



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

***THERAPEUTIC GOODS ACT 1989***

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**DIRECTION UNDER SECTION  
42DV**

**ISSUED TO: Phenix Health Pty Ltd  
(ABN: 22 607 822 266) (Business**

**[REDACTED]**

**ON: 20 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**

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**Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606**

**Contact Officer Name:**

**[REDACTED]**

**Contact Officer Telephone:**

**[REDACTED]**

**Contact Officer Email:**

**[REDACTED]**

## DIRECTION ABOUT AN ADVERTISEMENT

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

TO: Phenix Health Pty Ltd

By email only

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 TG 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:

**Cease** all advertising of nicotine vaping products to Australians, including but not limited to the advertising on your website at the following Uniform Resource Locator (**URL**) **the Website**.

This includes ceasing to represent 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 Phenix Health Pty Ltd or any related or future trading name '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:
  - i. [REDACTED]
  - ii. [REDACTED] and
  - iii. [REDACTED]

## CONDITIONS

### under subsection 42DV(3) of the TG Act

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

- (a) **complete** each action you are directed to carry out, including as required by these conditions, by **5pm on Friday, 19 August 2022**; and
- (b) **cease, for the period of 3 years, all advertising referred to at paragraph 0 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 Friday, 19 August 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 TG 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**.

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

DATED: 20 July 2022

Nicole McLay

<signed electronically>

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

## Attachment A

### Introduction

1. The substantive issue that is the subject of this direction is that the advertising on the Website promotes the use and supply of nicotine vaping products as a class of therapeutic goods. It does this by directing Australian consumers to use those 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.

#### *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 Therapeutic Goods Administration (**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.
11. 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.
12. 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.*
13. 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 TG Act and the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code)*.

14. 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 TG Act*

15. Subsection 3(1) of the TG 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.’
16. This is assessed according to what an ordinary viewer of the advertising material would believe when viewing the material.
17. When deciding whether information displayed on a website is an advertisement, the TGA takes into consideration the following factors:
  - a. the context in which the information or activity occurs;
  - b. the audience the information is directed to, what their likely take-out message is and are they likely to consider it to be promotional; and
  - c. the use of non-verbal and unwritten messages (such as pictorial elements). These may be just as important in assessing the communication and can alter the take-out message that viewers receive.
18. 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.
19. The TG 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 TG Act and the Code.

*Telephone conversation on 8 April 2022*

20. On 8 April 2022, a TGA case officer had a telephone conversation with an executive officer of the Company. The purpose of the telephone conversation was to establish the business structure of [REDACTED] and to identify their involvement, if any, as a pharmacy or pharmacy marketing group.
21. The executive officer advised that the Website and the relevant business operations commenced sometime in August 2021.
22. The Website boasted how easy it is for consumers to obtain a nicotine prescription. The 'Request a prescription' page did not request consumers to provide evidence regarding previous attempts for smoking cessation and/or previous consultations with doctors or similar.
23. The executive officer advised that [REDACTED] was part of one of the brands involved with Phenix Health Pty Ltd. The executive officer advised that Phenix Health Pty Ltd received clinical referrals from many marketing sources.
24. The executive officer advised that Phenix Health Pty Ltd only provided clinical services via tele-health means to many speciality models including medicinal cannabis, melatonin, nicotine, chronic disease management, respiratory testing and general consultations that may result in a prescription being issued by one of their AHPRA registered professionals.
25. The executive officer advised that the website did not market, advertise or sell any product/s and that Phenix Health Pty Ltd did not receive any incentives for their services.
26. The executive officer advised that the name of the website, being, [REDACTED] was duly based on the fact that many of Phenix Health Pty Ltd clinical services offered vaping delivery methods. [REDACTED] also advised that the name of the website related to their services to provide consumers with prescriptions to vape nicotine, vape medicinal cannabis and vape melatonin, not just nicotine.

**Correspondence with the Advertiser**

27. On 20 April 2022, the TGA sent a letter enclosing a proposed direction under section 42DV of the Act to Phenix Health and its executive officers inviting submissions and/or comments in relation to the proposed direction notice on or before 5PM, 28 April 2022.

28. The proposed direction notice addressed the issue that the advertising on the Website, including the business name, [REDACTED], includes an implied reference to nicotine vaping products. The advertisement on the Website is likely to be taken by a consumer as promoting the use and supply of nicotine vaping products as a class of therapeutic goods by clearly directing Australian consumers to use those products in connection with their smoking cessation as opposed to promoting 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.
29. On the same day, an executive officer for Phenix Health confirmed receipt of the correspondence dated 20 April 2022.
30. On 6 May 2022, the TGA received correspondence from an executive officer of Phenix Health. While a week late, the TGA understood this to be Phenix Health's submissions and it states:

*"Hope you are well.*

*Further to your communications on the 20th April regarding our brand [REDACTED] we have edited and rebranded this whole website to now [REDACTED]. I am hoping this is seen by the TGA as an emphasis on smoking cessation rather than your suggestion of promoting nicotine vaping.*

*We have taken the website out of maintenance mode and gone live this morning to allow you to check. I would like the opportunity to talk with you through any other issues you feel are outstanding.*

*Please contact me on 04xxxxxxx if this is required."*

### **Material findings of fact**

I make the following material findings of fact.

*The persons apparently responsible for the advertising*

31. Phenix Health Pty Ltd (ACN: 607 822 266) is an Australian Proprietary Company limited by shares which was registered on 24 August 2015.
32. [REDACTED] is a business name held by Phenix Health Pty Ltd.
33. The listed business location on the Home Page of [REDACTED]. This is consistent with Phenix Health Pty Ltd's principal place of business, as noted on the Australian Securities and Investments Commission company search.



34. Phenix Health Pty Ltd is the registrant of the domain, [REDACTED]
35. Phenix Health Pty Ltd is apparently responsible for the material that appears on the URL [REDACTED]
36. Phenix Health Pty Ltd is not a pharmacy or pharmacy marketing group.
37. The Website appears to have been set up to facilitate the transaction between a medical practitioner, patient and supplier of nicotine vaping products, as well as other therapeutic goods such as medical cannabis and melatonin.

*The Website prior to the proposed direction notice*

38. The primary objective of the website was to provide prescriptions for patients to obtain nicotine vaping products.
39. The material on the Websites was publicly accessible.
40. The Website's homepage included the following:
  - a. A banner with [REDACTED] phone number and email address with a green tab which stated, "GET MY PRESCRIPTION";
  - b. The logo for [REDACTED] was located to the far left followed by the Website's tabs. These tabs were, "About us", "News", "Blog", "Quit App", "FAQ" and "Health Professionals".
  - c. A large image set out how to a reasonable consumer may access the services. The process was as follows:
    - i. 01: 'COMPLETE PATIENT HISTORY FORM'
    - ii. 02: 'GET CONNECTED TO A HEALTH PROFESSIONAL IN MINUTES'
    - iii. 03: 'RECEIVE SCRIPT AND SHOP AT A PREFERRED PHARMACY'
    - iv. This includes a large green box which states 'BOOK CONSULTATION' below the instructions.
  - d. The price of obtaining a prescription was \$49.00 for an initial consult and \$0.00 for repeat scripts.
  - e. Contact form which provided [REDACTED] the following contact details:
    - i. [REDACTED]
    - ii. [REDACTED]

iii. [REDACTED]

41. The Website's About Us tab included statements from Health Practitioners who appear to a reasonable consumer to be employees of [REDACTED] promoting the use of nicotine vaping. The statements include:
- a. *"Smoking kills almost 20,000 Australians each year. Compared to smoking, vaping is a better option;*
  - b. *Nicotine is similar to other addictions and with the evidence base available to us, lower risk nicotine like vaping will deliver mental and physical health benefits; and*
  - c. *At V [REDACTED], we take a multidisciplinary approach to quitting smoking that goes beyond just providing a nicotine prescription. We pride ourselves on follow-up and support to give you the best chance of success."*
42. The Website's Blog tab included an article entitled "Getting the Nicotine Prescription Online".
43. The Website's Health Practitioners tab included a video entitled [REDACTED] Health Professional introduction". This video appeared to recruit other health practitioners to onboard with [REDACTED] and become prescribers. The bottom half of this webpage includes a fillable form for health practitioners to enter their details with the note that says, "our clinical team will be in touch to get you onboarded with [REDACTED]".

#### *The amendments to the Website*

44. The Website was amended following the proposed direction notice. These amendments included:
- a. Adding the word "[REDACTED]" before "[REDACTED]" in the logo so it now reads as "[REDACTED]".
  - b. Adding the word "quit" whenever it is succeeded with the words [REDACTED] on some of the webpages.
  - c. Adding a disclaimer which states "[REDACTED] does not promote any products. We are a clinical service only. We provide consultation with specialised Authorised Prescribers and SAS B approved Healthcare Professionals for a variety of TGA listed treatments using Medicinal Cannabis, [Nicotine] and Melatonin".
  - d. Amending the Health Practitioners' statements in the "About us" tab by removing all references to nicotine vaping.

- e. Removing the video entitled “ [REDACTED] Health Professional Introduction” from the Health Practitioners tab.

*The Website after the proposed direction notice*

45. 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 the Google search results.
46. The following open-source searches provide [REDACTED] as a result on the first page of Google search results:
  - a. [REDACTED]’; and
  - b. ‘nicotine scripts’.
47. The public website description for [REDACTED] on the Google search engine displays ‘At [REDACTED], we take a multidisciplinary approach to quitting smoking that goes beyond just providing a nicotine prescription.’
48. A consumer clicking on the [REDACTED] URL is directed to the Home page which is described as follows:
  - a. At the top left of the screen appears a phone number [REDACTED]’ and an email address [REDACTED]. Below this is what appears to be a logo which reads ‘quit vaping scripts’.
  - b. On the top right of the screen appears a button which states ‘BOOK CONSULTATION’ in a small green box. Below this are a series of tabs which direct the consumer to different areas of the [REDACTED] website. From left to right, they read; ‘ABOUT US’, ‘NEWS’, ‘BLOG’, ‘QUIT APP’, ‘FAQ’, ‘HEALTH PROFESSIONALS’.
49. The process for consumers to obtain a prescription for nicotine vaping products is depicted on the website home page, as follows:
  - a. 01: ‘COMPLETE PATIENT HISTORY FORM’
  - b. 02: ‘GET CONNECTED TO A HEALTH PROFESSIONAL IN MINUTES’
  - c. 03: ‘RECEIVE SCRIPT AND SHOP AT A PREFERRED PHARMACY’
  - d. This includes a large green box which states ‘BOOK CONSULTATION’ below the instructions.

50. Towards the bottom left of the Website's homepage is a representation of 'Initial Consult' followed by a series of representations with a tick icon in a circle. These representations include 'GP Prescription'.
51. If a consumer clicks the 'About Us' tab at the top of the home page, they are redirected to [REDACTED] which promotes the use of nicotine. The page advises 'Nicotine is similar to other addictions. Evidence based research has shown when you quit smoking a person will experience mental and physical benefits'.
52. If a consumer clicks the 'News' tab at the top of the home page they are redirected to [REDACTED]. The page is titled 'Here you will find global and local news related to smoking cessation.' The page contains news articles about e-cigarettes and nicotine vaping products. The consumer will not be exposed to any news relating to other forms of smoking cessation.
53. If a consumer clicks the 'Blog' tab at the top of the home page they are redirected to [REDACTED]. The blog contains articles titled 'How To Get Online Prescription in Australia?' accompanied by images of tobacco cigarettes. These articles advise consumers about how to purchase liquid nicotine in Australia and how to obtain a nicotine prescription. A consumer who clicks through to read the blog article at [REDACTED] will see the following representations:
- a. At the top of the page; 'Here you will find global and local news related to vaping and e-cigarette nicotine.'
  - b. At the bottom of the page; 'Working 24 hours round the clock and 7 days of the week, [REDACTED] provides scripts for melatonin and medicinal cannabis along with nicotine. There is a step to step process to get hold of your valid prescription. Before consulting [REDACTED], do consult your general physician for a complete checkup.'
54. A consumer who clicks the 'FAQ' tab on the home page will be redirected to [REDACTED] the that includes headings [REDACTED] FAQ', 'Health FAQ', 'Legal FAQ', and 'Prescribing FAQ'. The questions contained within these sections are directed towards vaping as opposed to smoking cessation.
- a. Looking under the 'Health FAQ' heading, a consumer will see the section titled 'What is quit vaping for?' which provides the following explanation:
    - i. [REDACTED] is mainly used as a short-term aid to quitting smoking, or as a long-term substitute for smoking by smokers who are otherwise unable or unwilling to quit smoking or nicotine on their own or with the available treatments. Switching to a less harmful

alternative such as quit vaping (known as ‘tobacco harm reduction’) reduces the health risks without quitting the ‘smoking’ behaviour.’

b. Looking under the ‘Prescribing FAQ’ heading, a consumer will see the section titled ‘How do I get a prescription?’ which provides the following statement:

i. ‘You’ve come to the right place. [REDACTED] doctors can prescribe e-cigarette nicotine if you have not been successful at previous quit attempts using patches, gum, lozenge and the like.

Go to [REDACTED] and click on Get My Prescription, and you will fill out a patient registration form. You will be contacted by the [REDACTED] ripts team to connect you with an Authorised Prescribing doctor.

We will send your prescription to your email address.’

55. The FAQ page also contains a ‘Useful links’ section which are predominantly about nicotine e-cigarettes. These include:

- a. ‘Nicotine e-cigarettes (TGA)’ which links to <https://www.tga.gov.au/nicotine-vaping-products>.
- b. ‘Nicotine e-cigarettes: Information for consumers (TGA)’ which links to <https://www.tga.gov.au/nicotine-vaping-products-information-consumers>.
- c. ‘Nicotine e-cigarettes: Questions and answers (TGA)’ which links to <https://www.tga.gov.au/nicotine-vaping-products-frequently-asked-questions>.
- d. ‘TGO 110 Guidance for Therapeutic Goods (Standard for Nicotine Vaping Products) (TGA PDF)’ which opens a pdf at the link [https://www.tga.gov.au/sites/default/files/nicotine-vaping-products-and-vaping-devices\\_0.pdf](https://www.tga.gov.au/sites/default/files/nicotine-vaping-products-and-vaping-devices_0.pdf).
- e. ‘ATHRA info & resources for Australian GPs (ATHRA Resources)’ which links to <https://www.athra.org.au/health-professionals/how-to-write-a-nicotine-prescription/>.
- f. ‘Supporting Smoking Cessation Report – A Guide for Health Professionals’ which opens a pdf at the link <https://cdn.shopify.com/s/files/1/0125/5365/0233/files/Smoking-cessation-guideline.pdf?7525> .

### **Reasons for decision**

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

### Power to issue Direction

57. Subsection 42DV(1) of the TG Act provides that if, in relation to the advertising of therapeutic goods, the Delegate is satisfied that there has been a contravention of the TG Act or the 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.

### Phenix Health Pty Ltd is apparently responsible for the Website

58. I am satisfied that Phenix Health Pty Ltd (**the Company**) is apparently responsible for the Website for the following reasons:
- a. They are the registrant of the domain for the Website; and
  - b. The business name, [REDACTED] is held and traded under by the Company.

### The Website promotes the use and supply of nicotine vaping products

59. I am satisfied that the Website promotes the use and supply of nicotine vaping products for the reasons set out below (when considering the factors outlined at [15] – [19]).
60. The Website purports to provide nicotine vaping product prescription services for the cessation of smoking.
61. Notably, the URL of the Website [REDACTED] (**the URL**) refers to ‘vaping’ 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.
62. I refer to your submission that the Website has been rebranded to [REDACTED]. I understand that your intention was to show the “emphasis on smoking cessation rather than [the TGA’s] suggestion of promoting nicotine vaping.”
63. I acknowledge the efforts and the changes made to the Website so far. These include:
- a. Changed the tile purporting to be the logo of the Website from [REDACTED].
  - b. Removed articles from the ‘NEWS’ page which directly referred to the steps to obtain a prescription. However, I note that these articles now appear on the new ‘BLOG’ page.

- c. Included a 'QUIT APP' tab which directs consumers to download a 'digital health coach' for assistance with the process of smoking cessation.
  - d. Included a 'HEALTH PROFESSIONALS' tab which is purportedly directed towards health professionals registering. However, I note that this tab, as well as the rest of the website remains visible and therefore advertised to the Australian public.
64. I have considered the changes to the Website to date and I am of the view that, given the context in which the business is conducted, a reasonable consumer would view the website's URL and business name in the context of the website as a whole, and the pages therein to be directly promoting the use or supply of nicotine vaping products.
65. I formed the view that a reasonable consumer undertaking search engine enquiries of websites such as google for information about how to access nicotine vaping products and prescriptions for this purpose, would be directed to the Website.
66. I am satisfied that the representations on the Website would appear to a reasonable consumer to be promoting the use or supply of nicotine vaping products and therefore amount to 'advertising' within the meaning of that term under the TG Act.
67. I am further satisfied that the Website was intended to promote the use or supply of Nicotine Vaping Products for the following reasons:
- a. The URL continues to refer to 'vaping', a colloquial term which a reasonable consumer would understand to refer to nicotine vaping products;
  - b. The business name, [REDACTED], appears throughout the Website prefixed by 'quit', however, continues to refer to 'vaping';
  - c. The ordinary use of the word, 'script' in this context is a reference to obtaining a prescription;
  - d. Pricing options for either initial consult or repeat scripts are designed to promote the supply of the nicotine vaping products;
  - e. Pricing options for the initial consult or repeat scripts indicate that they include a 'GP prescription';
  - f. Step 3 of the prescription service being 'Receive script to your preferred pharmacy;'
  - g. The 'Home Page' advises consumers that you provide scripts for medicinal cannabis, melatonin and nicotine, however, the remainder of the Website only includes advertising about obtaining e-cigarette nicotine; and

- h. The 'Blog' page only includes advertising about smoking and nicotine vaping;
  - i. The 'Blog' page includes several articles in relation to obtaining vape prescriptions. A majority of the articles only refer to vaping as the only option for smoking cessation; and
  - j. The 'FAQ' page only includes information relating to smoking and nicotine vaping.
68. Further, for the reasons outlined above, I consider that changing the name from [REDACTED] to [REDACTED] continues to promote the use and supply of nicotine vaping products.
69. The Website notably provides consumers with a three-step method in obtaining a prescription. The method is summarised at [49].
70. Likewise, only promoting the use of nicotine vaping products as opposed to alternative forms of smoking cessation is likely to be taken by an ordinary viewer as promoting the use of nicotine vaping products over those other goods.
- a. The material on the Website solely promotes nicotine vaping products and does not expressly promote any other treatments. I do not consider the material on the 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 Website 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.
71. To avoid any doubt, I am making a finding that the way the material is depicted on the 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 Website is advertising specific therapeutic goods, being nicotine vaping products.
72. I am further satisfied that the material on the Websites 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 TG Act could apply.
73. This is because the Website is publicly available to Australian consumers.



### Nicotine vaping products are therapeutic goods

74. The Website clearly represents that the intended end product from the provision of an ‘e-cigarette nicotine’ prescription is a ‘TGO-110 compliant nicotine product’.<sup>1</sup>
75. I am satisfied that this is a reference to a therapeutic good, in this case being a nicotine vaping product.
76. The Website promotes nicotine vaping products as ‘mainly used as a short-term aid to quitting smoking, or as a long-term substitute for smoking by smokers who are otherwise unable or unwilling to quit smoking or nicotine on their own or with the available treatments.’
77. I am satisfied that the Website as a whole promotes therapeutic goods, being nicotine vaping products, which are ‘*represented in any way to be...for therapeutic use*’. That is 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 (**smoking cessation**).
78. I note also that the Website is promoting the use and supply of prescription only medicines, being nicotine vaping products.

### The Website being an advertisement contravened subsection 42DLB(1) of the TG Act

79. Subsection 42DLB(1) of the TG Act, being a civil penalty provision in Part 5-1 of the TG Act, provides that a person contravenes the subsection if:
- (a) *the person:*
    - (i) *advertises, by any means, therapeutic goods; or*
    - (ii) *causes the advertising, by any means, of therapeutic goods; and*
  - (b) *subsection (2), (3), (4), (5), (6), (7), (8) or (9) applies to the advertisement.*
80. Contraventions of subsection 42DLB(1) of the TG 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.
81. Subsection 42DLB(7) of the TG Act applies to an advertisement if it, relevantly, refers to substances, or goods containing substances, included in Schedule 4 to the

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<sup>1</sup> <https://www.legislation.gov.au/Details/F2021L00595/Download>

The Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 (TGO 110) is a product standard made under section 10 of the TG Act. TGO 110 sets out minimum safety and quality requirements for nicotine vaping products that are not registered in the ARTG and that are imported into, supplied in, or exported from Australia.

current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference required by a government or government authority.

82. 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'.
83. I am satisfied that the nicotine vaping products promoted on the Website are 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'.
84. I am further satisfied that the references to nicotine on the Website were not required by a government or government authority.
85. Consequently, I am satisfied that subsection 42DLB(7) of the TG Act applies to the Website.
86. Subsection 42DLB(9) of the TG Act applies to an advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
87. For the reasons set out above, I am satisfied that Phenix Health Pty Ltd and its executive officers being the Registrant the Website, were apparently responsible for advertising the use and supply of nicotine vaping products.

### Conclusion

88. Having regard to the above, I am satisfied that the Website contravened subsection 42DLB(1) of the TG Act (where subsection 7 and subsection 9 of the TG Act apply), and that Phenix Health Pty Ltd and its executive officers are the persons apparently responsible for advertising the goods.
89. 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.
90. I therefore make the Direction set out above together with the associated conditions. I have decided to allow you until **5pm, Friday, 19 August 2022**.
91. 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 TG Act (as noted above), and section 42DX of the TG Act, in relation to your failure to comply with this Direction.

92. 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 Website.

## **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 TG Act, is a criminal offence under section 42DW of the TG Act, and may give rise to civil penalties under section 42DX, which could lead to court action against you.

The TGA could also 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 TG Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

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

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

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

### Guidelines for requesting reconsideration of an initial decision

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

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

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

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

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

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

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

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