NT Health Submission

Consultation on the proposed reforms to the regulation of vapes

Proposal One

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?*

NT Health strongly supports 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. The evidence on harms of vaping is increasing, and long-term impacts remain largely unknown.

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

NT Health anticipates that current vapers will not be supportive of the ban on importation, manufacture and supply of non-therapeutic vapes. NT Health notes that industry comments are likely to come from retail business currently breaching legislation on NVP supply as non-nicotine-vapes is believed to make up an insignificant market share.

There is likely to be a large number of people who will simultaneously go through nicotine withdrawal when supply is disrupted during implementation of reforms. Appropriate supports and interventions will need to be in place, including improved access to Nicotine Replacement Therapy (NRT) and other pharmacotherapies.

Extensive education campaigns with prescribing doctors will need to be conducted to encourage appropriate prescribing of therapeutic vapes. NT Health advocates for further TGA assessment of safety, quality and efficacy of therapeutic vapes, and inclusion of products in the ARTG, to enhance prescriber confidence when prescribing.

NT Health anticipates strong industry opposition to bans on the importation, manufacture and supply of non-therapeutic vapes, and attempts to create black market supply. An ongoing multi-agency enforcement regime will need to be in place prior to implementation of reforms, to send a strong and consistent message to industry.

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

NT Health strongly supports the proposal to remove the personal importation scheme exception for vapes. Overseas suppliers cannot be relied upon to abide by Australia's strict bans on illegal diluents, ingredients and packaging requirements. Licensed tobacco retailers in the Northern Territory have been contacted by overseas suppliers of NVP advising them that product labelling can be customised to meet local requirements on request.

Compliance and enforcement activity in Australia is severely compromised by the inability to rely on product labelling to determine ingredients without further costly and time consuming testing.

Overseas products are also not required to meet all of the Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) requirements for safety.

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

NT Health is unconvinced about the need for a substantial travellers exemption. If an exemption is retained, strict limits on quantity of vapes for travellers should apply. The proposed limits of three months' treatment, or a numerical limit of 60 vapes and 2 vaping devices, subject to a consideration of the period of time the passenger will be in Australia, are considered generous.

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

To stop aggressive marketing to children and adolescents, NT Health strongly supports prohibiting the advertisement of vapes consistent with prohibition of advertising of other prescription-only and certain pharmacist-only medicines.

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]?
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?

Proposal Two

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

NT Health supports introducing a requirement for companies intending to supply vapes (which are of 'therapeutic intent 'although 'unapproved' as they are not listed in the ARTG) to notify the TGA regarding their products' compliance with enhanced minimum quality and safety standards in TGO 110. This must be supported by rigorous independent testing.

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?*

N/A

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?*

NT Health does **not** support the proposed access to vapes under the SAS C notification system in principle as it applies to non-ARTG listed Nicotine products. While this would reduce administrative burden on medical practitioners by not requiring pre-approval or authority under the TG Act, the recent learnings from the medicinal cannabis access scheme has shown significant market leakage through uncontrolled prescribing and supply. We believe this situation would be repeated with Nicotine.

Noting the TGA's current lack of definition of 'vape' in this context, the NT assumes if the regulation was to be applied to 'non-disposable vape devices' which accept either liquid nicotine or cartridge, this would be a large range of products and as such a Cat-C "category approach" would be taken. This carries risk of correct oversight and control by the TGA on what is being authorised, which as above raises risk of market leakage.

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

N/A

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

N/A

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?*

N/A

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?*

NT Health agrees with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity. Appropriate wording must be considered to ensure that products such as nebulisers are not unintentionally included in regulations.

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

NT Legislation adapts the Therapeutic Goods Act as law of the Territory, with the exception of Appendix D of the Poisons Standard. NT Law also provides that an offense against the national law can be enforced as an offence against an individual person in the NT. NT has no local manufacturing or supply for NVP that we are aware of, so impact to industry is negligible.

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

No. NT law already allows enforcement of proposed national changes.

Proposal Three

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

NT Health supports the use of the following flavours and definitions, as proposed to be included in TGO 110:

> • Mint flavour: the taste and aroma commonly associated with herbaceous plants in the Mentha genus of the family Lamiaceae, including for example peppermint, spearmint, horsemint and corn mint.
> • Tobacco flavour: the taste and aroma derived from a combination of substances commonly associated with herbaceous plants in the Nicotiana genus of the family Solanaceae.

NT notes that the only product currently legally available on prescription (Nicovape Q) is also available in a Cherry flavour.

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

NT Health supports the proposal to restrict menthol to a maximum limit of 0.1% w/v in vapes.

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

N/A

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?*

NT Health supports the proposal to require pharmaceutical-like packaging and presentation for vapes to send a strong message that they are for therapeutic purposes only and to limit the appeal to youth.

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?*

N/A

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?*

NT Health agrees with the approach to allow only permitted ingredients in vapes. This reduces the various additives and harmful chemicals being inhaled directly into the lungs, and eliminates the need to maintain lists of prohibited ingredients.

Additives such as colourings, sweeteners and flavourings are known to enhance the appeal to youth.

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?

N/A

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

NT Health supports applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs.

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

N/A

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

NT Health agrees with the below proposed requirements under TGO 110 that will apply to unapproved device components of vapes:

- ensure vaporisation process and dosing controls.
- ensure the device component conforms with minimum safety principles to reduce user risk, having regard to the generally acknowledged state of the art.
- ensure the device component performs and operates safely during its expected lifetime (including storage).
- demonstrate device physical, thermal, material, and electrical safety, including battery safety.
- minimise risks to the user associated with contaminants, residues, and leachable substances (and their degradation and reaction products).
- ensure any risks of fire or explosion occurring during normal use of the device are removed or minimised.
- ensure programmed features or software perform appropriately and any resulting risks are minimised.
- ensure suitable labelling of the device and instructions for use.
- maintain certification of the manufacturer to international standards for Quality Management Systems (consistent with ISO9001, ISO13485)

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

N/A

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?*

N/A

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?*

N/A

Proposal Four

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

Planning is required for an alternative control mechanism if importation of vapes cannot be reduced sufficiently to prevent a substantial black market developing.

Supplementary questions:

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.*

N/A

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?*

N/A