Response to TGA *Proposed reforms to the regulation of vapes* survey

Privacy and your personal information

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

Agree

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.

Introduction

1. What is your name?

Melanie Walker

2. What is your email address?

[redacted]

3. What is your organisation name?

Australian Alcohol and other Drugs Council

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

Health professionals' peak body

5. Which best describes your response?

I am responding on behalf on an organisation.

6. Are you an authorised prescriber?

No.

Conflicts of interest (actual or perceived)

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.

No.

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

Not applicable.

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.

No.

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

Not applicable.

Responses to Proposals 1-4

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?

No comment

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

Australian Border Force has previously suggested that new regulations are likely to have only limited impact on reducing the availability of imported vapes in Australia. The outcome of the ban on importation, manufacture and supply of non-therapeutic vapes is that consumers will likely continue to use these products, however will instead access them through unauthorised and unregulated sources. Parallels can be made with illicit drugs where, despite their illegal status, 16% of Australians over the age of 14 years have used an illicit drug in the past 12 months and 43% have used an illicit drug in their lifetime.

3. Do you support the proposal to remove the personal importation scheme exception for vapes? If not, what would be the impact on you?

No comment

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

No comment

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

No comment

6. [If applicable] Suppliers, what part of the supply chain do you occupy? For example, are you an importer, manufacturer, warehouser, wholesaler, retailer or a combination of these (please specify)?

Not applicable

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

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

c. What impact would the proposed measures have on your sales volumes?

d. What impact would the proposed measures have on your sales revenues?

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

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

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

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

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

No comment

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?

Not applicable

9. Do you support the proposed access to vapes under the SAS C notification system? What impact would this pathway have on facilitating patient access to therapeutic vapes?

No comment

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

Not applicable

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

Not applicable

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?

Not applicable

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?

No comment

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

No comment

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

No comment

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

No comment

17. Do you agree with the proposed upper limit on the concentration of menthol in vapes?

If not, please provide reasons.

No comment

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

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?

No comment

20. [If applicable] What impact will the labelling and packaging changes have and how long would you need to transition your product to comply with the proposed requirements?

Not applicable

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?

No comment

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? How long will you need to make these changes? And what financial or business impacts would be associated with them?

Not applicable

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

No comment

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

Not applicable

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

No comment

26. [If applicable] Suppliers, do you intend to include any vaping device on the register as an approved medical device? If not, why?

Not applicable

27. [If applicable] Importers, manufacturers and suppliers, are you familiar with, and do your vapes currently comply with, relevant US FDA or MRHA guidance, and/or EU standards covering vaping devices? If not, what requirements do you meet, and how long would it take to achieve compliance?

Not applicable

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?
Not applicable

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

The proposal to create a new criminal and civil offences related to unlawful possession of vapes does not contain sufficient detail about the scope of these offences, what constitutes 'possession for personal use' or the relationship with existing state and territory legislation which creates offences for the unauthorised possession of Schedule 4 medications. AADC is also concerned that the proposal to create a new criminal and civil offences related to unlawful possession of vapes does not take into account or align with Australia's National Tobacco Strategy (2023-2030) and Australia's National Drug Strategy (2017-2026) that explicitly support harm reduction interventions and policies.

In our submission to the TGA's consultation on nicotine vaping products in January 2023, AADC highlighted the range of existing penalties across each state and territory related to unauthorised Schedule 4 medication possession. These range from provisions to divert people away from the justice system in some circumstances in Queensland through to fines of up to $45,000 in Western Australia and up to two years imprisonment in the Australian Capital Territory.

AADC is concerned that, although the TGA consultation paper states that new offences are not designed to target personal unlawful possession of vapes, a lack of detail about these offences and their relationship to existing state and territory legislation will increase the risk of criminalising people who use vapes. AADC also notes that vapes containing no nicotine ("zero-nicotine therapeutic vapes") are proposed under Proposal 3.1.3 to be regulated as a Schedule 4 medication in the same way as vapes containing nicotine. In effect, new regulations may risk expanding the scope of criminalisation under state and territory legislation, given that these existing offences currently only apply to Schedule 4 medications (currently only vapes containing nicotine) and not nicotine-free vapes.

This is particularly important as the Australian Border Force has previously reported that new regulations are likely to have only limited effect on reducing the availability of imported vapes in Australia. Parallels can be made with illicit drugs where, despite their illegal status and the existence of border controls, the National Drug Strategy Household Survey finds that 16% of Australians have used an illicit drug in the past 12 months and 43% have used one in their lifetime. As such, it is likely that vapes will continue to be available and accessed through unapproved sources despite these new regulations. The application of criminal penalties related to vape possession in both new and existing offences, as well as the possibility of an expanded scope of criminalisation, risks exacerbating the harms related to vape use.

This exacerbated harm is likely to be most felt by population groups experiencing significant marginalisation. In Australia, smoking continues to disproportionally affect particular population groups, including Aboriginal and Torres Strait Islander people, low income groups, people experiencing mental health and substance use issues. Consequently, smoking continues to be a major contributor to health and financial inequalities, and creating new criminal offences will not assist to improve these inequalities, but in fact further cause disadvantage and harm.

In this context, AADC strongly recommends that unlawful possession of vapes should not be a criminal offence, and that further detail on the scope of any proposed new offences and how these will interact with existing state and territory legislation be provided.

30. [If applicable] Suppliers, please confirm if you intend to continue to supply therapeutic vapes under the proposed reforms described? If so, please outline the product range and the length of time it would take to meet the new requirements.

Not applicable

31. [If applicable] Suppliers, please confirm if you intend to register your therapeutic vapes in the next 2 years? If so, what guidance and/or clarity of supporting data requirements do you need from TGA?

Not applicable