TGA Consultation on 'Proposed reforms to the regulation of vapes' – Responses to the online survey questions

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?
   - **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?

   * Please provide answer here.

With regard to the response of industry to a ban on the importation, manufacture and supply of non-therapeutic vapes, we know that for many years, the tobacco and vaping industries have employed a variety of tactics, including lobbying politicians, manipulating public opinion, discrediting the evidence, fabricating support through front groups and threatening litigation, in order to weaken Australia's regulatory controls on vapes. The tobacco and vaping industries have focused on vapes as a new product pipeline, to restore long-term market sustainability as tobacco use declines, and have called for nicotine vapes to be a consumer product to allow them to be widely sold in general retail stores. We anticipate that the tobacco and vaping industries will continue their strong opposition to the proposed reforms and seek to undermine and delay them.

With regard to the response of consumers to a ban on the importation, manufacture and supply of non-therapeutic vapes, we anticipate that this will result in an increased uptake of medical prescriptions for therapeutic vapes, as the process for accessing vaping products for therapeutic purposes (smoking cessation or treatment of nicotine dependence) is made easier, while recreational or non-therapeutic vaping is expected to decrease, reducing the harm to young people and non-smokers.

Importantly, industry claims that most adults who vape will relapse to smoking in response to the proposed reforms, have not been supported by research data. For example, as part of a campaign evaluation, 119 adult residents in Western Australia who currently vape were asked about their intentions following the announcement in May that non-prescription vapes would be banned, including disposables. Respondents were asked to consider how the ban would change their vaping habits. Around half (51 percent) indicated that they would try to quit vaping, while a further 12 percent intended to obtain a prescription for vapes, consistent with the objectives of the proposed reforms. Only 14 percent anticipated that they would use tobacco instead of vaping, but these respondents were almost all current smokers at the time of the survey. Only one ex-smoker intended to relapse smoking, but that person reported quitting smoking only one week prior to the survey.

The widespread availability of vapes has been a key driver of use by young Australians, who have reported that accessing these products is relatively easy, with retailers illegally displaying and selling products. It is therefore anticipated that the proposed reforms, which aim to reduce unlawful importation and supply, will lead to a marked decrease in vaping prevalence among young people. The absolute ban on disposable single use vapes in particular is expected to dramatically decrease the availability of vapes for children and adolescents. Disposable vapes are one of the most common vaping product used by young people, and are highly attractive because they are easy for beginners to use, are affordable and often contain nicotine salts, increasing nicotine inhalation with less throat irritation. Notably, disposable vapes have been implicated in recent seizures of illegal products around Australia, and research suggests they represent a high proportion of nicotine vapes used by never smokers. In addition, other aspects of the proposed reforms such as the ban on all but two flavours and the requirement for pharmaceutical-style packaging, will decrease the appeal of vapes to young people.

3. Do you support removal of the personal importation scheme exception for vapes?
    - **Yes**
    - No

    If not, what would be the impact on you?

4. Do you agree with the proposal to retain a traveller's exemption, including the proposed limits?
    - **Yes**
    - No

5. Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)?
    - **Yes**
    - No

6. [If applicable] Suppliers, what part of supply chain do you occupy?
    - Raw material supplier
    - Manufacturer
    - Sponsor
    - Importer
    - Warehousing provider
    - Wholesaler
    - Retailer
    - Other*
    - **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).

Not applicable

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).

Not applicable

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

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

Not applicable

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

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

Not applicable

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).

Not applicable

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).

Not applicable

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).

Not applicable

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).

Not applicable

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

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

    Not applicable

9. Do you support the proposed access to vapes under the SAS C notification system?
    - **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).

For those medical practitioners who choose to prescribe therapeutic vapes, where it is clinically appropriate to do so, Stroke Foundation supports measures such as this, aimed at reducing the administrative burden that they face and facilitating improved patient access to these products. Further to this, we defer to the expertise of the TGA regarding the appropriateness of allowing access to vapes under the SAS C notification system. We note that ordinarily, prescription medicines in Australia have to meet the TGA's rigorous standards for safety, quality and efficacy, and as such, the expansion of alternative access pathways for vapes represents a departure from standard practice. We recommend the TGA ensure that manufacturers and importers of vapes are actively encouraged to work towards registration of products on the ARTG, which will offer maximum protection to public health.

10. [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?
    - Yes (*please tell us how)
    - No
    - **Not a prescriber of vapes**

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

11. [If applicable] For prescribers, which access pathway (SAS B, SAS C, or AP) would you envisage using to prescribe therapeutic vapes? Why?
    - 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?
    - 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?
    - **Yes**
    - No

14. Will these changes have direct or indirect impact on you? Please provide details.
    - Yes (please provide details below)
    - **No**

Please provide details here:

15. Do you require time to adjust to these requirements? If yes, how long?
    - Yes
    - **No**

15(a). How long do you require to adjust to these requirements?
    - 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 nicotine and mint flavours appropriate? If not, please provide reasons.
    - **Yes**
    - No (*please provide reason below)

*Please provide reason here.

17. Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons.
    - **Yes**
    - No (*please provide reason below)

*Please provide reason here.

18. [If applicable] Importers, manufacturers and suppliers, would the restrictions on flavour proposed above impact you?
    - 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?
    - **Yes**
    - No (*please provide reason below)

*Please provide reason here.

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

*Please provide reason here.

Not applicable

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

- 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?
    - **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?
    - Yes
    - No
    - **Not applicable**

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

- 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'.

Not applicable

23. Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?
    - **Yes**
    - No

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

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

    Not applicable

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

    - **Yes**
    - No

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

    - 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?

    - Yes
    - No
    - **Not applicable**

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

- 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?

- 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?

    - Yes
    - No
    - **Not applicable**

Proposal 4 - Strengthening domestic compliance and enforcement mechanisms

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

- **Yes (*provide your comments below)**
- No

Stroke Foundation strongly supports the measures to strengthen domestic compliance and enforcement mechanisms set out in Proposal 4.