The Thoracic Society of Australia and New Zealand's response to the Therapeutic Goods Administration's Proposed Reforms to the Regulation of Vapes.

The Society operates in compliance with the Medicines Code of Australia. Please see the TSANZ' (Thoracic Society of Australia and New Zealand) Sponsorship Policy for more information.

Introduction

The Thoracic Society of Australia and New Zealand (TSANZ) is a health promotion charity whose mission is to lead, support and enable all health workers and researchers who aim to relieve disability caused by lung disease. The TSANZ is the only peak body in Australia and New Zealand that represents all health professionals working in all fields of respiratory health.

The TSANZ has a membership base of over 1,800 individual members from a wide range of health and research disciplines. The TSANZ is a leading advocate and provider of evidence-based policy for the prevention and management of respiratory conditions in Australia and New Zealand, undertakes professional education and training, is responsible for significant research administration, and coordinates an accredited respiratory laboratory program.

As the leaders in lung health, we promote the:

- Highest quality and standards of patient care.
- Development and application of knowledge about respiratory health and disease.
- Highest quality air standards including a tobacco smoke free society and effective regulation of novel nicotine delivery systems.
- Collaboration between all national organisations whose objects are to improve the wellbeing of individuals with lung disease and to promote better lung health for the community.
- Professional and collegiate needs of the Membership.

The TSANZ is submitting a response to the Therapeutic Goods Administration's (TGA's) Reforms to the Regulation of Vapes. We continue to advocate for evidence-based practice and policy to improve respiratory health for all.

Consultation Topic

To inform the development of the tobacco control reforms, the TGA is currently 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.

The TSANZ' recommendations

The TSANZ has responded to the TGA's online questionnaire but would also like to expand on some aspects of our response. Our full and final response is detailed below.

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. TSANZ remains strongly supportive of the proposed approach that, as it stands, offers fair access for targeted use of unapproved NVPs yet may begin to address startling patterns of off target use in young people. The data recently released by CBRC for DOHA suggest strongly that the concerns we expressed in 2021 were soundly based and require a comprehensive response.

Australia is not alone in the specific concern about disposables. New Caledonia has specifically banned these. This digest of policy discussions was recently produced by Physicians for a Smokefree Canada.

▪ the Irish government consulting on disposable e-cigarettes (June 2023).
▪ the English government including disposables in its consultation on measures to reduce youth vaping (closed June 2023).
▪ Switzerland finalizing a higher tax on single use e-cigarettes than other e-liquids (CHF1 per ml vs CHF0.20 pr ml). (June 2023).
▪ the New Zealand health ministry announcing its intention to reduce the maximum allowable nicotine in disposable e-cigarettes and to require batteries to be removable (June 2023).
▪ the French health minister (Francois Braun) saying he was personally in favour of banning them and hoped to work with parliamentarians to include them in the governments upcoming tobacco strategy renewal. (May 2023).
▪ the German Bundesrat (federal council of states) calling on government to work towards banning single use e-cigarettes on the national and EU level (March 2023).
▪ The introduction of a cross-party private members' bill to ban disposable e-cigarettes to the U.K. House of Commons. (February 2023).

TSANZ considers the environmental impact of disposable devices to be significant and important. If this did not exist, there would still be a sound rationale for the approach proposed on health grounds.

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

We expect that there will be a mixed response from potential suppliers. Some at the more ethical end, accept the hazards of off target use and will work within the new model. They would understand that high concentration solutions will retain EC users longer and may oppose this specific measure from self-interest.

Those suppliers that are subsidiaries of major tobacco companies, or who are closely associated, will do everything possible to undermine the effect of changes. They have always sought to maximise profit at the expense of those who are harmed by the products that they manufacture and sell. As it has been with other public health initiatives, there will be fear of contagion from this Australian action and the affected parties will try to render change less effective in a variety of fashions.

In terms of public commentary, we can expect a patterned, co-ordinated campaign against this sound set of policies with a very limited number of local 'mouthpieces' who consistently exaggerate benefits and dismiss harms. Some in this group act as if they are oblivious to the subtle effect of their disclosed conflicts of interest. There will be continued selective quotation of data, often out of date. Endless comparison will be made with the outlier position of England on consumer access and, one suspects, no allusion at all to the increasing concern about disposable ECs in England and the rest of the UK, Ireland, and Europe. Attempts to disparage the "Australian approach" by the UK Vaping Industry Association are an example.

There will be 'libertarian front' organisations. The 'industry' will be in the background mainly but carefully studying the impact and seeking to learn how they can adapt to respond when similar policies are implemented in other countries.

TSANZ remains strongly supportive of the proposed approach.

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

TSANZ remains strongly supportive of the proposed ban on personal importation. It is not required for access for therapeutic use. It has no merit and is ripe for manipulation/exploitation. Its removal creates no risk for smoking cessation.

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

The key context here is that Australia has rejected EC as a consumer product.

Any exemption should be very limited. This will be contested by certain parties with false arguments that it will reduce tourist or business flow. This has not been seen as a consequence of high tobacco taxation and Australia would not be in a dissimilar position from the growing list of countries that have banned EC completely.

We oppose any travellers' exemptions for disposable vapes.

We support access equivalent to one month supply:

- This covers most short-term visitors.
- Longer term stayers have the option of discontinuing use before travel or tapering and stopping after their arrival once they are over jet lag.
- For those travelling long distances they will already have been in aircraft and airport environments where vaping is not permitted.

NRT is available OTC in Australia and inconvenienced travellers could access this to palliate withdrawal symptoms.

As to quantity, we suggest either:

a. A certain number of pods (say 30) plus a compatible device and a spare;
b. One tank or mod device only – these are readily purchasable for anyone with e-liquid; or
c. A maximum volume of 50-100mls in one childproof container.

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

The only promotion permitted within the Medical Access Framework should be that consistent with other approved therapeutic products that are available only by prescription. There will be a role for prescriber education, reasonable information about product differentiation and instructions in relation to device use. Therapeutic claims to prescribers and Pharmacists in relation to specific products would need to be based on proven evidence. Otherwise, promotion should be limited to constituents and device characteristics as appropriate.

Availability promotion at Pharmacies could be permitted as in the current TGO110 but all forms of direct-to-consumer promotion and marketing should be banned. Social media platforms should be held responsible for their content and subject to appropriate, substantial sanction.

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 to TSANZ. However, we make the comment that the amount of non-compliant stock held should not impact on policy or its timing. Businesses of all description

need to make wise business choices and the lead time has been significant. Technology and the business environment change rapidly – whatever happened to Kodak and Fujifilm? There is no need to protect any business in this sector. As for the often-discussed wider economic impact, consumers who choose not to spend their disposable income on EC devices and liquids will spend elsewhere to the benefit of other businesses and revenue, taxation and employment will elsewhere benefit.

a. What proportion of your sales volumes is attributable to vape sales [i.e. quantity of vapes sold]? Proposed reforms to the regulation of vapes: Consultation paper Page 21 of 32 September 2023

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?

Manufacturers operating in other markets should be required to disclose this from those markets and relevant trends.

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?

Proposal 2 - changes to market accessibility/regulation of device components:

7. Do you support the approach to require a pre-market notification of compliance with TGO 110? Proposed reforms to the regulation of vapes: Consultation paper Page 23 of 32 September 2023

A pre-market notification system is acceptable. It should not be used misleadingly by any supplier as equivalent to an approval.

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?

Comments on this question should only be accepted from current suppliers through local access Pharmacies.

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?

This comment covers all the prescription questions.

TSANZ supports the Medical Access Framework, but it must be credible. It will be too easily criticised as an effective ban if prescribers are not engaged.

At the present time, any prescriber can issue a prescription that permits personal importation. As noted, a limited number have applied to be authorised prescribers.

We support the position that any prescriber can issue a script for local supply after a face-to-face consultation. For rural and remote areas, telehealth could be permitted where there has been a telehealth doctor-patient relationship for 3 months.

Although not asked in this consultation, the duration of prescribed supply should not be more than 2 months with a further prescription based on another clinical interaction. This is consistent with the short-term role of NVPs in smoking cessation.

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

No

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

No comment

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

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?

Our advice to TGA is to avoid any approval process for devices. We reason that:

1. Metals with known harms are shed from EC devices of all types and there is no understanding of safe lower levels of exposure if there are any;
2. Devices that have modifiable parameters may create differing biohazards;

3. Devices that have replaceable parts such as heater coils cannot be standardised for all possible parts; and
4. In pod devices the pod interacts with the core device backbone.

For all these reasons, we strongly encourage TGA to avoid device regulation. It leaves the situation as “let the buyer beware” but there is no better option.

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

No

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

No

Proposal 3 - quality standards:

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

The TSANZ would like to make clear that our position remains unchanged, there is no proven therapeutic value in providing flavour options to help support smoking cessation efforts. In fact, flavours make e-cigarette use more appealing to vapers, and contain toxic chemicals with measurable adverse effects on lung health, as well as other chemicals where the effects are not yet known, as well as interactions between these chemicals when heated.

However, the TSANZ also acknowledges that a pragmatic approach to support existing e-cigarette users who want to quit is required, and our advice takes into account the current legislative and regulatory parameters of the tobacco control reforms.

As such, we support the following measures:

1. We support the most restrictive level of flavour options possible, with the composition of chemicals considered and publicly noted when approving any flavour.
2. We would prefer that tobacco not be a flavour descriptor but use a term such as 'classic' or 'plain' flavour.
3. If mint is to be used as a flavour it should be defined by a limited range of approved ingredients with maximum concentrations rather than a name.

As shown by Krüsemann, in an analysis of manufacturers’ reported ingredients, even the most common chemicals for tobacco and mint flavours were present in no more than 31.2% and 58.6% of products respectively. Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid’s flavour category (bmj.com).

Therefore, we strongly suggest that TGA should compile a list of allowable, defined chemical flavourings with maximum concentrations and the manufacturers can choose from that list. The two flavour ***categories*** can be mint and tobacco (but we would not recommend using these category names).

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

Of all the potential constituents in EC fluid there is sufficient evidence that menthol is selectively harmful to greatly restrict or eliminate it. Most EC users also smoke. Dual users who self-report menthol flavour use have lower lung function that those who do not independent of age, gender, race, pack-years of smoking, and use of nicotine or cannabis-containing vaping products. 10% difference in FEV1 as a reflection of airway function is very significant.

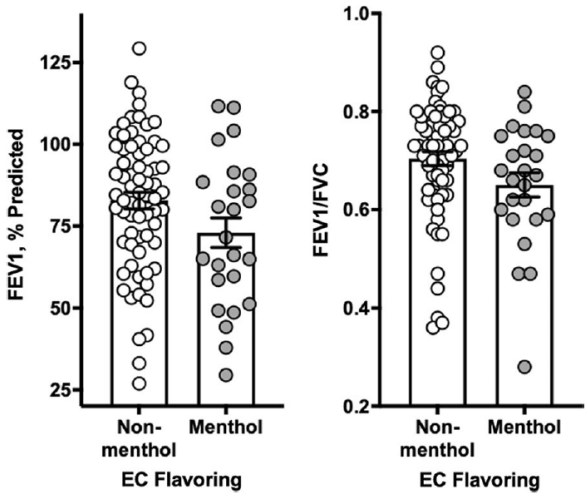

Fig. 3 Association Menthol Flavoring in Electronic Cigarettes with Lung Function. The mean FEV1 was 9.9% predicted lower (95% CI 0.1, − 19.8% pred; $P=0.053$) while the mean FEV1/FVC was 0.06 lower (95% CI 0.002, − 0.11; $P=0.058$) in an unadjusted comparison of 25 users of menthol-flavored ECs with 69 users of other flavored ECs in the COPDGene cohort (see Table 3). These associations persisted after adjustment for age, gender, race, pack years of smoking, as well as the use of nicotine or cannabis-containing vaping products in multivariate models. Specifically, menthol users had on average 9.6% predicted lower FEV1 (95% CI − 0.2, − 19.1% pred; $P=0.04$) and 0.06 lower FEV1/FVC (95% CI − 0.01, − 0.12; $P=0.01$) compared to users of other flavored products adjusted for these covariates. *FEV1* Forced Expiratory Volume in the First Second, *FVC* Forced Vital Capacity, *COPDGene* Chronic Obstructive Lung Disease Gene study

There is no proven incremental utility for cessation, and the harm:benefit ratio generally is so marginal that the menthol decision is quite a straightforward one. The low level permitted as part of mint flavouring is probably acceptable even if the concentration/harm relationship for menthol is uncertain at the present time. It remains open to EC device and fluid manufacturers to prove that there is a benefit for cessation from the inclusion of greater concentrations of menthol.

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

No comment

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?

TSANZ supports consistent neutral colouring that should be dissimilar from that required for approved pharmaceutical products. As such, white is not our preference and black may create unhelpful imagery. It should also be dissimilar from plain tobacco packaging. A matt grey could be suitable with black the only permitted colour for text. There should also be colour restrictions on permitted devices or pods. That should be the same approved grey tone with black the only contrast colour. As was the case with plain tobacco packaging, the opinions of TSANZ in this response would best be explored with targeted research but there is no time to waste and educated judgment may be necessary.

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?

TSANZ is not affected. A scale of a few months is all that is needed.

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?

TSANZ supports this as long as 'permitted' is in no way equated to safe or effective. In England, use of language is lax and there is a remarkably common use of the term approved product when they operate a notification system. We must avoid this language trap.

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?

This does not apply to TSANZ, but recent history tells us that there is remarkable flexibility amongst manufacturers/suppliers. See evidence of this from the recent BAT/Imperial Tobacco Canada business update[1]. Submissions to the contrary are disingenuous and should be dismissed.

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

[1] BAT Canada. **New Category Acceleration Drives Profitability Forward to 2024** https://www.bat.com/group/sites/uk__9tvmh3.nsf/vwPagesWebLive/DO9TVMVE/$FILE/medMDCNZCBR.pdf?openelement (accessed September 2023)

Zero-nicotine EC have no therapeutic value and there is considerable basic sciences evidence of harm. It is consistent with the policy objective of restricting EC use to smoking cessation that zero-nicotine products should be banned. There are also compliance monitoring advantages.

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?

Yes

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

No comment

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? Proposed reforms to the regulation of vapes: Consultation paper Page 30 of 32 September 2023

No comment

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?

No comment

Proposal 4 - compliance and enforcement

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

It is critical that rigorous border enforcement is implemented in unison with impending legislative changes, and that adequate legal penalties underlie any border infringement going forward.

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.

No comment.

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?

No comment.

Concluding remarks

As a leading health promotion charity for lung health professionals in Australia and New Zealand, our membership includes world leading clinicians, multidisciplinary respiratory health professionals, and researchers. We welcome the opportunity to engage with you further on this topic. We can be contacted at: advocacy@thoracic.org.au.