Proposed reforms to the regulation of vapes (Therapeutic Goods Administration, TGA)

Asthma Australia Submission, September 2023

ABOUT ASTHMA AUSTRALIA

Asthma Australia is a for-purpose, consumer organisation that has been improving the lives of people with asthma since 1962. Asthma affects one in nine Australians or 2.7 million people. Asthma is an inflammatory condition of the airways, restricting airflow and can be fatal. There is no cure, but most people with asthma can experience good control.

Our purpose is to help people breathe better so they can live freely. We deliver evidence-based prevention and health strategies to more than half a million people each year. Asthma Australia has an ambitious goal to halve avoidable hospital presentations for asthma by 2030, with an initial focus on reducing preventable hospitalisations in children aged 5-9.

ASTHMA AUSTRALIA'S SURVEY RESPONSE

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 question.)

Yes.

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

Asthma Australia regularly hears from consumers about how vaping smoke affects their health and triggers their asthma symptoms. While the long-term e-health effects of vaping are still not known, alongside are an array of short-term health impacts to those you use them, it is known that vaping causes indoor and outdoor air pollution and increased uptake of smoking in non-smokers. Both of these outcomes detrimentally affect people with asthma through acting as triggers to asthma symptoms and flare-ups and both are risks factors to its development.[2] **People with asthma are hence likely to strongly support the improved regulation and enforcement of e-cigarettes so that recreational vaping on our streets is no longer prevalent.**

In addition, increasing research has shown support amongst the Australian population more widely for better regulation of e-cigarettes. For example, the Cancer Council Victoria undertook an Australian-wide survey in 2022 of adults aged 18 and over about their perceptions and support for regulatory policies in relation to the availability and use of e-cigarettes.[2]

Most respondents agreed, and support had grown significantly from the previous year, that:

- E-cigarettes are highly addictive (81%),
- E-cigarettes should be carefully regulated to stop a new generation of Australians from becoming addicted to nicotine (87%), and
- The promotion and marketing of e-cigarettes through social and digital media (84%) or in and around shops (82%) should not be allowed.

In addition, although older respondents (aged 70 years and above) were more likely to support increased regulation on vapes and advertising, 18–24- year-olds were just as likely as adults aged 25-44 years and adults aged 45-69 years to support the policy measures. **Such high levels of support for greater regulation of vapes across the ages indicates that consumers would support the prohibiting of the importation, manufacture and supply of non-therapeutic vapes.**

In this survey, it was found that Australian adults living in low SES areas were less likely than those living in mid-high SES areas to support some of the e-cigarette policies considered, and that Australian adults who speak a language other than English were less likely to support some of the e-cigarette policies highlighted compared to Australians who only speak English at home. **Hence**

alongside policy reform, communication and support will have to be tailored to different population groups to ensure that they both understand policy reform in the area and what it means to them, as well as the risks of e-cigarettes to their health and where they can find help to quit.

REFERENCES

1. Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

2. Bain E, Mitsopoulos E, Durkin S. (2023). Perceptions of and support for policies concerning the availability and use of e-cigarettes among Australian adults, 2021 and 2022. Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Available from https://www.cancervic.org.au/downloads/cbrc/E-cig-policies2023-PUBLIC.pdf

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

Yes.

*** What would be the impact on you?:**

This measure is likely to greatly help reduce the illegal use of e-cigarettes in Australia through making it harder to access them online.

4. Do you agree with the proposal to retain a traveller's exemption, including the proposed limits? (Yes/No question.)

Yes.

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

Yes. We strongly support the prohibition of the advertising of vapes generally, particularly to stop aggressive and excessive marketing of vapes to children and adolescents. This will help to address the unfolding public health crisis relating to NVP use in younger generations and the unravelling of the trailblazing progress Australia has achieved in reducing smoking rates. The proposed prohibition will also complement the ban on e-cigarette advertising and sponsorship set out in *the Public Health*

(Tobacco and Other Products) Bill 2023 (Cth). We support the Cancer Council Australia's recommendation in relation to this issue that asks that the prohibition of advertising is supported by a system of effective monitoring and reporting of non-compliant advertising of vapes, and that enforcement action on this issue is made a priority for the TGA.

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)?

N/A.

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

N/A.

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

N/A.

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

N/A.

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

N/A.

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

N/A.

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

N/A.

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

N/A.

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

N/A.

PROPOSAL 2: CHANGES TO MARKET ACCESSIBILITY REQUIREMENTS, INCLUDING BETTER REGULATION OF DEVICE COMPONENTS

Questions 7. Do you support the approach to require a pre-market notification of compliance with TGO 110? (Yes/No question.)

Yes.

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?

While we support the approach, in our previous consultation response to TGA vaping reforms, Asthma Australia advocated for an exemption to the prohibition for access under medical supervision to only NVPs that have undergone stringent regulatory approval processes, such as the processes required for registration on the Australian Register of Therapeutic Goods (ARTG). This would mean the products have successfully demonstrated quality, safety and efficacy. In the absence of such a regulatory process, there is a strong risk that consumers and healthcare professionals will misconstrue pre-market notification and compliance with TG) 110 as TGA approval and/or endorsement of vapes as therapeutic products like all other TGA registered goods.

We support the following recommendations that the Cancer Council Australia has made in their consultation submission to the TGA to help prevent this possible misinterpretation, including:

- The creation of a specific offence in relation to the making of misleading claims (whether publicly or to health practitioners) regarding the safety, quality or efficacy of products that comply with TGO 110. In particular, describing notified products using phrasing like 'meets Australian standards' or 'meets minimum quality/safety requirements' should be prohibited due to its potential to mislead consumers and health professionals.
- The labelling of products should be required to include an additional prominent warning very clearly conveying that the product has not been assessed by the TGA for quality, safety, efficacy or long-term health effects.
- The introduction of significant penalties for parties who provide false or misleading information as part of the notification process.

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? (Yes/No question.)

Yes.

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

As noted previously, Asthma Australia advocates that the availability of NVPs for therapeutic use follow normal Australian practice. Processes required such as those for the Australian Register of Therapeutic Goods (ARTG) would demonstrate NVP quality, safety and efficacy as a smoking cessation aid. NVPs should have to undergo similarly stringent regulatory approval processes. We therefore support the Cancer Council Australia's recommendation in their consultation submission that manufacturers and importers of vapes should be actively encouraged to work towards registration of products on the ARTG.

In addition, we note and support the Cancer Council Australia's response in relation to the dramatic increase in telehealth "online vaping script" services, with many businesses now offering online vaping scripts following a short phone call with the consumer. These services are likely to undermine the intent of the proposed regulatory model and should not be permitted.

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? (Yes/No question.)

Yes.

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

No. While we support the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity, we note and share the Cancer Council Australia's concern in their consultation response in relation to the proposed reform that a prescription would not be required to access device components, but that device components would

only be available for supply in pharmacies. This is of concern as vape devices are much more liable to misuse than other medical devices, with it not being uncommon for mod/tank devices to be used to inhale other drugs.[1] We support the Cancer Council Australia's recommendation that that device components only be made available when accompanied by a prescription for e-liquid, and that pharmacies should be required to store devices behind the counter.

1. Roberts E, Taylor E, Cox S, et al. Pattern and prevalence of vaping nicotine and non-nicotine drugs in the United Kingdom: a cross-sectional study. BMJ Open 2023;13:e066826. doi: 10.1136/bmjopen-2022-066826. Available from: https://bmjopen.bmj.com/content/13/4/e066826

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

Yes. We note the Cancer Council Australia's response to this question in the survey and support it.

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

Yes. We note the Cancer Council Australia's response to this question in the survey and support it.

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? (Yes/No question.)

Yes.

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? (Yes/No question.)

Yes.

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? (Yes/No question.)

Yes.

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/No question.)

Yes.

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?

Asthma Australia strongly welcomes the proposed reforms and the commitment of the Government to ending recreational vaping for the health benefits that this will bring to people who vape, to people with asthma and other health conditions affected by passive smoking, and for helping to prevent another generation of people in Australia becoming addicted to nicotine and taking up tobacco smoking.

We are deeply concerned about the adverse health impacts of using nicotine vaping products, given the conclusive evidence that e-cigarette use causes a range of adverse health impacts, including respiratory disease.[1] Vaping products should not be used by non-smokers or young people because of the known short and mid-term adverse health impacts and risk of development of chronic lung disease.[2]

The TGA consultation papers have recognised the increasing practice of hiding the presence of nicotine in NVPs, making it extremely hard for border control and enforcement to identify and prevent the illegal use of NVPs that contain nicotine. As a result, while NVPs can only be legally obtained by adults with a doctor's prescription, they are being illegally accessed by children, adolescents and adults. On the other hand, non-nicotine containing vaping products have no valid purpose and prohibiting their importation would greatly assist enforcement agencies currently struggling to identify and control mislabelled NVPs. The TGA should be able to regulate all NVPs, regardless of whether or not they are correctly labelled as containing nicotine.

In addition, we note the environmental impact of disposable, single use NVPs and strongly support the expansion of the TG Act to prohibit the importation, manufacture and supply of them irrespective of nicotine content or therapeutic claims.

However, as noted previously, Asthma Australia advocates that the availability of NVPs for therapeutic use follow normal Australian practice. Processes required such as those for the Australian Register of Therapeutic Goods (ARTG) would demonstrate NVP quality, safety and efficacy. NVPs for therapeutic use should have to undergo similarly stringent regulatory approval processes.

Asthma Australia would like to see these proposed reforms be accompanied by programs to support young people and adults now addicted to nicotine as a result of current access to unregulated vaping products.

1. Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

2. Ibid.

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.