



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

**DIRECTION UNDER SECTION
42DV**

**ISSUED TO: MDNE Enterprises Pty
Ltd ACN 654 012 156 and [REDACTED]
[REDACTED] DOB [REDACTED]**

ON: 20 September 2022

**ABOUT: Advertising nicotine vaping
products for use and supply to
Australian consumers**

BY:

**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:
02 [REDACTED]

Contact Officer Email:
[REDACTED]@health.gov.au

DIRECTION ABOUT AN ADVERTISEMENT

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

TO: MDNE Enterprises Pty Ltd
ACN 654 012 156

[REDACTED]

AND

[REDACTED]

By post and by email: [REDACTED]@gmail.com, [REDACTED]@gmail.com,
[REDACTED]@ [REDACTED].com.au, [REDACTED]@ [REDACTED].com.au

I, a 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 has been a contravention of the *Therapeutic Goods Act 1989* (**the Act**) in relation to the advertising of therapeutic goods; namely, nicotine vaping products

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 to Australians, including but not limited to the advertising on your website at the following Uniform Resource Locators (**URLs**):
 - a. [www.\[REDACTED\].com.au](http://www.[REDACTED].com.au) (the [REDACTED] **Website**);
 - b. [www.\[REDACTED\].com.au](http://www.[REDACTED].com.au) (the [REDACTED] **Website**);
 - c. [www.\[REDACTED\].com.au](http://www.[REDACTED].com.au) (the [REDACTED] **Website**);
 - d. [www.instagram.com/\[REDACTED\]](http://www.instagram.com/[REDACTED]); and
[www.instagram.com/\[REDACTED\]](http://www.instagram.com/[REDACTED]) (collectively, the [REDACTED] **Instagram Accounts**)

CONDITIONS

under subsection 42DV(3) of the 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 19 October 2022**; and
- (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 **5pm on 19 October 2022**.

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 Act relevant to the making of this **Direction** 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 unlawful advertisements are set out in **Attachment E**.

Please note, under subsection 42DV(6) of the 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: 20 September 2022

Nicole McLay

signed electronically

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

Attachment A

Introduction

1. This direction concerns the alleged unlawful promotion of the use and supply of nicotine vaping products on websites, and social media in contravention of the *Therapeutic Goods Act 1989* (Cth).

Nicotine vaping products

2. 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 (**ARTG**) that have been approved by the TGA for safety, quality and efficacy.
3. Nicotine vaping products are finished products that contain nicotine (in base and/or salt form(s)) in solutions 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.
4. Nicotine vaping products are considered to be therapeutic goods because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use, specifically for use in ceasing or partially substituting for the consumption of tobacco products (in particular, cigarettes), including for the prevention of diseases, ailments, defects or injuries caused by the use of tobacco.

Regulation of nicotine vaping products

5. 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.
6. There are currently no nicotine vaping products approved by the TGA and registered in the ARTG. Medicines that are not in the ARTG 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**).
7. Pharmacists can dispense a prescription for nicotine vaping products with evidence of an AP or SAS B approval, subject to any applicable state or territory restrictions or requirements. The Pharmaceutical Society of Australia (**PSA**) [Guidelines for pharmacists providing smoking cessation support \(link is external\)](#) (**PSA Guidelines**) describes the professional obligations of pharmacists providing smoking cessation services.

Advertising of nicotine vaping products

8. 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.
9. 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'.
10. Pharmacies and pharmacy marketing groups must ensure that such advertising is within the terms of the Permission.

Advertising under the Act

11. Subsection 3(1) of the Act defines “advertise” ‘in relation to therapeutic goods as including ‘any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design.’
12. This is assessed according to what an ordinary viewer of the advertising material would believe when viewing the material.
13. The Act applies to digital communications channels such as websites, social networking sites, blogs and discussion forums when these are used to promote therapeutic goods.

Material findings of fact

I make the following material findings of fact.

The persons apparently responsible for the advertising on the Websites

14. MDNE Enterprises Pty Ltd (**the Company**) and [REDACTED] were apparently responsible for the [REDACTED] Website and the Instagram accounts associated with it.
15. [REDACTED] was apparently responsible for the [REDACTED] Website, the [REDACTED] Website and the [REDACTED] Website.

The [REDACTED] Website

- a. The [REDACTED] Website was registered with .au Domain Administration Limited by 'MDNE' and ABN 44 654 012 156 was provided in connection with this registration;
- b. ABN 44 654 012 156 was the Australian Business Number associated MDNE Enterprises Pty Ltd;
- c. The registrant contact name was an individual named, [REDACTED] and [REDACTED]@gmail.com was provided as the contact email;
- d. We understand that [REDACTED] resides at [REDACTED] the Company;
- e. Information held by the TGA indicates that a phone number registered to [REDACTED] was apparently used in connection with the [REDACTED] Website;
- f. Information held by the TGA indicates that a bank account registered to [REDACTED] was apparently used in connection with the supply of nicotine vaping products from the [REDACTED] Website;
- g. The 100% shareholder and one of the Directors of the Company is [REDACTED];

The [REDACTED] Website

- a. The [REDACTED] Website was registered with .au Domain Administration Limited by [REDACTED] and ABN [REDACTED] was provided in connection with this registration;
- b. The registrant contact name provided was [REDACTED];
- c. The ABN [REDACTED] was an Australian Business Number associated with [REDACTED]; and
- d. Information held by the TGA indicates that a bank account registered to [REDACTED] was apparently used in connection with the supply of products from the [REDACTED] Website;

[REDACTED] Website

- a. The [REDACTED] Website was registered with .au Domain Administration Limited by [REDACTED] and ABN [REDACTED] was provided in connection with this registration;
- b. The ABN [REDACTED] is an Australian Business Number associated with [REDACTED];
- c. The registrant contact name was [REDACTED], and the email address, [REDACTED]@gmail.com was provided as the contact email. Information

held by the TGA confirms that this email address is also associated with the Company; and

- d. Information held by the TGA indicates that a bank account registered to [REDACTED] was apparently used in connection with the supply of products from the [REDACTED] Website.

Chronology of the unlawful advertising by the Company and [REDACTED]

16. I consider that the primary objective of the Websites was to promote the use and supply of nicotine vaping products.
17. The material on the Websites was publicly accessible.

The [REDACTED] Website

18. On 11 November 2021, the TGA received a report of unlawful advertising via the [REDACTED] Website.
19. The TGA's investigation revealed that the [REDACTED] Website was promoting the use and supply of vaping products, including products which the TGA reasonably believed contained nicotine. The [REDACTED] Website's homepage relevantly included the following:
 - a. A moving banner which consecutively reads as, "Black Friday Sale On Now", "Enough Stock! For a limited time only while stocks lasts... going fast", and "Due to 1st October vape ban on importing vapes in to Australia we are selling as usual until we run out of stock!";
 - b. A listing of the products available for purchase namely, [REDACTED] Vape [REDACTED] 1800 Puffs 6 flavour bundle pack for \$65, [REDACTED] Vape [REDACTED] 1800 Puffs BS for \$15, and [REDACTED] Wholesale Buk Packs Qty 25, 50 and 100 with a starting price of \$225 for a quantity of 25;
 - c. A moving banner including testimonials from what appear to be previous customers. The reviews found in this banner include:
 - i. "Super fast shipping thanks [REDACTED]! I know that Auspost had slight delays but go here in 2 business days! - [REDACTED] K;
 - ii. "Will order more, best vapes!! - [REDACTED] T;
 - iii. Thanks, soo much arrived so fast! - [REDACTED] R; and
 - iv. You are awesome, will definitely buy some more and recommend to all my friends! - [REDACTED] E".
 - d. A section for customers to add their email address in order to be added in the [REDACTED] Website's newsletter; and

- e. A footer menu which includes hyperlinks to, “Search”, “Contact” and “Shipping & Returns”.
20. The product page for the “ [REDACTED] Vape [REDACTED] 1800 Puffs x6 Bundle Pack” includes the following:
- A product picture of [REDACTED] Vapes;
 - The pricing of \$65 next to word SALE; and
 - 20 individual 5 star reviews from previous customers. These reviews included statements and pictures of the products received.
21. The Shipping and Returns webpage states:
- “For all orders placed, we fulfil orders via Auspost from Monday-Friday. Auspost have advised us there will be some slight delays with the impacts of covid-19, but this can be shown on the tracking which we will update you, once we fulfil your order. For any further updates please contact us on our contact form.”*
22. On 23 November 2021, the TGA sent a warning email to [REDACTED]. The warning email requested that [REDACTED] remove the unlawful advertising of the nicotine vaping products from the [REDACTED] Website.
23. On, or about the same day, the TGA Case Officer subscribed to the [REDACTED] Website’s newsletter. The purpose of the subscription was to receive email updates and review the advertising sent by email.
24. On 24 November 2021, the TGA uploaded the contents of the warning email to the [REDACTED] Website’s “Contact Us” form to ensure that it is received.
25. On 26 November 2021, [REDACTED] responded to the warning email stating,
- “Dear [TGA Case Officer] we do not sell actual vapes we sell Vape bumper stickers image attached below of our product and the product description on our website.”* [REDACTED] also attached a picture of what appears to be a bumper sticker.
26. The TGA reviewed the [REDACTED] Website and note that changes were made to the product titles. The words “Bumper Stickers” were added to the product title. The product listing found on the home pages now reads, [REDACTED] Vape [REDACTED] 1800 Puffs 6 flavour bundle pack Bumper Stickers for \$65, [REDACTED] XXL 1800 Puffs BS Bumper Stickers for \$15, and [REDACTED] Wholesale Buk Packs Qty 25, 50 and 100 Bumper Stickers with a starting price of \$225 for a quantity of 25.
27. On 2 December 2021, the TGA Case Officer responded to [REDACTED] informing him that his response of 26 November 2021 has been noted however, the TGA Case Officer considered that given the price for the “bumper stickers”

were identical to the price of the previously advertised vaping products, it is likely that [REDACTED] was advertising and supplying nicotine vaping products. As such, [REDACTED] was given one final opportunity to cease the unlawful advertising and supplying of nicotine vaping products.

28. The TGA Case Officer also put [REDACTED] on notice that he has been educated and warned about the consequences of contravening the Act should he not cease the unlawful conduct.
29. On the same day, at 9:43 AM, [REDACTED] responded to the TGA Case Officer's email stating "*Website has been taken down as of now.*"

The [REDACTED] Website

30. On the same day, at 4:43 PM, the TGA Case Officer received a newsletter from [REDACTED]@[REDACTED].com.au with the subject line "[REDACTED] HUGE STOCK SALE". The email newsletter contained the following:
 - a. A message which reads "SHOP NOW! Buy any 5, get one free. Fast shipping with tracking";
 - b. An image of 22 [REDACTED] disposable vapes lined up in two rows;
 - c. Further four individual images of [REDACTED] disposable vapes with pictures of fruits behind each disposable vape. The images of the fruits behind the disposable vapes are, kiwifruit, Watermelon with ice cubes, grapes, and blackberries. The TGA Case Officer understood these fruit pictures to be the flavours; and
 - d. A message which gives the reader an option to unsubscribe should they no longer wish to receive the newsletter emails.
31. The TGA's investigation revealed that the person apparently responsible for the [REDACTED] Website was [REDACTED] and that [REDACTED] was allegedly unlawfully advertising nicotine vaping products on this new website.
32. The TGA Case Officer understood that the reason the email newsletter referred to in paragraph [30] above was sent to the TGA Case Officer's email address was because [REDACTED] used the data collected from the [REDACTED] Website to set up the Aussievape Website.
33. The [REDACTED] Website's homepage included:
 - a. A large banner which states "NO PRESCRIPTION REQUIRED! As we send from New Zealand straight to you in Australia via Auspost";
 - b. A secondary banner which states, "50% off storewide sale!"; and

- c. Rows of nicotine vaping products including, [REDACTED], [REDACTED] and a [REDACTED] bundle pack.
34. The [REDACTED] Website's "Shop All" tab included a range of nicotine vaping products.
 35. The TGA Case Officer reviewed the product pages and could see that the products were advertised to contain nicotine. An example of a product page included:
 - a. A picture of an [REDACTED] product;
 - b. A product title, "Black berry – [REDACTED]" with the price \$15.00 AUD next to the word SALE;
 - c. The product description which states, "[REDACTED] disposable vape is designed as disposable devices for leisure vaping, made of light SS material & providing comfortable hand feeling. Each device contains 7ml e-liquid of 50mg nicotine, with a battery of 950mAh to keep the device running up to 1800 puffs;
 - d. The [REDACTED] disposable features state that the device's nicotine strength is 5% (50mg); and
 - e. A product warning which states, "This product contains nicotine. Nicotine is an addictive chemical."
 36. On 18 January 2022, the TGA sent a further warning email to [REDACTED]. This warning email put him on notice that the TGA is preparing to take regulatory action against which may include the preparation of the matter for criminal prosecution, or the seeking of civil penalties. This email also referred to the maximum penalty for alleged contraventions of the Act.
 37. On 20 January 2022, the [REDACTED] Website was no longer available to be viewed by the public.

The [REDACTED] Website and the [REDACTED] Instagram Accounts

38. The [REDACTED] Website's homepage included the following:
 - a. The logo for [REDACTED] was located to the centre of the webpage. Below the logo were the tabs, "Do I Need a Prescription?", "Shop All", "[REDACTED]", "[REDACTED]", "[REDACTED]", "[REDACTED]", "Bundles + Deals", "Bulk Orders", and "F.A.Q".
 - b. An artwork of what appears to be a sunset with kangaroos as background with the sentence, "Order from Aus? Don't worry, we have the answers".

- c. A display of nicotine vaping products available to be purchased from the [REDACTED] Website. These are displayed in rows of four products.
- d. The [REDACTED] Website had a section in relation to the legalities of supply of nicotine vaping products and how the business operates. The section is entitled, “How Many Vapes Can I Legally Order Australia?”. This was followed by information provided by [REDACTED] which state:
 - i. “You can order up to 3 months supply of vapes equalling to approximately 50 vapes with one prescription (we don’t require prescription to be sent to us).
 - ii. Prescription? – Prescription or not we will send out your order, we advise having a prescription but if not your order will be sent out as usual.
 - iii. Warranty – We 100% guarantee the quality and authenticity of all our vapes, if they simply do not work unto your standards contact us and we will organise a refund/replacement.
 - iv. Prices – We are Australia’s & New Zealand cheapest and most secure Vaping Business, rest assured our prices are the most competitive in the market.
 - v. Bulk – Want to purchase vapes for resale of to save a lot of money in the long run, and share among friends contact us at [REDACTED]@ [REDACTED].com.au and we will provide pricing.”

39. The TGA reviewed the product pages and could see that the products were advertised to contain nicotine. An example of a product page included:

- a. A picture of an [REDACTED] product;
- b. A product title, “[REDACTED] 3000 puffs Strawberry Kiwi” with the price \$31.95 AUD next to the word SALE;
- c. The product description which states, “[REDACTED] disposable device is an immaculately classy device with its metal body and ergonomic mouthpiece, it boasts 3500 + Puffs with some of the most fruity and authentic tasting flavors. No need to charge, pre-filled, no need for messy refills, easy to use, lots of delicious flavours to [choose]; and
- d. A bullet point of what the TGA Case Officer understood to be the product features. The nicotine bullet points states, “Nicotine: 5% Nicotine Salt”.

40. The [REDACTED] Website was also advertising to wholesalers of nicotine vaping products.

41. The [REDACTED] Instagram Accounts contained unlawful advertising of nicotine vaping products. An example of the advertising included:
- a. A picture containing two rows of ten individual [REDACTED] products. The packaging has a warning label which states, “WARNING this product contains nicotine. Nicotine is an addictive chemical.”; and
 - b. An Instagram caption which states, “Shop now at [REDACTED] (link in bio) [REDACTED] australia # [REDACTED] vape [REDACTED] - - AU wide shipping”.
42. I consider that the Company and [REDACTED] appeared to use Instagram influencers to promote the use and supply of nicotine vaping products on the Websites. I understand that this involved the Instagram influencers creating video or photo content of them using the nicotine vaping products, posting the video or photo content via an Instagram post or an Instagram story, tagging the [REDACTED] Instagram Accounts, and the [REDACTED] Instagram Accounts then reposting the content.
43. The Instagram influencers include:
- a. @ [REDACTED]
 - b. @ [REDACTED]
 - c. @ [REDACTED]
 - d. @ [REDACTED]
 - e. @ [REDACTED]
 - f. @ [REDACTED]
44. It is noted that some of the Instagram influencers also had their own discount codes to share with their followers. The TGA understands that this is a common social media marketing practice to drive more sales and followers to the business.
45. On 28 April 2022, the TGA sent the Company and [REDACTED] a cease-and-desist letter requesting the Company and [REDACTED] immediately cease and desist from unlawfully advertising nicotine vaping products on the [REDACTED] Website and the [REDACTED] Instagram Accounts by 5:00 PM, 29 April 2022.
46. This cease-and-desist letter set out [REDACTED]’s compliance history with the TGA noting that the [REDACTED] Website (and its associated Instagram Accounts) was the third website for which alleged unlawful advertising of nicotine vaping products was identified. The cease-and-desist letter also informed the Company and [REDACTED] that the TGA is concerned about their attitude to regulatory compliance given his compliance history with the TGA.

47. The cease-and-desist letter also informed the Company and [REDACTED] that the TGA was strongly considering taking enforcement action against them consistent with the TGA's approach to compliance and enforcement.
48. The TGA did not receive a response to this cease-and-desist letter.
49. On 29 April 2022, the TGA noted that the [REDACTED] Instagram Account found on [www.instagram.com/\[REDACTED\]](http://www.instagram.com/[REDACTED]) was no longer available to be viewed by the public. However, a [REDACTED] Instagram Account could be found on [@\[REDACTED\]](http://www.instagram.com/[REDACTED]) (“@[REDACTED]”).
50. The [REDACTED] Instagram Accounts are identical in nature and the TGA Case Officer understood that the Company and/or [REDACTED] amended the username by removing the underscore (_) between the words [REDACTED] and aus.
51. The TGA viewed @ [REDACTED] and found the following announcements on the Instagram story:
 - a. “Due to some issues we are officially closing down. We will be taking order till end of business day tomorrow and process and send them off as usual. All stock on our website has been reduced to clear. Please remember to make the purchases ASAP and purchase as much as possible as these prices will never be [happening] ever. DM us for large order. Pricing can do asap – *link inserted* [www.\[REDACTED\].com.au](http://www.[REDACTED].com.au)”;
 - b. “[REDACTED] are now \$15 each that's unheard off shop now going fast *link inserted* [www.\[REDACTED\].com.au](http://www.[REDACTED].com.au)”;
 - c. “If you want to place a larger order DM us and we will provide qtys”;
 - d. “We are officially closing down end of business day today everything has been discounted heavily checkout now everything is going fast”.
52. On 31 May 2022, @ [REDACTED] was no longer available to be viewed by the public.
53. On 4 May 2022, the [REDACTED] Website was also no longer available to be viewed by the public.

Notice under 42DR of the Act

54. On 28 April 2022, the TGA issued the Company with a notice under section 42DR of the Act (**the 42DR Notice**). The purpose of the notice was to require the Company to give the Secretary specified information relating to the unlawful advertising on the [REDACTED] Website and the [REDACTED] Instagram Accounts.

55. The 42DR Notice specifically sought for information in relation to the 61 individual nicotine vaping products advertised on the [REDACTED] Website and the [REDACTED] Instagram Accounts. The information related to:
- a. whether each of the goods were advertised on the [REDACTED] Website and the [REDACTED] Instagram Accounts respectively from 1 October 2021;
 - b. if the goods were not advertised on the [REDACTED] Website and the [REDACTED] Instagram Accounts between 1 October 2021 and the date of the 42DR Notice, the date on which the goods were first advertised on the [REDACTED] Website and/or the [REDACTED] Instagram Accounts respectively;
 - c. whether the goods continue to be advertised on the [REDACTED] Website and/or the Instagram Accounts as of the date of the 42DR Notice;
 - d. if the goods are no longer being advertised on the [REDACTED] Website and/or the Instagram Accounts as at the date of the 42DR Notice, the date on which the advertisement of the goods on the [REDACTED] Website and/or Instagram Accounts ceased; and
 - e. if, at any time, the goods were temporarily not advertised on the [REDACTED] Website and/or the Instagram Accounts, the date(s) on which that occurred and the period of time for which the NVP was not advertised.
56. The 42DR Notice also required the Company to provide a copy of all correspondence by any employee, director or agent of the Company relating to the advertisement of any goods on the [REDACTED] Website and the Instagram Accounts, including but not limited to letters (expressly including correspondence with Instagram influencers).
57. On 24 May 2022, the TGA received an email from, [REDACTED]@gmail.com. The email states:

“To whom it may concern, please stop emailing us as we do not hold any online health businesses. We have also received a letter to our address MDNE Enterprises which is not associated with the organisation in question.”

Correspondence with the Advertisers in relation to this direction

58. On 27 July 2022, the TGA sent a letter to the Company and [REDACTED] in his capacity as a director for the Company. The purpose of the letter was inform the Company and [REDACTED] that a delegate of the Secretary of the Department of Health and Aged Care was considering issuing both entities with a Direction under section 42DV of the Act as well as giving both entities infringement notices under 42YK of the Act.

59. The Company and [REDACTED] were given 14 days to provide any representations, including why the direction and the infringement notices should not be issued.
60. On the same day, the TGA sent a separate letter to [REDACTED] in his personal capacity and his responsibility for the [REDACTED] and the [REDACTED] Websites. The purpose of the letter was inform [REDACTED] that a delegate of the Secretary of the Department of Health and Aged Care was considering issuing him with a Direction under section 42DV of the Act as well as giving him infringement notices under 42YK of the Act.
61. [REDACTED] was given 14 days to provide any representations, including why the direction and the infringement notices should not be issued.
62. On the same day, the TGA received an email response from [REDACTED]@gmail.com. The TGA understood this response to be from the Company as it was responding directly to the email sent to the Company. The email states:
- “This vape business you are referring to has been ceased as operator did not understand or was educated on the matters of the legality and regulations including the prescription use all the orders had been cancelled the website and page was very new, all pages and website address noted do not exist. No orders had been processed or delivered as no prescriptions had been sent. The objective of the site was to connect overseas website and legal importation relating to the rules under the tga vape importation regulation.”*
63. On 4 August 2022, the TGA attempted to call the two phone numbers.
64. On 9 August 2022, the TGA sent an email reminder to [REDACTED] reminding him that his opportunity to make any representations as to why the TGA should not issue him with a direction and/or infringement notices is due on 10 August 2022.
65. On the same day, the TGA received an email from [REDACTED]@gmail.com. The email states:
- “A submission was sent to you previously these companies are not existent and have all been erased as outlined in previous emails. This has been done so a long time ago.”*
66. The TGA understood this response to be from [REDACTED] as it was responding directly to the email sent to [REDACTED]
67. The TGA understood the email responses referred to in paragraphs [62] and [65] above collectively form part of the Company and [REDACTED]s submission as

to why a Direction under 42DV of the Act and infringement notices under 42YK of the Act should not be issued.

Reasons for decision

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

Power to issue Direction

69. Subsection 42DV(1) of the Act provides that if, in relation to the advertising of therapeutic goods, the Delegate is satisfied that there has been a contravention of the Act or 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 advertisement in question, and ceasing making a particular claim or representation made by the advertisement.

The Company and [REDACTED] are apparently responsible for the Websites

70. I am satisfied that the Company and [REDACTED] are apparently responsible for the Websites for the following reasons:
- a. The Company was the registrant of the domain for the [REDACTED] Website;
 - b. The posts, captions, and biography found on the [REDACTED] Instagram Accounts contain links to the [REDACTED] Website;
 - c. [REDACTED] was the registrant of the domains for the [REDACTED] and the [REDACTED] Websites;
 - d. The TGA received correspondence from [REDACTED] confirming that the Websites have been closed. I refer specifically to the emails referred to in paragraphs [25] and [29];
 - e. The TGA received submissions from the Company and [REDACTED] and
 - f. The email address, [REDACTED]@gmail.com is associated with both the Company and [REDACTED].

The Websites promote the use and supply of nicotine vaping products

71. I am satisfied that the Websites promoted the use and supply of nicotine vaping products. This is primarily because the Websites and associated social media were clearly intended to facilitate trade and commerce in Australia involving nicotine vaping products.

72. The advertising found on the [REDACTED] Website contained advertisements for which the nicotine content were not specified in the advertisements of the goods. However, the TGA held a reasonable belief that the goods contained nicotine.
73. The advertising found on [REDACTED] Website contained express references to nicotine.
74. The advertising found on the [REDACTED] Instagram Accounts contained express references to nicotine.
75. I am satisfied that the representations on the Websites would appear to a reasonable consumer to be promoting the use or supply of nicotine vaping products and therefore amounted to ‘advertising’ within the meaning of that term under the Act.
76. I am further satisfied that the Websites were intended to promote the use or supply of nicotine vaping products for the following reasons:
 - a. The Websites were publicly available to Australian consumers’
 - b. Information found on the [REDACTED] Website informed customers that the nicotine vaping products will be available for purchase regardless of whether the customer provides the business with a prescription;
 - c. The [REDACTED] Website acknowledged the legal changes in supplying nicotine vaping products within Australia and informed customers that despite these changes, they will continue to supply until stock is exhausted;
 - d. The [REDACTED] Website included a description of the nicotine vaping products which specify the nicotine strength percentage; and
 - e. Social media posts found on the [REDACTED] Instagram Accounts include social media influencer collaborations which specifically includes personalised discount codes for consumers to use when purchasing from the [REDACTED] Website.

The Websites being an advertisement contravened subsection 42DLB(1) of the Act

77. Subsection 42DLB(1) of the Act, being a civil penalty provision in Part 5-1 of the 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 (2), (3), (4), (5), (6), (7), (8) or (9) applies to the advertisement.*

78. Contraventions of subsection 42DLB(1) of the Act may result in the imposition by a court of civil penalties of up to 50,000 penalty units for a body corporate. Noting that the current value of a penalty unit is \$222, this amounts to a maximum penalty of \$11.1 million.
79. Subsection 42DLB(7) of the 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.
80. I am satisfied that nicotine is a substance included in Schedule 4 to the current Poisons Standard as a prescription only medicine when used in preparations for human use, except 'in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations; or in tobacco prepared and packed for smoking'.
81. I am satisfied that the nicotine vaping products promoted on the Websites were promoted for human use, and are not 'preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations; or in tobacco prepared and packed for smoking'.
82. I am further satisfied that the references to nicotine on the Websites were not required by a government or government authority.
83. Consequently, I am satisfied that subsection 42DLB(7) of the Act applies to the Websites.
84. Subsection 42DLB(9) of the 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 authority).

Conclusion

85. Having regard to the above, I am satisfied that the Websites contravened subsection 42DLB(1) of the Act (where subsection 7 and subsection 9 of the Act apply), and that MDNE Enterprises Pty Ltd and [REDACTED] were the persons apparently responsible for advertising the goods.
86. I have further concluded, having regard to the background to this matter as set out above that it is necessary and appropriate to direct you to cease advertising nicotine vaping products. On the basis of the background of this matter, and most notably the attitude to compliance; I cannot be confident that future unlawful advertising is not going to occur in the future.

87. I therefore make the Direction set out above together with the associated conditions. I have decided to allow you until **5pm, 19 October 2022**.
88. 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 42DLB of the Act (as noted above), and section 42DX of the Act, in relation to your failure to comply with this Direction.
89. 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 Websites.

Attachment B

EFFECT OF NOT COMPLYING WITH THIS/THESE DIRECTIONS

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

The TGA could also give 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 advertisements or generic information

42DV Directions about advertisements or generic information

Advertisements

- (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 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 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 Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.