's Baz...'. The post has 3 likes and 2 shares. At the bottom of the screenshot, there is a system tray showing the URL 'https://www.facebook.com/midispensary.com.au/posts/pfbid02Re9JMNH8XCJJPvnQogKBm1mPTPycrKH1eyqDjCrNs1QV1HfniRXVjmBxBk15sUL5Z1', the browser 'Google Chrome 105.0.5195.127', the time '11:06:56 AM 26/09/2022', and the system 'Windows 10 Enterprise 64-bit Build 19044'.

**From:** s22  
**To:** "info@caclinics.com.au"  
**Cc:** s22; s22  
**Subject:** Letter from the Therapeutic Goods Administration to Biologics Research Institute Australia Pty Ltd – AC-000000002822 [SEC=OFFICIAL]  
**Date:** Tuesday, 16 August 2022 4:50:00 PM  
**Attachments:** [image003.gif](#)  
[Letter from the TGA to Biologics Research Institute Australia Pty Ltd dated 16 August 2022.pdf](#)

---

Dear s22,

Please find **attached** a letter from the Therapeutic Goods Administration for your attention.

We ask that you confirm receipt of this letter by **10:00 AM** on **Wednesday 18 August 2022**.

Yours sincerely,

s22

s22  
s22  
Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.



## Australian Government

### Department of Health and Aged Care

Therapeutic Goods Administration

s22

Biologics Research Institute Australia Pty Ltd  
Level 20, Market Street  
Sydney, NSW 2000

Our Reference: AC-000000002822

By express post and by e-mail: [info@caclinics.com.au](mailto:info@caclinics.com.au)

16 August 2022

Dear s22

#### Subject: Notice of intention to commence enforcement action

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care, and is responsible for regulating the safety, quality, efficacy and advertising of therapeutic goods in Australia under the *Therapeutic Goods Act 1989* (the Act).

The purpose of this letter is to provide Biologics Research Institute Australia Pty Ltd (Biologics) with an opportunity to make submissions before a decision is made about what enforcement action should be taken in relation to alleged unlawful advertising which appears on CA Clinics and CA Connect's platforms and for which Biologics appears to be responsible. They include:

- <https://caclinics.com.au/> and <https://caconnect.com.au/> (the Websites)
- <https://www.facebook.com/caclinicsaus>
- <https://www.facebook.com/profile.php?id=100077878614738>
- <https://www.instagram.com/caclinics/>
- <https://www.instagram.com/caconnectaustralia/>
- <https://twitter.com/caccessclinics?lang=en>
- <https://au.linkedin.com/company/australian-cannabis-clinics> (collectively, the Social Media).

The enforcement action being considered by the TGA includes issuing infringement notices for contraventions of the Act arising from the advertising on the Websites and Social Media.

#### Action required

We request that Biologics take the following actions:

1. Confirm receipt of this notice within one business day from the time stamp on the covering email.
2. Carefully consider the information provided below.
3. Provide your submissions by **31 August 2022** as to:

- a. whether the advertising on the Websites and Social Media summarised below (and any other content on the Websites and Social Media containing similar references, statements or representations) contravenes the Act, if that is disputed; and
- b. any other matter which you wish the TGA to consider in deciding whether enforcement action should be taken in relation to the alleged unlawful advertising identified below.

**Note:** this notice canvasses some and not all of the alleged contraventions that we may pursue.

### **Summary of alleged contraventions**

We have identified representations on the Websites and the Social Media which we allege advertise therapeutic goods, being medicinal cannabis products, in circumstances where the advertisements:

1. refer to goods that are not entered in the Australian Register of Therapeutic Goods (the Register).
2. refer to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard.
3. contain prohibited representations and/or restricted representations (being references to serious forms of diseases, ailments and conditions) without TGA permission or approval.
4. contain a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority.

For example, we allege that the Websites contain:

1. statements which appear to promote the use of medicinal cannabis products, including specific products such as 'LGP Classic 10:10', in connection with the treatment of serious medical conditions, for example *'we can aid those suffering from conditions such as anxiety, insomnia and chronic pain.'*
2. statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government in relation to the use of medicinal cannabis products in the treatment of medical conditions, for example *'[t]he TGA have approved use of medicinal cannabis products'* for conditions such as epilepsy, chronic pain and multiple sclerosis.
3. statements on CA Connect's website which allegedly advertise the supply of medicinal cannabis products by stating the price of medicinal cannabis treatment options.

In addition, we allege that the Social Media contains:

4. posts which include pictorials, hashtags and statements that appear to promote the use of medicinal cannabis products in the treatment of named medical conditions, including *#HIV, #cancerpain* and *#medicinalcannabis*.
5. posts which suggest or imply that medicinal cannabis products supplied through CA Clinics have been approved or recommended by a government authority in the treatment of medical conditions such as epilepsy and chronic pain.

### **Notice of intention to take enforcement action**

We are writing to you to put Biologics on notice of our intention to take enforcement action in relation to the alleged unlawful advertising on the Websites and the Social Media of the kinds summarised above. That enforcement action will not be limited to the provided examples and may extend to any other unlawful advertising of the kinds identified above.

Biologics submissions will be taken into account by the delegate of the Secretary of the Australian Government Department of Health and Aged Care in exercising their discretion

whether to take enforcement action against Biologics. The action under consideration includes giving infringement notices to Biologics in relation to contraventions of the kind set out above on the Websites and Social Media.

Should Biologics remove any of the alleged unlawful advertising in response to this letter, we note that the delegate is not prevented from considering taking enforcement action against Biologics.

Please note that information about any compliance action taken against Biologics may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

To avoid being liable for further contraventions of the Act, Biologics should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting we reserve our rights in relation to any further non-compliance we identify. Should Biologics respond to this letter by removing any of the alleged unlawful advertising, we note that the delegate is not prevented from considering taking the proposed enforcement action against Biologics.

### **Other information**

- The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the Act and the *Therapeutic Goods Regulation* 1990.
- It is illegal under section 42DL of the Act for a person to advertise or cause the advertising of therapeutic goods in circumstances where the advertisement:
  - refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, such as medicinal cannabis products, and that reference is not authorised by an Australian government or government authority
  - refers to therapeutic goods (being the Product) that are not entered in the Register nor subject to any exemption, approval or authority under the Act, and that reference is not authorised by an Australian government or government authority
  - contains a prohibited representation, such as cancer, and no permission is in force in relation to that prohibited representation
  - contains a restricted representation, such as epilepsy, and neither a permission nor a TGA approval is in force in relation to that restricted representation
  - contains a statement, pictorial representation or design suggesting or implying the Product has been recommended or approved by or on behalf of a government or government authority, and no exception applies.
- A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
- It is the responsibility of advertisers to ensure that their advertising material is compliant with the relevant legislation.
- Biologics may also wish to refer to the following guidance provided by the TGA:
  - [Advertising guidance for businesses involved in medicinal cannabis products](#)
- If Biologics requires help in understanding the advertising requirements, we recommend that Biologics consider engaging a regulatory affairs consultant or a lawyer to assist it.
- The TGA takes non-compliance with the regulatory scheme seriously, especially where a breach of the advertising requirements has resulted in, or poses, a threat to public health

and safety. A range of compliance and enforcement tools are available to address non-compliance and may include infringement notices, criminal or civil court proceedings, which can result in substantial penalties, fines, or imprisonment.

Please contact s22 on s22 or by email at s22@health.gov.au should you wish to discuss this matter further.

Yours sincerely

s22

s22

Acting Assistant Secretary  
Regulatory Compliance Branch



From: s22  
To: s22  
Cc: s22  
Subject: Biologics Research Institute Australia  
Date: Thursday, 18 August 2022 4:50:40 PM

---

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

Thank you for your letter dated August 16, which I received late yesterday.

We take compliance matters seriously and I thank you for the opportunity to respond to the matters raised in the Letter. I confirm that we are willing to cooperate with the TGA regarding any concerns it may have, and address those matters without the need for the TGA to take enforcement action against us.

We are working through the Letter and have already mobilised a team of internal resources, supported by external counsel, to review our online content in light of the issues raised in the Letter. This team has created a draft project plan with the intention of completing many of the tasks referred to in the Letter ASAP, and prior to August 31. I note that there may be some matters that may take longer to action in order to avoid disruption / adverse consequences to patients and we'll come back to you on those matters.

On a without admissions basis, so far we have already disabled a number of our social media accounts including:

<https://twitter.com/caccessclinics?lang=en>  
<https://www.linkedin.com/company/ca-connect-australia/>

I intend to send you a more substantive update next week on our progress before our final submission to you on or before the August 31 deadline. In the meantime, please rest assured that we are taking the Letter seriously and are working through the matters contained therein.

If you need to contact me directly I am on s22

As a minor note, the website <https://www.linkedin.com/company/australian-cannabis-clinics/?originalSubdomain=au> referred to in the Letter does not belong to us.

Regards  
s22  
s22, Biologics Research Institute Australia

---

*This message is confidential and should only be used by the intended addressee. If you were sent this email by mistake, please inform us by reply email and then destroy this message. The contents of this email are the opinions of the author and do not necessarily represent the views of the Southern Cannabis Holdings.*

---

*This message is confidential and should only be used by the intended addressee. If you were sent this email by mistake, please inform us by reply email and then destroy this message. The contents of this email are the opinions of the author and do not necessarily represent the views of the Southern Cannabis Holdings.*

**From:** s22 [REDACTED]  
**To:** s22 [REDACTED]  
**Subject:** Response to your letter of Aug 16 2022  
**Date:** Tuesday, 30 August 2022 4:16:37 PM  
**Attachments:** [TGA Response.pdf](#)

---

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22 [REDACTED],

Please find the attached correspondence addressed to s22 [REDACTED] in response to the TGA letter dated August 22 2022. I'd appreciate if you can confirm receipt of this letter.

Thank you

s22 [REDACTED]

---

*This message is confidential and should only be used by the intended addressee. If you were sent this email by mistake, please inform us by reply email and then destroy this message. The contents of this email are the opinions of the author and do not necessarily represent the views of the Southern Cannabis Holdings.*

---

*This message is confidential and should only be used by the intended addressee. If you were sent this email by mistake, please inform us by reply email and then destroy this message. The contents of this email are the opinions of the author and do not necessarily represent the views of the Southern Cannabis Holdings.*

From: s22  
s22, Biologics Research Institute Australia  
Level 5, 2 Barrack St  
Sydney 2000

To: s22  
Acting Assistant Secretary  
Regulatory Compliance Branch  
By email to : s22@health.gov.au  
Your reference: AC-000000002822

August 30, 2022

Dear s22,

I write in response to your letter of 16 August 2022 to Biologics Research Institute Australia (**BRIA**). (**the Letter**). We also refer to our email dated Thursday, 18 August 2022, in respect of this matter.

This response covers and is in respect to the queries raised in respect of :

<https://caclinics.com.au/> and <https://caconnect.com.au/> (**the Websites**)

As well as:

- <https://www.facebook.com/caclinicsaus>
- <https://www.facebook.com/profile.php?id=100077878614738>
- <https://www.instagram.com/caclinics/>
- <https://www.instagram.com/caconnectaustralia/>
- <https://twitter.com/caccesclinics?lang=en>

(collectively, **social media**).

We do not believe that further action is warranted by the TGA, over and above the Letter, for reasons outlined in this response.

- ❖ We are an Australian-based company and take compliance seriously. To the extent that there has been any breach of the *Therapeutic Goods Act 1989* (which is not admitted), that breach was inadvertent. Further, it was never our intention to do or say anything that resulted in, or poses, a threat to public health and safety. In fact, we respectfully say that the matters raised in the Letter do not constitute matters that could reasonably be said to be a threat to public health and safety due to the discrete nature of the services we offer and in the context of the nature of the matters raised in the Letter.
- ❖ We have already taken action in response to your Letter and are willing to continue to cooperate with the TGA as the medicinal cannabis legislative landscape, regulations and TGA guidance around those matters continues to evolve.

In respect of each matter raised in the Letter we respond as follows:

## 1.0 Summary

BRIA does not market, offer for sale or sell medicinal cannabis products. We are a multi-service specialist medical clinic that considers, among other things, patient eligibility for alternative therapies and medicinal cannabis prescriptions, as well as ongoing monitoring and care of those patients.

BRIA publishes online content with the intent of educating patients on regulations and access pathways for medicinal cannabis.

No patient is able to access medicinal cannabis products or treatments without a prescription from a qualified medical professional, which includes pain specialists, oncologist, psychiatrists, addiction medicine specialists, GPs and nurses. BRIA patients are offered ongoing consultations to ensure continuity of care and management of the patient's condition and treatment.

Our websites contain over 300 pages of educational content and blogs concerning plant-based therapies and we ask that any examples of possible breaches be taken in the context and tone of the Websites and social media, and not in isolation.

We recognize that the content of the Websites and social media, when considered from the end viewer's point of view, can vary from person to person. It is our submission that when a reasonable person views the Website and social media that it cannot reasonably be said that BRIA has breached an legislation. The legislation around medicinal cannabis is in its infancy and, in our view, there is little precedent to guide cross-industry participants on day-to-day activities, particularly in respect of a multi-service specialist medical clinic. With this in mind we continuously look for ways to strengthen our compliance activities to reflect the periodic updates to published TGA guidance.

As outlined in our 18 August email, we have already taken actions in response to the Letter, described in further detail below.

## 2.0 Response to specific alleged breaches

### 2.1 Alleged breach 1

***“statements which appear to promote the use of medicinal cannabis products, including specific products such as ‘LGP Classic 10:10’, in connection with the treatment of serious medical conditions, for example ‘we can aid those suffering from conditions such as anxiety, insomnia and chronic pain.’***

In our opinion BRIA did not make statements that promote the use of medicinal cannabis products.

BRIA does not sell medicinal cannabis products and generally will not refer to any product names.

The reference to LGP Classic 10:10 ([link](#)) is in the context of a publication of results in a peer-reviewed scientific journal, regarding an ethics approved study that CA Clinics participated in. In our view the ethics approval, and peer review of the results, was factual

and balanced, informative in nature and not promotional

In general, it is the intention of BRIA that the Websites and social media contain content that complies with advertising guidelines, while balancing the legitimate need of patients to access educational and informative material. In our view, the Websites provide a balanced view and summary of the information that has been published in this area. It also makes it clear to patients and prospective patients that BRIA only offers doctor and treatment services to assess the suitability (or otherwise) of patients and to provide ongoing care for eligible patients. Some of the ways we achieve this is by:

- a) Clearly and repeatedly stating that we do not market, offer for sale or sell medicinal products. Also, that access to any product is subject to doctor consultation, approval and at doctor discretion. Some examples include:

*. we do not dispense medical cannabis products” ([link](#))*

*“The prescribing doctor will evaluate the benefit to risk ratio in each individual case before recommending any medical cannabis” ([link](#))*

*“In Australia, access to medicinal cannabis is entirely subject to doctor consultation and discretion” ([link](#))*

- b) Ensure that any reference to ailments or diseases is done so in a broad context of a holistic approach to treatment research and third party published material, without claiming our views of any benefits (or perceived benefits) that may be associated with the products. Some examples include:

*Medical cannabis for epilepsy was one of the first childhood **conditions** where grassroots movements pushed ahead of clinical research ([link](#))*

*Not all patients or conditions are suitable for medical cannabis therapies ([link](#))*

*The clinic does not accept walk-in patients as there are qualifying criteria that must be met ([link](#))*

- c) Presenting a balanced and accurate view of the product. We do not, or do not intend to make any prohibited or restricted statements. We are mindful of our compliance obligations in this regard, and attempt to balance this against ensuring that patients are fully informed of the options, risks and effects of the products before considering whether to acquire ours or a third party’s services. Some examples include:

*“Commonly experienced side effects of CBD oil include; drowsiness, dry mouth, and gastrointestinal discomfort. Other less common adverse events include altered liver enzymes and drug-drug or drug-nutrient interactions” ([link](#))*

*.Medicinal cannabis, like all medications, can have **side effects**, specifically drowsiness or gastrointestinal discomfort are common. Most human studies report...”([link](#))*

*“There are many risks of using cannabis-based products without a doctor’s monitoring” ([link](#))*

*“Both CBD and THC have been investigated for their capacity to decrease uptake of folic acid in human cell lines simulating chronic cannabis use. Similar in vitro research points to cannabinoids reducing levels of other important cellular growth factors” ([link](#))*

*“There are some indications that cannabinoid medicines may directly impact immune and inflammatory markers that perpetuate the disease and worsen symptoms. “ ([link](#))*

*“there is still much we don’t understand and concerns to be aware of. THC has the potential to disrupt regulatory processes and hormones that maintain healthy menstrual cycles. ([link](#))*

- d) Ensuring patients are informed, and have access to information from the literature that informs them, that treatments may not be effective for certain individuals. Some examples include:

*“We **do not** have any evidence that medical cannabis can stop the underlying problem of endometriosis” ([link](#))*

*“Not all patients or conditions are suitable for medical cannabis therapies. According to TGA guidelines, there must be some evidence that medicinal cannabis treatment can be applied to your condition and that you have exhausted conventional therapies” ([link](#))*

*“WHEN ARE CANNABINOID BASED TREATMENTS CONTRAINDICATED?”*

*There are different kinds of medicinal cannabis therapies, and some or all may not be suitable for your condition. If any of the following apply to you, please discuss with your doctor:*

- *Allergic to any ingredient used in cannabinoid product*
- *Have unstable cardio-pulmonary disease or cardiovascular disease*
- *Have previous psychotic or concurrent active mood disorder*
- *Have severe anxiety*
- *Are pregnant or breastfeeding*

***Relative contraindications:** These conditions may not necessarily prevent prescribing medicinal cannabis, though should also be discussed with the medical practitioner.*

- *Severe liver or renal disease.*
- *Drug, alcohol or nicotine dependence*
- *Paediatric and elderly patients*
- *Individuals with a past medical or family history of schizophrenia*

## 2.1 Alleged breach 2

***statements which suggest or imply that medicinal cannabis products have been approved or recommended by a government in relation to the use of medicinal cannabis products in the treatment of medical conditions, for example ‘[t]he TGA have approved use of medicinal cannabis products’ for***

***conditions such as epilepsy, chronic pain and multiple sclerosis.***

In our view, BRIA has never, or did not intend to claim that medicinal cannabis has been approved by the TGA as a registered medicine. Any reference to TGA approval(s) on the Websites or social media is intended in the context of approvals under the Special Access Scheme Cat B or the Authorised Prescriber Scheme of which there have been more than 100,000 approvals since the legalisation of cannabis in Australia. To the extent that the Websites made reference to any other matter, that reference was inadvertent. There are numerous, repeated examples of statements throughout the Websites that reflect this position and we submit that a reasonable person would understand the purpose of, and not be misled by, the text. A small sample of the statements on the Websites include:

*“Cannabis has not been approved as a medicine in Australia. The Therapeutic Goods Administration (TGA) provides guidance on the application of medicinal...” [\(link\)](#)*

*Under Therapeutic Goods Administration (TGA) guidelines, these **doctors** must apply for TGA **approvals** with each patient's specific use of medical cannabis [\(link\)](#)*

*“It is a requirement for **TGA approval** that there is some preclinical or clinical evidence that **medical cannabis** or CBD oil will benefit your condition” [\(link\)](#)*

*“the time it takes to approve is usually at the **discretion** of the TGA” [\(link\)](#)*

*“How long does it take to be **approved** for a prescription? The **approval** time is usually within one week after the application submission date” [\(link\)](#)*

### **2.3 Alleged breach 3**

***“Statements on CA Connect’s website which allegedly advertise the supply of medicinal cannabis products by stating the price of medicinal cannabis treatment options”***

It is our view that the material on the Websites is not (and wasn't intended to be) an advertisement for medicinal cannabis products.

As referred to above, BRIA does not offer for sale or sell medicinal cannabis products.

The aim of CA Connect is to assist patients with pain management and other conditions. The intent of the website (and the Websites generally) is to educate patients about treatment options, including the price of our services.

BRIA does not state the price of medicinal cannabis products, nor does it advertise for sale any specific product names or brands. The pricing relates to the services of our professionals, including doctor consultations and ongoing care via scheduled follow up calls from our clinical team.

Further, the Websites link to material with balanced information on the range of treatment options for pain management.

This secondary material, while it may refer to medicinal cannabis products does so in the context of information about a range of treatments and results, it does not promote the use of medicinal cannabis by emphasising its benefits over other treatments, nor does the



reference to price promote its supply.

As mentioned above, patients do not automatically receive a treatment plan. This is at the sole discretion of the medical / healthcare practitioner assessing their symptoms, wellbeing and eligibility at the time.

s47G(1)(a)

A large black rectangular redaction box covers the majority of the page content below the 's47G(1)(a)' label.

## 2.4 Alleged breach 4

***posts which include pictorials, hashtags and statements that appear to promote the use of medicinal cannabis products in the treatment of named medical conditions, including #HIV, #cancerpain and #medicinalcannabis.***

BRIA does not intend for any pictorials or hashtags to be taken as advertising.

Our use of pictorials in any online content is intended to be educational and we believe that all pictorials and the content they accompany meet the advertising guidance of being factual, and fair and balanced.

Regarding the use of hashtags on social media, we are not aware of any regulatory guidance that specifically prevents the use of a hashtag. BRIA's use of hashtags is intended to help patients find factual and balanced educational content relating to the topic referred to therein. This is a common and accepted use of hashtags.

The point of using hashtags on social media is that you are indicating to a follower/user and algorithm that your content relates to a specific topic or category. Ultimately, it helps users to find relevant content easily across platforms so your content is accessible to the appropriate (or niche) audience.

We would be happy to discuss the use (or otherwise) of hashtags further with the TGA if this is considered by the TGA to be advertising and/or promotion.

We would be happy to review, and comment upon, any more specific examples of concern that the TGA may have relating to pictorials or hashtags.

## 2.5 Alleged breach 5

***posts which suggest or imply that medicinal cannabis products supplied through CA Clinics have been approved or recommended by a government authority in the treatment of medical conditions such as epilepsy and chronic pain.***

In our opinion, BRIA has not made claims that medicinal cannabis has been approved or recommended by a government authority for the treatment of medical conditions such as epilepsy and chronic pain. We refer to our response in response to alleged breach 2 above.

### 3.0 Historical Actions to Date

In this fast-paced and evolving industry, we continuously look for ways to strengthen our compliance activities to reflect the periodic updates and TGA guidance provided in this area. BRIA is an Australian-based company that wishes to provide options to its patients in the context of them dealing with health and/or medical issues. We are in our infancy but intend to continue to grow our operations. We are therefore committed to continuing to work with the TGA to ensure compliance and the sustainability of our business operations so that we may continue to provide options to Australians by improving patient access to alternative plant-based medications.

Some examples of our dedication to these matters prior to the Letter include:

- 10 May 2018 - meeting with John Skerit of the TGA to discuss the launch and branding of our original 'Cannabis Access Clinic';
- In response to updated guidance relating to non-usage of cannabis in clinic names, we promptly updated our trading name to CA Clinics in March 2020.
- In response to updated TGA guidance in 2020 we had numerous email and zoom conversations with TGA officers s22 and s22 as well as an in-person meeting on 23 November 2020 in Canberra with s22 to ensure we were meeting TGA expectations as they were at that point in time. These discussions resulted in no objections however we took it upon ourselves to undertake some website and communications updates in the spirit of self-policing for compliance.
- Further guidance was issued by the TGA on 22 January 2021, which we promptly complied with, meeting the deadline of 5 February 2021. This was acknowledged the same day by s22.

As foreshadowed in our 18 August email to the TGA, upon receipt of the Letter we promptly took the following actions (on a without admissions basis):

- An internal taskforce was formed to review all online content for regulatory compliance;
- We commenced a fulsome review of the content on the Websites and social media (as to which see below).
- We have engaged a regulatory lawyer to assist with this and future compliance matters; and
- Our internal guidelines for website and social media content have been updated.

As referred to above, we have voluntarily implemented a process to strengthen compliance in light of the Letter are ongoing, and our team is currently reviewing and updating content across the Websites and social media. This review is currently consuming a substantial amount of our resources on a daily basis and, despite our best efforts to conclude this work by August 31, the task is not yet complete. We anticipate that this review will require an additional 2 weeks to complete, with an anticipated completion date of September 15 or thereabouts. We will provide a further update on the status of these efforts, and a confirmation that they have been completed, as soon as possible.

### 4.0 Summary

As outlined above, BRIA is committed to operating consistently with Australian legislation. It wishes to continue to work with the TGA to ensure that that happens, and that BRIA remains a sustainable Australian-based business that continues to provide reasonable and appropriate options to its patients.

BRIA does not offer for sale or sell medicinal cannabis products - it provides services only. In addition to providing a mechanism by which patients can access medical / healthcare practitioners that are experts in the area of medicinal cannabis, its intention has been to provide accurate and balanced information services on the matter.

We respectfully submit that as a result of:

- ❖ the prompt action by BRIA following receipt of the Letter;
- ❖ BRIA's good history in the area of medicinal cannabis compliance;
- ❖ the evidenced intention of BRIA to actively work with the TGA to promptly address any concerns it may have;
- ❖ the above submissions in respect of the matters raised by the TGA in the Letter; and
- ❖ that there has been no actual or potential harm to consumers as a direct result of the matters raised in the Letter,

the TGA is not required to take any enforcement action against BRIA in respect of the matters raised in the Letter.

If, notwithstanding the above, the TGA is considering imposing a monetary penalty on BRIA in respect of the matters referred to in the Letter please note that BRIA is a small, loss-making organisation that has not made a profit since its inception. As a result, BRIA has not received any financial gain to date from our patient consultation activities, which are aimed at supporting patients in the medicinal cannabis space, or any matter referred to in the Letter. We would be happy to provide the TGA with tax returns to support this statement, if required.

Please let us know if you require any further information or clarification in relation to any matter referred to above.

Yours faithfully

s22

s22

s22

Biologics Research Institute Australia

**From:** s22  
**To:** "info@caclinics.com.au"  
**Cc:** "info@caconnet.com.au"; s22@caclinics.com.au; s22  
**Subject:** Infringement Notices from the Therapeutic Goods Administration to Biologics Research Institute Australia Pty Ltd - AC-000000002822  
**Date:** Monday, 31 October 2022 1:18:00 PM  
**Attachments:** [image005.gif](#)  
[Cover letter and Infringement Notices to Biologics Research Institute Australia Pty Ltd - 31 October 2022.PDF](#)

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Dear s22,

Please find attached a letter and 10 infringement notices from the Therapeutic Goods Administration to Biologics Research Institute Australia Pty Ltd.

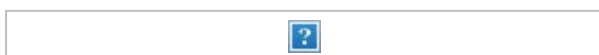
We ask that you confirm receipt of our correspondence by **5:00 PM on Tuesday 1 November 2022**.

Yours sincerely,

s22  
Investigator  
Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street  
 Sydney NSW 2000

Our Reference: AC-000000002822

By express post and Email at: [info@caclinics.com.au](mailto:info@caclinics.com.au); Cc: [info@caconnect.com.au](mailto:info@caconnect.com.au) and  
 s22 [@caclinics.com.au](mailto:s22@caclinics.com.au)

31 October 2022

Dear s22

**Infringement notices given to Biologics Research Institute Australia Pty Ltd**

Infringement Notice	Amount	Payment Due by
TGAIN- AC-000000002822/2022-1	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-2	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-3	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-4	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-5	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-6	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-7	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-8	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-9	\$13,320.00	29 November 2022
TGAIN- AC-000000002822/2022-10	\$13,320.00	29 November 2022

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**Total** **\$ 133,200.00**

- I refer to our previous correspondence regarding this matter, including our letter to Biologics Research Institute Australia Pty Ltd (Biologics) dated 16 August 2022, written submissions from Biologics dated 30 August 2022 and financial information received 5 October 2022.
- I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
- Having considered Biologics' submissions, I have decided to give 10 infringement notices (enclosed to this letter) to Biologics under Part 5A-2 of the Act, on the basis that I reasonably believe Biologics has contravened subsection 42DLB(1) of the Act, where subsections (2), (4), (6), and (7) applied.
- The infringement notices are enclosed to this letter and include information on how to pay the penalty amount, how to request an extension of the compliance period for payment, how to request that the infringement notices be withdrawn, and the actions that we may take in the event of non-payment of the infringement notices. It is important that Biologics carefully read the infringement notices and the information contained within.

5. Infringement notices are an opportunity for Biologics to pay an amount as an alternative to having court proceedings brought against Biologics in relation to the alleged contraventions described in each of the notices.
6. Biologics should be aware of the possible consequences for not paying an infringement notice. If Biologics chooses not to pay the penalty amount, proceedings may be brought against Biologics for the alleged contraventions described in the infringement notices. We note that the maximum civil penalty that a court can impose on a company for a contravention of subsection 42DLB(1) of the Act is \$11.1 million per contravention. In a recent decision by the Federal Court, non-payment of a single infringement notice issued against a company resulted in the court ordering a total of \$96,000 in penalty against both the company and its executive directors.<sup>1</sup>
7. I note that there have been recent Federal Court decisions in which the Court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.<sup>2</sup> Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those from the outset.<sup>3</sup>
8. To avoid being liable for further contraventions of the Act, Biologics should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting that we reserve our rights to take enforcement action in relation to any further non-compliance we may identify.
9. For more information about infringement notices, I refer Biologics to the following on the TGA website:
  - a. [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#).
  - b. [Infringement notices | Therapeutic Goods Administration \(TGA\)](#).

#### **Delegate comments and concerns**

10. While I am not required to provide reasons for giving an infringement notice under the Act, I offer the following comments to assist Biologics to understand why I have decided to take this particular action.
11. I note that Biologics has previously been made aware of the advertising restrictions under the Act on at least the following occasions:
  - a. In July 2020, Biologics were given a cease-and-desist letter in relation to the alleged unlawful advertising of medicinal cannabis products.
  - b. In November 2020, Biologics attended a meeting (video conference) with the TGA and were provided with guidance in relation to the advertising of medicinal cannabis products to the public.
  - c. In January 2021, Biologics were provided with further guidance relating to the advertising of medicinal cannabis products to the public.
12. I have reviewed the following platforms for which Biologics appear to be responsible:
  - a. <https://caclinics.com.au/> and <https://caconnect.com.au/> (the Websites)

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<sup>1</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

<sup>2</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865 \(fedcourt.gov.au\)](#) at paragraph [76].

<sup>3</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

- b. <https://www.facebook.com/caclinicsaus/>
  - c. <https://www.facebook.com/profile.php?id=100077878614738/>
  - d. <https://www.instagram.com/caclinics//>
  - e. <https://www.instagram.com/caconnectaustralia//>
  - f. <https://twitter.com/caccessclinics?lang=en/>
  - g. <https://www.linkedin.com/company/caclinics//>, and
  - h. <https://www.linkedin.com/company/ca-connect-australia//> (collectively, the Social Media).
13. While not all information released to the public about therapeutic goods is advertising, I consider that the Websites and the Social Media unlawfully advertise medicinal cannabis products, being a class of therapeutic goods as defined in section 3(1) of the Act, for the following reasons:
- a. The Websites and Social Media contain statements and pictorial representations which were intended, either directly or indirectly, to promote the use or supply of medicinal cannabis products. For example (but not limited to):
    - i. The webpages on the Websites and/or the posts on the Social Media (being advertisements) directed the reader to a means of accessing medicinal cannabis products. For example, having a prominently displayed link on the CA Clinics Website, which allowed consumers to book a telehealth appointment with a health practitioner, “specialised in medicinal cannabis.”
    - ii. The use of hashtags in Social Media posts, a function which is predominantly used to promote the content, referring to medicinal cannabis such as ‘#medicinalcannabis’, ‘#cbd’, ‘#cbdoil’.
    - iii. The Websites and Social Media made unauthorised therapeutic claims, regarding the efficacy of medicinal cannabis products. For example, making references to serious forms of a disease, ailment or condition, in circumstances which inferred (directly or indirectly) that medicinal cannabis may be, or is, a suitable treatment for the medical condition mentioned.
  - b. The advertisements:
    - i. refer to substances which are included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard
    - ii. contain prohibited representations, such as cancer, and/or restricted representations, such as multiple sclerosis and epilepsy, being references to serious forms of diseases, ailments and conditions without TGA permission or approval, and
    - iii. contain statements, pictorial representations or designs suggesting or implying the goods have been recommended or approved by or on behalf of a government authority.
14. As outlined in the written submissions dated 16 August 2022, amongst other steps taken by Biologics to come into compliance, significant changes appear to have been made to the Websites and Social Media, including the removal of numerous alleged contraventions. In addition, since at least 31 August 2022, Biologics have taken down several alleged non-compliant Social Media platforms including Twitter.
15. Each instance of non-compliant advertising on each day constitutes a separate contravention of the Act. We hold evidence that the contraventions as particularised in the infringement notices occurred from at least late April 2022 to at least 4 August 2022.

16. Taking into account the written submissions and changes made to the Website and Social Media, I have decided not to give Biologics infringement notices for all identified alleged contraventions of the Act at this time, including those:
- a. occurred on the CA Connect Social Media platforms
  - b. occurred prior to 4 August 2022
  - c. arose from the same restricted or prohibited representations which were made across multiple platforms (Website and/or Social Media), and
  - d. arose from a reference to the same distinct medicinal cannabis products, which appeared multiple times on the Website and/or Social Media.

Please contact s22 [REDACTED] by email at s22 [REDACTED]@health.gov.au should Biologics wish to discuss this matter further.

Yours sincerely



Nicole McLay

Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration.





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au)  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-1

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(6) applied.

The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caclinics.com.au/medicinal-cannabis-programs/>.

The advertisement contained statements, suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority, other than a statement of the availability of the goods as a pharmaceutical benefit, or authorised or required by a government or government authority or prescribed by the regulations.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-1  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-1  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [redacted] [@health.gov.au](mailto:[redacted]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:

**Medical Cannabis Programs**

**Rural & Remote**

CA Clinics has been able to deliver our services through telehealth, virtual consultations. This means a convenient, quality, accessible approach to health care.

**How to access medicinal cannabis treatments in rural Australia?**

CA Clinics can arrange for the assessment to be held in rural areas which would avoid the need for travel to the city. Our team of allied health professionals can provide you with the necessary support and information to ensure that you can access the care you need. Please contact us for more information.

**Veteran Health**

CA Clinics understands the unique needs of our veterans and offers a range of services to support their health and wellbeing. We have a dedicated team of allied health professionals to support you.

**A 15 minute call to assess suitability for medical cannabis therapies with our allied health professionals.**

**How CA Clinics' Veteran Health works?**

CA Clinics provides a range of services to support your health and wellbeing. We have a dedicated team of allied health professionals to support you.

**TGA application and approval**

**Pain specialist letter of support**

**How we help your veteran patient**

**DVA application and approval**

**Stay updated on medicinal cannabis**

**CA Clinics**

**Company**

**Patients**

**Doctors**

1300 456 456

1300 456 456

1300 456 456



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-2

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

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Nicole McLay,  
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The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caclinics.com.au/medicinal-cannabis-conditions/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to multiple sclerosis, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-2  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-2  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)



the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:

The screenshot displays the 'Medical Conditions' page on the CA Clinics website. At the top, the navigation bar includes the CA Clinics logo, contact information (1300 991 477, info@cadclinics.com.au), and menu items for 'About us', 'Patients', and 'Education'. A search bar and a 'Treatments' button are also present.

The main content area features a teal header with the text 'Medical Conditions'. Below this, the section is titled 'CA Clinics Conditions'. The text explains that CA Clinics has specialists and doctors who attend to a range of medical conditions supported by evidence that medical cannabis might have an effect. It further states that medical cannabis can be beneficial for a large range of medical conditions, but treatments require Therapeutic Goods Administration (TGA) Special Access Scheme approval. Below this, a list of conditions is provided, each with a right-pointing arrow:

- > Appetite
- > Addiction
- > Anxiety
- > Arthritis
- > Autism
- > Alzheimer's
- > Back Pain
- > Cancer
- > Chronic pain
- > Diabetes
- > Dystonia
- > Endometriosis
- > Epilepsy
- > Fibromyalgia
- > HIV
- > IBD
- > IBS
- > Insomnia
- > Multiple Sclerosis
- > Palliative care
- > Parkinsons
- > Psoriasis
- > PTSD
- > Stress

A green button labeled 'Book a Screening Appointment' is positioned below the list.

Below the list is a teal banner with the text 'Stay updated on medicinal cannabis'. It includes a name input field, an email input field, and a green 'SUBSCRIBE!' button. Social media icons for Facebook, Twitter, YouTube, and Instagram are also present.

The footer contains the CA Clinics logo, contact information, and three columns of links:

- Company:** Our story, How it works, Single, FAQ, Research & Studies, Pricing, Contact us
- Patients:** Medicinal cannabis Australia, OSD in Australia, Conditions, DVA, Treatment, Patient consent form
- Doctors:** Work with us, Referral form, Products, How we help

At the bottom, a copyright notice reads: '© 2022 CA Clinics & CA Connect are registered business names of Biologics Research Institute Australia Pty Ltd.' The Windows taskbar at the bottom shows 'Windows Explorer', 'Windows 10 Enterprise 64-bit Build 19044', and the date '12:20:13 PM 4/08/2022'. A watermark 'S22' is visible in the bottom right corner of the screenshot.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-3

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at  
<https://www.facebook.com/caclinicsaus/photos/a.106596167731909/523336702724518/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to human immunodeficiency virus (HIV). No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN- AC-000000002822/2022-3** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN- AC-000000002822/2022-3** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

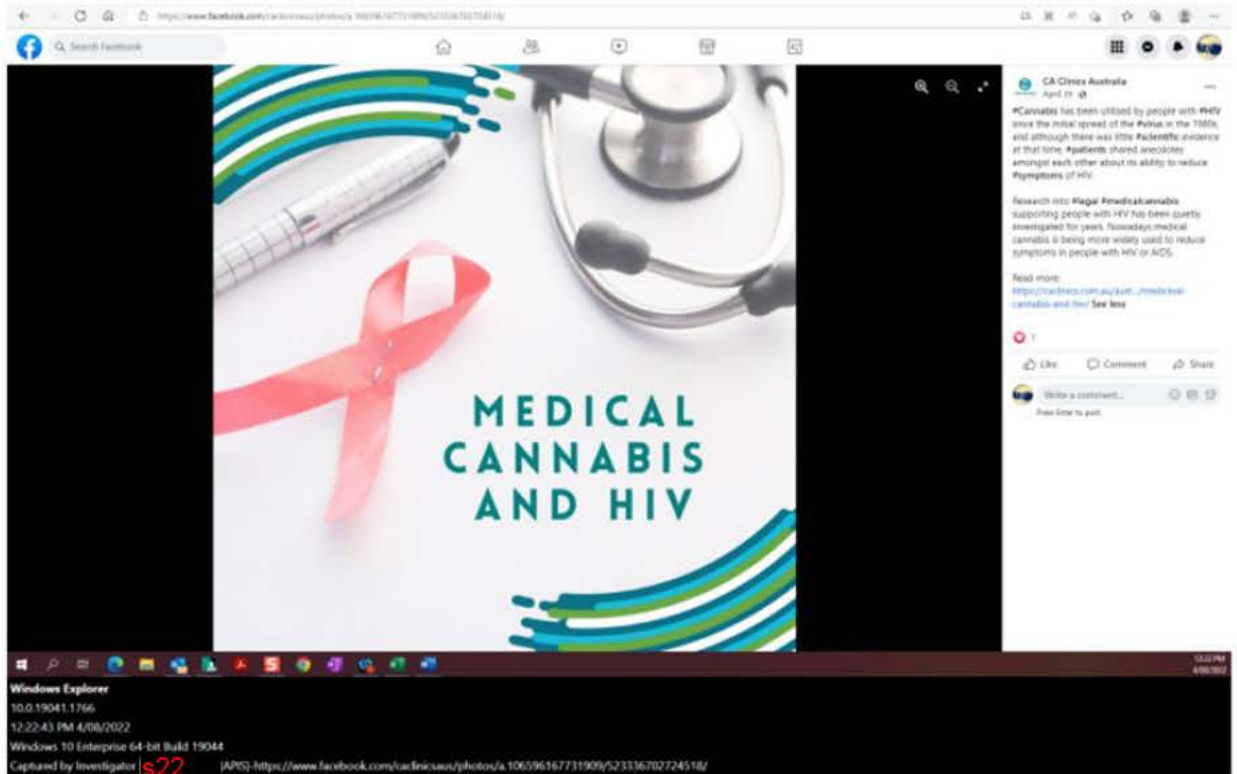
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-4

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at  
<https://www.facebook.com/caclinicsaus/photos/a.106596167731909/523336702724518/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the [current Poisons Standard](#), such as cannabidiol or cannabis, but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-4  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-4  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

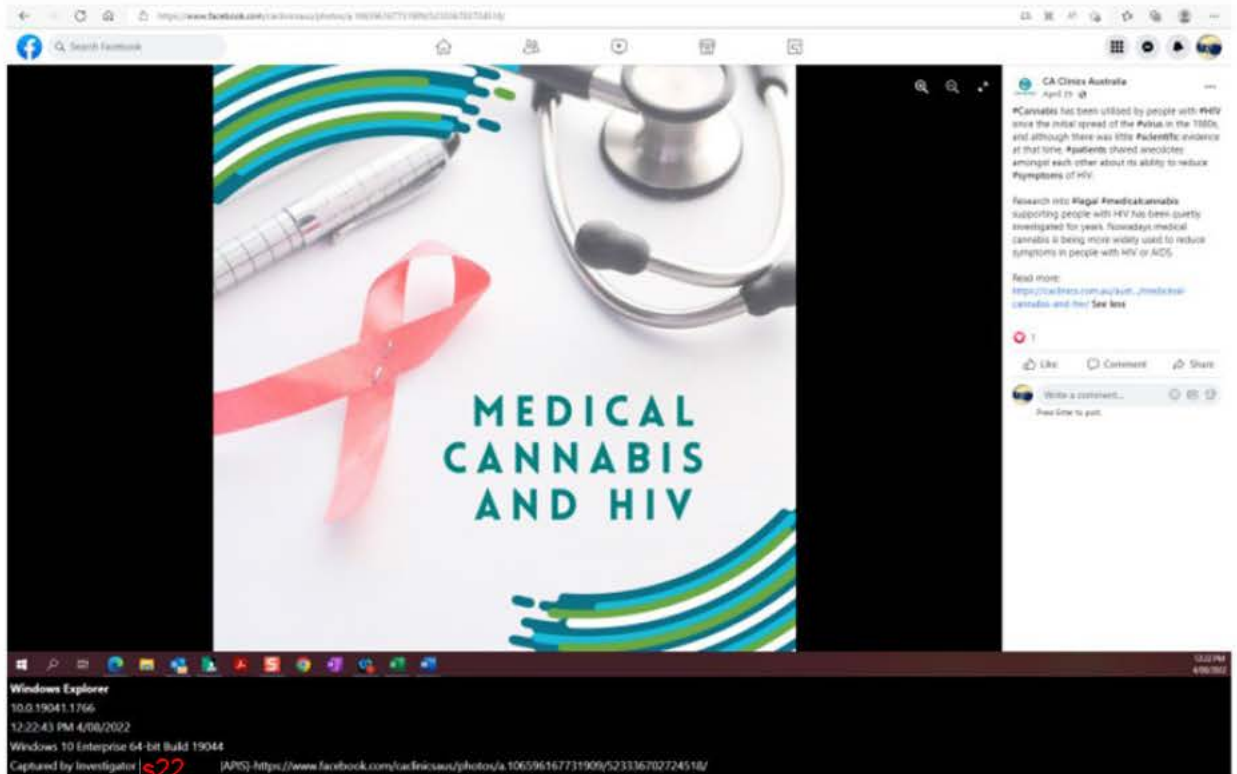
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-5

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CcEwXP7LtqH/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to epilepsy, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-5  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-5  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

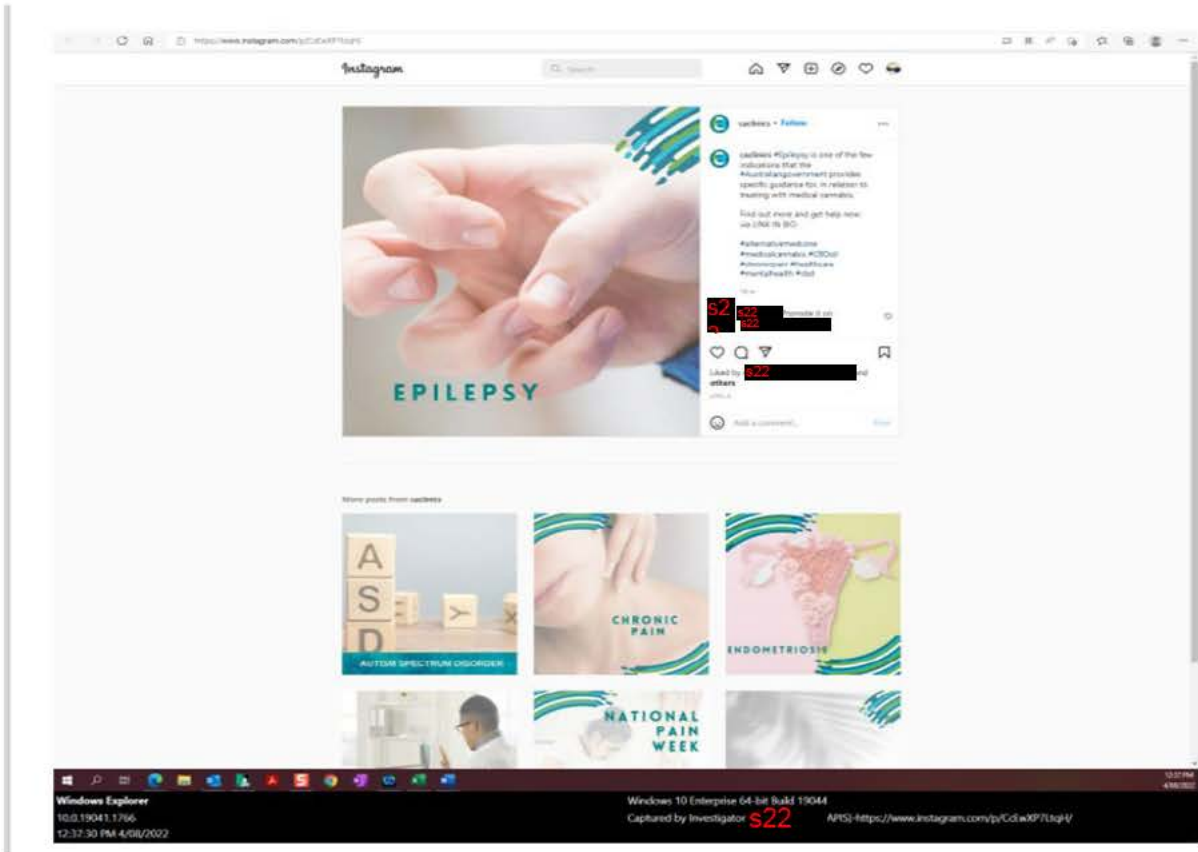


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022



ANNEXURE A:





## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
ACN 619 487 286  
2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
TGAIN- AC-000000002822/2022-6

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

#### INFRINGEMENT NOTICE GIVEN TO *Biologics Research Institute Australia Pty Ltd*

##### PART A: Infringement Notice given by

Nicole McLay,  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

##### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 04 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at  
<https://twitter.com/caccessclinics/status/1535026490005508115?cxt=HHwWpsC-mbadwc0qAAAA>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to arthritis, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN- AC-000000002822/2022-6** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN- AC-000000002822/2022-6** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED] [@health.gov.au](mailto:[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

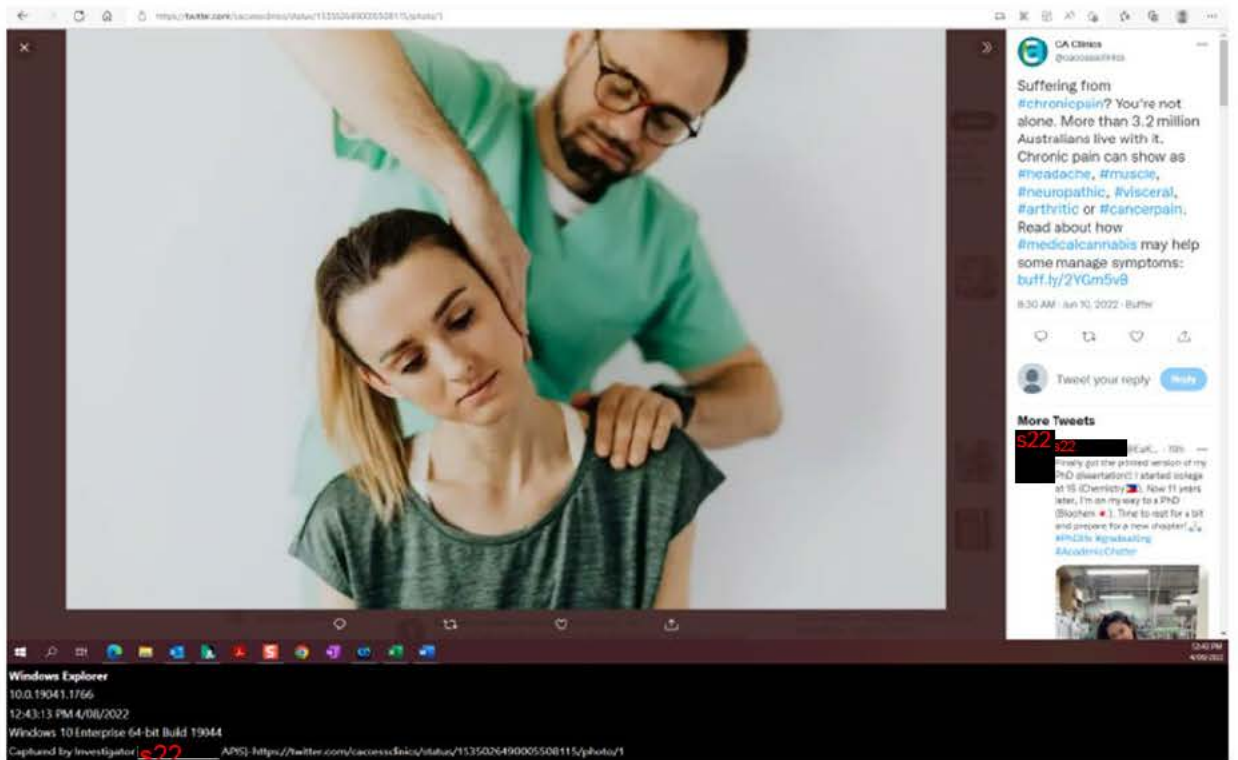
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-7

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 [REDACTED]  
**Telephone:** s22 [REDACTED]  
**Email:** s22 [REDACTED]@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 4 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caconnect.com.au/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to anxiety. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-7  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-7  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
 ACN 619 487 286  
 2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
 TGAIN- AC-000000002822/2022-8

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22 [REDACTED]  
**Telephone:** s22 [REDACTED]  
**Email:** s22 [REDACTED]@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Biologics Research Institute Australia Pty Ltd*

**PART A: Infringement Notice given by**

Nicole McLay,  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 4 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caconnect.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to chronic pain, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-8  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-8  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:

**CA Connect** | About Us | Pricing | Why CBD? | Education | FAQs | Log In

## Australian CBD Oil Treatment made simple

Access to quality medicinal CBD oil has never been easier. Our mission is to improve patient access to affordable CBD oil in Australia without sacrificing patient care.

[Get Started](#)

### Your CBD Oil Journey

- 1. CBD OIL PRESCRIPTION**  
Complete your free virtual consult form to determine your eligibility for CBD oil.
- 2. BUY CBD OIL AUSTRALIA**  
Purchase your CBD oil treatment from our online pharmacy.
- 3. CBD OIL ONLINE DELIVERY**  
Our team will create your consult and dispatch your CBD oil within 48 business hours.
- 4. ONGOING PATIENT CARE**  
Renewal, ongoing care and consultations are all made easy through our online portal.

[Get Started](#)

### Who is CA Connect for?

CA Connect's mission is to improve patient access to CBD oil in Australia without sacrificing patient care. We care for those suffering from conditions such as anxiety, insomnia and chronic pain, just like the rest of Australians who have found relief with natural alternatives.

[Learn More](#)

### Happy Australian Patients

We are incredibly fortunate to have so many Australian patients with transformative CBD oil treatments.

<p>My experience with CA Connect was super simple! The online application was very quick.</p> <p><b>Shelley C.</b></p> <p>★★★★★</p>	<p>Amazing service and delivery. Very easy on my treatment however so far so good!</p> <p><b>Kerry B.</b></p> <p>★★★★★</p>	<p>Simple online experience and I appreciate the ongoing support to monitor my progress.</p> <p><b>Alfred K.</b></p> <p>★★★★★</p>
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[Read More](#)

**CA Connect**  
181 814 6666  
11, 12, 13/100 D'Oro St, Sydney NSW 2000

**Get Started**  
About Us  
How it works  
Pricing  
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**Subscribe to our newsletter**

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Email:   
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© 2023 CA Connect is a registered trademark of CA Connect. All rights reserved. Privacy Policy | Address: Level 11, 100 D'Oro St, Sydney NSW 2000  
Windows 10 Enterprise 22H2 Build 19H4  
Captured by Screenshot-Toolbox.com





## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
ACN 619 487 286  
2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

**Infringement Notice Number:**  
TGAIN- AC-000000002822/2022-9

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22  
**Telephone:** s22  
**Email:** s22 @health.gov.au

### INFRINGEMENT NOTICE GIVEN TO *Biologics Research Institute Australia Pty Ltd*

#### PART A: Infringement Notice given by

Nicole McLay,  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4)(a) applied.

The details of the alleged contravention are that:

On 4 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caconnect.com.au/why-cbd/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to endometriosis, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

## PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-9  
 as reference to identify your  
 payment



### ELECTRONIC FUNDS TRANSFER

#### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-9  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup>[Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)

the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

#### **How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au ; or
- PO Box 100; WODEN ACT 2609

#### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:

**CA Connect** | About Us | Pricing | Why CBD? | Education | FAQs | Log In

## Why CBD oil?

CBD (cannabidiol) is a type of pure chemical or phytochemical found in the cannabis plant species. It is extracted from the plant (or made synthetically) and when ingested triggers a range of medical and therapeutic actions in our endocannabinoid system (ECS).

The ECS is a biological system in the human body that regulates specific functions including sleep, mood, appetite and memory.

CBD is one type of medical cannabis product available to suitable patients in Australia. It is generally considered non-intoxicating and unlikely to induce feelings of euphoria or a "high". The medically qualified CA Connect team is here to prescribe the most appropriate CBD oil medication for you.

**CA Connect provides CBD oil treatments to aid with the below health conditions**

### Anxiety

CBD oil has been prescribed as a therapeutic medication for patients suffering from mood or psychological disorders. Research suggests CBD can possibly reduce experiences of anxiety and may have mood-elevating qualities. More research is needed, but in the meantime quality, consistent and ongoing prescription by doctors provide a foundation for CBD oil in the alleviation of mood disorders.

[Read More](#)

### Chronic Pain

CBD oil interacts with chemical messengers in the brain that control pain sensations. Medical cannabis and CBD oil are also being investigated for their oxygen-sparing capacity, meaning patients off opioids for pain relief to cannabis medicines with a significantly lower risk of dependency. Medical cannabis has been recognised by the TGA for access under the SAS-01 scheme for chronic pain patients in Australia.

[Read More](#)

### Insomnia

CBD oil has been used to aid in the treatment of insomnia in legal cannabis markets for many years. In the context of CBD, some other compounds have been researched for its sedating effect that does not impact next day cognition.

[Read More](#)

### Other conditions

CBD oil is being researched for a range of other conditions including Epilepsy, Multiple Sclerosis, Tourette/Ticcing, PTSD, Traumatic Stress Disorder, appetite disorders, endometriosis, Alzheimer's, Parkinson's, Autism and a range of other inflammatory conditions.

If you are interested in Medical Cannabis to assist with these conditions see [info@caconnect.com.au](mailto:info@caconnect.com.au) or reach out to 03 9333 6160.

Note: CBD treatments and therapy may not be suitable for all patients. It's important to work with a qualified medical practitioner. See how at CA Connect to find the right product and correct dosage for your condition.

For up to date information from the Therapeutic Goods Administration on medicinal cannabis, [click here](#).

**DISCLAIMER:** The information on this page and throughout our website is not meant to promote medical cannabis as a definite treatment, but rather to inform and educate. CA Connect takes our best to comply with TGA guidelines for the dispensing of cannabis. Also note that medical cannabis effects can vary depending on individual patients according to factors such as size, age and dosage. If patients need information, they are advised to discuss with their registered doctor.

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**CA Connect**

info@caconnect.com.au  
 03 9333 6160

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Windows 10 Enterprise 64-bit Build 19H2  
 Captured by Screen Recorder s22  
 11:48:36 PM 4/26/2023



## Australian Government

### Department of Health and Aged Care

Therapeutic Goods Administration

Biologics Research Institute Australia Pty Ltd  
ACN 619 487 286  
2 Barrack Street, Sydney NSW 2000

By Express Post and Email at:  
[info@caclinics.com.au](mailto:info@caclinics.com.au),  
[info@caconnect.com.au](mailto:info@caconnect.com.au)

#### Infringement Notice Number:

TGAIN- AC-000000002822/2022-10

**Date given:** 31/10/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 29/11/2022

**Enquiries:** s22

**Telephone:** s22

**Email:** s22 @health.gov.au

### INFRINGEMENT NOTICE GIVEN TO

*Biologics Research Institute Australia Pty Ltd*

#### PART A: Infringement Notice given by

Nicole McLay,  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care.

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Biologics Research Institute Australia Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Biologics Research Institute Australia Pty Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2)(a) applied.

The details of the alleged contravention are that:

On 4 August 2022, Biologics Research Institute Australia Pty Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://caconnect.com.au/why-cbd/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to post-traumatic stress disorder. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>1</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-10  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN- AC-  
 000000002822/2022-10  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>1</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability. For further information about infringement notices, including the publication of notices, please refer to the TGA website.<sup>2</sup>

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after

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<sup>2</sup> [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#)



the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [redacted] [@health.gov.au](mailto:[redacted]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 31/10/2022

ANNEXURE A:

**CA Connect** About Us Pricing Why CBD? Education FAQs Log In

## Why CBD oil?

CBD (cannabidiol) is a type of plant chemical or phytochemical found in the cannabis plant species. It is extracted from the plant (or made synthetically) and when ingested triggers a range of medicinal and therapeutic actions in our endocannabinoid system (ECS).

The ECS is a biological system in the human body that regulates specific functions including sleep, mood, appetite and memory.

CBD is one type of medical cannabis product available to suitable patients in Australia. It is generally considered non-intoxicating so it's unlikely to trigger feelings of euphoria or a "high". The medically qualified [CA Connect team](#) is here to provide the most appropriate CBD oil medication for you.

**CA Connect provides CBD oil treatments to aid with the below health conditions**

### Anxiety

CBD oil has been prescribed as a therapeutic medication for patients suffering from mood or psychological disorders. Research suggests CBD oil can possibly reduce experiences of anxiety and may have mood-elevating qualities. More research is needed, but in the meantime doctors, clinicians and ongoing prescription specialists provide a prescription for CBD oil in the alleviation of mood disorders.

[Read More](#)

### Chronic Pain

CBD oil interacts with chemical messengers in the brain that control pain sensations. Medical cannabis and CBD oil are also being investigated for their neuro-protective capacity, allowing patients to off-spike for pain relief to curable medicines with a significantly lower risk of dependency. Medical cannabis has been approved by the TGA for access under the S45.B scheme for chronic pain patients in Australia.

[Read More](#)

### Insomnia

CBD oil has been used to aid in the treatment of insomnia in large cannabis markets for many years. In the correct dose, CBD (and some other cannabinoids) have been responsible for its sedating effect that does not impact next day cognition.

[Read More](#)

### Other conditions

CBD oil is being researched for a range of other conditions including Epilepsy, Multiple Sclerosis, Neurodegeneration, Post-Traumatic Stress Disorder, Appetite disorders, endometriosis, Alzheimer's, Parkinson's, Autism and a range of other inflammatory conditions.

If you are interested in Medical Cannabis to assist with these conditions we recommend you reach out to CA Connect.

**CA Connect**

29 Fildes@connect.com.au  
 5, 12 4032 1242

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 Pricing  
 FAQs

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 Terms & Conditions  
 Privacy & Security  
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**Subscribe to our newsletter**

Name

Email

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**From:** s22  
**To:** s22@mgcpharma.com.au  
**Cc:** info@mgcpharma.eu; s22; s22; s22  
**Subject:** Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]  
**Date:** Tuesday, 16 August 2022 4:55:00 PM  
**Attachments:** [image002.gif](#)  
[Letter from the TGA to MGC Pharmaceuticals Ltd dated 16 August 2022.pdf](#)

---

Dear s22,

Please find **attached** a letter from the Therapeutic Goods Administration for your attention. We ask that you confirm receipt of this letter by **10:00 AM on Thursday 18 August 2022**.

Yours sincerely,

s22

Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

s22

MGC Pharmaceuticals Ltd  
1202 Hay Street  
West Perth  
Western Australia, 6005

Our Reference: CC-MSD0IHC8/2019

By express post and email at: [s22@mgcpharma.com.au](mailto:s22@mgcpharma.com.au)  
Cc: [info@mgcpharma.eu](mailto:info@mgcpharma.eu)

16 August 2022

Dear s22

#### Subject: Notice of intention to commence enforcement action

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care, and is responsible for regulating the safety, quality, efficacy and advertising of therapeutic goods in Australia under the *Therapeutic Goods Act 1989* (the Act).

The purpose of this letter is to provide MGC Pharmaceuticals Ltd (MGC) with an opportunity to make submissions before a decision is made about what enforcement action should be taken in relation to alleged unlawful advertising which appears on the following platforms and for which MGC appears to be responsible:

- <https://mgcphama.com.au/> (the Website)
- [https://twitter.com/mgc\\_pharma?lang=en](https://twitter.com/mgc_pharma?lang=en)
- [https://www.instagram.com/mgc\\_pharma/](https://www.instagram.com/mgc_pharma/)
- <https://www.facebook.com/mgcpharmaceuticals/> (collectively, the Social Media).

The enforcement action being considered by the TGA includes issuing infringement notices for contraventions of the Act arising from the advertising on the Website and Social Media.

Our reference number for this matter is CC-MSD0IHC8/2019. We note that this correspondence, and the conduct it relates to, is separate and distinct from the TGA warning letter to MGC dated 13 July 2022 with TGA's reference number AC-000000003712.

#### Action required

We request that MGC take the following actions:

1. Confirm receipt of this notice within one business day from the time stamp on the covering email.
2. Carefully consider the information provided below.
3. Provide your submissions by **31 August 2022** as to:

- a. whether the advertising on the Website and Social Media summarised below (and any other content on the Website and Social Media containing similar references, statements or representations) contravenes the Act, if that is disputed; and
- b. any other matter which you wish the TGA to consider in deciding whether enforcement action should be taken in relation to the alleged unlawful advertising identified below.

**Note:** this notice canvasses some and not all of the alleged contraventions that we may pursue.

### **Summary of alleged contraventions**

We have identified representations on the Website and the Social Media which we allege advertise therapeutic goods, being medicinal cannabis products, in circumstances where the advertisements:

- refer to goods that are not entered in the Australian Register of Therapeutic Goods (the Register);
- refer to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard;
- contain prohibited representations and/or restricted representations (being references to serious forms of diseases, ailments and conditions) without TGA permission or approval;
- contain a reference to the Act; and/or
- contain a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority.

For example, we allege that the Website contains:

1. statements by Australian patients that the products 'MP1:1 25mg/ml CBD 25mg/ml THC' and 'MGC's CannEpil' are effective in the treatment of chronic back pain and Shingles
2. statements which refer to the use or effectiveness of medicinal cannabis products, including MGC products, to treat a range of medical conditions such as dementia, cancer and Crohn's disease.

In addition, we allege that the Social Media contains:

1. posts made on Instagram, Facebook and Twitter which allegedly advertise 'EXTRAX CBD Vape pens' which are described to have been 'successfully listed as an Unapproved Therapeutic Good' in Australia
2. a post made on Facebook which appears to promote 'TGC THC20 Whole Flower' and states that the good is 'available to patients in Australia'
3. posts made on Instagram and Twitter which appear to promote 'CannEpil@Plus', stating that the good is 'available through early patient access schemes in Australia' and 'used as a treatment for refractory epilepsy'.

### **Notice of intention to take enforcement action**

We are writing to you to put MGC on notice of our intention to take enforcement action in relation to the alleged unlawful advertising on the Website and the Social Media of the kinds summarised above. That enforcement action will not be limited to the provided examples and may extend to any other unlawful advertising of the kinds identified above.

MGC's submissions will be taken into account by the delegate of the Secretary of the Australian Government Department of Health and Aged Care in exercising their discretion whether to take enforcement action against MGC. The action under consideration includes giving infringement

notices to MGC in relation to contraventions of the kind set out above on the Website and Social Media.

Please note that information about any compliance action taken against MGC may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

To avoid being liable for further contraventions of the Act, MGC should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting we reserve our rights in relation to any further non-compliance that we identify. Should MGC remove any of the alleged unlawful advertising in response to this letter, we note that the delegate is not prevented from considering taking enforcement action against MGC.

### Other information

- The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the Act and the *Therapeutic Goods Regulation 1990*.
- It is illegal under section 42DL of the Act for a person to advertise or cause the advertising of therapeutic goods in circumstances where the advertisement:
  - refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, such as medicinal cannabis products, and that reference is not authorised by an Australian government or government authority
  - refers to therapeutic goods (being the Product) that are not entered in the Register nor subject to any exemption, approval or authority under the Act, and that reference is not authorised by an Australian government or government authority
  - contains a prohibited representation, such as cancer, and no permission is in force in relation to that prohibited representation
  - contains a restricted representation, such as chronic pain, and neither a permission nor a TGA approval is in force in relation to that restricted representation
  - contains a reference to the Act, other than in a statement of the registration number, listing number or device number of the goods
  - contains a statement, pictorial representation or design suggesting or implying the Product has been recommended or approved by or on behalf of a government or government authority, and no exception applies.
- A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
- It is the responsibility of advertisers to ensure that their advertising material is compliant with the relevant legislation.
- MGC may also wish to refer to the following guidance provided by the TGA:
  - [Advertising guidance for businesses involved in medicinal cannabis products](#)
- If MGC requires help in understanding the advertising requirements, we recommend that MGC consider engaging a regulatory affairs consultant or a lawyer to assist it.
- The TGA takes non-compliance with the regulatory scheme seriously, especially where a breach of the advertising requirements has resulted in, or poses, a threat to public health and safety. A range of compliance and enforcement tools are available to address non-compliance and may include infringement notices, criminal or civil court proceedings, which can result in substantial penalties, fines, or imprisonment.

Please contact **s22** and **s22** by email at **s22** [@health.gov.au](mailto:s22@health.gov.au) and **s22** [@health.gov.au](mailto:s22@health.gov.au) should you wish to discuss this matter further.

Yours sincerely

A black rectangular box containing the red text 's22', which is a redacted signature.A black rectangular box containing the red text 's22', which is a redacted name.

Acting Assistant Secretary  
Regulatory Compliance Branch

**From:** s22 [redacted] | MGC Pharma  
**To:** s22 [redacted]  
**Cc:** s22 [redacted]; s22 [redacted]; s22 [redacted]; s22 [redacted] | MGC Pharma  
**Subject:** FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]  
**Date:** Friday, 26 August 2022 1:48:53 PM  
**Attachments:** [Letter from the TGA to MGC Pharmaceuticals Ltd dated 16 August 2022.pdf](#)

---

Dear s22 [redacted],

Thank you for your letter on 16 August 2022 bringing attention to MGC pharmaceuticals alleged unlawful advertising on the Website and the Social Media. MGC has taken the following actions to address the issues and prevent any further potential concerns:

1. MGC Pharmaceuticals has reviewed the website and social media channels addressed in the attached letter and removed any items that could be perceived as a breach of the Act
2. MGC has implemented a more stringent review and approval of website and social media content moving forward.

If there are still any identified alleged breaches, please bring them to my attention directly and I will address them personally.

Much thanks,

s22 [redacted]

---

**From:** s22 [redacted] <s22 [redacted]@Health.gov.au>

**Date:** Tuesday, 16 August 2022 at 09:56

**To:** s22 [redacted] | MGC Pharma <s22 [redacted]@mgcpharma.eu>

**Cc:** MGC Pharmaceuticals Ltd <info@mgcpharma.eu>, s22 [redacted]

<s22 [redacted]@Health.gov.au>, s22 [redacted]

<s22 [redacted]@Health.gov.au>, s22 [redacted]

<s22 [redacted]@Health.gov.au>

**Subject:** Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Dear s22 [redacted],

Please find **attached** a letter from the Therapeutic Goods Administration for your attention.

We ask that you confirm receipt of this letter by **10:00 AM on Thursday 18 August 2022**.

Yours sincerely,

s22 [redacted]  
[redacted]

Advertising and Product Investigations Section



Regulatory Compliance Branch

Phone: s22 [REDACTED]  
Email: s22 [REDACTED]@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

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**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22

MGC Pharmaceuticals Ltd  
1202 Hay Street  
West Perth  
Western Australia, 6005

Our Reference: CC-MSD0IHC8/2019

By express post and email at: [s22@mgcpharma.com.au](mailto:s22@mgcpharma.com.au)  
Cc: [info@mgcpharma.eu](mailto:info@mgcpharma.eu)

16 August 2022

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**Action required**

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- a. whether the advertising on the Website and Social Media summarised below (and any other content on the Website and Social Media containing similar references, statements or representations) contravenes the Act, if that is disputed; and
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For example, we allege that the Website contains:

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2. a post made on Facebook which appears to promote 'TGC THC20 Whole Flower' and states that the good is 'available to patients in Australia'
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notices to MGC in relation to contraventions of the kind set out above on the Website and Social Media.

Please note that information about any compliance action taken against MGC may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

To avoid being liable for further contraventions of the Act, MGC should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting we reserve our rights in relation to any further non-compliance that we identify. Should MGC remove any of the alleged unlawful advertising in response to this letter, we note that the delegate is not prevented from considering taking enforcement action against MGC.

### Other information

- The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the Act and the *Therapeutic Goods Regulation 1990*.
- It is illegal under section 42DL of the Act for a person to advertise or cause the advertising of therapeutic goods in circumstances where the advertisement:
  - refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, such as medicinal cannabis products, and that reference is not authorised by an Australian government or government authority
  - refers to therapeutic goods (being the Product) that are not entered in the Register nor subject to any exemption, approval or authority under the Act, and that reference is not authorised by an Australian government or government authority
  - contains a prohibited representation, such as cancer, and no permission is in force in relation to that prohibited representation
  - contains a restricted representation, such as chronic pain, and neither a permission nor a TGA approval is in force in relation to that restricted representation
  - contains a reference to the Act, other than in a statement of the registration number, listing number or device number of the goods
  - contains a statement, pictorial representation or design suggesting or implying the Product has been recommended or approved by or on behalf of a government or government authority, and no exception applies.
- A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
- It is the responsibility of advertisers to ensure that their advertising material is compliant with the relevant legislation.
- MGC may also wish to refer to the following guidance provided by the TGA:
  - [Advertising guidance for businesses involved in medicinal cannabis products](#)
- If MGC requires help in understanding the advertising requirements, we recommend that MGC consider engaging a regulatory affairs consultant or a lawyer to assist it.
- The TGA takes non-compliance with the regulatory scheme seriously, especially where a breach of the advertising requirements has resulted in, or poses, a threat to public health and safety. A range of compliance and enforcement tools are available to address non-compliance and may include infringement notices, criminal or civil court proceedings, which can result in substantial penalties, fines, or imprisonment.

Please contact **s22** and **s22** by email at **s22** [@health.gov.au](mailto:s22@health.gov.au) and **s22** [@health.gov.au](mailto:s22@health.gov.au) should you wish to discuss this matter further.

Yours sincerely

A black rectangular redaction box containing the text 's22' in red font.

**s22**  
Acting Assistant Secretary  
Regulatory Compliance Branch

**From:** s22  
**To:** MCLAY, Nicole  
**Cc:** s22 ; s22 ; s22 ; s22 ; s22 ; s22  
**Subject:** TRIM: RE: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]  
**Date:** Friday, 9 September 2022 4:14:09 PM  
**Attachments:** [image002.png](#)  
[image003.png](#)  
[image004.gif](#)  
[image005.png](#)  
[image006.jpg](#)  
[image007.gif](#)  
[MGC - Letter to TGA - 9 Sep 2022.pdf](#)

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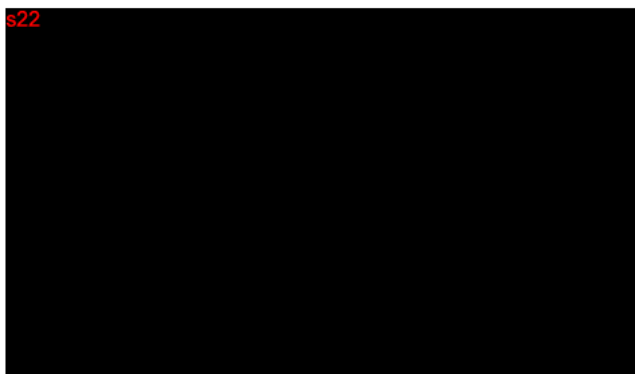
**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi Nicole

Please see the attached letter further to your correspondence with s22, below.

Kind regards

s22



---

**From:** MCLAY, Nicole <Nicole.McLay@health.gov.au>  
**Sent:** Friday, 2 September 2022 8:42 AM  
**To:** s22 >; s22 <s22@Health.gov.au>  
**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>  
**Subject:** RE: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Thanks s22

I agree to the extension as requested.

I'm pleased that you'll be working with MGC Pharma to potentially amend their online content. While submissions should address any changes made or planned, and this will be taken into account, the TGA reserves the right to take action in relation to alleged findings

of past offences. In that regard submissions may also consider whether MGC Pharma consider our findings to be invalid.

I look forward to hearing from you.

Kind regards

Nicole

**Nicole McLay**  
Assistant Secretary, Regulatory Compliance

---

Regulatory Practice and Support Division | Health Products Regulation Group  
Regulatory Compliance Branch  
Australian Government Department of Health and Aged Care  
T: 02 6289 3637 | E: [nicole.mclay@health.gov.au](mailto:nicole.mclay@health.gov.au)  
Location: 27 Scherger Drive, Fairbairn, ACT  
PO Box 100, Woden ACT 2606, Australia



*The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.*

---

**From:** s22 >  
**Sent:** Thursday, 1 September 2022 5:40 PM  
**To:** s22 <s22@Health.gov.au>  
**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; MCLAY, Nicole <[Nicole.McLay@health.gov.au](mailto:Nicole.McLay@health.gov.au)>  
**Subject:** RE: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

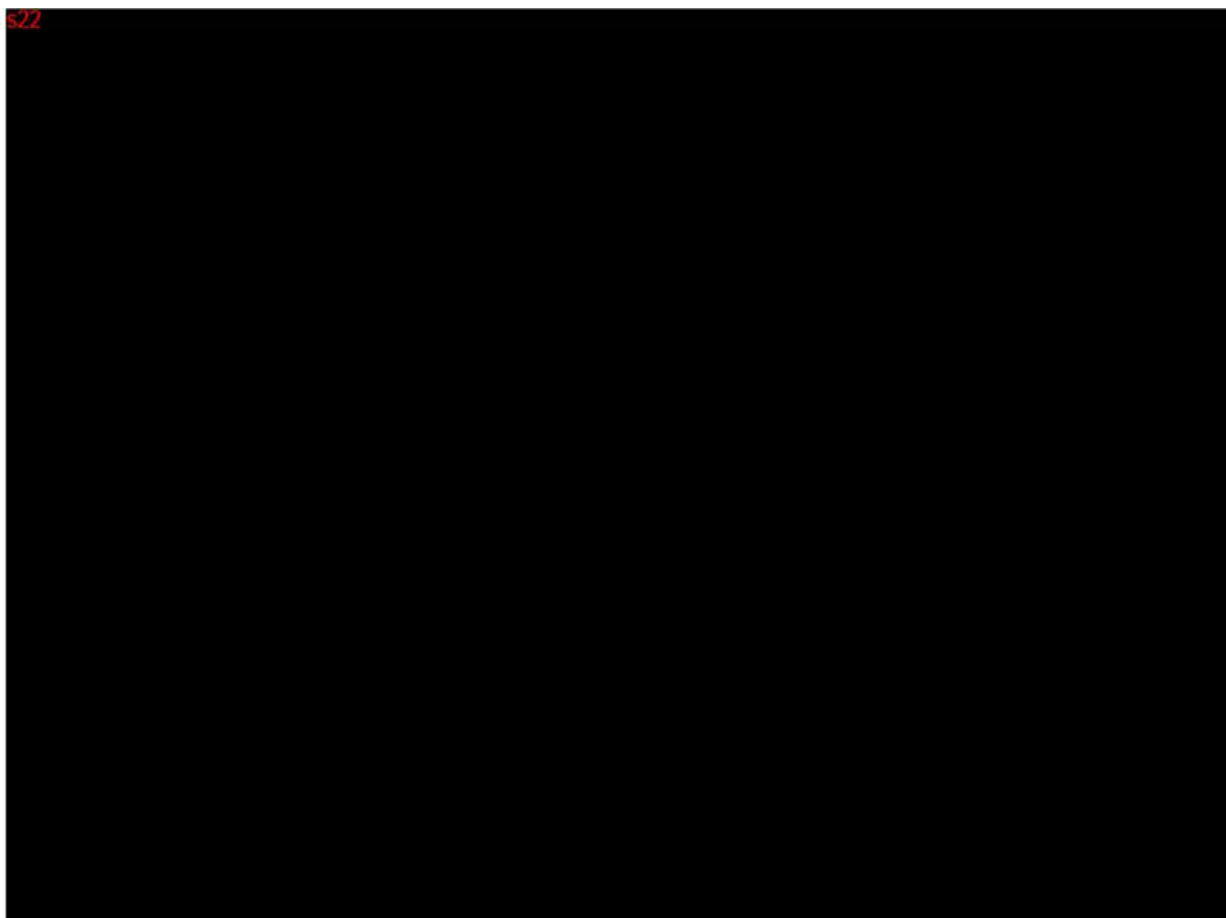
**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good afternoon s22. We have been instructed by MGC Pharma to provide advice in relation to recent letters received from the TGA (reference numbers AC-000000003712 and CC-MSD0IHC8/2019). I note your email below granting an extension of 2 days in which to make written submissions. However, as the correspondence pertaining to this matter was only provided to us today, we respectfully request that my client be afforded an extension of another week in which to respond, to allow us to advise them appropriately. Our advice will naturally prioritise a review of the MGC website and social media sites referred to in your correspondence relating to matter CC-MSD0IHC8/2019.

As there is no apparent urgency which would require our client to respond by tomorrow, I would be grateful if the timeframe in which to respond could be extended as requested, noting that our intention is to provide every assistance to our client to address any regulatory concerns raised by the TGA's letters.

We look forward to your response.

Kind regards



**From:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Sent:** Thursday, 1 September 2022 5:22 PM  
**To:** s22 >; s22 | MGC Pharma <s22@mgcpharma.eu>  
**Subject:** Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Good news in the last hour the TGA has granted the extension **until close of business (5pm) Friday 2 September 2022**

s22  
s22 | MGC Pharmaceuticals Ltd.  
M s22 s22 | s22@mgcpharma.eu | www.mgcpharma.com.au

---

**From:** s22 <s22@Health.gov.au>  
**Sent:** Thursday, September 1, 2022 2:35 PM  
**To:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>  
**Subject:** RE: FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]



Dear s22,

I write in relation to your request for an extension until 6 September 2022, to provide your submissions regarding the proposed enforcement action outlined in our letter dated 16 August 2022.

The delegate considered your request and has agreed to allow you **until close of business (5pm) Friday 2 September 2022** to provide your written submissions.

Please provide your submission(s) by the above due date and time for the delegates consideration.

Kind Regards,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

[Redacted signature box]

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---

**From:** s22  
**Sent:** Wednesday, 31 August 2022 4:37 PM  
**To:** s22 | MGC Pharma' <s22@mgcpharma.eu>  
**Cc:** s22 <s22@Health.gov.au>; s22  
<s22@Health.gov.au>; s22 <s22@Health.gov.au>  
**Subject:** RE: FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Dear s22,

Thank you for your email.

We have put forward your request for an extension of time to the delegate for consideration. However, given the short notice, it is difficult for us to advise you if a decision has been made before close of business today.

We will be in contact once a decision has been made.

Kind regards,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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---

**From:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Sent:** Tuesday, 30 August 2022 5:20 PM  
**To:** s22 <s22@Health.gov.au>  
**Subject:** RE: FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

MGC is preparing a formal response to the letter dated August 16<sup>th</sup>. Can we have an extension

please for 1 week until September 6<sup>th</sup> as we are addressing each item individually.

Much thanks,

s22

---

**From:** s22 <s22@Health.gov.au>  
**Sent:** Monday, 29 August 2022 10:51 AM  
**To:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 | MGC Pharma <s22@mgcpharma.eu>  
**Subject:** RE: FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Dear s22,

Thank you for your email, and for notifying us of the actions taken by MGC Pharmaceuticals following our letter dated 16 August 2022.

Could you please confirm whether MGC Pharmaceuticals intends to make written submissions, as referred to in our 16 August letter, in addition to your email of 26 August 2022?

Kind regards,

s22  
s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Sent:** Friday, 26 August 2022 1:48 PM  
**To:** s22 <s22@Health.gov.au>  
**Cc:** s22 @Health.gov.au; s22  
@Health.gov.au; s22 <s22@Health.gov.au>; s22  
s22 | MGC Pharma <s22@mgcpharma.eu>  
**Subject:** TRIM: FW: Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Dear s22,

Thank you for your letter on 16 August 2022 bringing attention to MGC pharmaceuticals alleged unlawful advertising on the Website and the Social Media. MGC has taken the following actions to address the issues and prevent any further potential concerns:

1. MGC Pharmaceuticals has reviewed the website and social media channels addressed in the attached letter and removed any items that could be perceived as a breach of the Act
2. MGC has implemented a more stringent review and approval of website and social media content moving forward.

If there are still any identified alleged breaches, please bring them to my attention directly and I will address them personally.

Much thanks,

s22

---

**From:** s22 <s22@Health.gov.au>  
**Date:** Tuesday, 16 August 2022 at 09:56  
**To:** s22 | MGC Pharma <s22@mgcpharma.eu>  
**Cc:** MGC Pharmaceuticals Ltd <info@mgcpharma.eu>, s22  
<s22@Health.gov.au>, s22  
<s22@Health.gov.au>, s22  
<s22@Health.gov.au>  
**Subject:** Letter from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSD0IHC8/2019 [SEC=OFFICIAL]

Dear s22,

Please find **attached** a letter from the Therapeutic Goods Administration for your attention.

We ask that you confirm receipt of this letter by **10:00 AM on Thursday 18 August 2022**.

Yours sincerely,

s22

s22

Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

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s22

[REDACTED]

9 September 2022

Ms Nicole McLay  
Assistant Secretary  
Australian Government Department of Health and Aged Care  
Regulatory Education and Compliance Branch  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

s22

[REDACTED]

Email: nicole.mclay@health.gov.au

Dear Ms McLay

**Regulatory Compliance Issues - Advertising of Therapeutic Goods:  
TGA Reference Numbers AC-000000003712 and CC-MSD0IHC8/2019**

1. As you are aware, we act for MGC Pharmaceuticals Ltd (**MGC**).
2. Thank you for your email dated 2 September 2022 and for providing our client with the opportunity to make submissions in response to letters (**Letters**) from the TGA dated 13 July 2022 (reference number AC-000000003712) and 16 August 2022 (reference number CC-MSD0IHC8/2019), which raised concerns regarding potential contraventions of the advertising provisions of the *Therapeutics Goods Act 1989* (**TG Act**).
3. In response to the Letters, MGC has retained us to provide them with regulatory compliance advice pertaining to advertising on their website and the social media accounts they control on Twitter, Instagram and Facebook (collectively, the **Sites**).
4. In this context, we acknowledge the TGA's position with respect to websites that publish information globally that compliance with another country's laws and an intention to advertise only to residents of that country does not relieve the website operator of its obligation to comply with Australian regulatory requirements if the advertising reaches an Australian audience. This is particularly so when the advertiser and operator of the website is an Australian legal entity or person.
5. As a result of the Letters, and our advice regarding the concerns raised in the Letters and our review of the Sites, MGC has taken immediate action to place the Sites into maintenance, which means that they are no longer accessible to the public. We are instructed that public access to the Sites will not be restored until amendments have been made to the content on the Sites, to ensure that all content complies with therapeutic goods advertising laws.

**NOTICE**

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s22

[REDACTED]

6. In addition, s47G(1)(a), the third party owner of the <https://artemic.shop> website (Artemic Website), has at MGC's request agreed to geo-block – and has geo-blocked – access to the Artemic Website for Australian IP addresses.
7. Further to the above, MGC has engaged us to assist in the creation of a new internet, social media and advertising policy to ensure that:
  - (a) all advertising to the general public undergoes a stringent approval process involving several stages of review and authorisation by appropriate senior personnel (or external consultants) before being published; and
  - (b) there is a procedure in place to review, moderate and control content that is posted on social media sites by MGC or posted on those sites by the general public.
8. For good order, in relation to the amendments MGC intends to make to the Sites to take account of the TGA's concerns, it should be acknowledged that there are 'grey' areas in the assessment of what is and is not permissible under therapeutic goods advertising laws. Accordingly, whilst MGC will use its best endeavours to make amendments to the Sites to ameliorate the TGA's concerns, once the Sites are made public again, it invites and would welcome feedback from the TGA in a facilitative and collaborative manner if the TGA considers that residual concerns remain regarding MGC's advertising.

### **Prior Notices and Possible Enforcement Action**

9. MGC regrets the concerns raised by the TGA in the Letters and wishes to assure the TGA that it takes its regulatory compliance obligations seriously. It is motivated to address those concerns and is committed to working with us to make amendments to the Sites in accordance with our frank advice and recommendations.

### **TGA Warning Letter – 13 July 2022**

10. In respect of the TGA's 13 July 2022 Letter, MGC has reached agreement with s47G(1)(a), the owner of the Artemic Website, to geo-block all Australian IP addresses. We confirm that we attempted to access the Artemic Website on the date of this letter and it appears to have been geo-blocked when accessed from a regular browser window and after a slight delay of 2-3 seconds. (Please note that we are unable to confirm that the geo-blocking measures implemented by s47G(1)(a) to date will universally prevent users in Australia from accessing the website, for example by the use of 'incognito' or 'private' browser settings, virtual private networks or other web access settings/functions/channels which render geo-blocking measures less effective).
11. Our client has also just requested s47G(1)(a) to geo-block for Australian IP addresses another Artemic-related website owned or operated by s47G(1)(a) at <https://www.artemic.info> (including the English language version of the site at <https://www.artemic.info/en>), which it hopes will be implemented in the same way in the near future.

### **TGA Notice of Intention to Commence Enforcement Action Letter – 16 August 2022**

12. In respect of the TGA's letter dated 16 August 2022, we note that MGC engaged us after it had already responded to that letter (by email dated 26 August 2022). We were engaged to assist MGC to overhaul its regulatory compliance standards and ensure it was fully addressing the TGA's concerns. In this regard, the concerns raised with respect to the specific advertisements referenced in the 16 August 2022 letter have, with the benefit of our advice, been re-evaluated by MGC as being so serious as to precipitate the decision to place the Sites into maintenance, while we work with the company to facilitate a thorough compliance review.
13. Noting the more positive responsive action described above, MGC wishes to acknowledge that the previous representatives of the company who responded to the Letters did so with insufficient insight into the company's regulatory compliance

obligations and the important role of the TGA's Advertising Compliance Branch. Our client appreciates that those responses may have come across as dismissive, for which it is deeply regretful; however, it assures the TGA that that was not the intention and does not reflect management's position.

### Submissions Regarding Further Actions

14. A relevant consideration for the TGA in deciding whether any regulatory action ought to be taken against our client is that, from our observations, there is widespread confusion within the industry in relation to what is and is not permissible when it comes to advertising therapeutic goods. This is not helped by the ongoing situation where companies that are brought to account feel that they are being singled out and they question why the advertising playing field is not levelled by sanctioning all noncompliant advertising. Rightly or wrongly, the current modus operandi in the industry is to look at what others are doing and fall in line, based on the misconceived principle that there is 'safety in numbers'.
15. We and our client appreciate that the TGA has the invidious responsibility of regulating an industry where noncompliant advertising appears to have become a runaway train. However, it does not assist our client and, indeed, other players in the market to understand their regulatory obligations when there are so many companies engaging in unlawful advertising, many of which are engaging in much more egregious advertising than what the TGA has outlined in the Letters, with apparently no consequences.
16. The above is not intended to in any way excuse potential contraventions by our client.  
s47G(1)(a)  
Our client has also engaged s47G(1)(a) as external regulatory consultants to provide compliance advice and review.
17. There is a fine balance between running a commercial enterprise, meeting the obligations of shareholders, complying with disclosure obligations and complying with regulatory frameworks all over the world simultaneously. It is a task more suited, at times, to an expert juggler and tightrope walker. However, our client understands that the ultimate consideration is ensuring the health and safety of the public and, on that basis, acknowledges and appreciates that the Letters are intended to facilitate our client's compliance.
18. MGC can do no more to demonstrate how seriously it takes that TGA's concern than its decisive action to place the Sites into maintenance, noting that this action has been taken with global effect. For a commercial enterprise, that decision will undoubtedly have material commercial consequences. We are aware that there have been previous instances of more egregious advertising in the sector where the placement of the impugned website into maintenance has been regarded by the TGA as sufficient mitigation to avoid regulatory action being taken against the advertiser. We therefore ask that the TGA take this positive responsive action by MGC into account in its deliberations and respectfully request the same leniency be extended to MGC.
19. We hope that this letter demonstrates that MGC has appropriately acted on the TGA's concerns, has sought our expert advice about its regulatory obligations and has prudently placed the Sites into maintenance, while genuinely trying to understand where the boundaries lie with respect to advertising and where their internal processes have fallen short.
20. There is no evidence of any wilful, reckless or negligent conduct on the part of our client, nor any suggestion that our client intends to carry on in blatant disregard for therapeutic



goods advertising laws. At worst, the issue we are dealing with is one of insufficient competency in regulatory compliance and the confusion about regulatory boundaries in an industry that is rife with noncompliant conduct.

21. We respectfully request that the above submissions on behalf of MGC be taken into account in deciding whether any regulatory action ought to be taken against our client.
22. If you have any questions or require further information, please do not hesitate to contact s22 on +s22 or s22.

s22  


s22  


**From:** s22  
**To:** s22 ; s22 ; s22  
**Cc:** s22 ; s22 ; s22  
**Subject:** Infringement Notices from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd - CC-MSDOIHC8/2019 [SEC=OFFICIAL]  
**Date:** Tuesday, 27 September 2022 3:23:00 PM  
**Attachments:** [image001.gif](#)  
[Cover Letter and Infringement Notices to MGC Pharmaceuticals Ltd - 27 September 2022.pdf](#)

---

Dear s22 ,

Please find attached a letter and 23 infringement notices from the Therapeutic Goods Administration to MGC Pharmaceuticals Ltd.

We ask that you confirm that you have instructions to accept service of the infringement notices on behalf of MGC Pharmaceuticals Ltd by **5:00 PM** on **Wednesday 28 September 2022**.

Yours sincerely,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22 @health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22

MGC Pharmaceuticals Ltd  
 1202 Hay Street  
 West Perth, WA 6005

Our Reference: CC-MSD0IHC8/2019

By Express Post and Email at: s22

s22

27 September 2022

Dear s22

**Infringement notices given to MGC Pharmaceuticals Ltd**

<b>Infringement Notice</b>	<b>Amount</b>	<b>Payment Due by</b>
TGAIN-CC-MSD0IHC8/2022-1	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-2	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-3	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-4	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-5	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-6	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-7	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-8	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-9	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-10	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-11	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-12	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-13	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-14	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-15	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-16	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-17	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-18	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-19	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-20	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-21	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-22	\$13,320.00	26 October 2022
TGAIN-CC-MSD0IHC8/2022-23	\$13,320.00	26 October 2022
<b>Total</b>	<b>\$ 306,360.00</b>	

- I refer to our previous correspondence regarding this matter, including our letter to MGC Pharmaceuticals Ltd (MGC) dated 16 August 2022, and submissions from MGC dated 9 September 2022.
- I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).

3. Having considered MGC's submissions, I have decided to give 23 infringement notices (enclosed to this letter) to MGC under Part 5A-2 of the Act, on the basis that I reasonably believe MGC has contravened subsection 42DLB(1) of the Act, where subsections (2), (4), (5), (6), (7) and (9) applied.
4. The infringement notices are enclosed to this letter and include information on how to pay the penalty amount, how to request an extension of the compliance period for payment, how to request that the infringement notices be withdrawn, and the actions that we may take in the event of non-payment of the infringement notices. It is important that MGC carefully read the infringement notices and the information contained within.
5. Infringement notices are an opportunity for MGC to pay an amount as an alternative to having court proceedings brought against MGC in relation to the alleged contraventions described in each of the notices.
6. MGC should be aware of the possible consequences for not paying an infringement notice. If MGC chooses not to pay the penalty amount, proceedings may be brought against MGC for the alleged contraventions described in the infringement notices. We note that the maximum civil penalty that a court can impose on a company for a contravention of subsection 42DLB(1) of the Act is \$11.1 million per contravention. In a recent decision by the Federal Court, non-payment of a single infringement notice issued against a company resulted in the court ordering a total of \$96,000 in penalty against both the company and its executive directors.<sup>1</sup>
7. To avoid being liable for further contraventions of the Act, MGC should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting that we reserve our rights to take enforcement action in relation to any further non-compliance we may identify.
8. For more information about infringement notices, I refer MGC to the following on the TGA website:
  - a. [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#).
  - b. [Infringement notices | Therapeutic Goods Administration \(TGA\)](#).

#### **Delegate comments and concerns**

9. While I am not required to provide reasons for giving an infringement notice under the Act, I offer the following remarks to assist MGC to understand why I have decided to take this particular action.
10. I note that there have been significant Federal Court decisions in which the Court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.<sup>2</sup> Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those from the outset.<sup>3</sup>
11. Additionally, I note that MGC has previously been made aware of the advertising prohibitions under the Act on at least three occasions:
  - a. in 2019, in relation to the alleged unlawful advertising of medicinal cannabis products at <https://stockhead.com.au/health/600-prescriptions-have-now-been-written-for-mgc-pharma-medicinal-cannabis-products/>.

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<sup>1</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

<sup>2</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865 \(fedcourt.gov.au\)](#) at paragraph [76].

<sup>3</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

- b. in 2021, in relation to the alleged unlawful advertising of medicinal cannabis at <https://www.medicinalcannabisclinics.com.au/> and [https://www.youtube.com/channel/UCq0H4ww2hVs1\\_XyMbk\\_boRA](https://www.youtube.com/channel/UCq0H4ww2hVs1_XyMbk_boRA) by one of MGC's subsidiaries, Medicinal Cannabis Clinics.
    - c. in 2022, in relation to the alleged unlawful advertising of ArtemiC, which is purported to treat Coronavirus disease, at <https://artemic.shop/>.
  12. I have reviewed the following platforms for which MGC appear to be responsible:
    - a. <https://mgcpharma.com.au/> (the Website)
    - b. [https://twitter.com/mgc\\_pharma/](https://twitter.com/mgc_pharma/)
    - c. [https://instagram.com/mgc\\_pharma/](https://instagram.com/mgc_pharma/), and
    - d. <https://facebook.com/mgcpharmaceuticals/> (collectively, the Social Media).
  13. While not all information released to the public about therapeutic goods is advertising, I consider that the Website and the Social Media unlawfully advertise medicinal cannabis products, as defined in section 3(1) of the Act, for the following reasons:
    - a. The Website and Social Media contain statements and pictorial representations which were intended, either directly or indirectly, to promote the use or supply of medicinal cannabis products. For example (but not limited to):
      - i. The Website contains statements presented to be testimonials from patients regarding the use of medicinal cannabis products to treat serious medical conditions such as chronic back pain and shingles.
      - ii. The use of hashtags in Social Media posts, a function which is predominantly used to promote the content, that referred to medicinal cannabis products such as #cbd #cbdproducts.
      - iii. The Website and Social Media made unauthorised therapeutic claims regarding the efficacy of medicinal cannabis. For example, making references to serious forms of a disease, ailment or condition, in circumstances which inferred (directly or indirectly) that medicinal cannabis may be, or is, a suitable treatment for the medical condition mentioned.
    - b. The advertisements:
      - i. refer to goods that are not entered in the Australian Register of Therapeutic Goods, such as the 'MP1:1 25mg/ml CBD 25mg/ml THC'.
      - ii. refer to substances which are included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard
      - iii. contain prohibited representations, such as cancer, and/or restricted representations, such as shingles, being references to serious forms of diseases, ailments and conditions without TGA permission or approval
      - iv. contain a reference to the Act, and
      - v. contain a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government authority.
  14. As outlined in its written submissions dated 9 September 2022, amongst other steps taken by MGC since receiving our letter of 16 August 2022, significant changes appear to have been made to the Website and Social Media, including the removal of all posts from its Instagram and Twitter pages, and suspension of the Website and its Facebook page.

15. Each instance of non-compliant advertising on each day constitutes a separate contravention of the Act. We hold evidence that the contraventions as particularised in the infringement notices occurred from at least late April 2022 to 1 August 2022.
16. Taking into account the written submissions and changes made to the Website and Social Media, I have decided not to give MGC infringement notices for all identified alleged contraventions of the Act at this time, including those:
  - a. occurring from April 2022 to 1 August 2022
  - b. in relation to the alleged unlawful advertising of the ArtemiC product which occurred on the Social Media, including in posts made following the correspondence referred to at paragraph [11.c.]
  - c. which occurred on the Social Media in posts made prior to December 2021
  - d. which appeared identical or sufficiently similar, to the advertising on another page of the Website or another Social Media post
  - e. arising from the same restricted or prohibited representation which was made multiple times on the Website and/or the Social Media, and
  - f. arising from a reference to the same distinct medicinal cannabis products, which appeared multiple times on the Website and/or the Social Media.
17. Please contact s22 [redacted] and s22 [redacted] by email at s22 [redacted]@health.gov.au and s22 [redacted]@health.gov.au should MGC wish to discuss this matter further.

Yours sincerely



Nicole McLay  
Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
ACN 116 800 269  
1202 Hay Street  
West Perth WA 6005

By Express Post and Email at:

s22  
s22  
s22

**Infringement Notice Number:**  
TGAIN-CC-MSD0IHC8/2022-1

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being MP1:1 25mg/ml CBD 25mg/ml THC on the web page located at <https://mqcpharma.com.au/>.

The advertisement contained a restricted representation (whether in express terms or by necessary implication), being a reference to chronic pain, about the good. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>4</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-1** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-1** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>4</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot displays the MGC Pharma website. At the top left is the MGC Pharma logo. The navigation menu includes 'Discover', 'About', and 'Research'. On the right, there are links for 'Australia', 'Contact', and 'Investor Centre', along with a search icon and a stock price of '\$0.018'. The main content area features a testimonial from a patient, accompanied by a photograph of an elderly woman with short white hair, smiling. The testimonial text reads: "Suffering from chronic back pain for over 15 years I have struggled to maintain effective sleep due to constantly tossing and turning to get comfortable. Using MP1:1 25mg/ml CBD 25mg/ml THC not only helps with my pain, but it also relaxes my body and ensures that my sleep patterns are more consistent." Below the text, it identifies the patient as being from Australia and includes left and right navigation arrows. The Windows taskbar at the bottom shows the system time as 8:31 AM on 2/08/2022, and the user is logged in as 's22'.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**

TGAIN-CC-MSD0IHC8/2022-2

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being MP1:1 25mg/ml CBD 25mg/ml THC on the web page located at <https://mqcpharma.com.au/>.

The advertisement referred to a good containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>5</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-2** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-2** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>5</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows the website for mgcpharma.com.au. The page features a testimonial from a patient in Australia. The patient is a woman with short white hair, smiling. The text of the testimonial reads: "Suffering from chronic back pain for over 15 years I have struggled to maintain effective sleep due to constantly tossing and turning to get comfortable. Using MP1:1 25mg/ml CBD 25mg/ml THC not only helps with my pain, but it also relaxes my body and ensures that my sleep patterns are more consistent." Below the testimonial, it identifies the patient as being from Australia. The website header includes navigation links for Discover, About, and Research, along with a search icon and a stock price of \$0.018. The browser's taskbar at the bottom shows the time as 8:31:14 AM on 2/08/2022.





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**

TGAIN-CC-MSD0IHC8/2022-3

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being MP1:1 25mg/ml CBD 25mg/ml THC, on the web page located at <https://mgcpharma.com.au/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>6</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-3** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-3** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.





Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



The screenshot shows a web browser window displaying the mgcpharma.com.au website. The page features the company logo, navigation links for 'Discover', 'About', and 'Research', and a stock price of \$0.018. The main content is a testimonial from a patient, including a portrait of an elderly woman and a quote about her experience with chronic back pain and the effectiveness of MP1:1 25mg/ml CBD 25mg/ml THC. The testimonial is labeled 'Patient Australia' and includes navigation arrows. The Windows taskbar at the bottom shows the system time as 8:31:14 AM on 2/06/2022, and the page was captured by S22.

mgcpharma  Discover About Research Australia Contact Investor Centre ADX:MG1 \$0.018 ↑0.003 (15.52%)



“  
Suffering from chronic back pain for over 15 years I have struggled to maintain effective sleep due to constantly tossing and turning to get comfortable. Using MP1:1 25mg/ml CBD 25mg/ml THC not only helps with my pain, but it also relaxes my body and ensures that my sleep patterns are more consistent.

Patient  
Australia

Windows Explorer 10.0.18362.2274 8:31:14 AM 2/06/2022 Windows 10 Enterprise 64-bit Build 19353 Captured by S22 8:31 AM 2/6/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-4

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil, on the web page located at <https://mqcpharma.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to shingles, about the good. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>7</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-4** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-4** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows the MGC Pharma website with a testimonial for CannEpiil. The testimonial features a photograph of an elderly woman and a text block describing her experience with shingles and how CannEpiil helped her. The website header includes navigation links for Discover, About, and Research, along with a search icon and a stock price for ASX:MGC at \$0.018. The footer of the browser window shows the Windows Explorer taskbar with the date 2/08/2022 and the time 8:32:43 AM.


Improving the Quality of Lives

mgcpharma.com.au

Australia Contact Investor Centre

ASX:MGC \$0.018

Discover About Research



CC

I was diagnosed with Shingles a few years ago and after being in constant pain I was advised to try CBD Oil. After trying a few different products, I decided to try MGC's CannEpiil and I have found that it has helped to reduce the severe headaches I was suffering from and made life so much brighter.

Patient  
Australia

← →

Windows Explorer 10.0.18362.2274 8:32:43 AM 2/08/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by s22 8:52 AM 2/08/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-5

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil, on the web page located at <https://mqcpharma.com.au/>.

The advertisement referred to a good containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>8</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-5** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-5** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>8</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** @health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows the mgcpharma.com.au website. At the top left is the mgcpharma logo. Navigation links include 'Discover', 'About', and 'Research'. On the right, there are links for 'Australia', 'Contact', and 'Investor Centre', along with a search icon and a stock price of '\$0.018'. The main content features a testimonial from a patient, accompanied by a photograph of an elderly woman. The testimonial text reads: 'I was diagnosed with Shingles a few years ago and after being in constant pain I was advised to try CBD Oil. After trying a few different products, I decided to try MGC's CannEpiil and I have found that it has helped to reduce the severe headaches I was suffering from and made life so much brighter.' Below the text, it identifies the patient as being from Australia. The Windows taskbar at the bottom shows the date as 8:32:43 AM 2/08/2022 and the system as Windows 10 Enterprise 64-bit (build 18363). The page was captured by 's22'.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-6

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil, on the web page located at <https://mqcpharma.com.au/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>9</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-6** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-6** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>9</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** @health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows the MGC Pharma website in a browser window. The browser's address bar displays 'mgcpharma.com.au'. The website header includes the MGC Pharma logo, navigation links for 'Discover', 'About', and 'Research', and a stock price for ASX:MGC at '\$0.018'. A testimonial from a patient in Australia is featured, accompanied by a photograph of an elderly woman. The testimonial text describes her experience with Shingles and how CannEpil helped reduce her headaches and improve her quality of life. The patient's name is redacted with two stylized 'F' characters. Below the text are navigation arrows and the patient's location, 'Australia'.

mgc pharma

Discover About Research

ASX:MGC \$0.018

““

I was diagnosed with Shingles a few years ago and after being in constant pain I was advised to try CBD Oil. After trying a few different products, I decided to try MGC's CannEpil and I have found that it has helped to reduce the severe headaches I was suffering from and made life so much brighter.

Patient  
Australia

← →

Windows Explorer 10.0 18362.2274 8:32:43 AM 2/08/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by s22 8:32 AM 2/08/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-7

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to epilepsy MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://mgcpharma.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to epilepsy, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>10</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-7** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-7** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>10</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [redacted] [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



# ANNEXURE A:

The screenshot shows the mgcpharma.com.au website. The header includes the company logo, navigation links for 'Discover', 'About', and 'Research', and a search bar. The main content area is titled 'Plant-based medicines to treat' and features a grid of six categories. The first category, 'Epilepsy', is highlighted with a light brown background and includes a descriptive paragraph. The other five categories are 'Dementia', 'COVID-19', 'Cancer', 'Crohn's Disease', and 'Cerebral Palsy', each in a light blue box. The Windows taskbar at the bottom shows the system tray with the date and time (8:34:26 AM 2/03/2022) and the Windows Explorer window title.

<b>Epilepsy</b> CBD-THC products have been shown to be safe and efficacious in real world settings when used to control seizures that could not be effectively managed by standard medical treatments.	<b>Dementia</b>	<b>COVID-19</b>	<b>Cancer</b>	<b>Crohn's Disease</b>	<b>Cerebral Palsy</b>
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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-8

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products on the web page located at <https://mqcpharma.com.au/discover/global-product-offerings/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to dementia, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>11</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-8** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-8** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>11</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** @health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [redacted] [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

# ANNEXURE A:

The screenshot shows the MGC Pharma website. The header includes the MGC Pharma logo, navigation links for 'Discover', 'About', and 'Research', and a stock price of \$0.018. The main content area is titled 'Plant-based medicines to treat' and features a grid of six disease categories. The 'Dementia' category is highlighted with a light beige background and contains the following text: 'Phytocannabinoid derived IMP's are currently in clinical development for the management of BPSD (Behavioural and Psychological Symptoms in Dementia), based on real world data which supports the potential for this implementation.'

Epilepsy	<b>Dementia</b> Phytocannabinoid derived IMP's are currently in clinical development for the management of BPSD (Behavioural and Psychological Symptoms in Dementia), based on real world data which supports the potential for this implementation.	COVID-19	Cancer	Crohn's Disease	Cerebral Palsy
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Windows Explorer | 100.18362.2274 | 8:39:28 AM 2/09/2022 | Windows 10 Enterprise 64-bit build 18363 | Captured by s22



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**

TGAIN-CC-MSD0IHC8/2022-9

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products on the web page located at <https://mqcpharma.com.au/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to cancer. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>12</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-9** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-9** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>12</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

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**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

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**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

# ANNEXURE A:

The screenshot shows the MGC Pharma website. The header includes the company logo, navigation links for 'Discover', 'About', and 'Research', and a search bar. A stock price of \$0.018 is displayed. The main content area is titled 'Plant-based medicines to treat' and features a grid of six categories: Epilepsy, Dementia, COVID-19, Cancer, Crohn's Disease, and Cerebral Palsy. The 'Cancer' category is highlighted and contains the following text:

**Cancer**  
Clinical experience supports the use of various cannabinoid-based formulations for the amelioration of a range of diseases and the treatment of related symptoms. These include various types of pain, pruritus (itching), sleep disorders, poor appetite, anxiety and more.

Windows Explorer | 10.0.18362.2274 | 8:34:47 AM 2/20/2022 | Windows 10 Enterprise G4-Lit-Bulk/18363 | Captured by s22 | 8:34 AM 2/20/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 [Redacted]

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-10

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

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The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products on the web page located at <https://mqcpharma.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to Crohn's disease, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>13</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-10** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-10** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>13</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

# ANNEXURE A:

The screenshot shows the MGC Pharma website. The header includes the MGC Pharma logo, navigation links for 'Discover', 'About', and 'Research', and a search icon. The main content area is titled 'Plant-based medicines to treat' and features a grid of six boxes representing different medical conditions. The 'Crohn's Disease' box is highlighted in a light brown color and contains the following text: 'Crohn's Disease', 'Germicidal, such as those made available in MGC products, have been used both historically and in recent times, with particular success in Crohn's disease for the management of symptoms such as pain, loss of appetite, and diarrhoea.' The other boxes in the grid are labeled 'Epilepsy', 'Dementia', 'COVID-19', 'Cancer', and 'Cerebral Palsy'. The browser's address bar shows 'mgcpharma.com.au/#/clinical-ppp-roglicam'. The Windows taskbar at the bottom shows the time as 6:35:17 AM on 2/08/2022, and the system tray includes 'Windows 10 Enterprise 64-bit Build 18363' and 'Captured by: 522'.





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-11

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products on the web page located at <https://mqcpharma.com.au/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to cerebral palsy, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>14</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-11** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-11** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>14</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows the MGC Pharma website. The header includes the company logo, navigation links for 'Discover', 'About', and 'Research', and a stock price of \$0.018. The main content area is titled 'Plant-based medicines to treat' and features a grid of six boxes representing different medical conditions: Epilepsy, Dementia, COVID-19, Cancer, Crohn's Disease, and Cerebral Palsy. The 'Cerebral Palsy' box is highlighted and contains a paragraph of text.

Epilepsy	Dementia	COVID-19	Cancer	Crohn's Disease	<b>Cerebral Palsy</b> Clinical experience corroborates the evidence-based use of cannabinoids for the management of seizures and spasticity, both of which have a substantial impact on the lives of those affected by cerebral palsy as well as their caregivers and families.
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Windows Explorer | 100.18362.2274 | 8:35:37 AM 2/08/2022 | Windows 10 Enterprise 64-bit Build 18363 | Captured by S22



## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
ACN 116 800 269  
1202 Hay Street  
West Perth WA 6005

By Express Post and Email at:

s22  
s22  
s22

**Infringement Notice Number:**  
TGAIN-CC-MSD0IHC8/2022-12

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

### INFRINGEMENT NOTICE GIVEN TO *MGC Pharmaceuticals Ltd*

#### PART A: Infringement Notice given by

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(5) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products on the web page located at <https://mqcpharma.com.au/discover/global-product-offerings/>.

The advertisement contained a reference to the *Therapeutic Goods Act 1989*, other than in a statement of the registration number, listing number or device number of the goods. That reference being 'MGC Pharmaceuticals Ltd is in strict compliance with the TGA's Therapeutic Goods Act 1989'.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>15</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-12** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-12** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>15</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

**ANNEXURE A:**

mypharmacoem.com.au/.../.../.../.../...

MGC Pharmaceuticals Ltd is in strict compliance with the TGA's Therapeutic Goods Act 1989 and Therapeutic Goods Advertising Code No.2, 2018. If you are an Australian health professional wanting further information on our products, please submit an enquiry below or refer to our global site for further information.

Leading the global shift towards plant-based, naturally harmonious medicines, improving lives and public health.

[Get Updates](#)

Windows Explorer 10.0.18362.2274 8:37:52 AM 2/09/2022 Windows 10, Enterprise 64-bit Build 18363 Captured by s22 8:38 AM 9/8/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-13

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil Plus, on the web page located at:  
[https://twitter.com/MGC\\_Pharma/status/1489301332427218945cxt=HHwWgoC5frqhg6spAAAA](https://twitter.com/MGC_Pharma/status/1489301332427218945cxt=HHwWgoC5frqhg6spAAAA).

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to epilepsy, about the good. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>16</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-13** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-13** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>16</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

MGC Pharmaceuticals on Twitter

mobile.twitter.com/MGCPharma/status/1489301312427216345

COVID-19 test kits

← Tweet

MGC Pharmaceuticals @MGC\_Pharma

The @WHO reports that 50 million people worldwide have #epilepsy 🌍

CannEpiPlus is a Phytocannabinoid derived IMP used as a treatment for refractory epilepsy, and is available through early patient access schemes: [MGCPharma.co.uk/discover/global...](https://MGCPharma.co.uk/discover/global...)

Australia and UK via cannabis access schemes

Search Twitter

New to Twitter?

Sign up how to get your own personalized timeline.

Sign up with Google

Sign up with Apple

Sign up with a phone number or email

By signing up, you agree to the Terms of Service and Privacy Policy, including Cookie Policy.

Relevant people

MGC Pharmaceuticals @MGC\_Pharma Follow

Epi-Pharma company utilizing the medical value of plant-based medicines to provide relief to people suffering across the globe 🌍

World Health Orga... @WHO Follow

We are the international health agency - @WHO/WHO. Always check our latest tweets on @WHO/WHO for updated advice/information.

What's happening

Now - Yesterday

MPS table bill to overturn ban on voluntary assisted dying delete

Don't miss what's happening

People on Twitter are the first to know

Log in Sign up

Windows Explorer 10.0.18362.2274 10:57:06 AM 2/18/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by s22 10:57 AM 2/18/2022



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-14

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil Plus, on the web page located at:  
[https://twitter.com/MGC\\_Pharma/status/1489301332427218945cxt=HHwWgoC5frqhg6spAAAA](https://twitter.com/MGC_Pharma/status/1489301332427218945cxt=HHwWgoC5frqhg6spAAAA).

The advertisement referred to a good containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>17</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-14** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-14** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>17</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [redacted] [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows a Twitter interface on a mobile site. The main content is a tweet from MDC Pharmaceuticals (@MDC\_Pharma) stating that the WHO reports 50 million people worldwide have epilepsy. The tweet includes a link to [MDCPharma.co.uk/discover/global](https://www.mdcpharma.co.uk/discover/global) and an image with the text "Australia and UK via cannabis access schemes". The image shows a laboratory setting with a pipette. The right sidebar contains a "New to Twitter?" section with sign-up options for Google, Apple, and phone number, and a "Relevant people" section listing MDC Pharmaceuticals and the World Health Organization. At the bottom, there is a "What's happening" section with a news item about MPs tabled to avert a ban on voluntary assisted dying. The Windows taskbar at the bottom shows the date and time as 10:57:06 AM 2/03/2022.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-15

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CannEpil Plus, on the web page located at:  
[https://twitter.com/MGC\\_Pharma/status/1489301332427218945cxt=HHwWgoC5frqh6spAAAA](https://twitter.com/MGC_Pharma/status/1489301332427218945cxt=HHwWgoC5frqh6spAAAA).

The advertisement referred to a therapeutic good, that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act nor an

exemption. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>18</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box  
9848, Canberra ACT 2601**  
with your cheque made  
payable to the Department  
of Health and Aged Care.  
Please allow 5 business  
days for payment to be  
received



#### CREDIT CARD

Use your credit card  
to pay your notice by calling  
the Collector of Relevant  
Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
TGAIN-CC-MSD0IHC8/2022-  
15  
as reference to identify your  
payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
TGAIN-CC-MSD0IHC8/2022-  
15  
in the description of your  
transfer and allow two  
business days for payment to  
be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>18</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED] [@health.gov.au](mailto:[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



# ANNEXURE A:

MGC Pharmaceuticals on Twitter · x

mobile.twitter.com/MGC\_Pharma/status/14859032642118450

COVID-19 test kits...

← Tweet

MGC Pharmaceuticals @MGCPharma

The @WHO reports that 50 million people worldwide have #epilepsy 🌍

CannEpi@Plus is a Phytocannabinoid derived IMP used as a treatment for refractory epilepsy, and is available through early patient access schemes: [MGCPharma.cc.uk/discover/global...](https://MGCPharma.cc.uk/discover/global...)

Australia and UK via cannabis access schemes

Don't miss what's happening  
People on Twitter are the first to know.

Log in Sign up

Windows Explorer 10.0.18362.2274 10:57:06 AM 2/08/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by S22 10:57 AM 2/08/2022



## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
ACN 116 800 269  
1202 Hay Street  
West Perth WA 6005

By Express Post and Email at:

s22  
s22  
s22

**Infringement Notice Number:**  
TGAIN-CC-MSD0IHC8/2022-16

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
Telephone: s22  
Email: s22 @health.gov.au

### INFRINGEMENT NOTICE GIVEN TO *MGC Pharmaceuticals Ltd*

#### PART A: Infringement Notice given by

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(6) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being Extrax CBD Vape Pens, on the web page located at <https://www.instagram.com/p/CXMKNXpszob/>.

The advertisement contained statements, suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority, other than a statement of the availability of the goods as a pharmaceutical benefit, or authorised or required by a government or government authority or prescribed by the regulations.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>19</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-16** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-16** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>19</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### **Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

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- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The image is a screenshot of a Windows Explorer window displaying an Instagram post. The browser address bar shows 'instagram.com/...'. The Instagram post is for the account 'mgc\_pharma'. The main image in the post features a dark green background with the 'mgcpharma' logo and 'EXTRAX' text. Below this, it says 'EXTRAX CBD Vape listed for use in Australia.' and shows three black vape pens labeled 'EXTRAX', 'EXTRAX', and 'EXTRAX'. The caption on the right reads: 'mgc\_pharma EXTRAX CBD Vape pens have been successfully listed as an Unapproved Therapeutic Good by @mgc\_pharma. This new way of consuming CBD is now available in Australia for the first time ever, allowing Australian consumers to take cannabis in a new, safe and clean way. @extrax.us is a UK based wellness company that operates with an ongoing agenda to rediscover compounds from plants and bring them to life through modern technologies in the shape of easy-to-use wellness products. EXTRAX Vapes contain hemp extract with 95% cannabinoids, to support well-being in people's everyday lives. #mgcpharma#eucopa #mgcpharma #cbd #cbdaustralia #medicalcannabis #bdvape #australia #cbdaustralia'. There are several comments from users with redacted names, including 'S22', '2', 'S2', '2', 'S2', '2', and 'S2'. The Windows taskbar at the bottom shows the date '11:07:35 AM 2/08/2022' and the system name 'Windows 10 Enterprise 64-bit build 18363'. The text 'Captured by S22' is visible in the bottom right corner of the screenshot.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-17

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being Extrax CBD Vape Pens, on the web page located at <https://www.instagram.com/p/CXMKNXpszob/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

Evidence of the advertisement taken by the Therapeutic Goods Administration is included at Annexure A to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>20</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return this notice to  
**Department of Health and  
Aged Care, Accounts  
Receivable, GPO Box  
9848, Canberra ACT 2601**  
with your cheque made  
payable to the Department  
of Health and Aged Care.  
Please allow 5 business  
days for payment to be  
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#### CREDIT CARD

Use your credit card  
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Monies directly on  
**(02) 6289 1095**.  
Please include the  
infringement notice number  
TGAIN-CC-MSD0IHC8/2022-  
17  
as reference to identify your  
payment



#### ELECTRONIC FUNDS TRANSFER Account name:

Department of Health and  
Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
Australia, London Circuit,  
Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
overseas deposits are  
relevant). Please include the  
infringement notice number  
TGAIN-CC-MSD0IHC8/2022-  
17  
in the description of your  
transfer and allow two  
business days for payment to  
be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>20</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The image is a screenshot of a social media post on a Windows desktop. The desktop background is a dark green advertisement for 'mgc\_pharma EXTRAX CBD Vape'. The ad features three vape pens and the text 'EXTRAX CBD Vape listed for use in Australia.' The social media post is from the account 'mgc\_pharma' and contains the following text:

mgc\_pharma EXTRAX CBD Vape pens have been successfully listed as an Unapproved Therapeutic Good by @mgc\_pharma.

This new way of consuming CBD is now available in Australia for the first time ever, allowing Australian consumers to take CBDs in a new, safe and clear way.

@extrax are a UK based wellness company that operate with an ongoing agenda to redistill compounds from plants and bring them to life through modern technologies, in the shape of easy-to-use wellness products. EXTRAX Vapes contain hemp extract with 10% cannabinoids, to support well-being in people's everyday lives.

#mgcpharmaceuticals #mgcpharma #cbd #cbdproducts #medicinalmarijuana #cbdaustralia #australia #cbdaustralia

The post includes several replies from users, some of whom are redacted with 'S22'. The desktop taskbar at the bottom shows the Windows Explorer icon, the IP address 10.0.18362.2274, the time 11:07:31 AM 2/03/2022, and the system information 'Windows 10 Enterprise G4-bit Build 18363'. The screenshot was captured by 'S22' at 11:07 AM 2/03/2022.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-18

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being Extrax CBD Vape Pens, on the web page located at <https://www.instagram.com/p/CXMKNXpszob/>.

The advertisement referred to therapeutic goods, being medicinal cannabis products, that are not entered in the Australian Register of Therapeutic Goods and that are prescribed goods, being therapeutic goods that are neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed goods is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>21</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-18** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-18** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>21</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot shows a social media post from 'mgcpharma' with the following content:

**mgcpharma** **EXTRAX**

**EXTRAX CBD Vape listed for use in Australia.**

mgcpharma EXTRAX CBD Vape pens have been successfully listed as an Unapproved Therapeutic Good by @mgcpharma.

The new way of consuming CBD is now available in Australia for the first time ever, allowing Australian consumers to take Cannabis in a new, safe and clean way.

@extrax.us are a UK based wellness company that operates with an ongoing agenda to rediscove compounds from plants and bring them to life through modern technologies. In the shape of easy to use wellness products EXTRAX Vapes contain hemp extract with 50% cannabidiol, to support well-being in people's everyday lives.

#mgcpharmaceuticals #mgcpharma #cbd #cbdproducts #medicinalmarijuana #cbdusage #australia #australian

Comments and replies:

- Comment: [Redacted] [Redacted]
- Reply: [Redacted]
- Comment: [Redacted] excellent work. I have a question as I'd like to try the vapes. Does it make sense to High TARIFF could I buy wholesale and sell to UK market?
- Reply: [Redacted]
- Comment: [Redacted]
- Reply: [Redacted]
- Comment: [Redacted] liked by [Redacted] and others
- Reply: [Redacted]

Windows Explorer 10.0.18362.2274 11:07:35 AM 2/09/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by s22 11:07 AM 2/9/2022





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-19

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 4 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being Extrax CBD Vape Pens, on the web page located at:  
<https://www.facebook.com/mqcpharmaceuticals/videos/504880911361942>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>22</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-19** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-19** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>22</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot displays a Facebook video player interface. The video content shows five black vape cartridges standing vertically against a dark background. The word "EXTRAX" is prominently displayed in white, bold, sans-serif capital letters across the center of the cartridges. To the left of the word is a white, stylized snowflake or leaf-like logo. Each cartridge has a small, colorful icon at the top and a label at the bottom: "EXTRAX DREAM" (with a blue icon), "EXTRAX CALM" (with a green icon), "EXTRAX BALANCE" (with a purple icon), "EXTRAX ELATE" (with a yellow triangle icon), and "EXTRAX FOCUS" (with a red icon). The video player includes a progress bar at the bottom left showing "0:01 / 0:01".

Facebook interface elements include the URL <https://www.facebook.com/mgcp pharmaceuticals/videos/504880911361942>, the page title "EXTRAX CBD Vape Formulations" by MGC Pharmaceuticals, and a video description. The description states: "MGC Pharmaceuticals partners with leading manufacturers, companies and growers worldwide to expand the agency of plant-based medicines, supporting unmet needs. This includes EXTRAX for a wellness-focused CBD vaping solution distributed via MGC's global network. EXTRAX Vapors contain hemp extract with 80% cannabinoids to support holistic well-being. <https://www.extrax.com/>"

At the bottom of the screenshot, the Windows taskbar is visible, showing "Windows 10 Enterprise 64-bit Build 18363" and "Captured by S22". The system tray on the right shows the time as 4:18 PM on 4/08/2022.



## Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
ACN 116 800 269  
1202 Hay Street  
West Perth WA 6005

By Express Post and Email at:

s22  
s22  
s22

**Infringement Notice Number:**  
TGAIN-CC-MSD0IHC8/2022-20

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 @health.gov.au

### INFRINGEMENT NOTICE GIVEN TO *MGC Pharmaceuticals Ltd*

#### PART A: Infringement Notice given by

Nicole McLay  
Delegate of the Secretary of the Australian Government Department of Health and Aged Care

#### PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 4 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being Extrax CBD Vape Pens, on the web page located at:  
<https://www.facebook.com/mgcpharmaceuticals/videos/504880911361942>.

The advertisement referred to therapeutic goods, that are not entered in the Australian Register of Therapeutic Goods and that are prescribed goods, being therapeutic goods that are neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed goods is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>23</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-20** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-20** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>23</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22** @health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

The screenshot displays a Facebook video player interface. The video content shows five black vape cartridges standing vertically against a dark background. The word "EXTRAX" is prominently displayed in the center in a white, serif font. To the left of the word is a white, stylized snowflake or leaf-like logo. Each cartridge has a small, colorful icon at the top and a label at the bottom: "EXTRAX DREAM" (with a blue 'W' icon), "EXTRAX CALM" (with a green leaf icon), "EXTRAX BALANCE" (with a white 'D' icon), "EXTRAX ELATE" (with a yellow triangle icon), and "EXTRAX FOCUS" (with a red 'SS' icon). The video player includes a progress bar at the bottom left showing "0:01 / 0:03".

Facebook interface elements include the URL <https://www.facebook.com/mgcpharmaceuticals/videos/504880911361942>, the page name "MGC Pharmaceuticals" dated "March 22", and the video title "EXTRAX CBD Vape Formulations". The post text reads: "MGC Pharmaceuticals partners with leading wellness companies and groups worldwide to expand the agenda of plant-based medicines supporting inner needs. This includes EXTRAX for a wellness-focused CBD vaping solution distributed via MGC's global network. EXTRAX vapes contain hemp extract with 80% cannabinoids to support healthy well-being. <https://www.extrax.co.uk>" The video has 15 likes and 139 comments. The "Up Next" section lists several videos, including "Awesome Kong w/ Raisha Saeed vs. InnaKart w/ Sabiq", "Skyler vs. Davierne - Full Match", "10 Dog Breeds Who Will Always Stand...", and "This is What a Billionaire's Life is...". The Windows taskbar at the bottom shows "Windows 10 Enterprise 64-bit build 18363" and "Captured by s22".



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-21

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 4 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CogniCann, on the web page located at <https://www.facebook.com/mgcpharmaceuticals/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to dementia, about the good. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>24</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-21** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-21** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>24</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.


**How this notice can be withdrawn**

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Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- **s22**  [@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

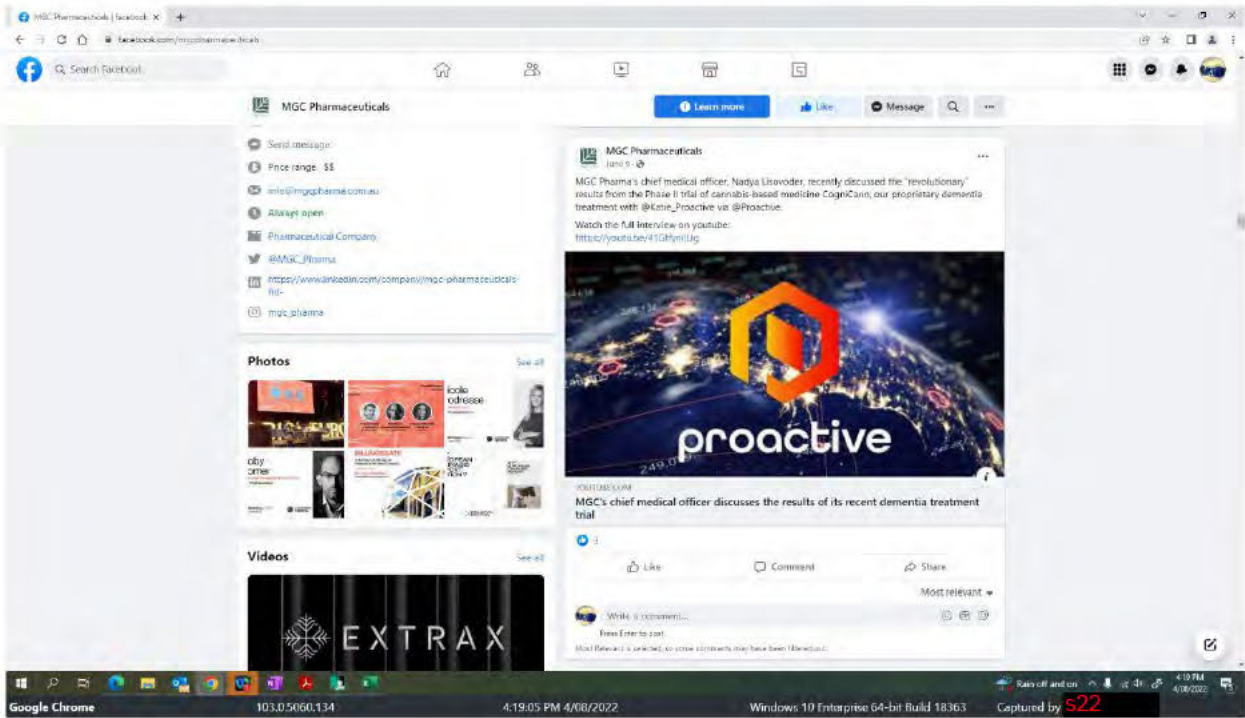
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-22

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 4 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, therapeutic goods, being CogniCann, on the web page located at <https://www.facebook.com/mgcpharmaceuticals/>.

The advertisement referred to a good containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>25</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-22** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-22** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>25</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

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Written representations can be made by sending them directly to:

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- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

MGC Pharmaceuticals | Facebook

MGC Pharmaceuticals

Jan 5

MGC Pharma's chief medical officer, Nadya Lisovoder, recently discussed the "revolutionary" results from the Phase II trial of cannabis-based medicine CogniCain, our proprietary dementia treatment with @Kane\_Proactive via @Proactive. Watch the 1.4 interview on youtube: <https://youtu.be/4G0Hm1Lg>

proactive

MGC's chief medical officer discusses the results of its recent dementia treatment trial

Like Comment Share

Write a comment...  
Press Enter to post.

Most relevant

Max 10 characters. Some characters may have been filtered out.

Google Chrome 103.0.5060.134 4:19:05 PM 4/08/2022 Windows 10 Enterprise 64-bit Build 18363 Captured by IS22



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

MGC Pharmaceuticals Ltd  
 ACN 116 800 269  
 1202 Hay Street  
 West Perth WA 6005

By Express Post and Email at:

s22  
 s22  
 s22

**Infringement Notice Number:**  
 TGAIN-CC-MSD0IHC8/2022-23

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*MGC Pharmaceuticals Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to MGC Pharmaceuticals Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that MGC Pharmaceuticals Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 4 August 2022, MGC Pharmaceuticals Ltd did advertise, or caused the advertising of, a therapeutic good, being CogniCann, on the web page located at <https://www.facebook.com/mgcpharmaceuticals/>.

The advertisement referred to a therapeutic good, that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act nor an exemption. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>26</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-23** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-CC-MSD0IHC8/2022-23** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>26</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.


This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- **s22** @health.gov.au; or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

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Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

### **Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

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Written representations can be made by sending them directly to:

- **s22** [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

### **Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

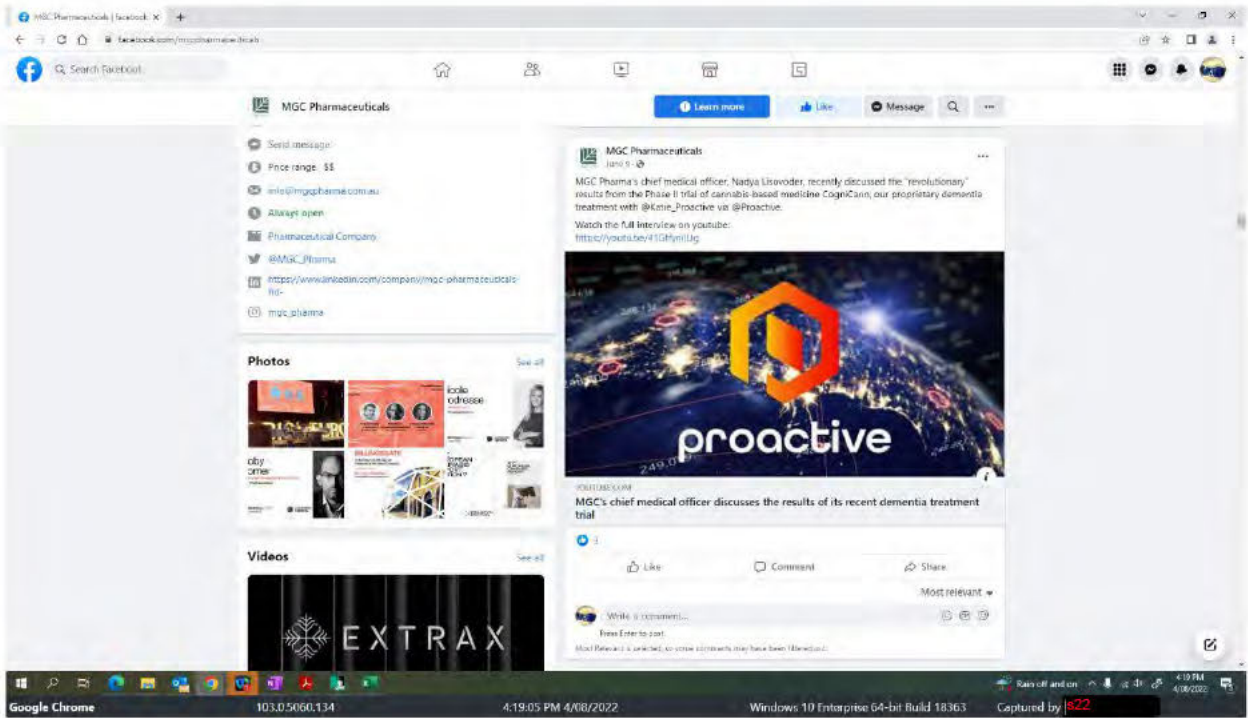


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



ANNEXURE A:



**From:** s22  
**To:** "s22@lqpharma.com.au"  
**Cc:** "info@littlegreenpharma.com"; s22; s22  
**Subject:** Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]  
**Date:** Tuesday, 16 August 2022 4:48:00 PM  
**Attachments:** [image001.gif](#)  
[Letter from the TGA to Little Green Pharma Ltd dated 16 August 2022.pdf](#)

---

Dear s22,

Please find **attached** a letter from the Therapeutic Goods Administration for your attention.

We ask that you confirm receipt of this letter by **10:00 AM on Thursday 18 August 2022**.

Yours sincerely,

s22  
[Redacted]  
Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22

Little Green Pharma Ltd  
Suite 2 Level 2  
66 Kings Park Road  
West Perth WA 6006

Our Reference: AC-000000002798

By express post and email at: [s22@lgpharma.com.au](mailto:s22@lgpharma.com.au); Cc: [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

16 August 2022

Dear s22

**Subject: Notice of intention to commence enforcement action**

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care, and is responsible for regulating the safety, quality, efficacy and advertising of therapeutic goods in Australia under the *Therapeutic Goods Act 1989* (the Act).

The purpose of this letter is to provide Little Green Pharma Ltd (LGP) with an opportunity to make submissions before a decision is made about what enforcement action should be taken in relation to alleged unlawful advertising which appears on the following platforms and for which LGP appears to be responsible:

- <https://www.littlegreenpharma.com/au/> (the Website)
- <https://www.instagram.com/littlegreenpharma/> and
- <https://www.facebook.com/littlegreenpharma/> (collectively, the Social Media).

The enforcement action being considered by the TGA includes issuing infringement notices for contraventions of the Act arising from the advertising on the Website and Social Media.

**Action required**

We request that LGP take the following actions:

1. Confirm receipt of this notice within one business day from the time stamp on the covering email.
2. Carefully consider the information provided below.
3. Provide your submissions by **31 August 2022** as to:
  - a. whether the advertising on the Website and Social Media summarised below (and any other content on the Website and Social Media containing similar references, statements or representations) contravenes the Act, if that is disputed; and
  - b. any other matter which you wish the TGA to consider in deciding whether enforcement action should be taken in relation to the alleged unlawful advertising identified below.

**Note:** this notice canvasses some and not all of the alleged contraventions that we may pursue.

## Summary of alleged contraventions

We have identified representations on the Website and the Social Media which we allege advertise therapeutic goods, being medicinal cannabis products, in circumstances where the advertisements:

1. refer to goods that are not entered in the Australian Register of Therapeutic Goods (the Register)
2. refer to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard
3. contain prohibited representations and/or restricted representations (being references to serious forms of diseases, ailments and conditions) without TGA permission or approval.

For example, we allege that the Website contains instructions as to how to use medicinal cannabis products which are not entered in the Register or contain substances included in Schedules 4 or 8 of the Poisons Standard, for example, the 'LGP CLASSIC 1:20'.

In addition, we allege that the Social Media contains:

1. posts which appear to promote the use and supply of medicinal cannabis products which are not entered in the Register and contain substances included in Schedules 4 or 8 of the Poisons Standard, for example, the 'LGP Flower CBD 14 – Sky Mist' and 'LGP CLASSIC 1:100'
2. posts which appear to promote the use and supply of medicinal cannabis in the treatment of named medical conditions including in pictorials and hashtags such as #depression, #cancer, #insomnia, and #PTSD
3. a post on Instagram which includes a comment from a third party user that references specific medicinal cannabis products, such as the 'LGP CLASSIC 20:5' and 'LGP Flower THC 22 – Desert Flame', in connection with the treatment of anxiety.

## Notice of intention to take enforcement action

We are writing to you to put LGP on notice of our intention to take enforcement action in relation to the alleged unlawful advertising on the Website and the Social Media of the kinds summarised above. That enforcement action will not be limited to the provided examples and may extend to any other unlawful advertising of the kinds identified above.

LGP's submissions will be taken into account by a delegate of the Secretary of the Australian Government Department of Health and Aged Care in exercising their discretion whether to take enforcement action against LGP. The action under consideration includes giving infringement notices to LGP in relation to contraventions of the kind set out above on the Website and Social Media.

Please note that information about any compliance action taken against LGP may be published on the TGA website under subsection 61(5A) of the Act, consistent with our usual practice.

To avoid being liable for further contraventions of the Act, LGP should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting we reserve our rights in relation to any further non-compliance that we identify. Should LGP remove any of the alleged unlawful advertising in response to this letter, we note that the delegate is not prevented from considering taking enforcement action against LGP.

## Other information

- The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the Act and the *Therapeutic Goods Regulation 1990*.
- It is illegal under section 42DL of the Act for a person to advertise or cause the advertising of therapeutic goods in circumstances where the advertisement:
  - refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, such as medicinal cannabis products, and that reference is not authorised by an Australian government or government authority
  - refers to therapeutic goods (being the Product) that are not entered in the Register nor subject to any exemption, approval or authority under the Act, and that reference is not authorised by an Australian government or government authority
  - contains a prohibited representation, such as cancer, and no permission is in force in relation to that prohibited representation
  - contains a restricted representation, such as epilepsy, and neither a permission nor a TGA approval is in force in relation to that restricted representation
  - contains a reference to the Act, other than in a statement of the registration number, listing number or device number of the goods
  - contains a statement, pictorial representation or design suggesting or implying the Product has been recommended or approved by or on behalf of a government or government authority, and no exception applies.
- A person who advertises or causes the advertising of therapeutic goods in the above circumstances may also be liable for civil penalties under section 42DLB of the Act.
- It is the responsibility of advertisers to ensure that their advertising material is compliant with the relevant legislation.
- LGP may also wish to refer to the following guidance provided by the TGA:
  - [Advertising guidance for businesses involved in medicinal cannabis products](#)
- If LGP requires help in understanding the advertising requirements, we recommend that LGP consider engaging a regulatory affairs consultant or a lawyer to assist it.
- The TGA takes non-compliance with the regulatory scheme seriously, especially where a breach of the advertising requirements has resulted in, or poses, a threat to public health and safety. A range of compliance and enforcement tools are available to address non-compliance and may include infringement notices, criminal or civil court proceedings, which can result in substantial penalties, fines, or imprisonment.

Please contact **s22** on **s22** or by email at **s22** [@health.gov.au](mailto:s22@health.gov.au) should you wish to discuss this matter further.

Yours sincerely

**s22**

**s22**  
Acting Assistant Secretary  
Regulatory Compliance Branch

**From:** s22  
**To:** s22  
**Cc:** s22 ; s22 ; s22 ; s22 ; s22  
**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-00000002798 [SEC=OFFICIAL]  
**Date:** Friday, 2 September 2022 7:40:25 PM  
**Attachments:** [image002.jpg](#)  
[image006.gif](#)  
[image007.jpg](#)  
[image008.jpg](#)  
[image009.jpg](#)  
[220902 LGP - response to TGA letter \(16 Aug 2022\) \(Combined\)\(Sent\).pdf](#)

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**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

Thanks again for meeting with us earlier in the week – we are really grateful.

Please find attached our written submission in response to your letter dated 16 August 2022.

Best Regards, s22

s22  
s22



Medicinal Cannabis

A world of *difference*

---

**From:** s22 <s22@Health.gov.au>  
**Sent:** Wednesday, 31 August 2022 7:37 AM  
**To:** s22 <s22@lgp.global>  
**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>  
**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-00000002798 [SEC=OFFICIAL]

**Caution: External Email**

Dear s22,

Thank you for meeting with us yesterday.

Should Little Green Pharma Ltd wish to make written submissions in response to our letter dated 16 August 2022, we confirm that the delegate is happy to receive those submissions by Friday 2

September 2022.

Kind regards,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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---

**From:** s22 <s22@lgp.global>

**Sent:** Saturday, 27 August 2022 2:01 PM

**To:** s22 <s22@Health.gov.au>

**Cc:** s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>

**Subject:** TRIM: RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-00000002798 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

That's great – thank you. 3pm on Tuesday will be fine.

Please invite the following attendees:

s22@lgp.global

s22@lgp.global

s22@lgp.global

s22@lgp.global

s22@lgp.global

Many Thanks, s22

s22

s22



## Medicinal Cannabis

A world of *difference*

**From:** s22  
**Sent:** Friday, 26 August 2022 1:01 PM  
**To:** s22  
**Cc:** s22 ; s22  
**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**Caution: External Email**

Dear s22

I refer to our email correspondence below.

We are happy to meet with Little Green Pharma Ltd, and propose to meet via video conference (Webex) on Tuesday 30 August 2022 at 3:00 PM, for one hour.

We ask that you confirm that the proposed time suits you as soon as possible, and would be grateful if you could provide the email addresses for your attendees so that they may be included in the meeting invitation.

Thanks in advance,

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 <s22@lgp.global>  
**Sent:** Wednesday, 24 August 2022 2:24 PM  
**To:** s22 <s22@Health.gov.au>  
**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

No problems – thanks s22 !

s22

s22





## Medicinal Cannabis

A world of *difference*

**From:** s22 <s22@Health.gov.au>

**Sent:** Wednesday, 24 August 2022 12:22 PM

**To:** s22 <s22@lgp.global>

**Cc:** s22 <s22@Health.gov.au>; PHELPS, Christopher  
<s22@Health.gov.au>

**Subject:** Re: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**Caution: External Email**

Dear s22,

Apologies for the delay in responding to you.

Thank you for providing the requested information, we will be in touch shortly.

Kind regards,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 <s22@lgp.global>

**Sent:** 18 August 2022 16:50

**To:** s22

**Cc:** s22; s22

**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is

safe.

Hi [REDACTED],

Thanks very much for your reply email – much appreciated.

We want to take you up on your offer to discuss the matters outlined in the recent letter you sent regarding possible unlawful advertising. We take this matter very seriously and as such have taken on board your comments and made some immediate changes. However, there are a couple of alleged contraventions that we would appreciate some clarity on and hoping you might be able to be more specific in relation to our website and social media pages before we make further changes. We have previously sought expert advice so we are eager to learn from you directly where possible.

Depending on time and availability, we may have some or all of the below LGP employees in attendance:

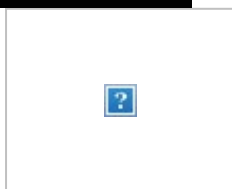
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

If preferred, we could meet post the submission date of 31 August, however we feel there are a couple of marginal cases in relation to our website and we'd prefer to run our proposed changes past you first if possible. Many thanks, I look forward to your response.

In Health, [REDACTED]

[REDACTED]

[REDACTED]



Medicinal Cannabis

A world of *difference*

**From:** [REDACTED] <[REDACTED]@Health.gov.au>

**Sent:** Thursday, 18 August 2022 9:08 AM

**To:** [REDACTED] <[REDACTED]@lgp.global>

**Cc:** [REDACTED] <[REDACTED]@Health.gov.au>; [REDACTED] <[REDACTED]@Health.gov.au>

**Subject:** RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**Caution: External Email**

Dear [REDACTED],

Thank you for your confirmation of receipt of our letter dated 16 August 2022.

I understand that you have requested a meeting to discuss the letter, which relates to the alleged unlawful advertising of medicinal cannabis products by Little Green Pharma Ltd.

To assist us in responding to your request, can you please provide us with the following information by **5:00 PM Friday 19 August 2022**:

1. An outline of the purpose of the meeting.
2. The particulars of what you wish to discuss.
3. The names and roles of your attendees.
4. Any other information you consider to be relevant to the meeting.

I note that you have requested the meeting take place next week (beginning 22 August). Once we receive the above information, we will contact you regarding your request and/or a suitable time and date for the meeting, should this be appropriate.

Kind regards,

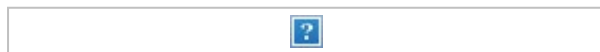
[REDACTED]

[REDACTED]

Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22  
Email: s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** s22 <s22@lgp.global>

**Sent:** Tuesday, 16 August 2022 5:55 PM

**To:** s22 <s22@Health.gov.au>

**Cc:** s22 <s22@Health.gov.au>; s22  
<s22@Health.gov.au>

**Subject:** TRIM: RE: Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

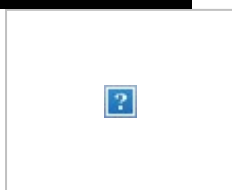
Hi s22,

Thanks for your email – Little Green Pharma acknowledges receipt and will action.

We'd appreciate the opportunity to catch up with you please to discuss. Do you have time next week for a meeting?

Many Thank and Regards,

s22  
s22  
s22



**From:** s22 <s22@Health.gov.au>

**Sent:** Tuesday, 16 August 2022 2:49 PM

**To:** s22 <s22@lgp.global>

**Cc:** [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com); s22 <s22@Health.gov.au>; s22  
<s22@Health.gov.au>

**Subject:** Letter from the Therapeutic Goods Administration to Little Green Pharma Ltd – AC-000000002798 [SEC=OFFICIAL]

**Caution: External Email**

Dear s22,

Please find **attached** a letter from the Therapeutic Goods Administration for your attention.

We ask that you confirm receipt of this letter by **10:00 AM** on **Thursday 18 August 2022**.

Yours sincerely,

s22

s22

Advertising and Product Investigations Section  
Regulatory Compliance Branch

Phone: s22

Email: s22@Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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s22

Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606

2 September 2022

## Re: Notice of intention to commence enforcement action (Ref: AC-000000002798)

Dear s22,

Thank you for your letter dated 16 August 2022 concerning the above proposed enforcement action as well as to your team for the subsequent follow up discussion between the TGA and Little Green Pharma (LGP)'s compliance team on Tuesday 30 August 2022.

Further to that letter, you requested that LGP provide submissions concerning whether the alleged unlawful advertising on the Website and Social Media (each as defined in the letter) contravened the Act, as well as on any other matter that LGP wished the TGA to consider in deciding whether enforcement action should be taken in relation to the alleged unlawful advertising identified in that letter.

To this end, we propose to first provide some context for LGP's use of the Website and Social Media, followed by addressing the specific concerns identified on page 2 of the letter concerning (a) the instructions on the Website relating to the use of medicinal cannabis products; and (b) posts on Social Media relating to the use and supply of medicinal cannabis products not entered on the ARTG; posts which appear to promote the use and supply of medicinal cannabis in the treatment of name medical conditions; and posts from third party users referencing specific medicinal cannabis products. We will then provide an overview of our actions following our broader review of the Website and Social Media and provide some closing comments.

### Background

Given the Australian medicinal cannabis industry's relative infancy and the unapproved nature of the majority of its products, from its beginning many industry participants have generally assumed a role in assisting and educating prescribers and patients in understanding the requirements relating to accessing medicinal cannabis in Australia, as well as assisting prescribers become more comfortable in prescribing medicinal cannabis products. This is often because, given time constraints and unfamiliarity with unapproved medicinal cannabis products, many medical practitioners and pharmacists are frequently unwilling or unable to assume the additional administrative burden associated with assisting patients to access medicinal cannabis, may not be aware of emerging findings and research concerning medicinal cannabis, or may be unfamiliar with less common or emerging dosing methods, including consuming oils or cannabis flower products. This typically leads to prescribers and patients reaching out directly to product manufacturers or suppliers for assistance.

To help with managing these queries and provide this assistance, LGP and other industry participants subsequently developed reasonably sophisticated websites and social media accounts to provide the required educational content or other information, including resources designed to handle common queries. LGP believes these resources remain a highly useful means of providing the additional support required for the industry and proposes to retain them more generally. However, LGP is also very conscious that these resources may stray into the inadvertent promotion or advertising of the underlying unapproved medicinal cannabis products to which these educational efforts and administrative support often indirectly relate.

From its inception in 2016, LGP has developed and implemented a robust compliance framework across all areas of its business, from production, manufacturing, supply, investor engagement, and business development. To that end, LGP is grateful to the TGA for bringing the matters outlined in the letter to its attention, and for providing the opportunity for LGP to discuss and work together with the TGA to ensure strict compliance with the laws governing the advertising and promotion of unapproved medicines in Australia. In particular, the Company was very pleased with the opportunity to discuss the specific examples raised in the TGA's letter with your team, and in doing so better understand the lens through which the TGA approaches the analysis and review of potentially infringing conduct.

### **Review of specific conduct examples**

Turning to the specific examples referred to in the letter, and further to our discussions with the TGA compliance team, we wish to refer you to the changes implemented to the Website and Social Media as shown in Schedule 1.

In broad terms, the changes seek to:

- remove any express references to LGP medicinal cannabis brands or product names
- remove any suggestions or implicit claims that LGP or other medicinal cannabis products may be used to treat any particular conditions, noting that LGP has retained or included links to third party sites (including the TGA) that provide peer-reviewed or other scientifically validated data on studies considering the use of medicinal cannabis generally
- moderate third-party content on Social Media where retention would imply LGP supports or endorses a statement that expressly or implicitly advertises or promotes an unapproved product.

### **Review of Website and Social Media**

The Company has also conducted a wider review of the Website and Social Media and has implemented further changes. In broad terms, the changes seek to:

- remove any express references to LGP medicinal cannabis brands or product names or references to cannabis strains or cultivars more generally
- re-align all Social Media to focus solely on guidance on accessing medicinal cannabis, finding prescribers comfortable prescribing medicinal cannabis, industry research & development updates, and corporate / investor news
- moderate all third-party content on Social Media to remove any references to LGP products or other medicinal cannabis products or their efficacy
- retain Website content which provides general guidance or educational resources on (a) accessing medicinal cannabis, including the identity of consenting practitioners who have experience in prescribing medicinal cannabis; (b) cannabis, cannabinoids and the endocannabinoid system generally; (c) how to correctly use LGP products, including proper ways to take medicinal cannabis oil; and (d) matters going to patient safety including side-effect / pharmacovigilance reporting and product quality requirements imposed by law.

### **Closing comments**

We believe these changes ensure the resulting Website and Social Media are entirely consistent with both the TGA published guidance on the marketing and advertising rules relating to unapproved medicinal products and the laws governing these matters in Australia. However, as always we would appreciate any further review or guidance you may wish to provide in relation to these matters.

We look forward to hearing from you.

In Health,

s22



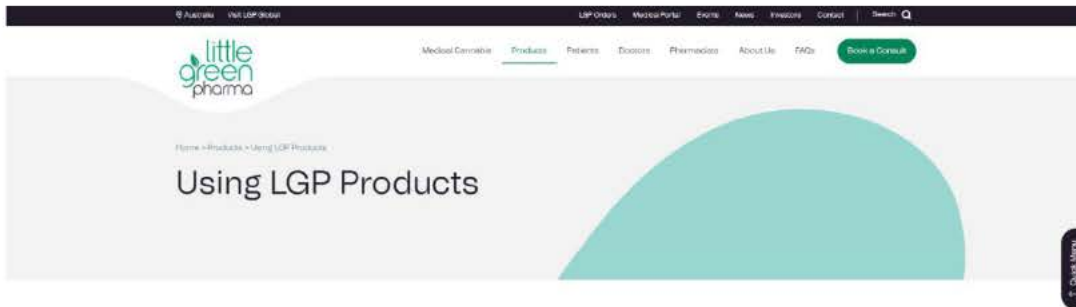
Little Green Pharma Ltd

Schedule 1

*[separate document]*

## Schedule 1 – Changes to Website and Social Media

The webpage: <https://www.littlegreenpharma.com/au/products/using-lgp-products/> was as follows:



### Instructional Video for Patients and Patient Carers

This instructional video presented by is aimed at patients or carers of patients who have been prescribed LGP Classic range medical cannabis with how to administer the product.

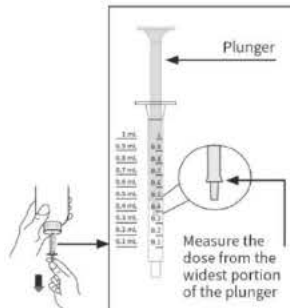


### How to use the LGP Classic range

#### Are you dosing correctly?

Please check the syringe (arrow) to ensure you are dosing to the correct part of the syringe.

**Please note:** Patients should draw liquid to the base of the syringe to extract the correct dosage. The shorter tip is not the correct area. Refer to the syringe to assist.



### Cannabis Medication FAQs

When should I start taking my cannabis medication?

How much oil or flower should I take?

When will I know if medical cannabis is working for me?

### Further Resources

#### Lost or misplaced your CMI?

If you have lost or misplaced your CMI leaflet, a pdf copy is available for download below.

- LGP CLASSIC product ranges: LGP CLASSIC 3:20, LGP CLASSIC 10:10, LGP CLASSIC 20:5
- LGP CLASSIC CBD50
- LGP CLASSIC 1:100
- LGP FLOWER THC 22 – Desert Flame
- LGP FLOWER THC 18 – Billy Buttons
- LGP FLOWER CBD 14 – Sky Mist

Or you can call or email Little Green Pharma at [info@lgp.com.au](mailto:info@lgp.com.au) or Ph 1300 703 999. Otherwise, please contact your doctor.

#### Want to track your dosing?

If you wish to obtain a dosing diary for personal use, you can request this at [info@lgp.com.au](mailto:info@lgp.com.au) or Ph 1300 703 999



#### Get in Touch

1300 703 999  
[info@lgp.com.au](mailto:info@lgp.com.au)

#### Quick Links

- Home
- Medical Cannabis
- Products
- Patients
- Doctors
- Pharmacists
- About Us

#### Newsletter

Subscribe and stay updated on the latest Little Green Pharma developments.

[Sign Up](#)



Now the same page <https://www.littlegreenpharma.com/au/products/using-lgp-products/> looks as below.

The screenshot shows the website's navigation bar with links for 'Medical Cannabis', 'Products', 'Patients', 'Dosing', 'Pharmacists', 'About Us', and 'FAQ'. A 'Book a Consult' button is also present. The main heading is 'Using LGP Products'. Below this is a section for an 'Instructional Video for Patients and Patient Carers', which includes a video player showing a syringe with 's22' markings. The video title is 'How to use the LGP medicinal cannabis oil'. Below the video is a diagram of the syringe with a plunger, labeled 'Plunger' and 'Measure the dose from the widest portion of the plunger'. The diagram shows a scale on the syringe with markings from 0.1 ml to 1.0 ml. Below the diagram is a section for 'Cannabis Medication FAQs' with three questions: 'When should I start taking my cannabis medication?', 'How much oil or flower should I take?', and 'When will I know if medical cannabis is working for me?'. At the bottom of the page is a 'Further Resources' section with two links: 'Lost or misplaced your CMI?' and 'Want to track your dosing?'. The footer contains contact information for Little Green Pharma, including a phone number (1300 703 889) and a website URL (www.littlegreenpharma.com.au). There is also a 'Quick Links' section with links to 'Home', 'Medical Cannabis', 'Products', 'Patients', 'Dosing', 'Pharmacists', and 'About Us'. A 'Newsletter' sign-up button is also visible.

The webpage <https://www.littlegreenpharma.com/au/patients/using-lgp-products/> was:

The screenshot shows the 'Using LGP Products' page on the Little Green Pharma website. The page features a navigation bar with links for Australia, Visit LGP Doctor, LGP Orders, Medical Portal, Events, News, Investors, Contact, and Search. The main content area includes a breadcrumb trail (Home > Patients > Using LGP Products), a title 'Using LGP Products', and a 'Book a Consult' button. The page is divided into several sections: 'How to use our products', 'Questions as you start your treatment', 'Want to track your dosing?', 'Are you dosing correctly?', and 'Read the Patient Leaflet (CMI)'. Each section contains informative text and a corresponding button (e.g., 'Treatment considerations', 'Dosing diary', 'How to use oil'). A large green banner at the bottom encourages users to 'Book a consultation with a qualified, specialist doctor.' The footer includes contact information, quick links, and a newsletter sign-up form.

**How to use our products**

Little Green Pharma offers a range of products with varying ratios from medicinal cannabis oil to dried whole flowers.

Your prescriber and the dispensing pharmacist will advise you on how to consume your Little Green Pharma medication as well as the dosage amount and how to titrate.

The Therapeutic Goods Administration (TGA) recommends a 'start low and go slow' approach to dosing in line with international guidelines. Dosing remains highly individualised and relies on you to work with your prescriber to find the dose that works best for you. The rate, speed of dose adjustment and total daily dose will depend on individual responses.

**Questions as you start your treatment**

As you start taking your LGP medication your prescriber will monitor you to see how you're responding. It's important to discuss your experiences with the prescriber, including any concerns you may have such as the amount and strength of medication you're taking as well as any side effects or other problems.

**Want to track your dosing?**

Little Green Pharma offers patient resources such as a Dosing Diary for patients. This is a useful tool for you to track how you're responding to the medicine and to use in discussions with your prescriber. You can download a dosing diary or request we send one to you in the mail.

**Are you dosing correctly?**

Little Green Pharma has prepared a video and step by step guides on how to administer the medicinal cannabis oil via the syringe.

**Read the Patient Leaflet (CMI)**

Each of our products are accompanied by a Consumer Medicine Information (CMI) leaflet which outlines the safe and effective use of our prescription medicines. This leaflet also includes important information such as any warnings and precautions, interactions the medicine might have with food or other medicines, side effects etc.

If you have lost your CMI please contact our team for assistance or you can download them below:

- [LGP CLASSIC product range: LGP CLASSIC 1:20, LGP CLASSIC 10:10, LGP CLASSIC 20:5](#)
- [LGP CLASSIC CBD:50](#)
- [LGP CLASSIC 1:100](#)
- [LGP FLOWER THC 22 - Desert Flame](#)
- [LGP FLOWER THC 10 - Billy Buttons](#)
- [LGP FLOWER CBD 14 - Sky Mist](#)

**Make a booking**

**Book a consultation with a qualified, specialist doctor.**

[Book a consultation now](#)

**Get in Touch**

1300 703 999  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Quick Links**

- [Home](#)
- [Medical Cannabis](#)
- [Products](#)
- [Patients](#)
- [Doctors](#)
- [Pharmacists](#)
- [About Us](#)

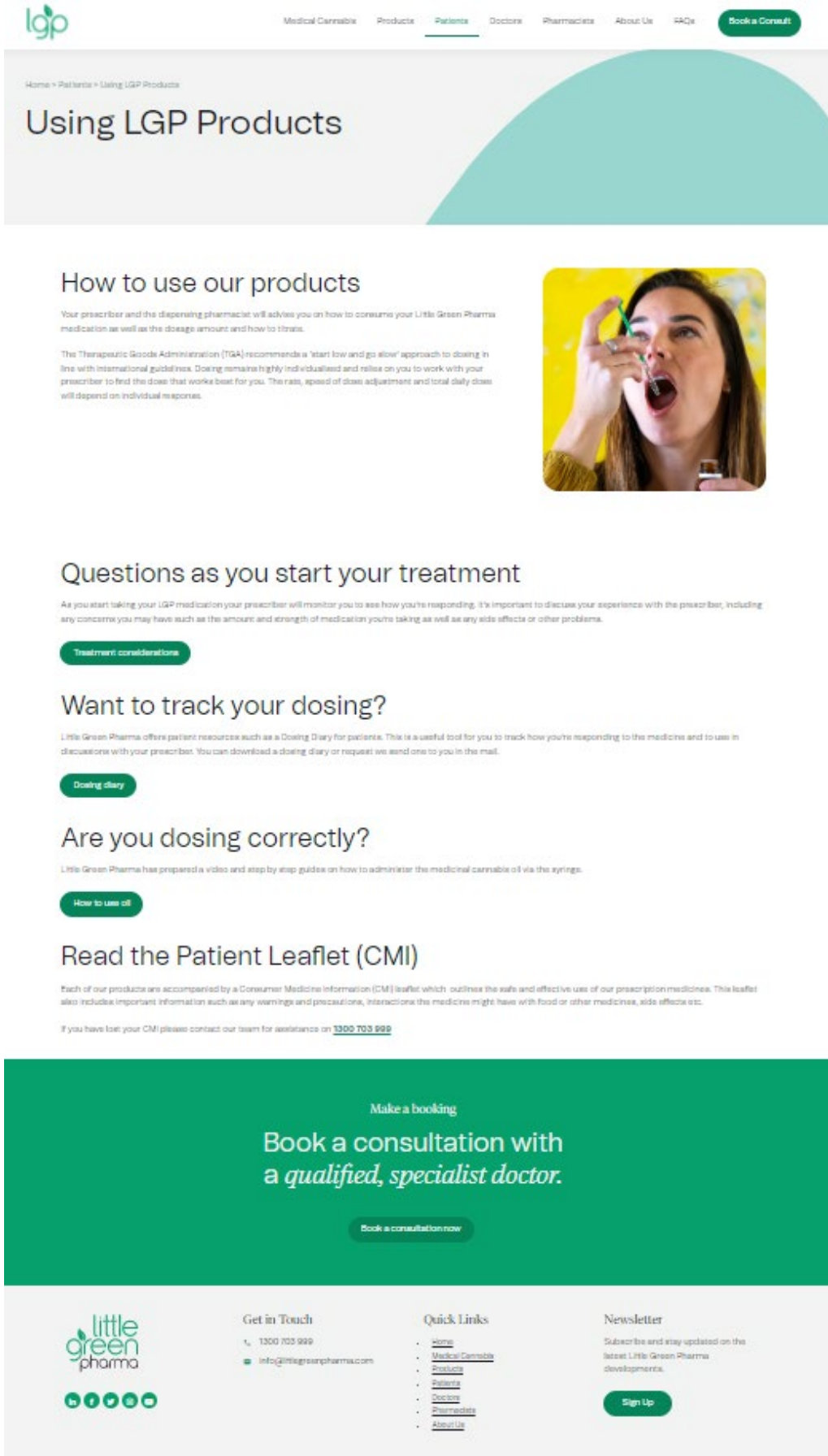
**Newsletter**

Subscribe and stay updated on the latest Little Green Pharma developments.

[Sign Up](#)

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The product CMIs have been removed and now same webpage looks as below:



The screenshot shows the website's navigation menu with 'Patients' selected. The main heading is 'Using LGP Products'. Below this, there are sections for 'How to use our products', 'Questions as you start your treatment', 'Want to track your dosing?', 'Are you dosing correctly?', and 'Read the Patient Leaflet (CMI)'. Each section includes a brief description and a call-to-action button. The footer contains contact information, quick links, and a newsletter sign-up form.

**Medical Cannabis** **Products** **Patients** **Doctors** **Pharmacists** **About Us** **FAQs** **Book a Consult**


Home > Patients > Using LGP Products

## Using LGP Products

### How to use our products

Your prescriber and the dispensing pharmacist will advise you on how to consume your Little Green Pharma medication as well as the dosage amount and how to titrate.

The Therapeutic Goods Administration (TGA) recommends a 'start low and go slow' approach to dosing in line with international guidelines. Dosing remains highly individualised and relies on you to work with your prescriber to find the dose that works best for you. The rate, speed of dose adjustment and total daily dose will depend on individual responses.



### Questions as you start your treatment

As you start taking your LGP medication your prescriber will monitor you to see how you're responding, it's important to discuss your experience with the prescriber, including any concerns you may have such as the amount and strength of medication you're taking as well as any side effects or other problems.

**Treatment considerations**

### Want to track your dosing?

Little Green Pharma offers patient resources such as a Dosing Diary for patients. This is a useful tool for you to track how you're responding to the medicine and to use in discussions with your prescriber. You can download a dosing diary or request we send one to you in the mail.

**Dosing diary**

### Are you dosing correctly?

Little Green Pharma has prepared a video and step by step guide on how to administer the medicinal cannabis oil via the syringe.

**How to use oil**

### Read the Patient Leaflet (CMI)

Each of our products are accompanied by a Consumer Medicine Information (CMI) leaflet which outlines the safe and effective use of our prescription medicines. This leaflet also includes important information such as any warnings and precautions, interactions the medicine might have with food or other medicines, side effects etc.

If you have lost your CMI please contact our team for assistance on [1300 703 999](tel:1300703999)

**Make a booking**

## Book a consultation with a qualified, specialist doctor.

**Book a consultation now**

**little green pharma**

**Get in Touch**

☎ 1300 703 999  
✉ [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Quick Links**

- [Home](#)
- [Medical Cannabis](#)
- [Products](#)
- [Patients](#)
- [Doctors](#)
- [Pharmacists](#)
- [About Us](#)

**Newsletter**

Subscribe and stay updated on the latest Little Green Pharma developments.

**Sign Up**

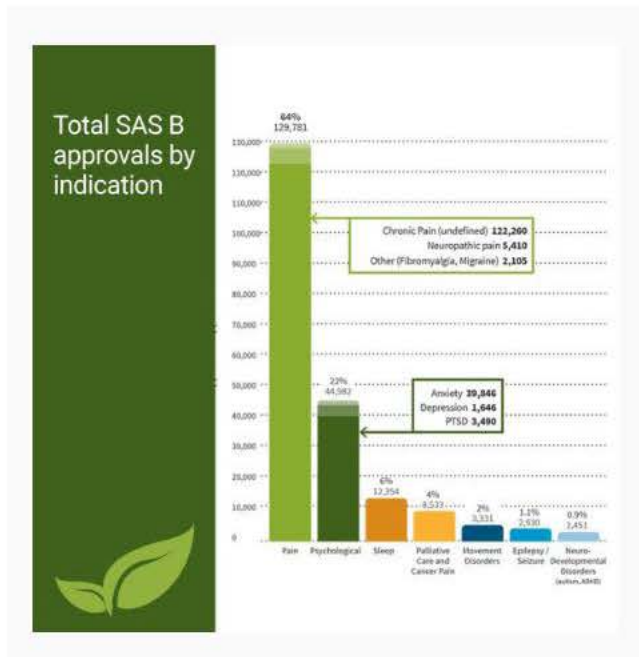
**Instagram** **Facebook** **Twitter** **LinkedIn** **YouTube**

## Social Media

The following posts have been removed from the LGP Instagram page:

<https://www.instagram.com/littlegreenpharma/>

### Instagram Post



### Instagram post with hashtags

**littlegreenpharma**

**View Insights**

As of January 2022, over 130 conditions had been accepted for medicinal cannabis use. The last year has seen an increase in TGA SAS B approvals for anxiety and other psychological indications, while overall approvals have more than doubled in number.

Are you surprised by any of these numbers?

#medicinalcannabis #cannabis #medicalcannabis #medical #doctor #anxiety #depression #pain #insomnia #PTSD #cancer #health #healthcare #australia #neurodivergent

Edited · 31 w

Surprised that Epilepsy is low on the chart.

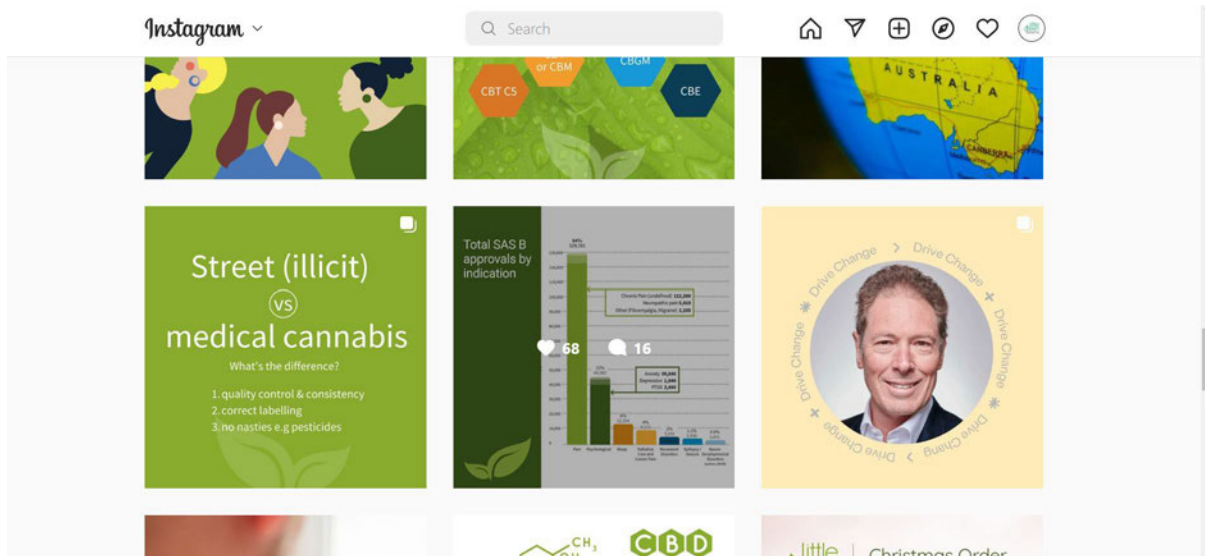
Liked by **s22** and 67 others

JANUARY 13

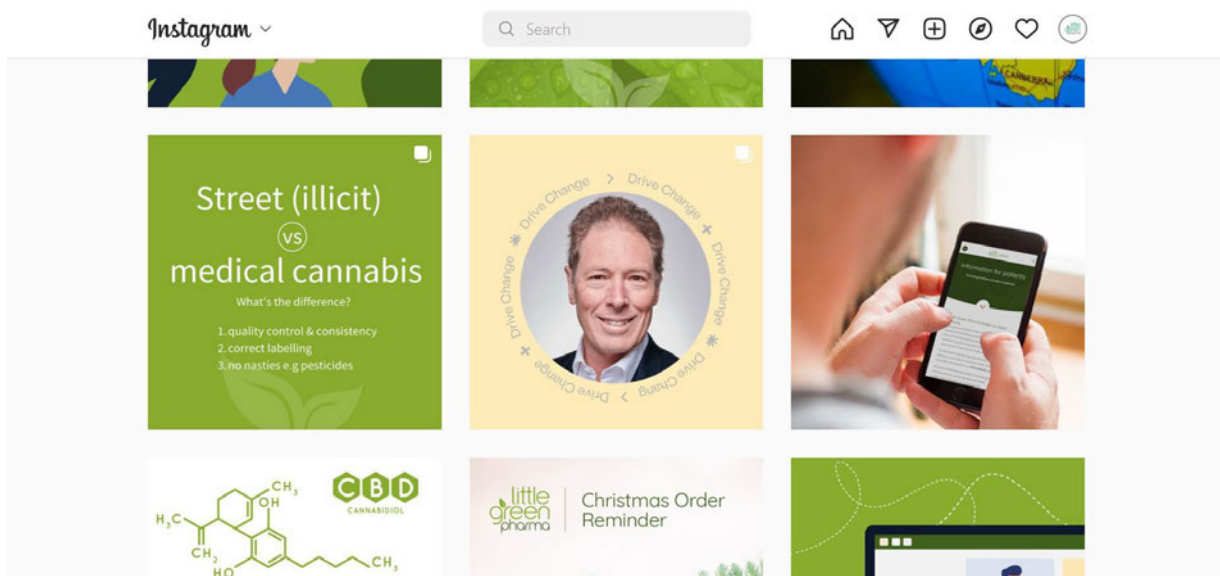
Add a comment...

Post


Instagram grid with post previously



Instagram grid with post removed



### Instagram strains post



**littlegreenpharma** ...

[View Insights](#)

**littlegreenpharma** With the wide and evolving range of terpenoids, flavonoids, and cannabinoids within the cannabis plant, Little Green Pharma is constantly involved in research and development of cannabis genetics, and how these genetics and strains can be used for clinical use.

Our latest genetic strain is 'Sky Mist' a high CBD sativa dominant hybrid. With a dominant Myrcene terpene composition, this strain has a fresh tropical profile. For information on this strain you can find more information on our website 📄  
<https://zcu.io/8lcc>

For its use in medicine and if medicinal cannabis is right for you please contact your doctor.

18 w

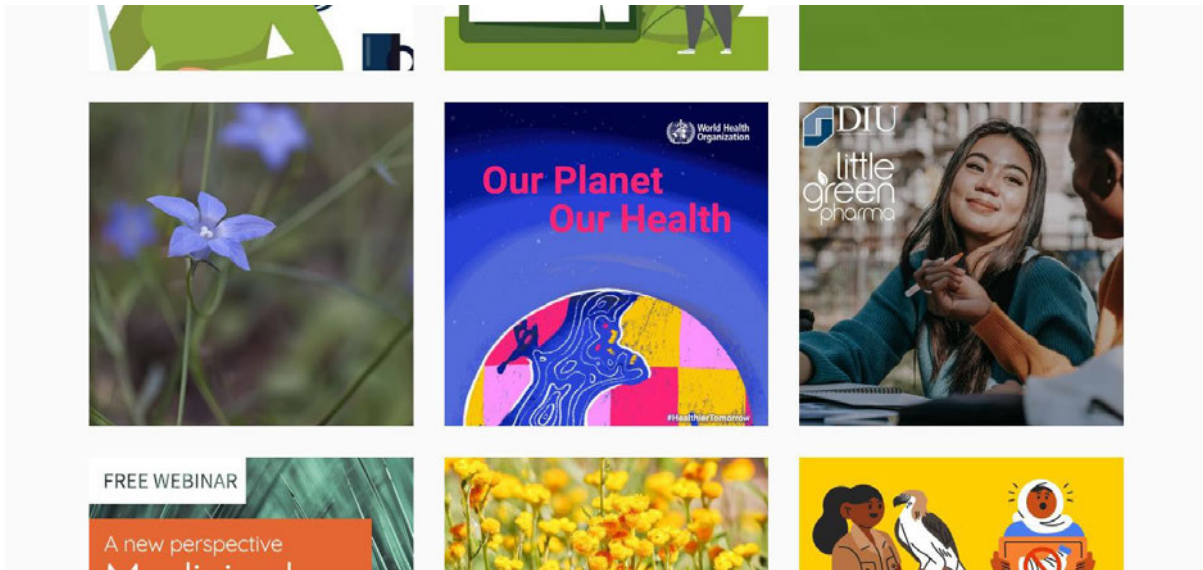
📄

Liked by **s22** and 13 others

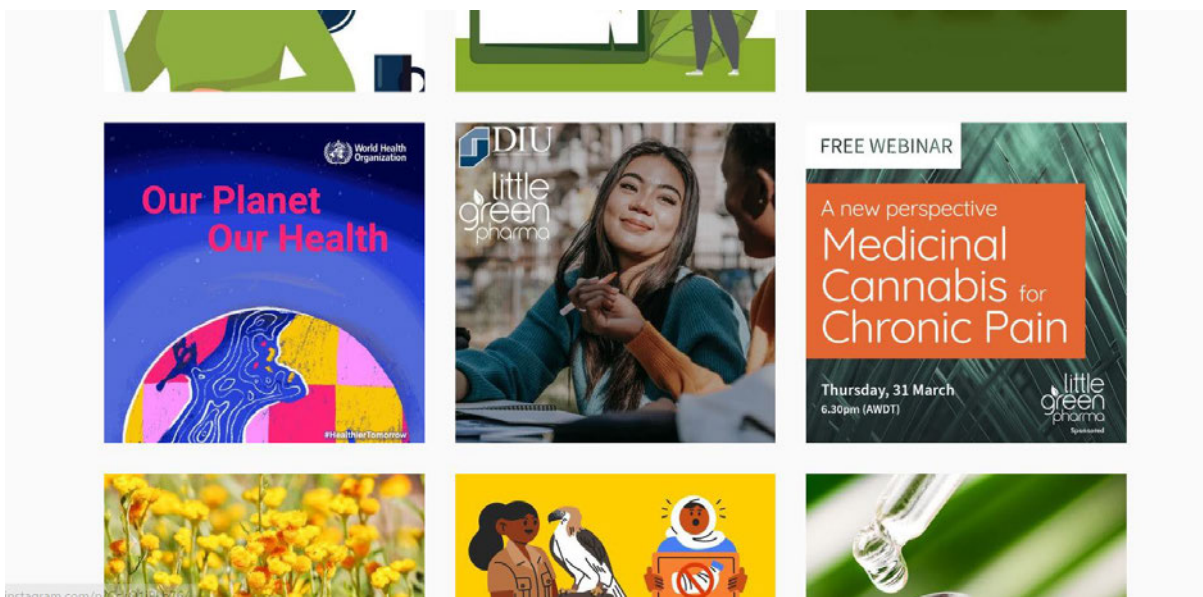
APRIL 13

😊 Add a comment... Post

### Instagram strain post grid previously



### Instagram strains post grid with image removed




### Instagram third party comment previously



littlegreenpharma

View Insights

What do you think are the reasons for this increase? Do you have a preference for dried flower over oil? Let us know!  
26 w



Liked by s22 and 42 others

FEBRUARY 12

Add a comment... Post

### Instagram third party comment removed



littlegreenpharma

View Insights

littlegreenpharma Dried medical cannabis flower as a treatment option is increasing, with TGA SAS approvals (January 2022) showing that flower accounts for almost one-third of applications.

What do you think are the reasons for this increase? Do you have a preference for dried flower over oil? Let us know!  
26 w

s22 🤔🤔🤔  
26 w Reply

Liked by s22 and 42 others

FEBRUARY 12

Add a comment... Post



References to indications or products removed – before and after posts



Screenshot of a social media post from littlegreenpharma. The post text reads: "prescribing? Or are more people educated on the potential benefits? We would love to hear your thoughts below 🙌". Below the text is a redacted image with the text "s22" in red on a black background. The post is dated "3 w" and has a "Reply" button.



Screenshot of a social media post from littlegreenpharma. The post text reads: "With half yearly SAS-B approvals up 18% (2021 to 2022) and the TGA approving more patients than ever, is access getting easier? Are more doctors comfortable prescribing? Or are more people educated on the potential benefits? We would love to hear your thoughts below 🙌". The post is dated "3 w" and has a "Post" button.



littlegreenpharma

View Insights

littlegreenpharma The cannabis plant has been used in traditional plant therapies for over 1000 years. Learn more about the cannabis plant and it's place in modern medicine here: <https://zcu.io/jqoJ>  
10 w

s22 Are you looking to provide an oil from a strain that has THCV to be able curb comfort eating for those that turn to the fridge during their anxious & depressive stages?  
4 w Reply

Hide replies

littlegreenpharma @s22 We have some new

Like Comment Share Save

liked by s22 and 23 others

JUNE 4

Add a comment... Post



littlegreenpharma

View Insights

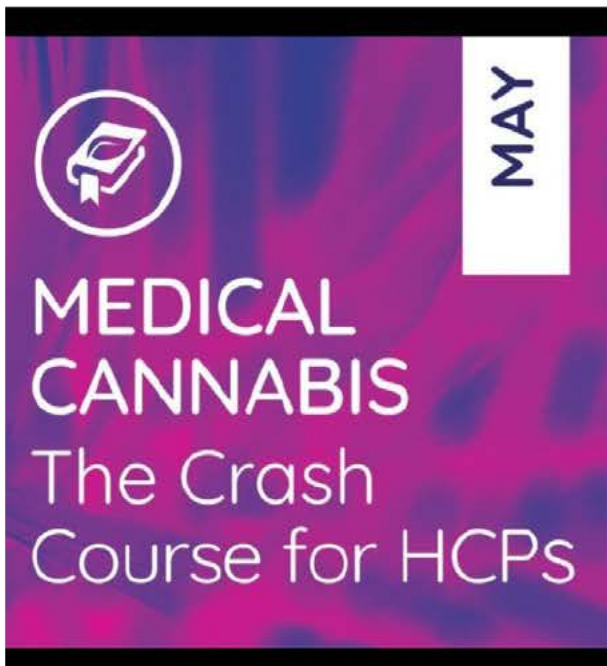
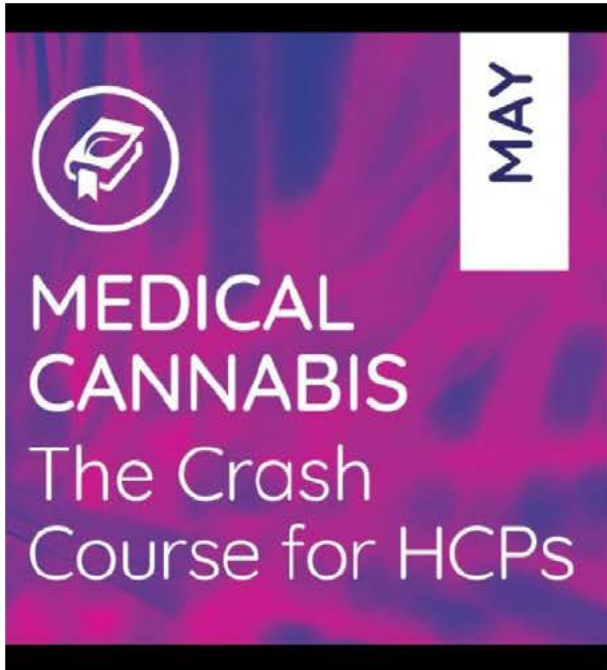
littlegreenpharma The cannabis plant has been used in traditional plant therapies for over 1000 years. Learn more about the cannabis plant and it's place in modern medicine here: <https://zcu.io/jqoJ>  
10 w


Like Comment Share Save

liked by s22 and 23 others

JUNE 4

Add a comment... Post




 littlegreenpharma

[View Insights](#)

This event is aimed at those new to prescribing and wanting to learn more about medicinal cannabis as a treatment option for unresolved chronic conditions.




This event is free for Healthcare Professionals. Register here: [https://us06web.zoom.us/webinar/register/WN\\_g9Gn8EWeQaWlrQOClxWXpw](https://us06web.zoom.us/webinar/register/WN_g9Gn8EWeQaWlrQOClxWXpw)


14 w

 s22


14 w · Reply

[View replies \(3\)](#)

 Liked by s22 and 15 others

MAY 10

 Add a comment... [Post](#)

 littlegreenpharma

[View Insights](#)

 littlegreenpharma Are you a Healthcare Professional thinking about prescribing medicinal cannabis but not sure how to get started? Register for our Crash Course this Thursday!

This event is aimed at those new to prescribing and wanting to learn more about medicinal cannabis as a treatment option for unresolved chronic conditions.

This event is free for Healthcare Professionals. Register here: [https://us06web.zoom.us/webinar/register/WN\\_g9Gn8EWeQaWlrQOClxWXpw](https://us06web.zoom.us/webinar/register/WN_g9Gn8EWeQaWlrQOClxWXpw)

14 w

 Liked by s22 and 15 others

MAY 10

 Add a comment... [Post](#)

### Facebook third party reference to condition



### Facebook third party reference to condition removed



### Facebook third party reference to Desert Flame

Demecan managing director Philipp Goebel said it marks the beginning of a "highly mutually beneficial partnership" that will provide "high-quality LGP medicinal cannabis products to our patients and patients in Germany, and beyond".



CANNABIZ.COM.AU

#### LGP strikes three-year German flower deal

Little Green Pharma's Danish operation will provide more than 1.3 tonnes of white-label flower...

979

People reached

111

Engagements

-

Distribution score

Boost post

23

5 Comments 2 Shares

Like

Comment

Share

All comments



Comment as Little Green Pharma



Love Reply Hide 3w

Write a comment...

### Facebook third party reference to Desert Flame removed

Demecan managing director Philipp Goebel said it marks the beginning of a “highly mutually beneficial partnership” that will provide “high-quality LGP medicinal cannabis products to our patients and patients in Germany, and beyond”.



CANNABIZ.COM.AU

#### LGP strikes three-year German flower deal

Little Green Pharma's Danish operation will provide more than 1.3 tonnes of white-label flower...

979

People reached

111

Engagements

–

Distribution score


Boost post

 23

4 Comments 2 Shares

 Like

 Comment

 Share

All comments ▼



Comment as Little Green Pharma

Write a comment...

**From:** s22  
**To:** s22  
**Cc:** "info@littlegreenpharma.com"; s22 ; s22  
**Subject:** Infringement Notices from the Therapeutic Goods Administration to Little Green Pharma Ltd - AC-000000002798 [SEC=OFFICIAL]  
**Date:** Tuesday, 27 September 2022 3:23:00 PM  
**Attachments:** [image001.gif](#)  
[Cover Letter and Infringement Notices to Little Green Pharma Ltd - 27 September 2022.pdf](#)

---

Dear s22 ,

Please find attached a letter and 28 infringement notices from the Therapeutic Goods Administration to Little Green Pharma Ltd.

We ask that you confirm receipt of our correspondence by **5:00 PM** on **Wednesday 28 September 2022**.

Yours sincerely,

s22

s22

Advertising and Product Investigation Section  
Regulatory Compliance Branch

Phone: s22

Email: s22 @Health.gov.au

Therapeutic Goods Administration  
Australian Government, Department of Health and Aged Care  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

s22

Little Green Pharma Ltd  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6005

Our Reference: AC-000000002798

By Express Post and By Email:

s22 @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

27 September 2022

Dear s22

**Infringement notices given to Little Green Pharma Ltd**

<b>Infringement Notice</b>	<b>Amount</b>	<b>Payment Due by</b>
TGAIN-AC-000000002798/2022-1	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-2	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-3	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-4	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-5	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-6	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-7	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-8	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-9	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-10	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-11	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-12	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-13	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-14	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-15	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-16	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-17	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-18	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-19	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-20	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-21	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-22	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-23	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-24	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-25	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-26	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-27	\$13,320.00	26 October 2022
TGAIN-AC-000000002798/2022-28	\$13,320.00	26 October 2022
<b>Total</b>	<b>\$ 372,960.00</b>	



1. I refer to our previous correspondence regarding this matter, including our letter to Little Green Pharma Ltd (LGP) dated 16 August 2022, and submissions from LGP dated 2 September 2022.
2. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act).
3. Having considered LGP's submissions, I have decided to give 28 infringement notices (enclosed to this letter) to LGP under Part 5A-2 of the Act, on the basis that I reasonably believe LGP has contravened subsection 42DLB(1) of the Act, where subsections (2), (4), (7) and (9) applied.
4. The infringement notices are enclosed to this letter and include information on how to pay the penalty amount, how to request an extension of the compliance period for payment, how to request that the infringement notices be withdrawn, and the actions that we may take in the event of non-payment of the infringement notices. It is important that LGP carefully read the infringement notices and the information contained within.
5. Infringement notices are an opportunity for LGP to pay an amount as an alternative to having court proceedings brought against LGP in relation to the alleged contraventions described in each of the notices.
6. LGP should be aware of the possible consequences for not paying an infringement notice. If LGP chooses not to pay the penalty amount, proceedings may be brought against LGP for the alleged contraventions described in the infringement notices. We note that the maximum civil penalty that a court can impose on a company for a contravention of subsection 42DLB(1) of the Act is \$11.1 million per contravention. In a recent decision by the Federal Court, non-payment of a single infringement notice issued against a company resulted in the court ordering a total of \$96,000 in penalty against both the company and its executive directors.<sup>1</sup>
7. To avoid being liable for further contraventions of the Act, LGP should immediately take steps to ensure that any compliance issues, including any beyond the scope of this letter, are identified and resolved, noting that we reserve our rights to take enforcement action in relation to any further non-compliance we may identify.
8. For more information about infringement notices, I refer LGP to the following on the TGA website:
  - a. [Information about infringement notices | Therapeutic Goods Administration \(TGA\)](#).
  - b. [Infringement notices | Therapeutic Goods Administration \(TGA\)](#).

#### **Delegate comments and concerns**

9. While I am not required to provide reasons for giving an infringement notice under the Act, I offer the following remarks to assist LGP to understand why I have decided to take this particular action.
10. I note that there have been significant Federal Court decisions in which the Court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.<sup>2</sup> Those who engage in businesses involving therapeutic goods have a

---

<sup>1</sup> [Enviro Tech Holdings and company officers ordered by the Federal Court to pay \\$96,000 for unlawful importation of surgical face masks | Therapeutic Goods Administration \(TGA\)](#).

<sup>2</sup> [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865 \(fedcourt.gov.au\)](#) at paragraph [76].

responsibility to be aware of the laws that govern those products, and to comply with those from the outset.<sup>3</sup>

11. Additionally, I note that LGP has previously been made aware of the advertising prohibitions under the Act on at least the following occasions:
  - a. in 2017, LGP received guidance from the Pharmacovigilance and Special Access Branch in relation to advertising restrictions, and
  - b. in 2019, LGP received guidance from the Regulatory Compliance Branch in relation to the alleged unlawful advertising of medicinal cannabis products.
- c. I have reviewed the following platforms for which LGP appear to be responsible:
  - a. <https://www.littlegreenpharma.com/au/> (the Website)
  - b. <https://www.instagram.com/littlegreenpharma/>, and
  - c. <https://www.facebook.com/littlegreenpharma/> (collectively, the Social Media).
- d. While not all information released to the public about therapeutic goods is advertising, I consider that the Website and the Social Media unlawfully advertise medicinal cannabis products, as defined in section 3(1) of the Act, for the following reasons:
  - a. The Website and Social Media contain statements and pictorial representations which were intended to promote the use or supply, either directly or indirectly, of medicinal cannabis products. For example (but not limited to):
    - i. The webpages on the Website and/or the posts on the Social Media (being advertisements) were close, or directed the reader, to a means of accessing medicinal cannabis products, such as a prominently displayed option on the Website to 'Book a Consult'.
    - ii. The use of hashtags in Social Media posts, a function which is predominantly used to promote the content, that referred to medicinal cannabis products by using the hashtags '#cannabis', '#medicinalcannabis', '#medicalcannabis'.
    - iii. The Website and Social Media made unauthorised therapeutic claims, regarding the efficacy of medicinal cannabis. For example, making references to serious forms of a disease, ailment or condition, in circumstances which inferred (directly or indirectly) that medicinal cannabis may be, or is, a suitable treatment for the medical condition mentioned.
  - b. The advertisements:
    - i. refer to goods that are not entered in the Australian Register of Therapeutic Goods, such as the LGP Classic 10:10
    - ii. refer to substances which are included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, and
    - iii. contain prohibited representations, such as anxiety, and/or restricted representations, such as epilepsy, being references to serious forms of diseases, ailments and conditions without TGA permission or approval.
12. As outlined in its written submissions dated 2 September 2022, amongst other steps taken by LGP since receiving our letter of 16 August 2022, significant changes appear to have been made to the Website and Social Media, including the removal of express references to medicinal cannabis products and the removal of multiple posts on the Social Media.

---

<sup>3</sup> [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

13. Each instance of non-compliant advertising on each day constitutes a separate contravention of the Act. We hold evidence that the contraventions as particularised in the infringement notices occurred from at least late April 2022 to at least 15 August 2022.
14. Taking into account the written submissions and changes made to the Website and Social Media, I have decided not to give infringement notices for all identified alleged contraventions of the Act at this time, including those:
  - a. occurring from April 2022 to 1 August 2022
  - b. which occurred on the Social Media in posts made prior to January 2022
  - c. which appeared identical or sufficiently similar, to the advertising on another page of the Website or another Social Media post
  - d. arising from the same restricted or prohibited representation which was made multiple times on the Website and/or the Social Media, and
  - e. arising from a reference to the same distinct medicinal cannabis products, which appeared multiple times on the Website and/or the Social Media.
15. Please contact s22 by email at s22 [@health.gov.au](mailto: @health.gov.au) should LGP wish to discuss this matter further.

Yours sincerely



Nicole McLay

Delegate of the Secretary of the Department of Health and Aged Care  
Therapeutic Goods Administration



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

§22 [REDACTED]@lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-1

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED]@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>4</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-1** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care

**BSB:** 092 009

**Account:** 114 071

**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601

**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-1** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

---

A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

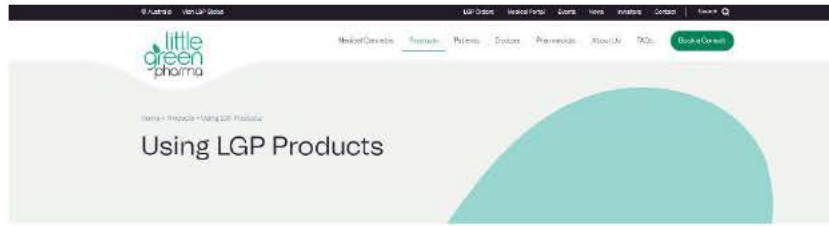
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video provides **step-by-step** to your patients or carers if a patient has been prescribed LGP Classic, and also includes information on how to use the product.

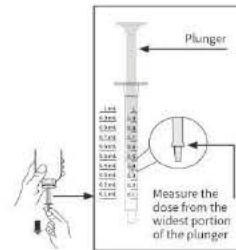


How to use the LGP Classic range

Are you dosing correctly?

Please check the dosage before use to avoid leading to the incorrect use of the product.

Please note: Patients should draw into the base of the syringe to avoid the needle being damaged. This will also ensure the correct dose is drawn into the syringe.



Cannabis Medication FAQs

**When should I start taking my cannabis medication?**

- Please follow your doctor's recommendations.
- Most doctors will advise the first dose should be taken with food to reduce the risk of nausea.
- You may have your medication during or after meals.

Some patients will experience their medical cannabis (CMC) through oral administration, such as capsules, and others will receive their medication through sublingual administration.

Please note: It is not recommended to consume LGP medication with any food and to avoid alcohol consumption or other medications.

**How much oil or flower should I take?**

- The patients to start with are advised to follow the instructions provided by your doctor.
- As per the doctor's instructions, patients may increase the dose of the product if needed.
- The medical cannabis should be used as follows:
  - When used as a sublingual product, patients should not swallow the product.
  - When used as an oral product, patients should swallow the product.

By consulting with your doctor, you can ensure you are taking the correct dose and that you are using the medication correctly.

**When will I know if medical cannabis is working for me?**

- Medical cannabis can be used for a variety of conditions, and the effects may vary depending on the condition being treated.
- It may take several days or weeks for the effects of the medication to be felt, depending on the condition being treated.
- It is important to continue to use the product as directed and to consult your doctor if you do not see any improvement in your symptoms.
- If your symptoms are not improved after 2-3 weeks, it may be necessary to consult your doctor. There are a number of other options available.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your doctor or the following information for assistance:

- [LGP CLASSIC \(Oral\) - LGR CLASSIC 300, LGR CLASSIC 600, LGR CLASSIC 900](#)
- [LGP CLASSIC \(Sublingual\)](#)
- [LGP CLASSIC \(Injectable\)](#)
- [LGP CLASSIC \(Topical\) - Creams, Gels, etc.](#)
- [LGP CLASSIC \(Dry Mouth\) - Dry Mouth](#)
- [LGP CLASSIC \(Other\) - Other](#)

For more information, please contact us at [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com) or call 0800 333 999 (toll-free), please contact your doctor.

Want to track your dosing?

If you want to track your dosing, please contact your doctor or the following information for assistance:

[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com) or 0800 333 999

Further Resources

Lost or misplaced your CMI? | Want to track your dosing?

Little Green Pharma logo

Get in Touch: 0800 333 999 | [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-2

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 1:20, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>5</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-2** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-2** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>5</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

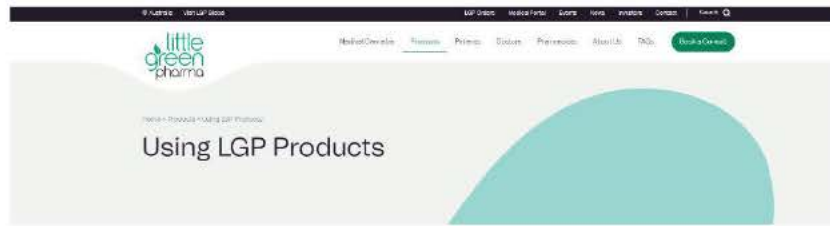
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is intended to help patients or carers of patients who have been prescribed LGP Classic range products to learn how to administer the product.

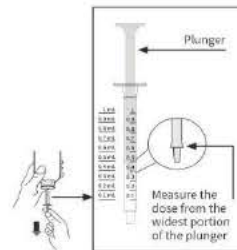


How to use the LGP Classic range

Are you dosing correctly?

Please ensure the plunger is always pushed down to the widest part of the plunger.

Please note: When dosing, always hold the device at the widest portion of the plunger. This will ensure you are dosing the correct amount. Refer to the image to the right.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Please follow your doctor's advice on when to start.
- Most doctors will advise the first dose should be taken when it is time to take your first dose of your medication.
- You can take your medication once, during or after meals.

Some patients may also experience a high when taking cannabis. This is a natural, expected side effect of the medication and is not a sign of overdose.

Please note: It is not necessary to consume LGP medication with any food and the advice is not applicable for other types of medication.

How much oil or flower should I take?

- The guidance is to start with a small amount (e.g. 10mg) and increase the dose as needed.
- Please refer to your instructions, however, our maximum dose is 20mg per litre for oral medication.
- The maximum dose is 20mg per litre.
- Please refer to your instructions for more information on how to use the product.

By increasing your dose you will increase your risk of side effects. Please refer to our medication leaflets for more information.

When will I know if medical cannabis is working for me?

- Medical cannabis often takes time to work and may not be effective immediately.
- It may take 2-4 weeks to see the full benefits of the medication, depending on the product.
- Keeping the dose low, starting with a small amount and increasing as needed.
- It is important to note that the effects of cannabis can be delayed.
- Please refer to our medication leaflets for more information on how to use the product. These include warnings of THC/CBD levels.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact us for a replacement.

- LGP CLASSIC (various strengths) LGP CLASSIC 250 LGP CLASSIC 500 LGP CLASSIC 1000 LGP CLASSIC 2000
- LGP CLASSIC 1000
- LGP CLASSIC 2000
- LGP CLASSIC 500
- LGP CLASSIC 1000 - Patient Support
- LGP CLASSIC 2000 - Patient Support
- LGP CLASSIC 500 - Patient Support
- LGP CLASSIC 1000 - Patient Support

Or you can contact us via our support line at 01203 200000 or via our website at [www.littlegreenpharma.com](http://www.littlegreenpharma.com)

Want to track your dosing?

If you want to track your dosing, please refer to our medication leaflets for more information.

Visit [www.littlegreenpharma.com](http://www.littlegreenpharma.com) or call 01203 200000



Get in Touch  
01203 200000  
info@littlegreenpharma.com

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-3

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 1:10, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>6</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-3** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-3** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>6</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

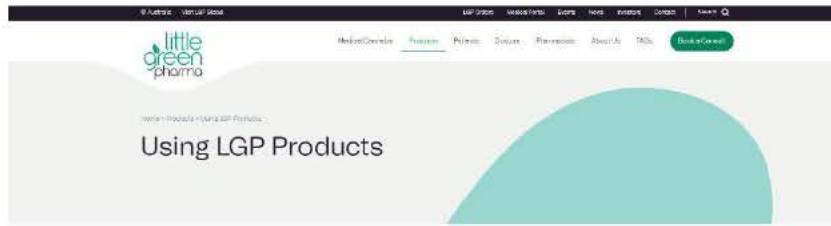
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

# ANNEXURE A:



## Instructional Video for Patients and Patient Carers

Find out more on our website [s22](#) for more details on each of a range of products we offer. See our LGP Classic range and our s22 range for more information.

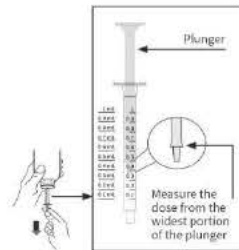


## How to use the LGP Classic range

Are you dosing correctly?

Please check that you are holding the syringe correctly to ensure you are dosing correctly.

Please note that the syringe is designed to be used with the LCP Classic range only. It is not designed to be used with other syringes. The syringe is not designed to be used with other syringes.



## Cannabis Medication FAQs

### When should I start taking my cannabis medication?

- Always follow your medical cannabis prescriber's advice.
- It may take a few weeks to feel the full benefits of your cannabis medication.
- You may have your medication stopped or changed if you are not responding to it.

Some patients need a longer time to feel the full benefits of their cannabis medication. The results of your cannabis medication may vary from one person to the next. It is important to talk to your doctor if you are not responding to your medication.

Please do not take more than your prescribed dose and do not take it with other cannabis products.

### How much oil or flower should I take?

- The full dose is on the label of the product.
- Please always follow the label on the packaging provided by your doctor.
- Please follow your doctor's instructions, your own medical cannabis prescriber's advice and the instructions on the packaging of the product.
- If you are taking more than your prescribed dose, you may experience side effects.
- Please do not take more than your prescribed dose and do not take it with other cannabis products.

If you are taking more than your prescribed dose, you may experience side effects. Please do not take more than your prescribed dose and do not take it with other cannabis products.

### When will I know if medical cannabis is working for me?

- Medical cannabis may take a few weeks to feel the full benefits of your cannabis medication.
- It may take a few weeks to feel the full benefits of your cannabis medication.
- Following the instructions on the packaging of the product is important for the full benefits of your cannabis medication.
- If you are taking more than your prescribed dose, you may experience side effects. Please do not take more than your prescribed dose and do not take it with other cannabis products.

## Further Resources

### Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your prescriber for a replacement.

- [LGP CLASSIC \(omnibar\) LCP CLASSIC 300 LCP CLASSIC 100 LCP CLASSIC 200](#)
- [LGP CLASSIC 100](#)
- [LGP CLASSIC 200](#)
- [LGP CLASSIC 300](#)
- [LGP CLASSIC 100 \(oil\)](#)
- [LGP CLASSIC 200 \(oil\)](#)
- [LGP CLASSIC 300 \(oil\)](#)

If you need more information, please contact us at [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com) or 0800 333 333. Alternatively, visit our website for more information.

### Want to track your dosing?

If you want to track your dosing, please contact your prescriber for more information.



### Get in Touch

- 0800 333 333
- [info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 s22 [REDACTED] [@lgp.global](mailto:s22@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-00000002798/2022-4

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22 [REDACTED]  
 Telephone: s22 [REDACTED]  
 Email: s22 [REDACTED] [@health.gov.au](mailto:s22@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 20:5, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>7</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-4  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601**  
**Swift: RSBKAU2S** (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-4  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>7</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

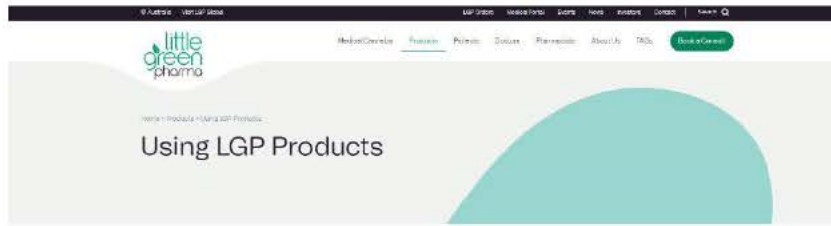
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is intended for patients and patient carers of a range of Little Green Pharma products. It provides detailed instructions on how to use the products.

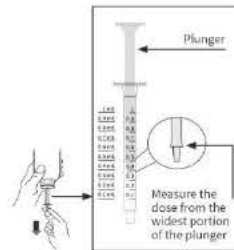


How to use the LGP Classic range

Are you dosing correctly?

Please check that the plunger is fully inserted into the top of the vial.

Please note that the plunger is inserted into the base of the vial, not the side. This is to ensure that the plunger is fully inserted into the vial.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical adviser's advice.
- It may take a few days for the medicine to start working. It is important to take it as directed.
- You may have your medication for a few days or longer.

Some patients need a longer time to start taking their medical cannabis. It is important to follow the advice of your medical adviser. It is important to take it as directed.

Please do not take more than your medical adviser has advised. It is important to take it as directed.

How much oil or flower should I take?

- The plunger is on the lowest position.
- Please always follow the instructions provided by your doctor.
- Please follow the instructions, you may not know how to use it. It is important to take it as directed.
- It is important to take it as directed.
- It is important to take it as directed.
- It is important to take it as directed.

It is important to take it as directed. It is important to take it as directed.

When will I know if medical cannabis is working for me?

- Medical cannabis will start working for you within a few days of starting to take it.
- It may take a few days for the medicine to start working. It is important to take it as directed.
- It is important to take it as directed.
- It is important to take it as directed.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact us for a replacement.

- LGP CLASSIC (omnibus range), LGP CLASSIC 300, LGP CLASSIC 300, LGP CLASSIC 300, LGP CLASSIC 300
- LGP CLASSIC 300
- LGP CLASSIC 300
- LGP CLASSIC 300
- LGP CLASSIC 300
- LGP CLASSIC 300

If you need more information, please contact us at 01453 666666 or 01453 666666.

Want to track your dosing?

If you want to track your dosing, please contact us for more information.



Get in Touch

- 01453 666666
- 01453 666666

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-5

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [REDACTED]  
 Telephone: <sup>s22</sup> [REDACTED]  
 Email: <sup>s22</sup> [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic CBD 50, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference



to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>8</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-5  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-5  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>8</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

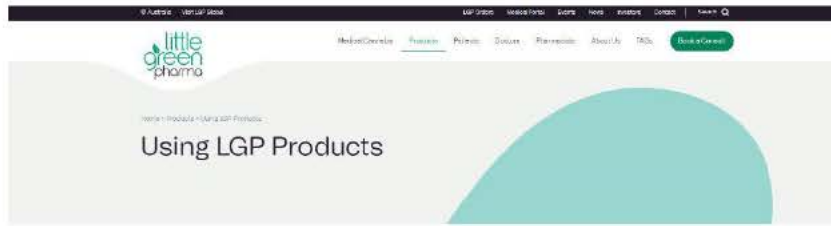
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

Clicking on the video thumbnail will lead to a page with a video demonstrating how to use the LGP Classic range of products.

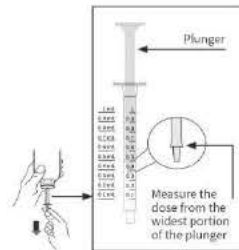


How to use the LGP Classic range

Are you dosing correctly?

Please check that the plunger is fully inserted into the top of the syringe.

Please note that the plunger is inserted into the base of the syringe and not the side. The plunger is not inserted into the side of the syringe.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical adviser's advice.
- It may take a few days to feel the effects of your cannabis medication.
- You may have your medication for a few days or longer.

Some patients need a longer time to feel the effects of their cannabis medication. The effects of cannabis medication can take a few days to feel the effects of the medication.

Please do not take more than your LGP medication daily and do not take more than your medical adviser's advice.

How much oil or flower should I take?

- The plunger is on the lowest position.
- Please always follow the instructions provided by your doctor.
- Please follow your medical adviser's advice on how much to take (see your medical adviser's advice).
- The amount of cannabis you take should be based on your medical adviser's advice.
- Please do not take more than your LGP medication daily and do not take more than your medical adviser's advice.

When will I know if medical cannabis is working for me?

- Medical cannabis will be working for you if you feel the effects of your cannabis medication.
- It may take a few days to feel the effects of your cannabis medication.
- Please follow your medical adviser's advice on how much to take (see your medical adviser's advice).
- The amount of cannabis you take should be based on your medical adviser's advice.
- Please do not take more than your LGP medication daily and do not take more than your medical adviser's advice.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your medical adviser for advice.

- LGP CLASSIC (cannabis oil) - LGP CLASSIC 300, LGP CLASSIC 150, LGP CLASSIC 75
- LGP CLASSIC 300
- LGP CLASSIC 150
- LGP CLASSIC 75
- LGP CLASSIC 300 - 150 - 75 - 30 - 15 - 7.5
- LGP CLASSIC 300 - 150 - 75 - 30 - 15 - 7.5

Want to track your dosing?

If you wish to track your dosing, please contact your medical adviser for advice.



Get in Touch

- 1800 750 000
- 1800 750 000

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-6

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 1:100, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>9</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-6** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-6** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>9</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

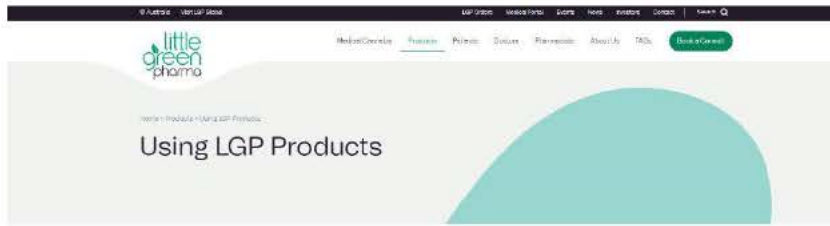


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is intended for patients and patient carers of a range of products from the LGP Classic range. It provides information on how to use the products.

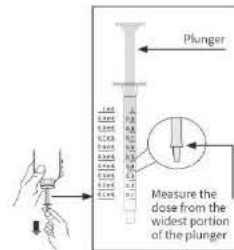


How to use the LGP Classic range

Are you dosing correctly?

Please check that you are holding the syringe correctly to the correct portion of the plunger.

Please note that the syringe is designed to be used with the plunger. The plunger is not designed to be used to draw the dose.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical adviser's advice.
- It may take a few weeks for the full effects to be felt.
- You may have your medication stopped or altered.

Some patients report a feeling of dizziness when taking their medical cannabis. This is a common side effect of the medication and should resolve on its own. If it does not, please contact your medical adviser.

Please do not take more than your prescribed dose and do not take more than one dose at a time.

How much oil or flower should I take?

- The product is a low-dose product.
- Please always follow the dosing schedule provided by your doctor.
- Please follow your medical adviser's advice. You may have your medication stopped or altered.
- You may have your medication stopped or altered.
- You may have your medication stopped or altered.

Please do not take more than your prescribed dose and do not take more than one dose at a time.

When will I know if medical cannabis is working for me?

- Medical cannabis will be used to treat your condition. It may take a few weeks for the full effects to be felt.
- It may take a few weeks for the full effects to be felt.
- You may have your medication stopped or altered.
- You may have your medication stopped or altered.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your medical adviser.

- LGP CLASSIC (oral suspension) LGP CLASSIC (oil) LGP CLASSIC (oil) LGP CLASSIC (oil)
- LGP CLASSIC (oil)
- LGP CLASSIC (oil)
- LGP CLASSIC (oil)
- LGP CLASSIC (oil)
- LGP CLASSIC (oil)

If you need more information, please contact your medical adviser.

Want to track your dosing?

If you wish to track your dosing, please contact your medical adviser.



Get in Touch

- 01203 251111
- info@lgreenpharma.com

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:§22@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-7

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:§22@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower THC 22 – Desert Flame, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>10</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-7  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-7  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the

<sup>10</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

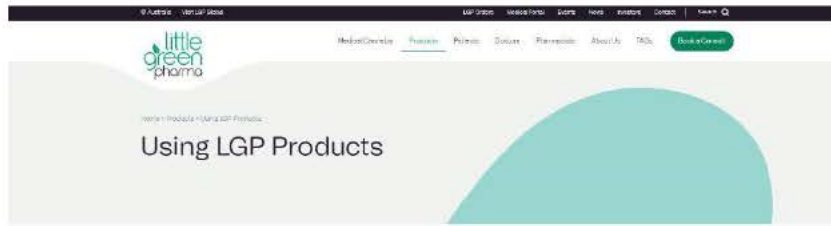
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is available in **English** for most subjects or copies of a manual in Hindi (see below) for LGP Classic range products. Please visit [www.littlegreenpharma.com](#) for more information.

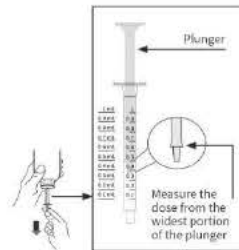


How to use the LGP Classic range

Are you dosing correctly?

Please check that you are holding the syringe correctly to the correct portion of the plunger.

Please note that the syringe is designed to be used with the base of the plunger inserted into the vial. The plunger is not designed to be used in the vial.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical adviser's advice.
- It may take a few weeks for the full effects to be felt.
- You may have your medication for a few days or longer.

Some patients report a feeling of dizziness when taking their medical cannabis. This is a common side effect of the medication and should resolve on its own. If you experience this, you should stop taking the medication and contact your medical adviser.

Please do not take more than your prescribed dose and do not take more than one dose at a time.

How much oil or flower should I take?

- The product is a low-dose product.
- Please always follow the dosing schedule provided by your doctor.
- Please follow your medical adviser's advice on how much to take.
- If you are taking more than your prescribed dose, you may experience side effects.
- Please do not take more than your prescribed dose.

By starting slowly, you can build up your tolerance to the medication over time.

When will I know if medical cannabis is working for me?

- Medical cannabis will be used to treat your condition, but it may take a few weeks for the full effects to be felt.
- It may take a few weeks for the full effects to be felt.
- Please follow your medical adviser's advice on how much to take.
- If you are taking more than your prescribed dose, you may experience side effects.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your medical adviser for more information.

- [LGP CLASSIC \(cannabis oil\)](#), [LGP CLASSIC \(cannabis flower\)](#), [LGP CLASSIC \(cannabis oil\)](#), [LGP CLASSIC \(cannabis flower\)](#)
- [LGP CLASSIC \(cannabis oil\)](#)
- [LGP CLASSIC \(cannabis flower\)](#)
- [LGP CLASSIC \(cannabis oil\)](#)
- [LGP CLASSIC \(cannabis flower\)](#)

If you need more information, please contact your medical adviser for more information.

Want to track your dosing?

If you wish to track your dosing, please contact your medical adviser for more information.

[LGP CLASSIC \(cannabis oil\)](#) or [LGP CLASSIC \(cannabis flower\)](#)



Get in Touch

- 01203 333333
- [info@litlegreenpharma.com](#)

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [redacted] [@lgp.global](mailto:@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-8

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [redacted]  
 Telephone: <sup>s22</sup> [redacted]  
 Email: <sup>s22</sup> [redacted] [@health.gov.au](mailto:@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower THC 19 – Billy Buttons, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>11</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-8  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-8  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>11</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22 \[REDACTED\]@health.gov.au](mailto:s22[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

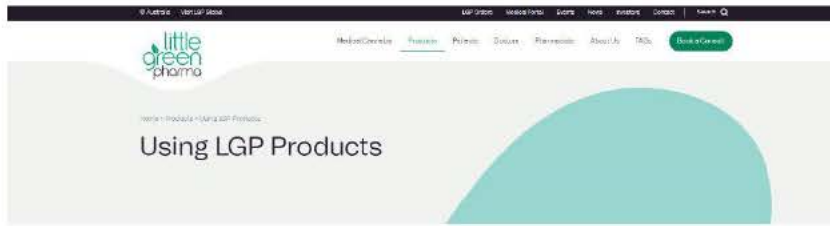
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is available in **s22** for individuals or carers of a patient who have been prescribed LGP Classic range products. It will show you how to use the products.

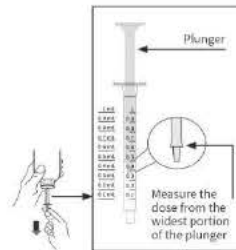


How to use the LGP Classic range

Are you dosing correctly?

Please check that you are following the instructions on the packaging of the product.

Please note that the plunger should be inserted into the base of the cartridge and not the side. The plunger should be inserted from the top to the bottom.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical cannabis therapist's advice.
- It may take a few weeks to feel the full effects of your medication. It is normal to feel some side effects.
- You may have your medication for a few days or longer.

Some patients need a longer time to feel the full effects of their medication. The full effects of your medication may not be felt for a few weeks. It is normal to feel some side effects.

Please do not take more than your medical cannabis therapist has advised. It is not safe to take more than your medical cannabis therapist has advised.

How much oil or flower should I take?

- The product is a low dose product.
- Please always follow the instructions on the packaging of your product.
- Please follow your medical cannabis therapist's advice on how much to take.
- It is important to follow your medical cannabis therapist's advice on how much to take.
- Please do not take more than your medical cannabis therapist has advised.

It is important to follow your medical cannabis therapist's advice on how much to take.

When will I know if medical cannabis is working for me?

- Medical cannabis will be prescribed to you if your medical cannabis therapist has advised.
- It may take a few weeks to feel the full effects of your medication. It is normal to feel some side effects.
- Please follow your medical cannabis therapist's advice on how much to take.
- It is important to follow your medical cannabis therapist's advice on how much to take.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your medical cannabis therapist for advice.

- [LGP CLASSIC \(omniterpenes\) LCP CLASSIC 300 LCP CLASSIC 100 LCP CLASSIC 200](#)
- [LGP CLASSIC 100](#)
- [LGP CLASSIC 200](#)
- [LGP CLASSIC 300](#)
- [LGP CLASSIC 100 \(oil\)](#)
- [LGP CLASSIC 200 \(oil\)](#)
- [LGP CLASSIC 300 \(oil\)](#)

If you need more information, please contact your medical cannabis therapist on 0800 333 333 or visit [www.littlegreenpharma.com](#).

Want to track your dosing?

If you wish to track your dosing, please contact your medical cannabis therapist for advice.



Get in Touch

- 0800 333 333
- [info@littlegreenpharma.com](#)

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**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 s22 [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-9

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22 [REDACTED]  
 Telephone: s22 [REDACTED]  
 Email: s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower CBD 14 – Sky Mist, on the web page located at <https://www.littlegreenpharma.com/au/products/using-lgp-products/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>12</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-9  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-9  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>12</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22 \[REDACTED\]@health.gov.au](mailto:s22[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

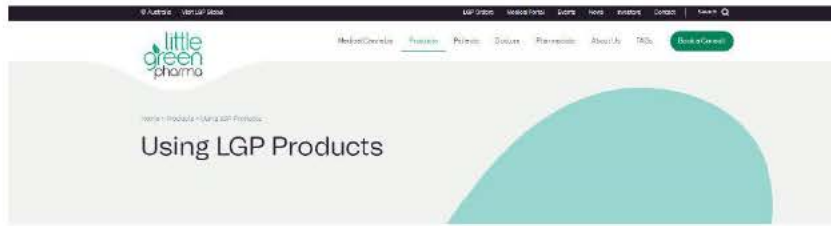
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:



Instructional Video for Patients and Patient Carers

This instructional video is available in **English** for most subjects or carers of a patient who has been prescribed LGP. It shows how to use the products and how to administer the product.

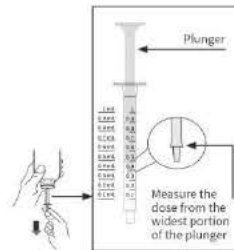


How to use the LGP Classic range

Are you dosing correctly?

Please check that the plunger has been inserted fully into the neck of the vial.

Please note that the plunger is inserted into the base of the vial and not the top of the vial. The plunger is not inserted into the neck of the vial.



Cannabis Medication FAQs

When should I start taking my cannabis medication?

- Always follow your medical adviser's advice.
- It may take a few weeks for the full effects to be felt.
- You may have your medication stopped or altered.

Some patients report a feeling of dizziness when taking their medical cannabis. This is a common side effect of the medication and should be reported to your medical adviser.

Please do not take any other cannabis medication with your food and do not take any other medication with your food.

How much oil or flower should I take?

- The plunger is on the lowest position.
- Please always follow the dosing schedule provided by your doctor.
- Please follow your medical adviser's advice on how much to take.
- If you are unsure how much to take, please contact your medical adviser.
- Please do not take any other cannabis medication with your food and do not take any other medication with your food.

When will I know if medical cannabis is working for me?

- Medical cannabis will be prescribed to you if your doctor believes it will help with your symptoms.
- It may take a few weeks for the full effects to be felt.
- Please follow your medical adviser's advice on how much to take.
- If you are unsure how much to take, please contact your medical adviser.
- Please do not take any other cannabis medication with your food and do not take any other medication with your food.

Further Resources

Lost or misplaced your CMI?

If you have lost or misplaced your CMI, please contact your medical adviser for a replacement.

- LGP CLASSIC (cannabis oil) - LGP CLASSIC 300, LGP CLASSIC 150, LGP CLASSIC 75
- LGP CLASSIC 300
- LGP CLASSIC 150
- LGP CLASSIC 75 - Dosing Guide
- LGP CLASSIC 300 - Dosing Guide
- LGP CLASSIC 150 - Dosing Guide
- LGP CLASSIC 75 - Dosing Guide

Want to track your dosing?

If you wish to track your dosing, please contact your medical adviser for a tracking device.



Get in Touch

- 1800 750 000
- [info@lgreenpharma.com](mailto:info@lgreenpharma.com)

Quick Links

- Home
- About Us
- Products
- Pricing
- Contact Us

Newsletter

Subscribe to our newsletter for the latest news and updates.







**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-10

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [REDACTED]  
 Telephone: <sup>s22</sup> [REDACTED]  
 Email: <sup>s22</sup> [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at [https://www.instagram.com/p/Cc\\_6o5SsS\\_W/](https://www.instagram.com/p/Cc_6o5SsS_W/).

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>13</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-10** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care

**BSB:** 092 009

**Account:** 114 071

**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601

**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-10** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>13</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

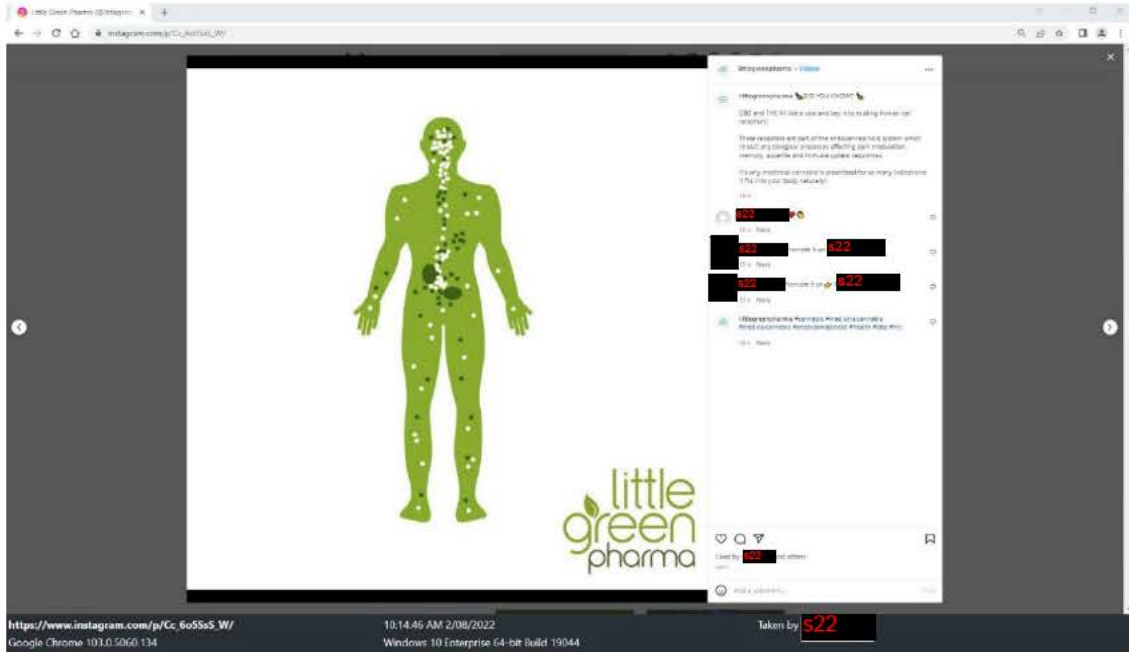
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 s22 [REDACTED] @lqp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-11

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22 [REDACTED]  
 Telephone: s22 [REDACTED]  
 Email: s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/Cc4CFGIBU5/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to anxiety. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>14</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-11** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care

**BSB:** 092 009

**Account:** 114 071

**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601

**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-11** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>14</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

Instagram post screenshot showing an illustration of a man with a magnifying glass over a checklist on a clipboard. The Instagram interface shows the post content, a caption in Malayalam, and a comment with a redacted name and the text 's22'. The browser address bar shows 'https://www.instagram.com/p/CcACFGIBUV5/'. The system tray at the bottom indicates the date and time as '10:16:55 AM 2/08/2022' and the device as 'Windows 10 Enterprise (64-bit; Build 19044)'. The text 'Taken by s22' is visible in the bottom right corner.



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [redacted] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-12

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [redacted]  
 Telephone: <sup>s22</sup> [redacted]  
 Email: <sup>s22</sup> [redacted] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/Cc4CFGIBU5/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to depression. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>15</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-12** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-12** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>15</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
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- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

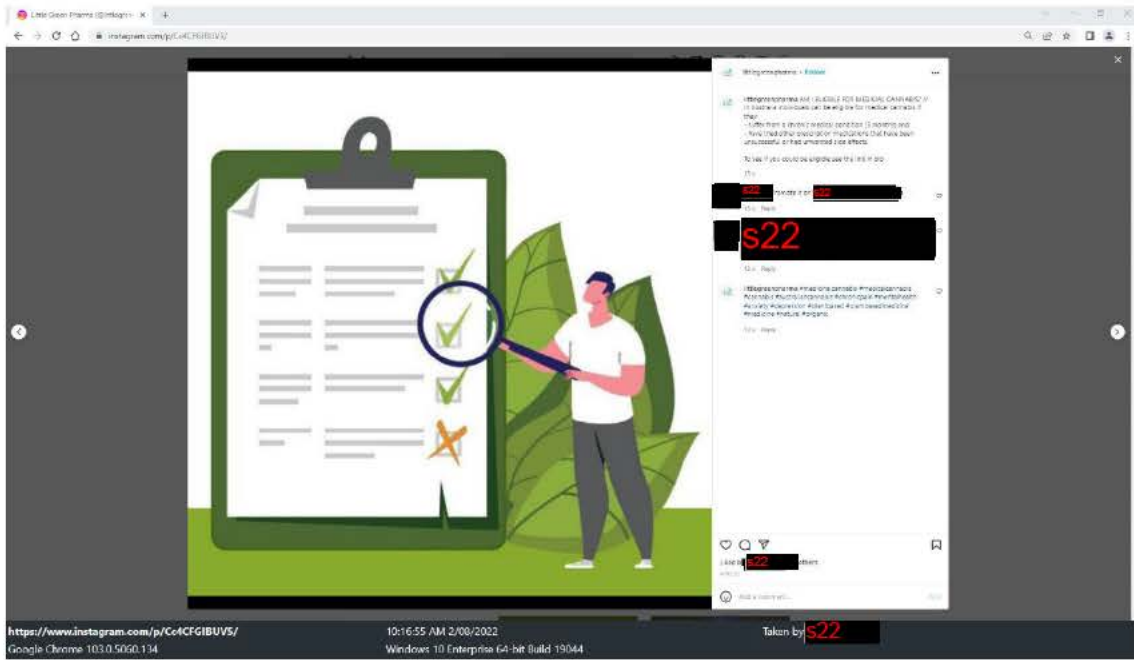
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-13

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/Cc4CFGIBU5/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to chronic pain, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>16</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-13** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-13** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>16</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22 \[REDACTED\]@health.gov.au](mailto:s22[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

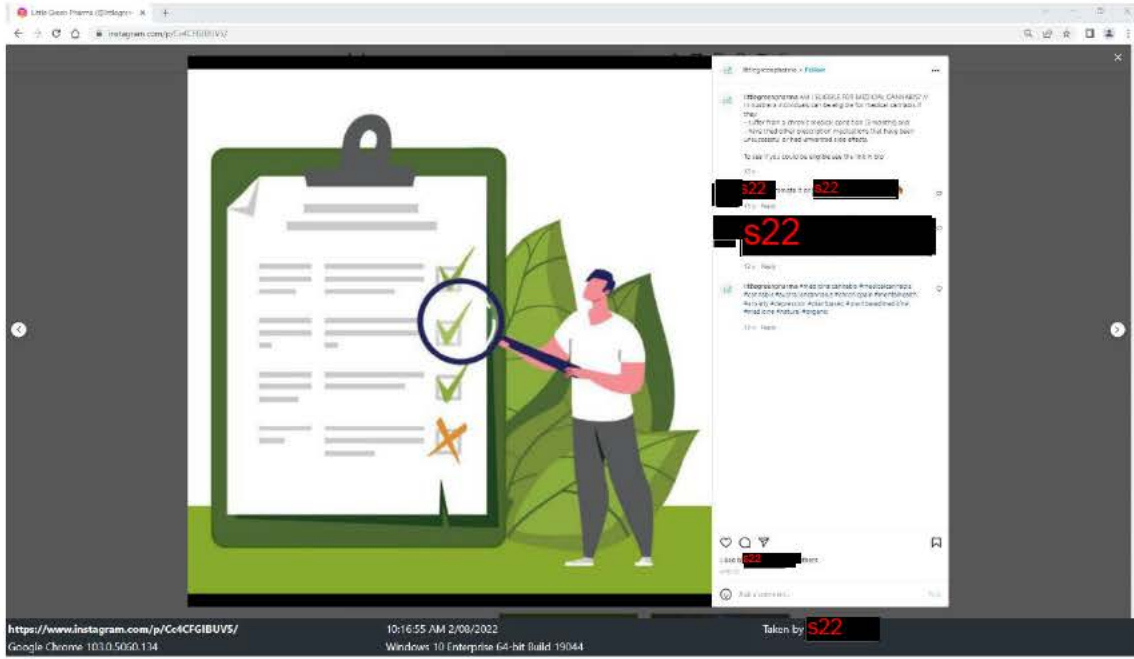
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

§22 [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-14

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]

Telephone: §22 [REDACTED]

Email: §22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower CBD 14 – Sky Mist, on the web page located at <https://www.instagram.com/p/CckQ1jPLb76/>.

The advertisement referred to a good containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>17</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-14** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-14** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>17</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

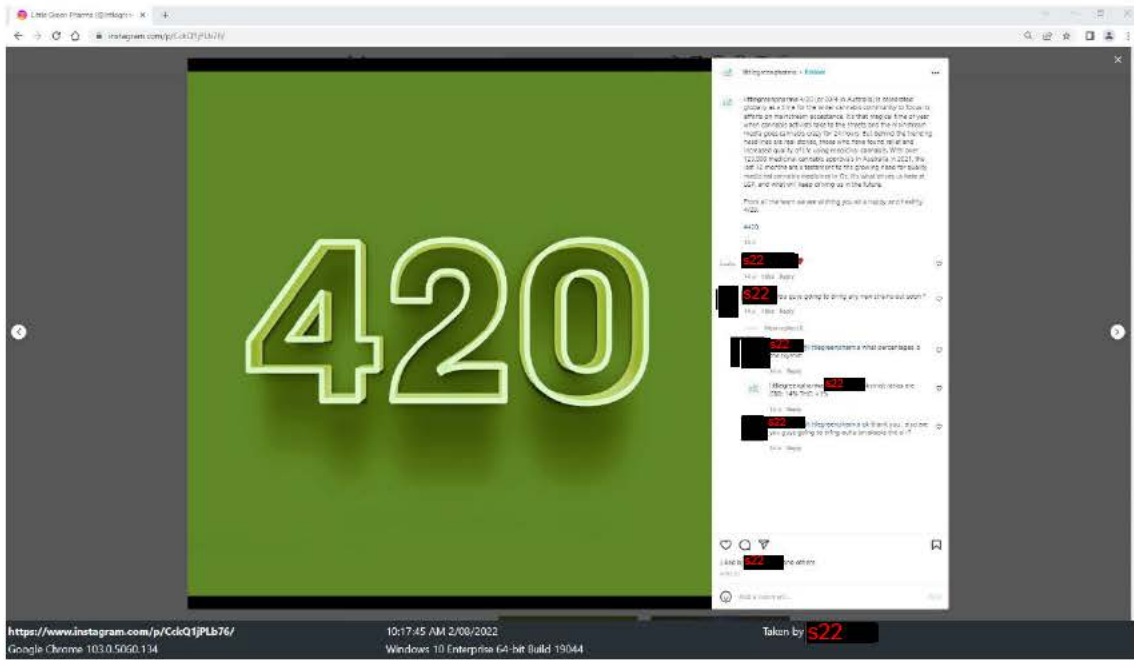


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [REDACTED]@lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-15

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [REDACTED]  
 Telephone: <sup>s22</sup> [REDACTED]  
 Email: <sup>s22</sup> [REDACTED]@health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower CBD 14 – Sky Mist, on the web page located at <https://www.instagram.com/p/CckQ1jPLb76/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>18</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-15  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-15  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>18</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

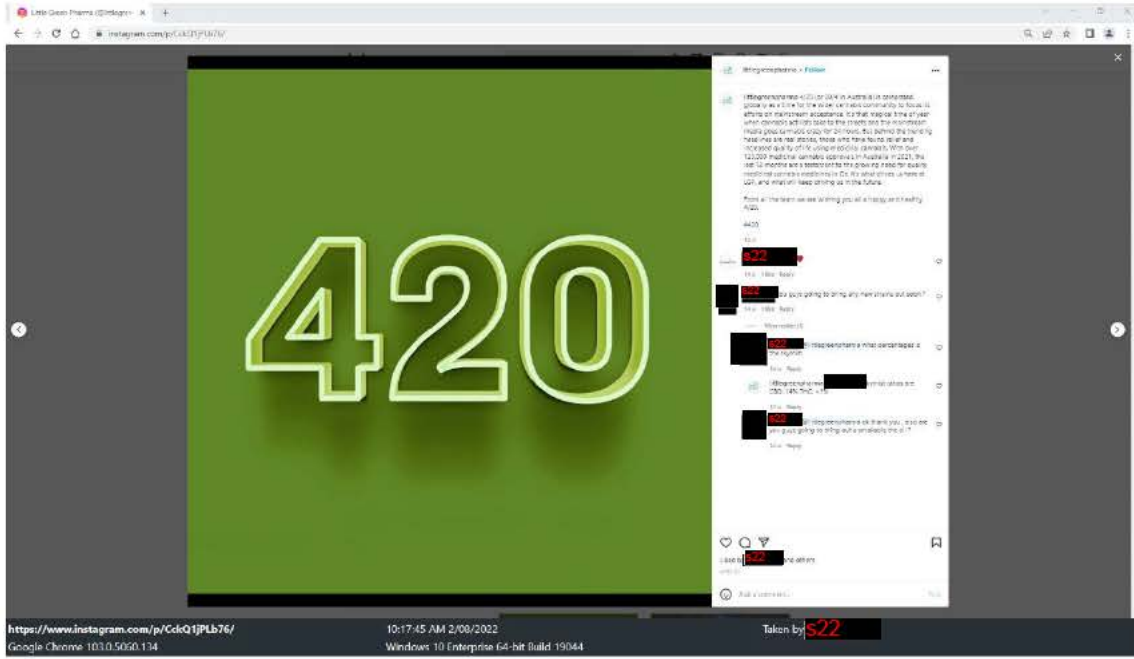
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-16

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22 [REDACTED]

Telephone: s22 [REDACTED]

Email: s22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at [https://www.instagram.com/p/CZ3cx\\_6qYIs/](https://www.instagram.com/p/CZ3cx_6qYIs/).

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>19</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-16** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care

**BSB:** 092 009

**Account:** 114 071

**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601

**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-16** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>19</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

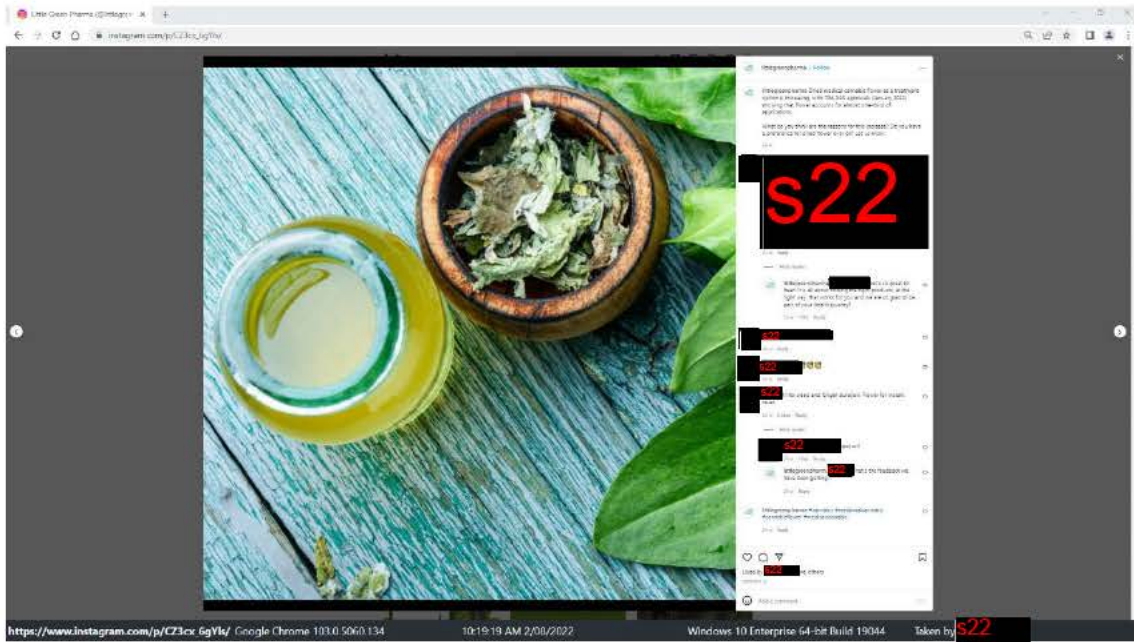
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-17

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 1:100, on the web page located at [https://www.instagram.com/p/CZ3cx\\_6qYIs/](https://www.instagram.com/p/CZ3cx_6qYIs/).

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>20</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-17  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-17  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>20</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

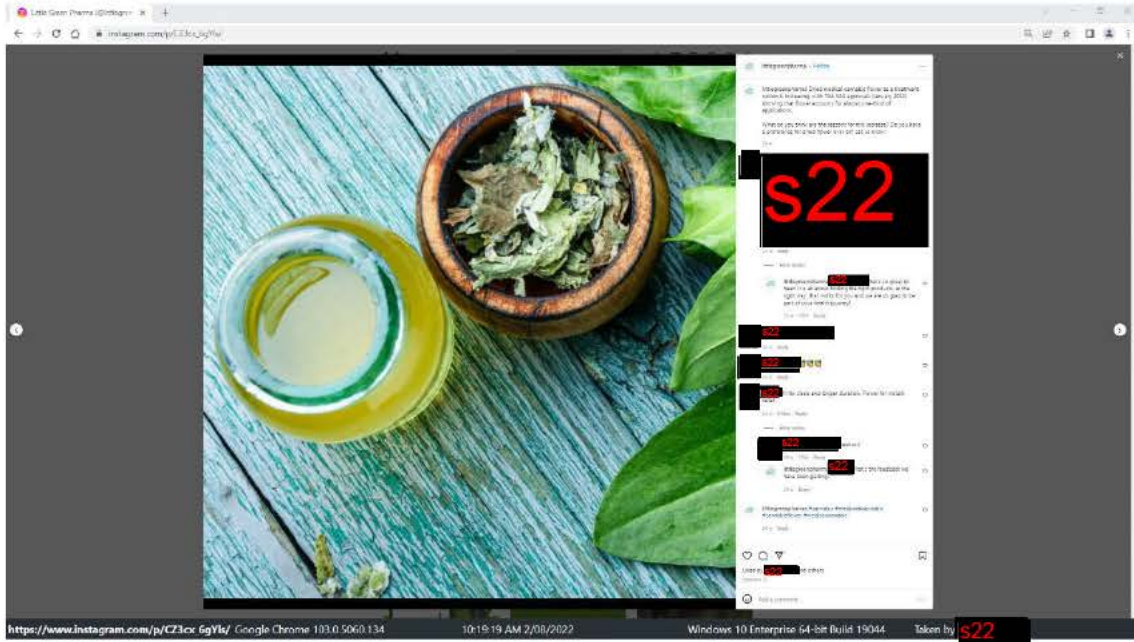
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:







**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-18

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:§22@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Classic 20:5, on the web page located at [https://www.instagram.com/p/CZ3cx\\_6qYIs/](https://www.instagram.com/p/CZ3cx_6qYIs/).

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>21</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-18  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-18  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>21</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

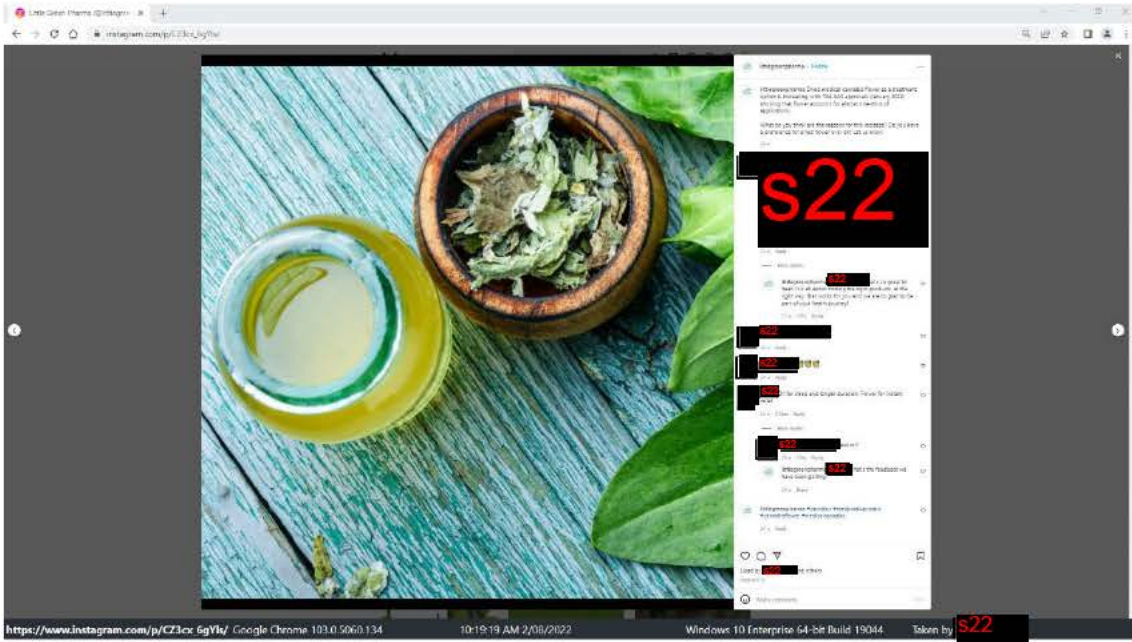
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [REDACTED] [@lqp.global](mailto:info@lqp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-19

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [REDACTED]  
 Telephone: <sup>s22</sup> [REDACTED]  
 Email: <sup>s22</sup> [REDACTED] [@health.gov.au](mailto:[REDACTED]@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to post-traumatic stress disorder. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>22</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-19** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:** Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-19** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>22</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

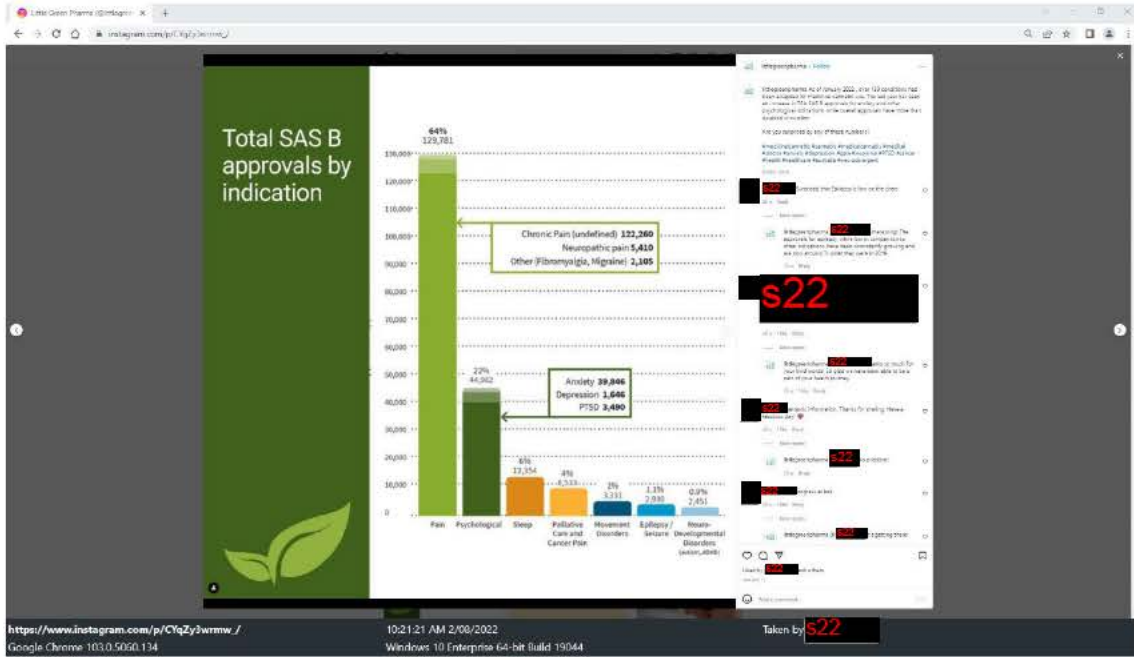
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lqp.global](mailto:info@lqp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-20

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(2) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a prohibited representation (whether in express terms or by necessary implication) about the goods, being a reference to cancer. No permission under section 42DK of the Act was in force in relation to the prohibited representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>23</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-20** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-20** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>23</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

<sup>s22</sup> [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-21

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

<sup>s22</sup> [REDACTED]  
 Telephone: <sup>s22</sup> [REDACTED]  
 Email: <sup>s22</sup> [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to autism spectrum disorder, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.



An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>24</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-21** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-21** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>24</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

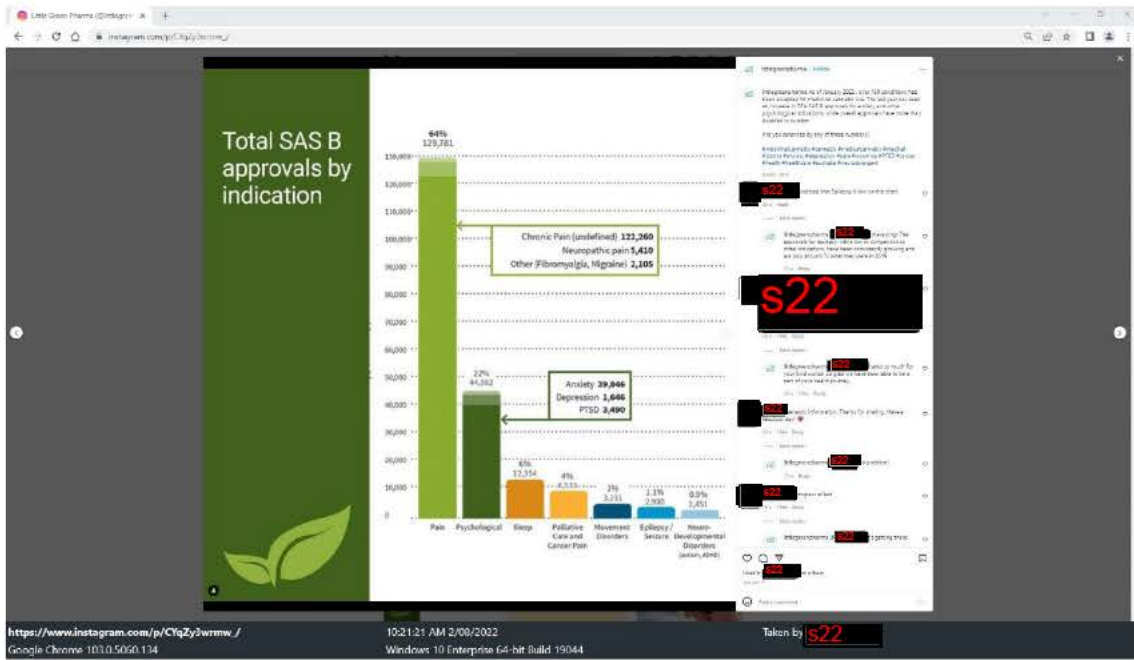
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

§22 [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-22

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to epilepsy, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>25</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-22** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-22** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>25</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

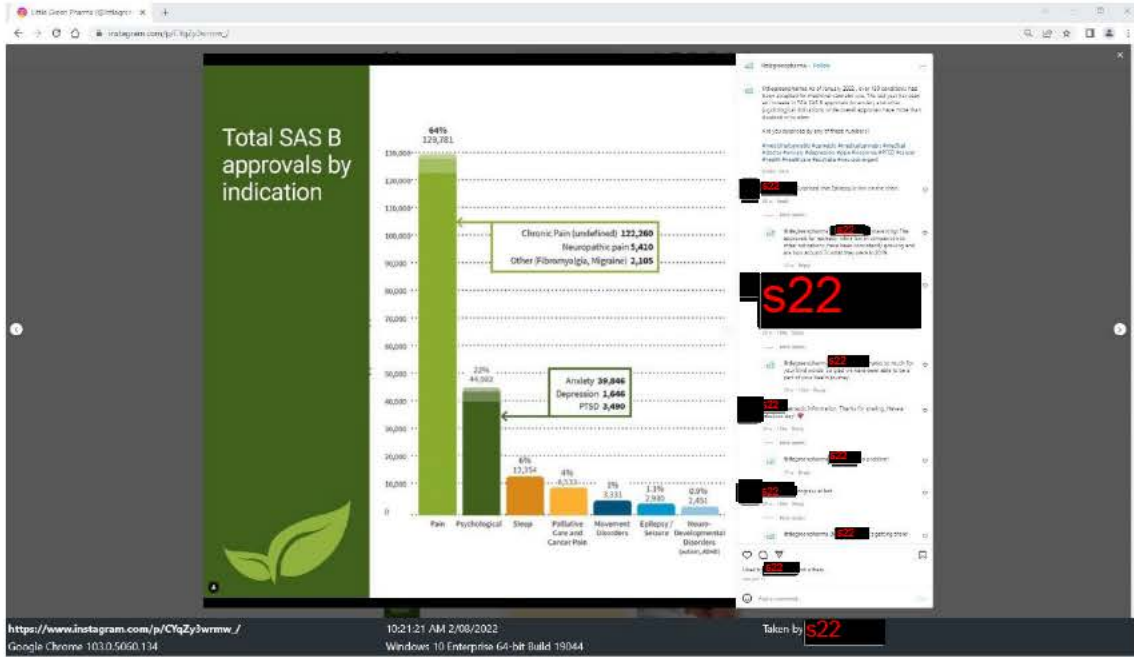


Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022



ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-23

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to insomnia, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>26</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-23** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB: 092 009**  
**Account: 114 071**  
**Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601**  
**Swift: RSBKAU2S** (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-23** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>26</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22 \[REDACTED\]@health.gov.au](mailto:s22[REDACTED]@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

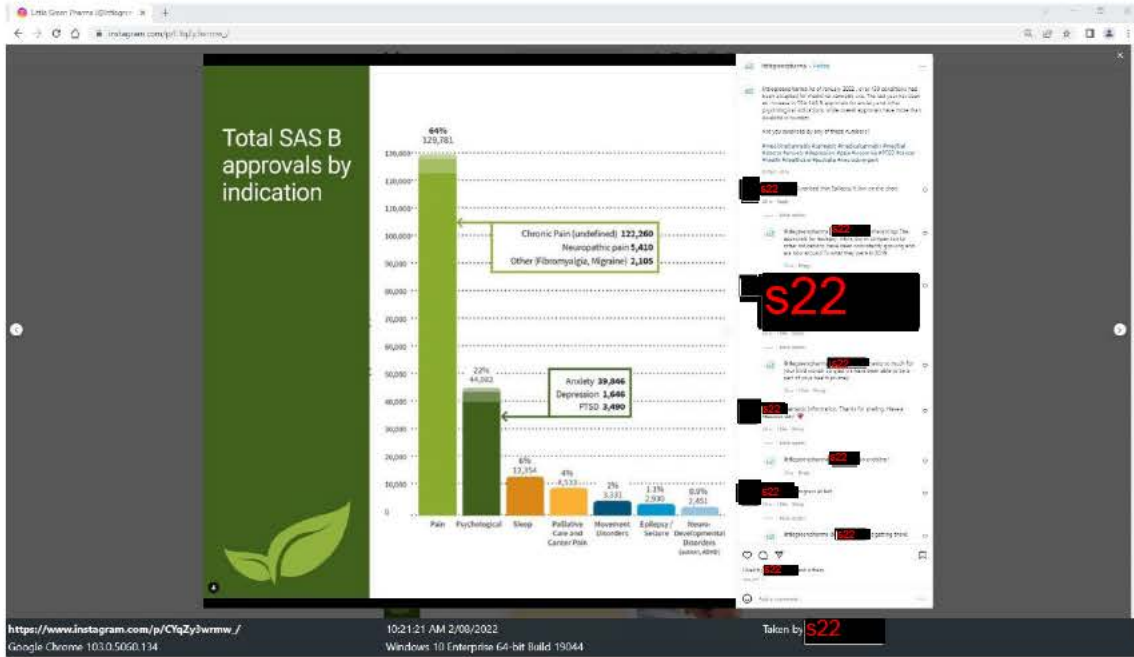
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

§22 [REDACTED] @lgp.global  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-24

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]

Telephone: §22 [REDACTED]

Email: §22 [REDACTED] @health.gov.au

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to fibromyalgia, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>27</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-24** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601  
**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-24** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>27</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).



## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- s22 [REDACTED]@health.gov.au; or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

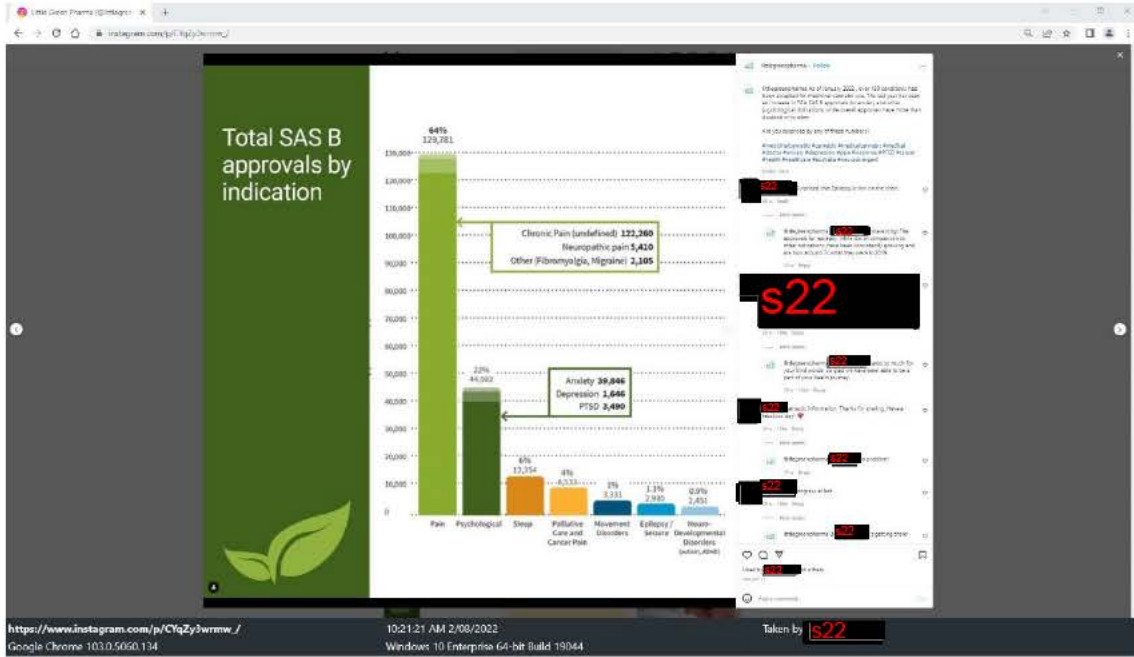
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-25

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22  
 Telephone: s22  
 Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(4) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being medicinal cannabis products, on the web page located at <https://www.instagram.com/p/CYqZy3wrmw/>.

The advertisement contained a restricted representation, (whether in express terms or by necessary implication), being a reference to attention deficit hyperactivity disorder, about the goods. Neither an approval under section 42DF of the Act, nor a permission under section 42DK of the Act was in force in relation to the restricted representation.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>28</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to **Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health and Aged Care. Please allow 5 business days for payment to be received



#### CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-AC-000000002798/2022-25** as reference to identify your payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**

Department of Health and Aged Care

**BSB:** 092 009

**Account:** 114 071

**Bank:** Reserve Bank of Australia, London Circuit, Canberra ACT 2601

**Swift:** RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-AC-000000002798/2022-25** in the description of your transfer and allow two business days for payment to be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>28</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

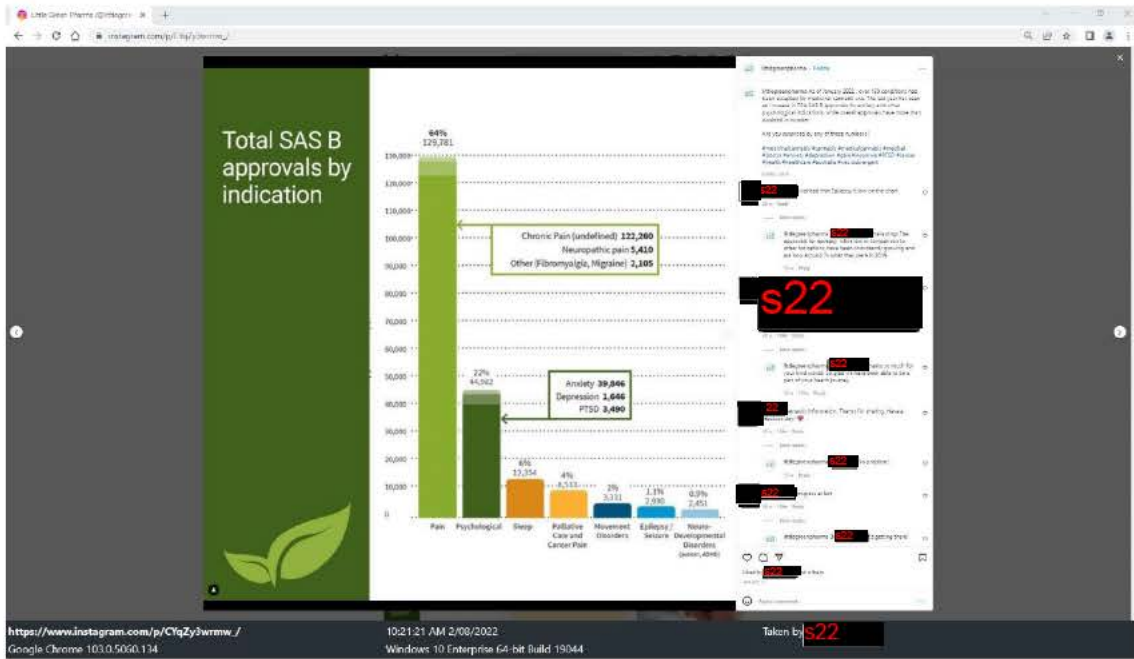
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:







**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:

s22 [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-00000002798/2022-26

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

s22

Telephone: s22

Email: s22 [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(7) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, therapeutic goods, being the medicinal cannabis products, on the web page located at <https://www.facebook.com/littlegreenpharma/photos/a.498524723849363/1636464993388658/>.

The advertisement referred to goods containing substances included in Schedule 3, 4 or 8 to the current Poisons Standard, such as cannabidiol or cannabis, but not in Appendix

H of the [current Poisons Standard](#), other than a reference authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>29</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-26  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-26  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>29</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

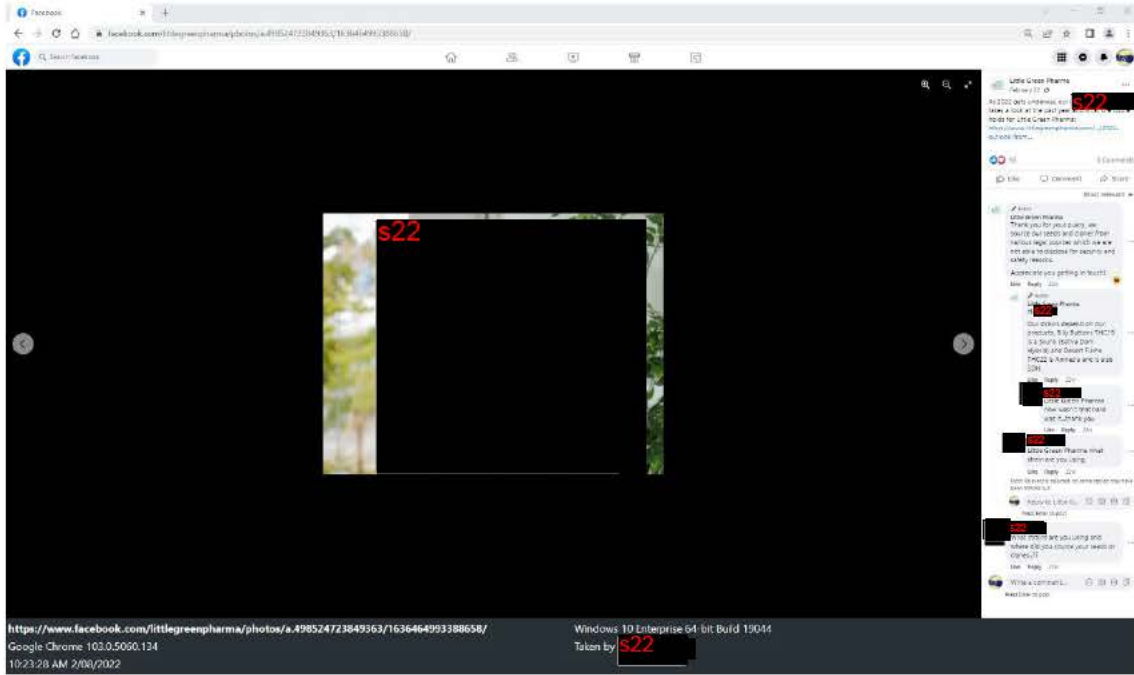
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-27

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

**PART A: Infringement Notice given by**

Nicole McLay  
 Delegate of the Secretary of the Australian Government Department of Health and Aged Care

**PART B: Details of alleged contravention**

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Little Green Pharma Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Little Green Pharma Ltd has contravened section 42DLB(1) of the Act, where subsection 42DLB(9) applied.

The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower THC 22 – Desert Flame, on the web page located at <https://www.facebook.com/littlegreenpharma/photos/a.498524723849363/1636464993388658/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>30</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
**Department of Health  
 and Aged Care,  
 Accounts Receivable,  
 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-27  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

##### Account name:

Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-27  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>30</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

### How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been paid by companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

### Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.



**Effect of the lapsing of the compliance period for the notice**

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

**How this notice can be withdrawn**

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

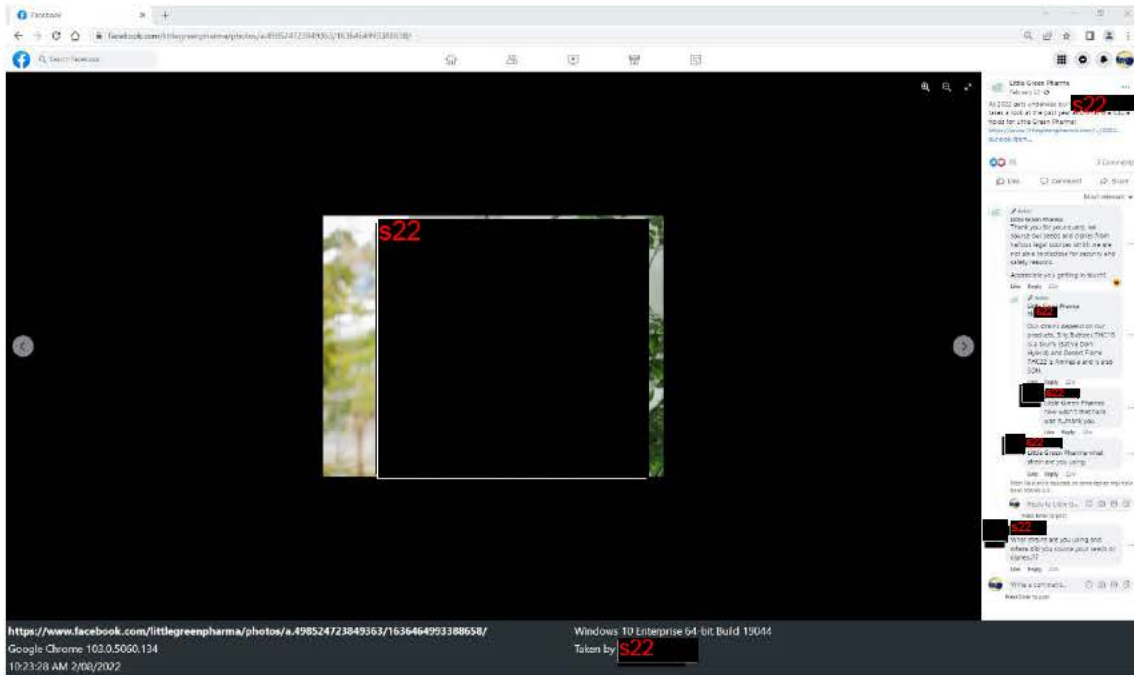
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:





**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

Little Green Pharma Ltd  
 ACN 615 586 215  
 Suite 2 Level 2  
 66 Kings Park Road  
 West Perth WA 6006

By Express Post and By Email:  
 §22 [REDACTED] [@lgp.global](mailto:info@lgp.global)  
[info@littlegreenpharma.com](mailto:info@littlegreenpharma.com)

**Infringement Notice Number:**  
 TGAIN-AC-000000002798/2022-28

**Date given:** 27/09/2022

**Penalty total:** \$ 13,320.00

**Payment due:** 26/10/2022

**Enquiries:**

§22 [REDACTED]  
 Telephone: §22 [REDACTED]  
 Email: §22 [REDACTED] [@health.gov.au](mailto:info@health.gov.au)

**INFRINGEMENT NOTICE GIVEN TO**  
*Little Green Pharma Ltd*

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The details of the alleged contravention are that:

On 2 August 2022, Little Green Pharma Ltd did advertise, or caused the advertising of, a therapeutic good, being LGP Flower THC 19 – Billy Buttons, on the web page located at <https://www.facebook.com/littlegreenpharma/photos/a.498524723849363/1636464993388658/>.

The advertisement referred to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and that is a prescribed good, being a therapeutic good that is neither the subject of an exemption, approval or authority under the Act. The reference

to the prescribed good is not authorised or required by a government or government authority.

An image of the advertisement taken by the Therapeutic Goods Administration is included at **Annexure A** to this notice.

The maximum penalty a court could impose on a company for a single contravention of subsection 42DLB(1) is 50,000 penalty units. For the above alleged contravention, this amounts to \$11,100,000.<sup>31</sup>

The amount payable under this notice is \$13,320. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

### PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



#### CHEQUE

Return **this notice** to  
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 and Aged Care,  
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 GPO Box 9848, Canberra  
 ACT 2601** with your  
 cheque made payable to  
 the Department of Health  
 and Aged Care.  
 Please allow 5 business  
 days for payment to be  
 received



#### CREDIT CARD

Use your credit card  
 to pay your notice by calling  
 the Collector of Relevant  
 Monies directly on  
**(02) 6289 1095**.  
 Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-28  
 as reference to identify your  
 payment



#### ELECTRONIC FUNDS TRANSFER

**Account name:**  
 Department of Health and  
 Aged Care  
**BSB:** 092 009  
**Account:** 114 071  
**Bank:** Reserve Bank of  
 Australia, London Circuit,  
 Canberra ACT 2601  
**Swift:** RSBKAU2S (if  
 overseas deposits are  
 relevant). Please include the  
 infringement notice number  
 TGAIN-AC-  
 000000002798/2022-28  
 in the description of your  
 transfer and allow two  
 business days for payment to  
 be received.

**Note:** The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

<sup>31</sup> A penalty unit is currently \$222 (section 4AA of the *Crimes Act 1914*).

## PART D: Information about this Infringement Notice

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- the effect of complying with this notice, and
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

### Compliance period

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- PO Box 100; WODEN ACT 2609

### Effect of complying with this notice

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Written representations can be made by sending them directly to:

- [s22@health.gov.au](mailto:s22@health.gov.au); or
- PO Box 100; WODEN ACT 2609

**Effect of withdrawal of this notice**

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.



Nicole McLay  
Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

Date: 27/09/2022

ANNEXURE A:

