MJ FERSON

Proposed reforms to the regulation of vapes

Overview

The Therapeutic Goods Administration (TGA) is undertaking extensive targeted consultation to seek comments from affected stakeholders on proposed reforms to the regulation of vapes in Australia.

The TGA conducted a public consultation from November 2022 to January 2023 to seek comments on potential reforms to the regulation of nicotine vapes to prevent children and adolescents from accessing nicotine vapes, while supporting lawful access to these products for smoking cessation.

Following the results of the 2022 consultation and advice from health experts, the Minister for Health and Aged Care announced on 2 May 2023 the Government's intention to take strong action to address the importation, manufacture and supply of unlawful vapes by introducing a comprehensive range of reforms, including those to:

- stop the importation of non-prescription vapes
- increase the minimum quality standards for vapes including by restricting flavours, colours, and other ingredients
- require pharmaceutical-like packaging
- reduce nicotine concentrations and volumes
- ban all disposable single use vapes
- end vape sales in convenience stores and other retail settings.

To inform the development of the reforms, the TGA is consulting on four broad proposals:

- **Proposal 1** - restricting importation, manufacture and supply of all vapes
- **Proposal 2** - enhancing market accessibility requirements for therapeutic vapes
- **Proposal 3** - heightening quality and safety standards for therapeutic vapes
- **Proposal 4** - strengthening domestic compliance and enforcement mechanisms.

Consultation paper

Consultation paper - Proposed reforms to the regulation of vapes. *<user_uploads/vaping-regulatory-reforms--consultation-paper-1.pdf>*

Making a submission

To make a submission:

1. Read the consultation paper about the proposed reforms to the regulation of vapes (see link above).
2. Go to the online consultation questions (see 'Give us your views' below), complete and submit your response.

This consultation will be open until COB 21 September 2023 and feedback can be provided via the 'Online Survey' link at the bottom of this page.

Note that if you make a submission, it will be published to comply with Australia's obligations under Article 5.3 of the World Health Organization **Framework Convention on Tobacco Control** *<https://fctc.who.int/publications/i/item/9241591013>* (WHO FCTC), which requires Australia to protect its public health policies from all commercial and other vested interests of the tobacco industry. Those interests may be related to tobacco products and electronic nicotine delivery systems, including for example, vapes. The **Guidelines for implementation of Article 5.3** *<https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-5.3>* require that the Australian Government ensures that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent.

On request, we will remove individuals' names from submissions before publication. We will not publish personal email addresses, telephone numbers or home addresses. On request, we will consider redacting sensitive commercial information.

Support services

Some people may find issues relating to the proposed vaping reforms distressing. If you or someone you know needs additional support, please contact any of the below crisis support helplines:

Adult

- Lifeline: 13 11 14
- Suicide Call Back Service: 1300 659 467
- Beyond Blue: 1800 512 348
- MensLine Australia: 1300 789 978

Youth

- Kids Helpline (5-25 years): 1800 551 800
- Headspace: 1800 650 890
- **ReachOut** *<https://au.reachout.com/>*

Why your views matter

The current evidence base suggests that the reforms, which commenced on 1 October 2021 relating to the scheduling of nicotine for human therapeutic use as a prescription medicine under the Poisons Standard, are not sufficiently achieving their objectives. Vape marketing and use in Australia has increased in recent years, particularly among young people. Vapes are being accessed by many users through illegitimate channels, rather than through lawful supply channels with a prescription. These developments pose a major risk to population health and have the potential to disrupt the significant achievements that Australia has made in tobacco control to date.

The TGA is seeking input from targeted stakeholders regarding support for, and the impact of, the proposed reforms.

Survey contents

You may choose to answer all or selective questions, however, the questions marked as 'Required', are **mandatory** - they **must** be completed in order to move to next page in the survey.

You will find a list of questions about yourself under the section titled 'Introduction'. Telling us about you and your organisation allows us to better understand your unique needs and perspective.

Thank you very much for your feedback - we look forward to learning more about your thoughts in relation to proposed reforms to the regulation of vapes

Privacy and your personal information

The Therapeutic Goods Administration (TGA), as part of the Department of Health and Aged Care (the Department), invites you to share your views on proposed reforms to the regulation of vapes.

Your personal information is protected by law, including the *Privacy Act 1988* (Privacy Act) and the Australian Privacy Principles, and is being collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to the proposed regulatory reforms for vapes. The Department will collect your personal information at the time that you provide a submission.

By providing a submission, you are consenting to having your submission published by the Department in full. However, the Department retains the right to not make publicly available submissions that contain offensive or defamatory comments, or which are outside the scope of the consultation.

Submissions will be published in accordance with Australia's obligations under Article 5.3 of the World Health Organization **Framework Convention on Tobacco Control** *<https://fctc.who.int/publications/i/item/9241591013>* (WHO FCTC). Consistent with those obligations and the National Tobacco Strategy 2023-2030, steps have been taken by the TGA as part of this consultation to protect Australia's public health policies from all commercial and other vested interests of the tobacco industry, including those related to tobacco products and electronic nicotine delivery systems (vapes). The **Guidelines for implementation of Article 5.3** *<https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-5.3>* require that the Australian Government ensures that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent.

On request, we will remove individuals' names from submissions before publication. We will not publish personal email addresses, telephone numbers and home addresses. On request, we will consider redacting sensitive commercial information.

Submissions which have been published on the Department's website can be accessed by the general public, including people overseas. Ordinarily, where the Department discloses personal information to an overseas recipient, Australian Privacy Principle (APP) 8.1 requires the Department to take reasonable steps to ensure that the overseas recipient does not breach the APPs. However, if you consent to the publication of your submission, APP 8.1 will not apply to this disclosure and the Department will not be accountable under the Privacy Act for any subsequent use or disclosure of the submission by an overseas recipient, and you will not be able to seek redress under the Privacy Act.

You should not include information in your submission about another individual who is identified, or reasonably identifiable. If you need to include information about another individual in your submission, you will need to inform that individual of the contents of this notice, and obtain their consent to the Department collecting their personal information.

You can get more information about the way in which the Department will manage your personal information, including our privacy policy, at **https://www.health.gov.au/resources/publications/privacy-policy** *<https://www.health.gov.au/resources/publications/privacy-policy>* . You can obtain a copy of the Department's privacy policy by contacting the Department using the contact details set out below. The Department's privacy policy contains information about:

how you may access the personal information the Department holds about you and how you can seek correction of it; and
how you may complain about a breach of

- the APPs; or
- a registered APP code that binds the Department; and

how the Department will deal with such a complaint.
You can contact the Department by telephone on (02) 6289 1555 or freecall 1800 020 103 or by using the online enquiries form at **www.health.gov.au** *<http://www.health.gov.au/>* .

I consent to the TGA collecting the information requested in this survey about me, including any sensitive information, for the purposes indicated above.

☑ Agree *(Required)*

Mark J. FERSON

Acknowledgement

By making a submission, I acknowledge that:

I understand that the giving of my consent is entirely voluntary.
I am over the age of 18 years.
I understand the purpose of the collection, use, publication or disclosure of my submission.
I understand that copyright in the content of my submission will vest in the Commonwealth of Australia.
Where relevant, I have obtained the consent of any individuals whose personal information is included in my submission, to the TGA collecting this information for the purposes outlined in this notice.
I understand that, where I have provided consent to my submission being published, the TGA has complete discretion as to whether my submission, in full or part, will be published.

I agree.

☑ Yes. *(Required)*

Introduction

1 What is your name?

Name *(Required)*

Prof. Mark J. FERSON

2 What is your email address?

[redacted]

3 What is your organisation name?

Organisation name or N/A *(Required)*

South Eastern Sydney Local Health District

4 Please choose a stakeholder group that best describes you or your organisation.

(Required)

Please select only one item

- ☑ Government agency
- ○ Public health organisation
- ○ Health professionals' peak body
- ○ University, researchers and experts
- ○ Schools and other educational institutions
- ○ Advocacy groups
- ○ Consumer groups and associations
- ○ Pharmacy retailers,
- ○ Vape stores
- ○ Convenience stores
- ○ Petrol stations
- ○ Other retailers
- ○ Vape manufacturers
- ○ Vape importers.
- ○ Pharmacy wholesalers
- ○ Pharma industry
- ☑ Others*

*If other, please specify:

NSW Public Health Unit

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5 Which best describes your response?

(Required)

Please select only one item

- ◯ I am responding on behalf of an organisation.
- ✓ I am responding as an individual.

6 Are you an authorised prescriber?

(Required)

Please select only one item

- ◯ Yes (please go to next question)
- ✓ No (please go to next page

Conflicts of interest (actual or perceived)

The following questions are concerned with any relationship you or your organisation has (or has previously had) with the tobacco and/or the e-cigarette industry. These questions acknowledge Australia's obligations under **Article 5.3** of the **World Health Organization Framework Convention on Tobacco Control** *<https://fctc.who.int/who-fctc/overview>* . They are also concerned with the need to protect Australia's public health policies from all commercial and other vested interests related to tobacco products and electronic nicotine delivery systems, for example e-cigarettes.

1 Have you or your organisation ever received services, assistance or support (whether monetary or non-monetary in nature) from the tobacco industry and/or e-cigarette industry? If this scenario applies to you or your organisation, please provide relevant details in the textbox.

(Required)

Please select only one item

- ◯ Yes
- ◯ No

If you have selected yes, please provide details here. Otherwise, please state 'Not Applicable': *(Required)*

2 Have you or your organisation ever provided services, assistance or support (whether monetary or non-monetary in nature) to the tobacco industry and/or the e-cigarette industry? If this scenario applies to you or your organisation, please provide further information in the textbox.

(Required)

Please select only one item

- ◯ Yes
- ◯ No

If you have selected 'yes', please provide details here. Otherwise, please state 'Not Applicable' *(Required)*

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Proposal 1 -Restrictions on importation, manufacture and supply of all vapes .

1 Do you support the proposed approach to ban disposable single use vapes absolutely and all other vapes, except those for legitimate therapeutic use in compliance with the TG Act?

(Required)

Please select only one item

- [x] Yes
- [ ] No

2 How would you anticipate industry and consumers to respond to a ban on the importation, manufacture and supply of non-therapeutic vapes?

Whilst the industry may object, we know that the vast majority of purchased (non-prescription vapes) contain nicotine & but are not labelled as such, so Legitimate importers, wholesalers & retailers should not object. Adult purchasers of e-cigs do so because the vapes illegally contain high concentrations of nicotine, so do not have grounds to object, and many including parents of children/young adults will agree with this approach.

3 Do you support removal of the personal importation scheme exception for vapes? If not, what would be the impact on you?

(Required)

Please select only one item

- [x] Yes
- [ ] No (* if not, what would be the impact on you?)

* What would be the impact on you?

4 Do you agree with the proposal to retain a traveller's exemption, including the proposed limits?

(Required)

Please select only one item

- [ ] Yes
- [x] No

There is no reason to have such high limits on a traveller's exemption.

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5 Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)?

(Required)

Please select only one item

- (✓) Yes
- ( ) No

6 [If applicable] Suppliers, what part of supply chain do you occupy?

(Required)

Please select all that apply

- [ ] Raw material supplier
- [ ] Manufacturer
- [ ] Sponsor
- [ ] Importer
- [ ] Warehousing provider
- [ ] Wholesaler
- [ ] Retailer
- [ ] Other (* specify below)
- [✓] Not applicable

* Other -specify your role in supply chain.

6 (a) What proportion of your sales volumes is attributable to vape sales [i.e. quantity of vapes sold]?

Please provide details here: (or mark Not applicable). *(Required)*

6 (b) What proportion of your sales revenue is attributable to vape sales [i.e. revenue earned from sales]?

Please provide details here: (or mark Not applicable). *(Required)*

6 (c) What impact would the proposed measures have on your sales volumes?

Please provide details here: (or mark Not applicable). *(Required)*

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6 (d) What impact would the proposed measures have on your sales revenues?

Please provide details here: (or mark Not applicable). *(Required)*

6 (e) What proportion of your vapes sales is attributable to disposable single use vapes versus refillable products?

Please provide details here: (or mark Not applicable). *(Required)*

6 (f) How would restricting the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes in Australia impact you?

Please provide details here: (or mark Not applicable). *(Required)*

6 (g) How much stock do you have in Australia currently and how long would it take to sell that stock?

Please provide details here: (or mark Not applicable). *(Required)*

6 (h) What would be the cost to you if you were required to dispose or otherwise move on existing stock?

Please provide details here: (or mark Not applicable).

Proposal 2 -Changes to market accessibility requirements, including better regulation of device components.

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7 Do you support the approach to require a pre-market notification of compliance with TGO 110?

(Required)
Please select only one item

- [x] Yes
- [ ] No

8 [If applicable] For suppliers of therapeutic vapes, what impact would the proposed notification system have on your supply model and what transition period would you require to comply with the new notification requirement?

Please provide details here: (or mark Not applicable). *(Required)*

N/A

9 Do you support the proposed access to vapes under the SAS C notification system?

(Required)
Please select only one item

- [x] Yes
- [ ] No

9 (a) What impact would this pathway have on facilitating patient access to therapeutic vapes?

Please provide details here: (or mark Not applicable).

Don't know

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10 [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?

(Required)

Please select only one item

- ◯ Yes (* please tell us how)
- ◯ No
- ✓ Not a prescriber of vapes

* How new pathway will change your approach to prescribing ttherapeutic vapes?

11 [If applicable] For prescribers, which access pathway (SAS B, SAS C, or AP) would you envisage using to prescribe therapeutic vapes? Why?

(Required)

Please select all that apply

- ☐ Authorised Prescriber scheme (AP)
- ☐ Special Access Scheme -B (SAS-B)
- ☐ Special Access Scheme C (SAS-C)
- ☑ Not a prescriber of vapes

Please tell us why

12 [If applicable] For prescribers, would integration of SAS or AP applications or notifications into existing clinical software systems ease the administrative burden and/or encourage you to use the new pathway?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ✓ Not a prescriber of vapes

13 Do you agree with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity?

(Required)

Please select only one item

- ✓ Yes
- ◯ No

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14 Will these changes have direct or indirect impact on you? Please provide details.

(Required)

Please select only one item

- ◯ Yes (please provide details below)
- ◉ No

Please provide details here:

15 Do you require time to adjust to these requirements? If yes, how long?

(Required)

Please select only one item

- ◯ Yes
- ◉ No

15 (a) How long do you require to adjust to these requirements?

Please select only one item

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 6 to 9 months
- ◯ 6 to 12 months
- ◯ More than 12 months

Proposal 3 - Improving quality standard for unapproved (unregistered) vapes)

16 Are the definitions of tobacco and mint flavours appropriate? If not, please provide reasons.

(Required)

Please select only one item

- ◯ Yes
- ◯ No (* please provide reason below)

* Please provide reason here.

Don't know.

M J FERSON

17 Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons.

(Required)

Please select only one item

- ◯ Yes
- ◯ No (* please provide reason below)

* Please provide reason here

Don't know

18 [If applicable] Importers, manufacturers and suppliers, would the restrictions on flavour proposed above impact you?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ◯ Not applicable

19 Do you agree with the proposal to require pharmaceutical-like packaging and presentation for vapes, e.g., vapes manufactured in black, white or grey coloured materials, predominantly white background on packaging, clear warning statements and other restrictions on labels in addition to other selective TGO 91 requirements for vapes?

(Required)

Please select only one item

- ◯ Yes
- ◯ No (* please provide reason below)

20 [If applicable] What impact will the labelling and packaging changes have on you?

* Please provide detail here.

"plain packaging" is a must to make vapes much less attractive to children and young adults.

MJ FERSON

20 (a) How long would you need to transition your product to comply with the proposed requirements?

Please select only one item

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 6 to 9 months
- ◯ 6 to 12 months
- ◯ More than 12 months

21 Do you agree with our approach to allow only permitted ingredients in vapes, instead of trying to prohibit individual chemical entities from use in e-liquids?

(Required)

Please select only one item

- ◯ Yes
- ◯ No

22 [If applicable] Importers, manufacturers and suppliers, will your therapeutic vapes need any re-formulation or other changes to comply with the permitted ingredients and ingredient quality requirements?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ◯ Not applicable

22 (a) If product re-formulation is required, how long will you need to make these changes?

Please select only one item

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 6 to 9 months
- ◯ 6 to 12 months
- ◯ More than 12 months

22 (b) If product re-formulation is required, what financial or business impacts would be associated with them?

Provide detail here or put 'Not Applicable' *(Required)*

N/A

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23 Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?

(Required)

Please select only one item

- ◯ Yes
- ◯ No

Don't know

24 What is the overall business cost on you to comply with a strengthened TGO 110?

Please provide details here: (or mark Not applicable). *(Required)*

N/A

25 Do you agree with the proposed requirements under TGO 110 that will apply to unapproved device components of vapes?

(Required)

Please select only one item

- ✓ Yes
- ◯ No

26 [If applicable] Suppliers, do you intend to register any vaping device on the register as an approved medical device?

Please select only one item

- ◯ Yes
- ◯ No (if no, why not?)

If no, why not?

27 [If applicable] Importers, manufacturers and suppliers, are you familiar with relevant US FDA, or MHRA guidance and/or EU standards covering vaping devices?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ✓ Not applicable

MJ FERSON

27 (a) Do your vapes currently comply with relevant US FDA, or MHRA guidance and/or EU standards covering vaping devices?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ✓ Not applicable

27 (b) If not, what requirements do you meet?

What requirements you currently comply with?

27 (c) How long would it take to achieve compliance with relevant standards?

Please select only one item

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 6 to 9 months
- ◯ 6 to 12 months
- ◯ More than 12 months

28 [If applicable] Importers, manufacturers and suppliers, are your vapes manufactured at facilities that hold relevant international standards for Quality Management Systems, such as ISO9001 or ISO 13485?

(Required)

Please select only one item

- ◯ Yes
- ◯ No
- ✓ Not applicable

Proposal 4 - Strengthening domestic compliance and enforcement mechanisms

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29 Do you have any other comments in relation to this proposal?

(Required)

Please select only one item

- [x] Yes (* provide your comments below)
- [ ] No

Comments

These important changes will only be effective if they are appropriately funded and carried out in coordination with other Aust. Govt agencies and with State and Territory governments.

Supplementary questions

30 [If applicable] Suppliers, please confirm if you intend to continue to supply therapeutic vapes under the proposed reforms described?

(Required)

Please select only one item

- [ ] Yes (*if yes, please outline your product range below)
- [ ] No
- [x] Not applicable

* Product range

30 (a) How long would it take to meet the new requirements?

Please select only one item

- [ ] Less than 3 months
- [ ] 3 to 6 months
- [ ] 6 to 9 months
- [ ] 6 to 12 months
- [ ] More than 12 months

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31 [If applicable] Suppliers, please confirm if you intend to register your therapeutic vapes in the next 2 years?

(Required)

Please select only one item

- ◯ Yes (if so, what guidance and/or clarity of supporting data requirements do you need from TGA)
- ◯ No
- ◯ Not applicable

What guidance and/or clarity of supporting data requirements do you need from TGA

Publication of submissions

While names of individuals (including officers of an organisation or company) can be redacted by the TGA on express request, it is not possible to make "in confidence" submissions to this public consultation. Accordingly, by providing a submission through this process, you are consenting to having your submission published by the Therapeutic Goods Administration (TGA) in full unless you have requested that the TGA does not publish your name. However, the TGA retains the right to not make publicly available any submissions that contain offensive or defamatory comments, or which are outside the scope of the consultation.

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the TGA.

Please note the TGA will be unable to accept:

comments which, in the opinion of the TGA, are inappropriate; and
comments received after the consultation deadline (11.59PM AEDT on 21 September 2023).

To proceed, please select from the options below how you would like the TGA to deal with your submissions:

(Required)

Please select only one item

- ◯ I agree to the TGA publishing my response in full.
- ◯ I agree to the TGA publishing my response with my organisation name (where applicable). However, I request that the TGA does not publish my name.

☐ I request the TGA to consider redacting sensitive commercial information from my response before publication

Please specify sensitive commercial inforation you want redatced