



**Australian Government**  

---

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

***THERAPEUTIC GOODS ACT 1989***

---

**DIRECTION UNDER SECTION 42DV**

**ISSUED TO: 13 Vape Pty Ltd ACN 652  
404 263 as trustee for 13 Vape  
Discretionary Trust and [REDACTED]  
[REDACTED]**

**ON: 1 July 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:**  
[REDACTED]

**Contact Officer Email:**  
[REDACTED] [@tga.gov.au](mailto:[REDACTED]@tga.gov.au)

**DIRECTION ABOUT AN ADVERTISEMENT**

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

TO: 13 Vape Pty Ltd  
ABN 82 744 583 729  
C/- [REDACTED]  
[REDACTED]  
Indooroopilly QLD 4068  
AND

[REDACTED]

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

**DIRECT** you, as the persons apparently responsible for the advertising or for causing the advertising of the Goods, to:

1. **Cease** all advertising of the Goods to Australians, including but not limited to the advertising on your websites at the following Uniform Resource Locators (**URLs**):

- a. [REDACTED]  
[REDACTED]  
[REDACTED]

**(the Websites)**

This includes ceasing representing material on the website in such a way that is promoting the use and supply of nicotine vaping products, as a class of therapeutic goods. As such you are directed to:

- A) cease using references in the URL of the Website or any related or future URL to ‘vape’ or any variation of the word such as ‘vaping’, in conjunction with words ‘prescription’, ‘medical’, ‘pharmacy’, or any variation of these words such as script.
- B) cease using references in the trading name of 13 Vape Pty Ltd as trustee for 13 Vape Discretionary Trust ABN and [REDACTED] or any related or future trading name or business venture to ‘vape’ or any variation of the word such as

‘vaping’, in conjunction with words ‘prescription’, ‘medical’, ‘pharmacy’, or any variation of these words such as script.

- C) Cease providing unbalanced information about nicotine vaping as a smoking cessation treatment option, including on the following URLs:
- a. [REDACTED]
  - b. [REDACTED];
  - c. [REDACTED]

### 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 29 July 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 29 July 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 alleged unlawful advertising is reproduced at **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: 1 July 2022

Nicole McLay

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

## Attachment A

### Introduction

1. There are two substantive issues that are the subject of this Direction:
  - a. The first is the direct advertising of nicotine vaping products for purchase by consumers; and
  - b. The second is that the Websites promote the use and supply of nicotine vaping products as a class of therapeutic goods, by directing consumers to use nicotine vaping products in connection with their smoking cessation as opposed to promoting health services relating to smoking cessation in which nicotine vaping is one of many options that **may** be considered by the relevant health practitioner in providing the health service.
2. The TGA is concerned with both of the above classes of alleged unlawful advertising of nicotine vaping products.

### Background

#### *Nicotine vaping products*

3. 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.
4. 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.
5. 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*

6. Since 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.
7. There are currently no nicotine vaping products approved by the TGA 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**).

8. 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*

9. 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.
10. 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'.
11. Pharmacies and pharmacy marketing groups must ensure that such advertising is within the terms of the Permission.
12. 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.
13. The TGA's guidance, [Advertising nicotine vaping products to the Australian public | Therapeutic Goods Administration \(TGA\)](#) (the **NVP Guidance**) 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.*

14. The TGA does not regulate the advertising of health services. However, if information released to the public intends (from the reasonable consumer’s point of view) to directly or indirectly promote the use or supply of a therapeutic good then the TGA is likely to consider it to be advertising and it must meet legislative requirements as set out in the Act and the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code)*.
15. The NVP Guidance also relevantly provides that a person “**must not** refer, either expressly or by implication, to nicotine vaping products in:
  - a. the company, business or trading name;
  - b. any other promotional material relating to your health service or business.

This includes using an abbreviation, acronym, synonym or colloquial name for nicotine vaping products or a particular nicotine vaping product (e.g. 'nicotine e-cigarette', 'nicotine e-liquid' or 'nicotine vape juice') and any other reference, including images, that is likely to draw a consumer's mind to a nicotine vaping product.”

#### *Advertising under the Act*

16. 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.’
17. This is assessed according to what a reasonable consumer viewing the advertising material would believe when viewing the material.
18. 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 consumers receive.
19. The Code specifies the requirements for advertisements to ensure that advertisements of therapeutic goods:
  - a. promote the safe and proper use of therapeutic goods;
  - b. are ethical and do not mislead or deceive consumers or create unrealistic expectation about the performance of the therapeutic goods; and
  - c. support informed health care choices.

20. The Act and the Code apply 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 Act and the Code.

### **Correspondence with the Advertiser(s)**

21. On 5 April 2022, the TGA contacted 13 Vape Pty Ltd through a telephone call. The purpose of the phone call was to ascertain whether or not [REDACTED] was a pharmacy. A summary of this phone call is found at paragraphs [95] to [97].
22. On 11 April 2022, the TGA sent 13 Vape Pty Ltd a letter requiring 13 Vape Pty Ltd to cease and desist from advertising nicotine vaping products on [REDACTED] (**the main website**).
23. On the same day, the TGA also sent a proposed direction notice under section 42DV of the Act to 13 Vape Pty Ltd and the executive officer inviting submissions and/or comments in relation to the proposed direction. The proposed direction notice addressed, amongst other things the two substantive issues outlined at paragraph [1] above.
24. On 12 April 2022, the executive officer confirmed receipt of the letter as well as the proposed direction notice through a telephone call to the case officer.
25. On the same day, the executive officer sent an email confirming that the direct advertising of nicotine vaping products had been removed from the main website and indicated that it was ‘unfair’ that the proposed direction notice was directing 13 Vape Pty Ltd to cease trading using the word ‘vape’.
26. Later that day, the case officer received a telephone call from the executive officer. The executive officer submitted that he did not agree with word ‘vape’ being a colloquial reference to nicotine vaping as it is also a colloquial reference to non-nicotine vapes including vaping devices.
27. On 22 April 2022, the executive officer made a submission on behalf of the company, and themselves in relation to the proposed direction. The submission was as follows:

*“Thank you for the letter regarding the purpose direction.*

*We would like to firstly apologise and have amended our website to remove any direct advertising issues as per the TGA Guidelines.*

*Please see below the response to the purpose direction, a purpose solution and a few questions so that we can move forward and close down our business because of our name if required?*

*We would like to keep the name if possible but it's now lawfully right to do so there is not much we can do.*

*We did not realise that the word 'Vape' referred only to a product understood to contain nicotine or that the business name '██████████' would be considered product advertising.*

*We have fixed the website issues that have given rise to this complaint.*

*1a. We will remove all content promoting the use and supply of NVP. Our purpose site will be transform to be factual and balance information about NVP so that it doesn't direct the public towards NVP.*

*1b. The direct advertising of NVP has been removed from the Pharmacy section of our website*

*30. This is the primary objective of most prescription site which also facilitates the supply of NVP*

██████████ – Script & Supply NVP

██████████ – Script & Supply NVP

██████████ - Script only

██████████ - Script & Supply NVP

██████████ - Script only

██████████ - Script only

██████████ – Script only but links to pharmacy to supply ██████████  
only products

██████████ - Script only but mainly for Personal Importation Scheme

██████████ Script only but mainly for Personal Importation Scheme

██████████ - NVP device and products sold at pharmacy's

*46a. The website and business name will now be a education centre / hub for doctors, pharmacist and patients to make well factual and balance information about vaping*

*The word vape in the business name is now only use purely for educational and informational purposes only. Please see below solution.*

*46b. Direct pathway to access nicotine will be removed as per the advertising guidelines*



46c. The new education centre will promote other treatments for smoking cessation as per the guidelines

Purpose solution if possible to keep the name?

New update site would include

- potential side-effects;
- the limited available evidence in relation to the safety or efficacy of nicotine vaping products; or
- possible alternative treatments
- The new site context and language will change to be informative and balance. The context of the information on the site will help doctors, pharmacist, and patients (our audience) obtain balance and factual information about NVP and other NRT such as nicotine patches, gum, lozenges, mouth sprays and inhalators, and some prescription medicines on the ARTG that have been assessed by the TGA for safety, quality and efficiency.

New site would be a digital platform that connects to different services for the public wanting to find information about quit smoking and other NRT.

New updated site will NOT have the booking for script and pharmacy directly on the website. (But will have links to other websites for these services)

Example is

[REDACTED]

[REDACTED]

### Material findings of fact

I make the following material findings of fact.

#### The persons apparently responsible for the advertising

28. The ABN listed on the main website, [REDACTED], is ABN 82 744 583 729. This ABN belongs to the Trustee for 13 Vape Discretionary Trust ABN 82 744 583 729 which was registered on 30 July 2021.
29. 13 Vape Pty Ltd ABN 32 652 404 263 is an Australian Proprietary Company limited by shares which was registered on 29 July 2021.
30. 13 Vape Pty Ltd is the trustee for 13 Vape Discretionary Trust.
31. [REDACTED]  
[REDACTED] and has a (separate) registered ABN being [REDACTED].

32. The business name is “ [REDACTED] ” and is held by ABN [REDACTED]
33. 13 Vape Pty Ltd as trustee for 13 Vape Discretionary Trust and [REDACTED] of 13 Vape Pty Ltd are apparently responsible for the material that appears on the following URLs:
  - a. [REDACTED] (main website)
  - b. [REDACTED] and
  - c. [REDACTED](the Advertisements).
34. The URL, [REDACTED] does not contain any substantial material or Facebook posts.
35. The URL, [REDACTED] does not contain any substantial material or Instagram posts.
36. The business purports to have an “integrated pharmacy” within the business as represented on the website under the frequently asked questions tab.
37. However, the business is not a pharmacy, nor a pharmacy marketing group.
38. The address provided as the business location for [REDACTED] is [REDACTED]  
[REDACTED]

*The main website prior to the proposed direction*

39. The primary objective of the main website was to provide nicotine vaping prescriptions for patients to obtain nicotine vaping products.
40. The process for obtaining a prescription for nicotine vaping products was depicted on the homepage under “How it’s done” and was summarised as follows:
  - a. “Book an appointment” – where a consumer books an appointment with [REDACTED] [REDACTED] to schedule a telephone consultation with a doctor;
  - b. “Have a chat with our doctors” – where a consumer speaks to a doctor to receive advice on their “quit-smoking goals”; and
  - c. “Delivered direct to you” – where a consumer then receives the prescription via email, orders the nicotine vaping products through the main website and have it delivered to their shipping address.
41. The main website facilitated the issuing of the prescription as well as supply of the nicotine vaping product, through its integrated pharmacy, to persons of different states and/or territories in Australia.

42. The Australian public could view the material on the Advertisements.

The amendments made to the main website

43. The main website was amended following the proposed direction. The amendments included:

- a. Amending the main website's banner from stating:
  - i. "Nicotine Prescription and Australia's First Online Nicotine Dispensary Service | Online Doctor Consultation | 12 months scripts \$60 | Call us on [REDACTED]"
  - to
  - ii. "Online Prescription | Online Doctor Consultation | Call us on [REDACTED]"
- b. Changing the nature of the service from
  - i. providing "medical nicotine prescription"
  - to
  - ii. providing "nicotine replacement therapy".
- c. Changing the final stage of the "how it's done" section, by specifically removing the sentence in relation to patients being able to "order [their] product and get it delivered straight to [their] door.
- d. Amending the statement about [REDACTED] committed to assisting its patients in quitting smoking through **nicotine vaping products** so it now reads as "committed to assisting its patients in quitting smoking through **Nicotine Replacement products**".
- e. Adding a tab called "Learning Centre".
- f. Adding reviews under the "Success Stories" tab.

The current main website

44. The current main website appears to continue to facilitate the transaction between a medical practitioner, patient and supplier of nicotine vaping products.
45. The primary objective of the current main website is to provide prescriptions for patients to obtain nicotine vaping products.

46. On 16 May 2022, a case officer conducted a search of the main website to consider how a consumer may access the main website.
47. Open-source searches using the Google search engine for the keywords, “vape quit smoking”, did not return [REDACTED] as a result on the first five pages of Google search results.
48. The following open-source searches provide [REDACTED] as a result on the first page of Google search results:
  - a. ‘[REDACTED]’; and
  - b. ‘nicotine scripts’.
49. The main website’s description visible on Google reads, “[REDACTED] is an Australian based company committed to assisting its patients in quitting smoking through Nicotine Replacement Products.”
50. A consumer clicking on the search result, [REDACTED] URL is directed to the main website. The following is a description of what a consumer could view:
  - a. The centre of the main website is a banner in a dark blue shade containing the words “Online Prescription | Online Doctor Consultation | Call us on [REDACTED] [REDACTED]”
  - b. To the top left-hand side of the main website is what I understand to be the [REDACTED] logo. The logo is what appears to be a capital V in dark blue font colour, an upside-down capital V depicting an A, in a multi-coloured shades of light neon blue, a capital P in dark blue font colour, a capital E in dark blue font colour, and the word “scripts” in lowercase, in a manuscript font and also in dark blue font colour. The logo reads to consumers as [REDACTED]
  - c. To the top centre of the main website is what is understood to be the toolbar. The toolbars are, “Home”, “Pharmacy”, “FAQs” “Contact”, “Success Stories” and “Learning Centre”.
  - d. To the top right-hand side of the main website, there are three icons. These are a magnifying glass, a person, and a shopping bag. The magnifying glass is understood to be the icon for consumers to search the main website. The person is understood to be an icon for consumers to create an account or log in if there is already an account created. The shopping bag icon is understood to be an icon where products are added to cart before checking out.
  - e. To the centre of the main website is an image of a male holding a mobile phone to his ear. He appears to be sitting down with a laptop and a notebook on the desk. This image has a text overlay which states, “Our doctors are ready to help

you. Let us assist you on your quitting journey! Book your consultation today for only \$60.” Under this text is a highlighted box which states, “Book your consultation here”. Clicking this box is a hyperlink which leads consumers to a booking system.

- f. Towards the bottom of the main website, a consumer is presented with what appears to be a summarised three-step method of how the service works. This is located under the “How it’s done” heading. The steps are as follows:
    - i. Book an appointment: where a consumer books an appointment via the process referred to in paragraph [50(e)] above.
    - ii. Have a chat with our doctors: where a consumer speaks to a doctor in relation to their goals of quitting smoking; and
    - iii. Prescription will be email[ed] to you: where [REDACTED] then email the prescription to the consumer.
  - g. The case officer scrolled down from the section described in paragraph [50(f)], there is a heading titled, “About [REDACTED]”. This section provides a summary in relation to the services provided by [REDACTED]. This section notes that [REDACTED] is an Australian based company committed to assisting its patients in quitting smoking through Nicotine Replacement products. This is through providing advice and a tailor-made plan for quitting smoking by prescribing liquid nicotine and other products related to nicotine replacement therapy offerings.
51. The case officer clicked on the “Pharmacy Tab” and a pop-up window appeared. The pop-up window asked whether the case officer was over the age of 18 and was provided with an option to answer “Yes” or “No”. When the case officer clicked “Yes”, the pop-up window disappeared and provided the case officer with an option to purchase the Goods referred to in paragraph [67].
  52. The case officer clicked on the “FAQs Tab” and was met with a series of frequently asked questions. These questions relatively answer questions about how [REDACTED] can assist consumers, questions in relation the prescription provided by [REDACTED], questions in relation to quitting smoking, and questions in relation to vaping.
  53. The case officer scrolled down to the bottom of the “FAQs Tab” there is a call-to-action heading entitled, “Ready to get Started?” combined with a highlighted box which states “Book your obligation free consultation today”. The case officer understood this box to be a hyperlink which leads a consumer to the booking system.
  54. The case officer clicked on the “Contact Tab” and a contact form is visible. This form asks for a consumer’s name, email address, phone number and a section to write the message in.

55. The case officer clicked on the “Success Stories Tab”, the bottom half of the main website shows reviews of consumers who have received a prescription and nicotine vaping products from [REDACTED]. There are six reviews visible, and three out of the six reviews refer directly to the provision of vape prescription and the subsequent provision of vaping products.
56. The case officer scrolled down to the bottom of the “Success Stories Tab” and there is a call-to-action heading entitled, “Ready to get Started?” combined with a highlighted box which states “Book your obligation free consultation today”. The case officer understood this box to be a hyperlink which leads a consumer to the booking system.
57. The case officer clicked on the “Learning Centre Tab” and I was directed to a webpage containing articles in relation to quitting smoking. The heading for these articles are:
  - a. What happens when you quit smoking;
  - b. Nicotine safe handling;
  - c. Nicotine replacement therapy – switch to a smoke-free lifestyle; and
  - d. Vaping in Australia – why did the law change.
58. The case officer navigated back to the homepage and clicked on the “Book your consultation” box and was directed to a booking system via the URL: [REDACTED]. The case officer could view the following:
  - a. On the left was the “appointment details” where a consumer could select a practitioner. A consumer is given the choice to select the “next available” practitioner or is given a selection of five doctors.
  - b. The “Clinic” location is purported to be “[REDACTED]” and the “Landline” is [REDACTED]
  - c. To the right was an option to select the service. The only service available to book is a 10-minute phone consultation for “smoking cessation initial consultation and prescription” for \$60.00.
  - d. The case officer clicked on the service was directed to a weekly calendar view where options to select a time, in ten-minute increments, were available. The case officer understood this to be a selection of booking time for the phone consultation.
  - e. The case officer scrolled down the page and could view a step-by-step guide into how a consumer may obtain a prescription and subsequently nicotine vaping products. The guide is located under the heading, “Quick Guide” and is summarised as follows:

- i. Step One: select the tobacco cessation option.
- ii. Step Two: select a convenient time to speak with our doctors.
- iii. Step Three: fill in your details and you will receive a patient intake form via email.
- iv. Step Four: After receiving your script, proceed to the [REDACTED] pharmacy to select your nicotine products.

#### ***Account Creation on the main website***

59. The case officer sent an email to the advertisers to remind them that on 11 April 2022, the TGA sent a cease-and-desist letter to immediately remove the direct advertising of NVPs on the main website. The case officer also reminded the advertisers that on 12 April 2022, they confirmed the advertising have been removed.
60. On the same day, 13 Vape Pty Ltd responded to the case officer and stated, “*There was update last night and **link came back without a login**. I have removed the link completely out of the website for now. Apologise for this*”.
61. The case officer formed a reasonable suspicion that consumers with a login could view the nicotine vaping products. The case officer registered an account on the main website.
62. To create an account, the main website asks for a consumer’s full name, email address and a password.
63. Once an account was created, the case officer was able to log in as a registered user and was able to view the Pharmacy tab as described on paragraph [67].

#### **Reasons for decision**

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

#### **Power to issue Direction**

65. 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.

13 Vape Pty Ltd as trustee for 13 Vape Discretionary Trust and [REDACTED] apparently responsible for the Advertisements:

66. I am satisfied based on paragraphs [28] – [32] that 13 Vape Pty Ltd as trustee for 13 Vape Discretionary Trust and its executive officer, [REDACTED] are apparently responsible for the Advertisements.

The Goods are therapeutic goods

67. The Goods that were found under the tab “Pharmacy” were advertised as follows:

- a. Nicotine concentrate 100mg/ml 100ml bottle – Nicotine salts: unflavoured 100mg/ml in propylene glycol (PG) for mixing with flavoured e-liquid;
- b. Nicotine concentrate 100mg/ml 100ml bottle – Freebase: unflavoured 100mg/ml in propylene glycol (PG) for mixing with flavoured e-liquid;
- c. NicShot – Salt Nicotine 10 bottles x 10mls. This product has an option to choose from three different nicotine strengths being, 18mg/ml, 36 mg/ml, and 72mg/ml and is described to be “designed for easy mixing with your zero nicotine vape juice... suitable for all vaping devices”; and
- d. NicShot – Freebase Nicotine 10 bottles x 10mls. This product has an option to choose from three different nicotine strengths being, 18mg/ml, 36 mg/ml, and 72mg/ml and is described to be “designed for easy mixing with your zero nicotine vape juice... suitable for all vaping devices”.

68. The Goods are represented to contain nicotine. Therefore, I am satisfied that the advertising of the Goods are therapeutic goods within the meaning of subsection 3(1) of the Act as goods ‘*represented in any way to be... for therapeutic use*’. This is because the main website is promoting prescription only medicines and nicotine vaping products for smoking cessation.

The Advertisements are an advertisement within the meaning of the Act

69. Subsection 3(1) of the Act provides that ‘*advertise*’, in relation to therapeutic goods, ‘*includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods*’.

70. I am satisfied that the Advertisements were intended to promote the use or supply of the Goods for the reasons set out below.

The Advertisements promote the use and supply of nicotine vaping products

71. Solely promoting a health service is not considered advertising of a therapeutic good and is not subject to the Act. Whereas an advertisement for a health service that also promotes the use or supply of a therapeutic good is subject to the Act.



72. When assessing the Advertisements, the entire context had been taken into consideration.
73. I consider that the Advertisements promote the use of nicotine vaping products for the following reasons:
- a. The trading name, [REDACTED] directly refers to ‘vape’, which is a colloquial reference to a nicotine vaping product (even if this is also a colloquial reference to non-nicotine vaping products);
  - b. The advertising markets a health service tailored to nicotine vaping for smoking cessation and promotes a direct pathway for consumers to obtain nicotine vaping products; and
  - c. Paragraph [67] describes the products that were available on the main website which expressly included nicotine vaping products.
74. I am satisfied that the Advertisements promote the use and supply of nicotine vaping products for the reasons set out in the following paragraphs.
75. Subsection 3(1) of the Act defines “advertise” as ‘in relation to therapeutic goods, includes make 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.’ This is assessed according to what a reasonable consumer would view of the advertising material would believe when upon viewing the material. The main website purports to provide nicotine vaping product prescription services for the cessation of smoking.
76. Notably, the URL of the Websites, [REDACTED], [REDACTED], and [REDACTED] refer to ‘vape’ or nicotine vaping products in conjunction with phrasing that indicates the provision of prescription services. It is the TGA’s view that a reasonable consumer is likely to understand the URL to be promoting the use of nicotine vaping products by providing easy access to prescriptions for nicotine vaping products.

Submission and changes to the main website since the Proposed Directions were issued

77. I refer to your submission that you will be transforming the main website “*to be factual and balance information about NVP so that it doesn’t direct the public towards NVP... The website and business name will now be a education centre / hub for doctors, pharmacist and patients to make well factual and balance information about vaping.*” You further stated that the “*New updated site will NOT have the booking for script and pharmacy directly on the website. (But will have links to other websites for these services).*”

78. While I note that you started making changes to the main website and have added a new tab called “Learning Centre” where consumers can access articles about quitting smoking, nicotine safe handling, why the laws in relation to vaping changed, and nicotine replacement therapy, there are no further significant changes to the main website to indicate your intention to transform the main website.
79. I have also reviewed the articles contained within the “Learning Centre” tab. There are four articles accessible on this tab. These are referred to in paragraph [57] above. Three out of the four articles refer to nicotine vaping. I consider this is not balanced and is clearly intended and could be taken by a reasonable consumer to be directed toward promoting the use of nicotine vaping product.
80. The articles also promote a direct pathway for consumers to obtain nicotine vaping products and presents this information in a way that places emphasis on nicotine vaping products the consumer will obtain rather than the service provided.
81. I note also that you have amended the main website to state that you are assisting patients by providing prescription for “nicotine replacement therapy” where previously you were advertising the prescription for “nicotine vaping products”.
82. I also refer to your submission that the word “vape” is not just a colloquial reference to nicotine vape but that it also refers to non-nicotine vapes or the vaping device which can be used for nicotine and non-nicotine juice. While that may be the case where that term is used in isolation, the TGA’s position is that where that term (or any variation thereof) is used in conjunction with the term prescription (or any variation thereof), a reasonable consumer would take those references in a URL or your website as intended to directly or indirectly promote the use or supply of nicotine vaping products, noting non-nicotine vaping products do not require a prescription.
83. I am satisfied that the representation on the main website would appear to a reasonable consumer to be promoting the use or supply of nicotine vaping products.
84. I am further satisfied that the Advertisements were intended to promote the use or supply of nicotine vaping products for the following reasons:
  - a. The URL continues to refer to ‘vape’, a colloquial term which a reasonable consumer would understand to refer to nicotine vaping products;
  - b. The business name, [REDACTED], appears throughout the Advertisements;
  - c. The ordinary use of the word, ‘script’ in this context is a reference to obtaining a prescription;
  - d. Step 3 of the prescription service being ‘emailed directly to you;’

- e. The 'Home Page' advises consumers that you provide scripts for nicotine replacement therapy, however, the remainder of the main website only includes advertising about obtaining e-cigarette nicotine;
  - f. The 'Learning Centre' page only includes advertising about smoking and nicotine vaping;
  - g. The 'Success Stories' page majorly include reviews in relation to obtaining vape prescriptions; and
  - h. The 'FAQ' page only includes information relating to smoking and nicotine vaping.
85. The main website notably provides consumers with a three-step method in obtaining a prescription. The method is summarised at [50.f)].
86. Likewise, only promoting the use of nicotine vaping products as opposed to alternative forms of smoking cessation is likely to be taken by a reasonable consumer as promoting the use of nicotine vaping products over those other goods.
- a. The material on the main website solely promotes nicotine vaping products and does not expressly promote any other treatments. I do not consider the material on the main website to be balanced; rather, I consider the material is intended to promote the use or supply of nicotine vaping products.
  - b. The material on the Advertisements promotes a direct pathway for consumers to obtain nicotine vaping products and presents this information in a way that places emphasis on the product the consumer will obtain rather than the health service provided.
87. To avoid any doubt, I am making a finding that the way the material is depicted on the main website is promoting the use and supply of nicotine vaping products, as a class of therapeutic goods. This is separate from my findings below that the Advertisements are advertising specific therapeutic goods, being nicotine vaping products.
88. This is because there is direct advertising of nicotine vaping products to Australian consumers.
89. I have also formed the view that a reasonable consumer undertaking search engine enquiry from search engines such as Google, for information about how to access nicotine vaping products and prescriptions for this purpose, would clearly be directed to the main website.
90. I consider that a reasonable consumer specifically undertaking a search engine enquiry about how to access nicotine vaping products for this purpose would search terms such as 'vape script', 'vaping script', and 'nicotine script'. A Google search enquiry of these

keywords provide reasonable consumers with search results in which the main website appears on the top results. See examples on Attachment E.

91. I consider that a reasonable consumer would likely click on one of the top results and is likely to view the content on the main website.
92. I consider that a reasonable consumer would be convinced by the content on the main website to obtain a prescription as a step to obtaining nicotine vaping products prior to a consultation with a medical practitioner.
93. In comparison, a reasonable consumer searching for nicotine vaping products for smoking cessation options will not be directed to the main website given it does not appear on the first five pages of a Google search result.
94. I consider that a reasonable consumer specifically undertaking a search engine enquiry about how to access nicotine vaping products for smoking cessation would search terms such as 'vape quit smoking' or 'quit smoking with vape'. A Google search enquiry of these keywords provide a reasonable consumer with search results of factual and balanced information about nicotine vaping products. The main website does not appear as a top result on Google. See examples on Attachment E.

The Permission does not apply as [REDACTED] is not a pharmacy

95. The Permission (as set out in paragraph [10]) allows pharmacies and pharmacy marketing groups to advertise, with conditions, where an individual may obtain nicotine vaping products with a prescription.
96. On 5 April 2022, a case officer within the TGA's Advertising and Products Investigation Section spoke to the executive officer on the phone. The purpose of the phone call was to clarify the business structure of [REDACTED] noting that the main website states that patients can "order [their] product and get it delivered straight to [their] door from [REDACTED]'s integrated] pharmacy in Australia".
97. The executive officer confirmed with the case officer that the integrated pharmacy is not owned by 13 Vape Pty Ltd and while the pharmacy's registered address is the same as [REDACTED], the business is structured so that [REDACTED] facilitates the consultation and subsequently issues the prescription while the pharmacy dispenses the nicotine vaping products. The executive officer referred to this business structure as a "joint venture".
98. I have considered whether a joint venture or a partnership, whether by conduct or by contract, means that [REDACTED] is a pharmacy for the purposes the Permission. I have considered the information provided by the executive officer, specifically that [REDACTED] facilitates the issue of prescriptions and the pharmacy dispenses the nicotine vaping products. I have also considered that the nicotine vaping products are advertised by [REDACTED] and not the pharmacy.

99. Given the above, I do not consider that [REDACTED] is a pharmacy and therefore the Permission does not to apply to [REDACTED] nor does it apply to the advertising on the main website.

Section 42AA of the Act does not apply

100. I am further satisfied that the material on the Advertisements were not directed exclusively to health professionals, nor was it, ‘advice or information’ that was ‘given directly to a patient by a health professional’ such that section 42AA of the Act could apply in relation to the Advertisements.
101. As set out in paragraphs [62] – [63], anyone who registered an account though the main website could view the Goods as particularised in paragraph [67] at that particular point in time.
102. I consider this to be inconsistent with the exclusion provided in section 42AA for certain types of advertising. Of particular relevance in this case, is subsection 42AA(4) of the Act.
103. Subsection 42AA(4) provides that Part 5-1 of the Act does not apply to advice or information if it is ‘given directly to a patient by’ a medical practitioner or other person listed at paragraphs 42AA(1)(a) or (c) of the Act ‘in the course of treatment of that patient’.
104. I am satisfied that the advertising of nicotine vaping products prior to the consultation was not ‘advice or information’ that was ‘given directly to a patient by a health professional’ such that section 42AA would apply. This is because the advertising was available to Australian consumers that registered an account on the main website prior to a consultation with a medical practitioner and prior to receiving a prescription.
105. Advice or information cannot be said to have been given ‘directly to’ a person by a medical practitioner if that person never had any contact with that medical practitioner.
106. Even if a person could only purchase the nicotine vaping products following such a consultation, I consider that the product descriptions, the representation that the product contains nicotine, and the price would amount to advertising under the Act.

The Advertisements contravened subsection 42DLB(1) of the Act

107. 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.*

108. 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 \$222.00, this amounts to a maximum penalty of \$11.1 million.
109. Subsection 42DLB(1)(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.
110. I am satisfied that nicotine is 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 Advertisements was not required by a government or government authority.
111. Consequently, I am satisfied that subsection 42DLB(1)(7) of the Act applies to the Advertisements.
112. Subsection 42DLB(1)(9) of the Act applies to an advertisement if it
  
113. For the reasons set out above, I am satisfied that 13Vape Pty Ltd as trustee for 13 Vape Discretionary Trust and [REDACTED], by posting the Advertisements, advertised the use and supply of nicotine vaping products.

### Conclusion

114. Having regard to the above, I am satisfied that the Advertisements contravened subsection 42DLB(1) of the Act (where subsection 7 and subsection 9 of the Act apply), and that 13 Vape Pty Ltd and its executive officer, [REDACTED] are the persons apparently responsible for advertising the Goods.
115. 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 the Goods.
116. I therefore make the Direction set out above together with the associated conditions. Noting the public health issues arising from advertising of this kind, I have decided to allow you until **5pm, 29 July 2022** to comply with this Direction.
117. 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.

118. 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 Advertisements.

## **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 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 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.hunt.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**  
**Suite M1 40**  
**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.