



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DIRECTION UNDER SECTION 42DV

ISSUED TO: [REDACTED]

ON: 24 January 2023

**ABOUT: Promoting the use and supply of
nicotine vaping products to Australian
consumers**

BY: [REDACTED]

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

Therapeutic Goods Administration

PO Box 100

Woden ACT 2606

Contact Officer Name:

[REDACTED]

Contact Officer Telephone:

[REDACTED]

Contact Officer Email:

[REDACTED]

DIRECTION ABOUT AN ADVERTISEMENT

Made Under Section 42DV of the *Therapeutic Goods Act 1989*

TO:

[REDACTED]
[REDACTED]
[REDACTED]

By express post and by email: [REDACTED]
[REDACTED]

I, delegate of the Secretary of the Australian Department of Health and Aged Care (**the Delegate**) in the Therapeutic Goods Administration (**TGA**), being satisfied, for the reasons set out in **Attachment A**, that there have been contraventions of the *Therapeutic Goods Act 1989* (**the TG Act**) in relation to the advertising of nicotine vaping products, including those goods set out at **Attachment E (the Goods)**.

DIRECT you, as the person apparently responsible for that advertising or for causing the advertising of the Goods, to:

1. **Cease** all advertising of nicotine vaping products, including but not limited to the advertising on the websites at the Uniform Resource Locators (**URLs**):
 - a. [REDACTED]; and
 - b. [REDACTED] (collectively, **the Websites**)

CONDITIONS

under subsection 42DV(3) of the TG Act

This **Direction** is subject to the following conditions that you must:

- a. **complete** each action you are directed to carry out, including as required by these conditions, by **5pm on 5 business days from date of this notice**;
- b. **cease**, for the period of 3 years, all advertising referred to at paragraph 1 above; and
- c. **email** evidence of your compliance with this **Direction** to the email address listed on the first page of this Direction by **5 business days from date of notice**.

OTHER INFORMATION

Important information about the reasons for making this **Direction** and its effect is set out in **Attachment A**. The possible consequences of failing to comply with this Direction are explained in **Attachment B**.

The sections of the TG Act relevant to the making of this **Direction** and The Therapeutic Goods (Restricted and Prohibited Representations - Nicotine) Permission (No. 2) 2021 are set out in **Attachment C**.

This is an initial decision and is reviewable. Your review rights are set out in **Attachment D**.

Examples of the alleged unlawful advertising is reproduced at **Attachment E**.

Please note, under subsection 42DV(6) of the TG Act, the TGA will publish this Direction on its website. Publication is planned to occur on or before **2 business days** from date of notice.

DATED: 24 January 2023

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

Attachment A

Introduction

Nicotine vaping products

1. There are many nicotine replacement therapies including nicotine patches, gum, lozenges, mouth sprays and inhalators, and some prescription medicines, in the Australian Register of Therapeutic Goods (**the Register**) that have been assessed by the TGA for safety, quality and efficacy.
2. Nicotine vaping products are finished products that contain nicotine (in base and/or salt form(s)) in solution that are intended to be vaporised and inhaled using a vaping device (e.g. an e-cigarette or other electronic nicotine delivery system). These products include nicotine vape liquids, e-liquids and e-juices and nicotine in disposable e-cigarettes.
3. Regulation 2 of the *Therapeutic Goods Regulations 1990* defines nicotine vaping products as meaning ‘*a medicine that:*
 - a. *contains nicotine in solution; and*
 - b. *is a finished product; and*
 - c. *is intended to be vaporised, and administered by inhalation, using a vaping device*’.

Regulation of nicotine vaping products

4. From 1 October 2021, all nicotine vaping products, such as nicotine e-cigarettes, nicotine pods and liquid nicotine, are regulated as Schedule 4 (prescription only) medicines. Consumers require a prescription for all purchases of nicotine vaping products.
5. There are currently no nicotine vaping products approved by the TGA registered in the Register. Medicines that are not in the Register are known as ‘unapproved’ medicines. There are established pathways for consumers to legally access unapproved nicotine vaping products, with a valid medical prescription. The main pathways for Australian pharmacies to dispense unapproved nicotine vaping products are the Authorised Prescriber (**AP**) scheme and Special Access Scheme Category B (**SAS B**).

Advertising of nicotine vaping products

6. The advertising of prescription medicines, including nicotine vaping products, to consumers is generally prohibited in Australia. A number of states and territories also restrict the promotion of vaping devices. However, a pharmacy may, in specified circumstances, advertise to consumers that they are able to dispense nicotine vaping products on prescription.
7. The TGA has granted a legal permission (*Therapeutic Goods (Restricted and Prohibited Representations – Nicotine) Permission (No. 2) 2021* (**the Permission**)) which allows pharmacies and pharmacy marketing groups to advertise (i.e. promote), with conditions, including specified media only, where an individual may obtain nicotine vaping products

with a prescription. In this context 'pharmacy marketing group' is taken to mean the overarching or 'banner' pharmacy group under which pharmacies of that 'brand' operate. The pharmacy marketing group frequently conducts the advertising activities for the individual pharmacies under its 'banner' and is often referred to as the 'pharmacy banner group'.

8. Pharmacies and pharmacy marketing groups must ensure that such advertising is within the terms of the Permission.
9. In addition, information shared between a doctor, pharmacist or nurse and their patient during consultation or treatment is not subject to the advertising rules for therapeutic goods, including the prohibition on advertising prescription medicines. Presenting factual and balanced information about using nicotine vaping products is also unlikely to be considered advertising, depending on the context in which the information is presented.
10. The TGA's guidance, Advertising nicotine vaping products to the Australian public | Therapeutic Goods Administration (TGA) relevantly provides the following:
 - a. *As a general guideline, if the content persuades consumers, for example through the use of promotional terms or language, (or through information that discusses the benefits but not the risks or limitations of evidence), to seek out nicotine vaping products, then it would be considered advertising.*
11. When deciding whether information displayed on a website is an advertisement, the TGA takes into consideration the following factors:
 - a. the context in which the information or activity occurs;
 - b. the audience the information is directed to, what their likely take-out message is and are they likely to consider it to be promotional; and
 - c. the use of non-verbal and unwritten messages (such as pictorial elements). These may be just as important in assessing the communication and can alter the take-out message that viewers receive.
12. The TG Act applies to digital communications channels such as websites, social networking sites, blogs and discussion forums when these are used to promote therapeutic goods. Even when these dissemination tools are not used with the conscious intent to promote therapeutic goods, if this is the likely effect of the material on the reasonable consumer, then the material would be subject to the TG Act.

Correspondence with [REDACTED]

13. On 25 November 2021, the TGA sent a warning letter addressed to you, for the alleged unlawful advertising of nicotine vaping products on the [REDACTED] Website. The warning letter also advised that removal or omission of the word 'nicotine' from an advertisement for a good containing nicotine, and subsequently supplying that good to a person in Australia may constitute supply of a counterfeit therapeutic good which is a criminal offence under section 42E of the TG Act.

14. On the same day, the TGA received an email response from an individual identified as [REDACTED] from [REDACTED] who advised the TGA that they had removed all nicotine vaping products from the [REDACTED] Website.
15. On 3 December 2021, in a phone call to you, a TGA investigator confirmed that some of the products have been removed however, some nicotine vaping products are still present on the [REDACTED] Website and requested the remaining issues be rectified. The TGA investigator specifically requested that you remove the advertising of [REDACTED] products. You confirmed that the [REDACTED] products will be removed. In relation to products that you claimed did not contain nicotine, the TGA investigator advised that products displayed with a nicotine warning label would need to be amended to ensure that it is clear to consumers that there is no nicotine.
16. On 6 December 2021, the TGA observed that sufficient changes were made to the [REDACTED] Website and subsequently sent an email advising you that the case would be closed. The closure email stated that the TGA may review the advertising in the future as part of its compliance monitoring activities.
17. On 23 September 2022, the TGA issued a second warning letter addressed to you regarding the alleged unlawful advertising of NVPs on the [REDACTED] website specifically the advertising of nicotine vaping products that was visible between 17 August 2022 and 7 September 2022.
18. The TGA did not receive a response to the second warning letter, however, a review of the [REDACTED] Website on 1 November 2022 showed further alleged unlawful advertising of nicotine vaping products on the [REDACTED] Website.

Material findings of fact

I make the following material findings of fact.

19. [REDACTED] is a natural person residing at [REDACTED].
20. It is noted that [REDACTED] is also known as [REDACTED].
21. [REDACTED] is the registrant of the [REDACTED] Website in [REDACTED] capacity as a sole trader [REDACTED].
22. The [REDACTED] is currently active and has been registered to [REDACTED] as an individual/sole trader since 15 November 2013.
23. [REDACTED] was the registrant of the [REDACTED] Website in [REDACTED] capacity as a sole trader [REDACTED].
24. [REDACTED] sole trader ABN [REDACTED] is listed on the Terms of Service page of the [REDACTED] Website.
25. The current registrant of the [REDACTED] Website is The Trustee for [REDACTED] Trust.
26. [REDACTED] is the trustee of [REDACTED] Trust [REDACTED].
27. [REDACTED] is an Australian Proprietary Company [REDACTED].

28. [REDACTED] is the sole shareholder of [REDACTED]. There are no appointed directors of [REDACTED].
29. [REDACTED] is an Australian Proprietary Company [REDACTED].
30. [REDACTED] is the sole director and shareholder of [REDACTED].
31. [REDACTED] is a business name registered to [REDACTED].
32. The business name [REDACTED] was registered to [REDACTED] sole trader ABN between 31 March 2016 and 14 November 2022.
33. The business name [REDACTED] has been registered to [REDACTED] since 13 October 2022.
34. The address [REDACTED] is listed on the home page of the [REDACTED].
35. [REDACTED] is leased to [REDACTED].

The [REDACTED] Website prior to the first warning

36. The [REDACTED] Website's home page displayed product tiles of [REDACTED] products under the heading "Best Selling".
37. Clicking on the "Vapes" tab at the top of the home page redirected to a page titled "Vapes" that displayed 22 product tiles including the following:
 - a. [REDACTED]
 - b. [REDACTED]
 - c. [REDACTED]
 - d. [REDACTED]
 - e. [REDACTED]
 - f. [REDACTED]
 - g. [REDACTED]
 - h. [REDACTED]
 - i. [REDACTED]
 - j. [REDACTED]
 - k. [REDACTED]
 - l. [REDACTED]
 - m. [REDACTED]
 - n. [REDACTED]
 - o. [REDACTED]
 - p. [REDACTED]
38. Clicking on the [REDACTED] product tile redirected to the product page. The product image displayed the chemical symbol for nicotine on the packaging.
39. Clicking on the [REDACTED] product tile redirected to the product page for [REDACTED]. A line in the product description stated "Concentration: 50mg/ml".

40. Clicking on the [REDACTED] product tile redirected to the product page. A line in the product description stated “Concentration: 50mg/ml”.
41. Clicking on the [REDACTED] product tile redirected to the product page. A warning label on the product packaging visible in the product image stated, “This Product Contains Nicotine Nicotine is an addictive chemical”. A smaller label on the packaging stated “3PCS/5.0%NIC”.
42. Each product page had a drop-down menu which provides the option to select flavours.
43. After selecting a flavour, the button for “Add to Cart” appeared.
44. Clicking on the “Add to Cart” button prompted a window titled “Added to cart successfully” to appear at the top of the screen and a window that had the text “I am over 18 years old” with a tick-box. A button with the text “Proceed to Checkout” appeared.
45. The “Shipping Policy” page on the [REDACTED] Website stated:
 - a. “Shipping to Australia within 3 to 7 business days”
 - b. “TNT courier For Interstate (Australia Wide)”
46. The “Terms of Service” page stated:
 - a. “NICOTINE WARNING The, e-liquids, herbal cigars, wraps and other similar products distributed by [REDACTED] may contain nicotine, a poisonous and addictive substance”.

The [REDACTED] Website following the first warning

47. On 6 December 2021, following the phone call referred to in paragraph [15], a TGA investigator observed that all products previously advertised as containing nicotine had been removed.
48. Clicking on the “Vapes” tab at the top of the home page redirected to a page titled “Vapes” that displayed 4 product tiles including the following:
 - a. [REDACTED]
 - b. [REDACTED]
 - c. [REDACTED]
 - d. [REDACTED]
49. All other aspects of the [REDACTED] Website remained unchanged.

The [REDACTED] Website prior to the second warning

50. A TGA Investigator recorded the following observations between 17 August 2022 and 5 September 2022.
51. The [REDACTED] Website’s home page displayed product tiles of [REDACTED] products under the heading “Best Selling”.
52. Searching [REDACTED] via the search bar at the top of the home page returned 31 results for

- ██████████ product tiles.
53. Clicking the first ██████████ product tile redirected to the product page for that ██████████ product.
 - a. The product page provided a drop-down menu on the right side of the page under the heading “Nicotine:”. The drop-down menu provided the following nicotine strength options: 0mg, 6mg, 12mg, 18mg.
 - b. When a nicotine concentration was selected from the drop-down menu, the product image changed to the corresponding image with packaging that depicted that concentration.
 - c. The product description stated “NICOTINE: Nicotine Free (0mg) / Low (6mg) / Medium (12mg) / High (18mg)”.
 54. Clicking each successive ██████████ product redirected to the respective product page which contained the same representations as described in paragraph [48].
 55. Clicking the “Vapes” tab at the top of the home page redirected to a page titled “Vapes” that displayed 8 product tiles.
 56. Clicking the ██████████ product tile redirected to the product page. The product image depicted a ██████████ product in the flavour “Apple Peach” with the label “WARNING THIS PRODUCT CONTAINS NICOTINE. NICOTINE IS AN ADDICTIVE CHEMICAL”.
 57. On 7 September 2022, a review of the ██████████ Website showed the “Vapes” tab was no longer visible and all nicotine vaping products had been removed. A search for ██████████ returned no results.

The ██████████ Website following the second warning

58. On 1 November 2022, the “Vapes” page on the ██████████ Website displayed 8 product tiles.
59. Clicking on the product tile for ██████████ redirected to the product page.
 - a. A line in the product description stated, “Nicotine strength 50mg”.
 - b. The product page provided a drop-down menu on the right side of the page under the heading “Choose:”.
 - c. When a flavour was selected from the drop-down menu, the product image changed to the corresponding image for that flavour.
 - d. The product images for “Double Apple Shisha” and “Blackcurrant Cotton Candy” depicted a warning label on the packaging that stated “WARNING This product contains nicotine. Nicotine is an addictive chemical”.
60. After selecting a flavour, the button for “Add to Cart” appeared.

61. A reasonable consumer who clicked on the “Add to Cart” button would be prompted with a window titled “Added to cart successfully” and was able to tick “I am over 18 years old” and click the “Proceed to Checkout” button.
62. All other products on the “Vapes” page did not disclose whether they contained nicotine.

The [REDACTED] Website following the second warning

63. On 14 November 2022, alleged unlawful advertising of nicotine vaping products was identified on the [REDACTED] Website.
64. The “Shipping Policy” page stated:
 - a. “Direct Delivery in Melbourne”
 - b. “Courier For Interstate, (Australia Wide)”
 - c. “Free Shipping For Orders Over \$200”
65. The “Terms of Service” page stated:
 - a. “[REDACTED] is noted as the supplier”
66. The [REDACTED] Website’s home page displayed the [REDACTED] logo under the section titled “OUR VENDORS”.
67. Searching [REDACTED] via the search bar at the top of the home page returned 50 [REDACTED] [REDACTED] product tiles. The product tiles depicted the [REDACTED] product with the outer packaging.
68. Clicking on the first [REDACTED] product tile redirected to the product page for that [REDACTED] product.
 - a. The product page provided 4 buttons on the right side of the page under the heading “Nicotine:” providing 4 nicotine strength options: 0mg, 6mg, 12mg, 18mg.
 - b. When a nicotine concentration was selected, the product image changed to the corresponding image with packaging that depicted that concentration.
 - c. The product description stated “NICOTINE: Nicotine Free (0mg) / Low (6mg) / Medium (12mg) / High (18mg)”.
69. Clicking each successive [REDACTED] product page redirected to the respective product pages which contained the same representations as described in paragraph [63].
70. The “All Categories” tab at the top of the home page brings up a window which shows a link to “Vapes” under the category “Shisha & Vapes”. Clicking the link to “Vapes” redirected to the “Vapes” webpage.
71. The “Vapes” webpage displayed product tiles for 197 products. The product tiles depicted disposable vaping products but had no product titles.
72. Clicking the third product tile that depicted a [REDACTED] product redirected to the product page for [REDACTED]. The product image

depicted a [REDACTED] product in the flavour “Pink Lemonade” with the label “WARNING: This product contains nicotine. Nicotine is an addictive chemical”. The label also depicted a white circle with the words “5% Nicotine”.

73. On the right side of the [REDACTED] page, a list of “Flavours” is seen below the section titled “Choose:”. When a flavour was selected, the product image changed to the corresponding image for that flavour.
74. After selecting a flavour or a nicotine concentration and clicking the “Login to view price”, a pop-up window appeared with a prompt to enter an e-mail and password as well as the option to create an account.

Reasons for decision

75. My reasons for making the Direction and associated conditions are set out below.

Power to issue Direction

76. Subsection 42DV(1) of the TG Act provides that if, in relation to the advertising of therapeutic goods, the Delegate is satisfied that there has been a contravention of the TG Act or the *Therapeutic Goods Regulations 1990* (**the Regulations**), the Delegate may, in writing, direct a person apparently responsible for advertising the therapeutic goods to do certain specified acts. Those specified acts include ceasing the advertising in question, and ceasing making a particular claim or representation made by the advertising.

You are apparently responsible for the advertising on the Websites.

77. I am satisfied on the basis of paragraphs [19] – [35] that you, [REDACTED], are apparently responsible for the advertising on the [REDACTED] Website and the [REDACTED] Website.
78. I am satisfied on the basis of your phone conversation with a TGA Investigator described in paragraph [15], that you have control of the Websites as the alleged unlawful advertising was subsequently removed from the [REDACTED] Website on or around 6 December 2021 before being re-advertised on the [REDACTED] Website and the [REDACTED] Website in 2022.

The Websites promote the use and supply of nicotine vaping products

79. The [REDACTED] Website and the [REDACTED] Website contained advertisements for nicotine e-liquid and disposable nicotine vaping products, which contained express references to nicotine in the product descriptions and/or the product images as part of the warning labels.
80. The express references to nicotine were found either:
 - a. in the product description on a product page;
 - b. in the product image on a product page as part of the packaging;
 - c. in the product image on a product page as part of a warning label on the packaging; or
 - d. in the section of a product page titled ‘Nicotine’ with an associated drop-down menu or selection buttons for various nicotine concentrations.

81. On the basis of paragraphs [40] and [59], I consider that a reasonable consumer would understand the ‘Shipping Policy’ pages on the Websites to mean that goods purchased from the Websites would be delivered to a nominated address Australia wide.
82. I also note that the products advertised on the Websites were able to be viewed by consumers across Australia, as you are based in New South Wales and a TGA Investigator was able to view the Websites in the Australian Capital Territory.
83. On the basis of paragraphs [37] – [38] and [55] – [56], I consider that a reasonable consumer would understand that the ‘Add to Cart’ option means that the advertised goods could have been purchased by Australian consumers.
84. Albeit the price of the [REDACTED] products were not advertised on the [REDACTED] Website as per paragraph [69], I still consider that a reasonable consumer would understand that if an account was created, the products would be able to be purchased and shipped to their nominated address Australia wide.
85. For the reasons set out above, I am satisfied that the material on the [REDACTED] Website and the [REDACTED] Website was directly promoting the use and supply of nicotine vaping products, therefore constituted ‘advertising’ within the meaning of the TG Act.

The advertising contravened subsection 42DL(2) of the TG Act

86. Subsection 42DL(2) of the TG Act, being a criminal offence in Part 5-1 of the TG Act, provides that a person contravenes the subsection if:
 - a. *the person:*
 - i. *advertises, by any means, therapeutic goods; or*
 - ii. *causes the advertising, by any means, of therapeutic goods; and*
 - b. *subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.*
87. Subsection 42DL(10) of the TG Act applies to an advertisement if it, relevantly, refers to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference required by a government or government authority.
88. I am satisfied that nicotine vaping products are included in Schedule 4 to the current Poisons Standard as a prescription-only medicine. I am further satisfied that the references to nicotine in the advertising on the Websites were not required by a government or government authority.
89. Subsection 42DL(12) of the TG Act applies to an 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
90. There are currently no nicotine vaping products entered in the Register.

91. For the reasons set out above, I am satisfied that you, by posting the advertising on the Websites, promoted the use and supply of therapeutic goods not entered in the Register. I am further satisfied that subsections 42DL(9) and 42DL(12) of the TG Act apply to the advertising on the Websites.
92. Having regard to the above, I am satisfied that the advertising contravened subsection 42DL(3) of the TG Act, where subsections 42DL(9) and 42DL(12) apply, and that you are apparently responsible for the advertising.
93. Given the continued alleged unlawful advertising on the Websites following multiple warnings and apparent attempt to avoid detection by moving the advertising of [REDACTED] [REDACTED] products to the [REDACTED] Website, I have decided to use my power under section 42DV(1) of the TG Act to direct you to cease advertising.
94. Accordingly, I direct you to:
 - a. **cease** all advertising of nicotine vaping products, including but not limited to the advertising on the websites at the Uniform Resource Locators (URLs) [REDACTED] and [REDACTED].
95. I make the Direction set out above together with the following conditions:
 - a. **complete** each action you are directed to carry out, including as required by these conditions, by **5pm on 5 business days from date of this notice**;
 - b. **cease**, for the period of 3 years, all advertising referred to at paragraph [89] above; and
 - c. **email** evidence of your compliance with this **Direction** to the email address listed on the first page of this Direction by **5 business days from date of notice**.
96. Noting the public health issues arising from advertising of this kind, I have decided to allow you until **5pm, 5 business days from the date of this notice** to comply with this Direction.
97. Failure to comply by that time will lead to further action by the TGA, which may include progressing a brief to the Commonwealth Director of Public Prosecutions or the commencement of proceedings seeking declaratory relief, injunctions and pecuniary penalties for contraventions of subsection 42DL(2) of the TG Act (as noted above), and section 42DX of the TG Act, in relation to your failure to comply with this Direction.
98. The TGA further reserves its rights, if it becomes necessary to do so, to seek an urgent interim injunction to secure the removal of the advertising from the Websites.

Attachment B

EFFECT OF NOT COMPLYING WITH THIS DIRECTION

Contravening a direction or a condition of a direction made under subsections 42DV(1) or (2) of the TG Act, is a criminal offence under section 42DW of the TG Act, and may give rise to civil penalties under section 42DX, which could lead to court action against you.

The TGA could also issue you an infringement notice as an alternative to these actions.

In conjunction with pursuing civil or criminal sanctions, the TGA may also seek an injunction from a Federal Court to immediately cease your advertising.

The TGA can also alert the public to its concerns about particular therapeutic goods advertising through the use of public warning notices (section 42DY).

Please Note:

Subsection 42DV(6) states

As soon as practicable after giving a direction under subsection (1) or (2), the Secretary **must** cause the direction to be published on the Department's website.

Attachment C

Therapeutic Goods Act 1989

Part 5-1—Advertising and generic information

Division 6 – Directions about advertising or generic information

42DV Directions about advertising or generic information

Advertising

- (1) If, in relation to the advertising of therapeutic goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the therapeutic goods, or for causing the advertising of the therapeutic goods, to do one or more of the following:
 - (a) cease the advertisement;
 - (b) make a retraction;
 - (c) make a correction;
 - (d) recover any advertisement that is still in circulation;
 - (e) destroy the advertisement;
 - (f) cease making a particular claim or representation made by the advertisement.

Generic information

- (2) If, in relation to the dissemination of generic information about therapeutic goods to the public or a section of the public, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following:
 - (a) withdraw the generic information;
 - (b) make a retraction;
 - (c) make a correction;
 - (d) recover any generic information that is still in circulation;
 - (e) destroy the generic information;
 - (f) cease making a particular claim or representation made by the generic information.

Conditions

- (3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.
- (4) Without limiting subsection (3), the conditions may relate to one or more of the following:
 - (a) the period for doing a thing the subject of the direction;
 - (b) in relation to the making of a retraction or correction, either or both of the following:
 - (i) the form and manner of the retraction or correction;

- (ii) the period for which the retraction or correction must be made publicly available;
- (c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

- (5) A direction under subsection (1) or (2) is not a legislative instrument.

Publication

- (6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

42DW Offences—contravening direction under section 42DV

- (1) A person commits an offence if:
 - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2) in relation to therapeutic goods; and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction; and
 - (d) either:
 - (i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
 - (ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and
 - (e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

- (2) A person commits an offence if:
 - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

- (3) A person commits an offence if:
 - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

- (4) An offence against subsection (3) is an offence of strict liability.

42DX Civil penalty for contravening direction under section 42DV

A person contravenes this section if:

- (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

Therapeutic Goods (Restricted and Prohibited Representations - Nicotine) Permission (No. 2) 2021

Schedule 1 – Permission

Column 2 – Representation

a representation that is:

- a. *[insert name of community pharmacy or community pharmacy brand]* can dispense nicotine prescriptions; or
- b. prescription nicotine is available *[(here) or (at) (insert name of community pharmacy or community pharmacy brand)]*; or
- c. nicotine prescribed for smoking cessation can be dispensed at *[insert name of community pharmacy or community pharmacy brand]*;

but may be modified in accordance with one or more of the following:

- d. the name of the community pharmacy mentioned in paragraph (a), (b) or (c) may include the location of that pharmacy;
- e. the name of the community pharmacy brand mentioned in paragraph (a), (b) or (c) may be substituted with a reference to *[select pharmacies]* with or without a reference to the name of the community pharmacy brand;
- f. the reference to the word nicotine in paragraph (a), (b) or (c) may be substituted with one or more of the following:
 - i. liquid nicotine;
 - ii. nicotine pods;
 - iii. nicotine e-cigarettes

Column 3- Advertisement

an advertisement about the therapeutic goods made by the relevant person mentioned in column 2, through one or more of the following media under the direct control of that person:

- a. a single tile on a website that is:
 - i. text only; and
 - ii. published using no more than three colours or shades in total;
- b. a post on social media that is:
 - i. text only; and
 - ii. published using no more than three colours or shades in total;

- c. a poster displayed inside, or immediately outside, the premises of a community pharmacy that:
 - i. does not exceed 594 mm by 420 mm (A2 size); and
 - ii. is text only; and
 - iii. is published using no more than three colours or shades in total;
- d. a single tile in other print media, including a catalogue that:
 - i. does not exceed 50 mm by 50 mm; and
 - ii. is text only; and
 - iii. is published using no more than three colours or shades in total

Column 4 – Therapeutic Goods

a nicotine vaping product, and any associated vaping device that is a medical device used exclusively for the vaporisation and administration by inhalation of the nicotine vaping product

Column 5 – Conditions

the advertisement must not:

- a. be transmitted by radio or television, including pay and streaming services; or
- b. be promoted:
 - i. by social media influencers or brand ambassadors; or
 - ii. through social media platforms using paid promotion; or
 - iii. on billboards; or
 - iv. in cinema advertising; or
- c. contain pictures or images of the therapeutic goods; or
- d. contain trade names, trademarks or logos relating to the therapeutic goods; or
- e. contain references to flavours

Attachment D

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the TG Act. Under section 60, a person whose interests are affected by a ‘reviewable’ initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the TG Act, the Minister (or the Minister’s delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister’s delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled “<insert person/company name> - **Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***” and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: ‘**Minister.Butler.DLO@health.gov.au**’ and copied to
‘**decision.review@health.gov.au**’

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health and Aged Care**
Suite MG 50
c/- Parliament House
CANBERRA ACT 2600

If upon reconsideration by the Minister (or the Minister's delegate), you are dissatisfied with that decision, you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision (see the *Administrative Appeals Tribunal Act 1975* (AAT Act)).

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the TG Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.