Attachment 1
Submission from SA Health in response to the Therapeutic Goods Administration's Public Consultation on TGO 110 – Standard for vaporiser nicotine products

Response contact information

1. What is your name?

SA Health

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3. Name of your organisation?

SA Health

Part 1: Proposed scope of the TGO 110

4. Do you think that export only vaporiser nicotine should be required to comply with TGO 110?

While no specific preference is nominated, the approach should consider the decision made by the Conference of the Parties (COP) 8 (FCTC/COP8(22)) to the World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC) that reminds Parties about their commitment under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products. In particular, Article 11 of the FCTC relates to 'packaging and labelling'.

5. Why/Why not?

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6. Do you think clinical trial products should be required to comply with TGO 110?

While no specific preference is nominated, the approach taken by the TGA should uphold the protection of the health and safety of the community.

7. Why/Why not?

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8. Do you think products that are the subject of an FDA PMTA marketing order, or that are supplied in the UK, EU, Canada, NZ and/or another country in accordance with the relevant requirements of that country, should be deemed to comply with TGO 110 (in whole or in part)?

Yes, provided that the applicable overseas requirements are equivalent or comparable to the Standard for TGO 110 (option one). Additionally, an ongoing mechanism should be in place in Australia for monitoring the requirements in place overseas, to assess their equivalence and remove the 'automatic' compliance with TGO 110, as required.

9. Why/Why not?

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10. Would any of these options, particularly the TGA's proposed options, have an impact on you? How?

SA Health is responsible for leading and delivering a comprehensive and sustainable health system in South Australia that aims to ensure healthier, longer and better lives. The Therapeutic Goods Order (TGO) applying to nicotine vaporiser products may have an impact on the health and wellbeing of the South Australian community, particularly in terms of the safety of these products and their attractiveness to young people.

The South Australian Select Committee on E-cigarettes[1] (which released its recommendation report on 24 February 2016) made recommendations in relation to a range of approaches for addressing e-cigarette-related harms, including both State-focussed regulation and national regulation. While the scope of the committee was focused on e-cigarette products more broadly, rather than specifically nicotine–containing e-cigarette products, the committee's recommendations are valuable for the development of the TGO 110 Standard, which is the subject of this consultation. The Select Committee report can be found at: https://consultations.health.gov.au/tga/tgo110-standard-for-vaporiser-nicotine/.

11. Do you have any other comments about the products covered by or excluded from draft TGO 110?

SA Health welcomes the introduction of a Standard for vaporiser nicotine products. It is important to ensure that the proposed requirements apply to all nicotine vaporiser products, including heat-not-burn tobacco products and liquid nicotine. It should also cover nicotine in containers or vials to be mixed by the consumer and those combined with flavours and other ingredients.

Part 2: Potential requirements for unapproved vaporiser nicotine products

- **Labelling – Ingredient Lists**

12. Which option (whether listed above or not? Do you prefer? Why?

The Final Report of the South Australian Select Committee on E-Cigarettes[2] includes discussion about the lack of transparency in terms of the contents and origin of e-liquids. The Select Committee's Recommendation 13 called for improvements to the communication of the contents of e-liquids and their potential effects, and highlighted that the European Union Tobacco Products Directive revisions[3] require e-cigarette and e-liquid manufacturers to state product ingredients in weighted order. The Select Committee report emphasised that mandating comprehensive ingredient listing will promote transparency for the consumer and accountability of producers.

[1] Catalogue.nla.gov.au. 2016. *Final report of the South Australian Select Committee on E-Cigarettes*, February 2016, *National Library of Australia,* [online] Available at: https://catalogue.nla.gov.au/Record/7386277 [Accessed 9 March 2021].

[2] Catalogue.nla.gov.au. 2016. *Final report of the South Australian Select Committee on E-Cigarettes*, February 2016, *National Library of Australia,* [online] Available at: https://catalogue.nla.gov.au/Record/7386277 [Accessed 9 March 2021].

[3] Ec.europa.eu. 2014. *Directive 2014/04/EU of the European Parliament and of the Council of 3 April 2014*, [online] Available at: https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf [Accessed 9 March 2021].

There is strong merit in option two, which proposes the listing of all active ingredients (which should only be nicotine) and excipient ingredients, and all other ingredients. This option is in line with the recommendation of the South Australian Select Committee on E-Cigarettes on this matter.

However, there is a need for greater detail in terms of listing chemicals in the flavouring. While the challenge of listing all the chemicals on a label for all the many available flavours is acknowledged, there is a risk in only listing the word –' flavour' or a particular flavour, such as 'chocolate'. Such generic labelling fails to provide adequate detail to the consumer on the chemicals in the flavours (as an example, chocolate flavouring listed on one product could consist of completely different chemicals to those in another product claiming to be chocolate - flavoured). An approach should be devised for enabling the consumer to access information about the chemicals in a product's flavours, such as through a flavour number. This would ensure that consumers make informed choices about the use of vaporiser nicotine products and the associated potential effects on their health.

13. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Inadequate and ambiguous ingredient listing may diminish the capacity of the consumer to make an informed decision about whether to use these products and their choice of products. In turn, this may compromise the health and safety of people choosing to use these products.

- **Labelling – Nicotine Concentration**

14. Which option (whether listed above or not) do you prefer? Why?

Option two is supported as there is strong merit in clearly specifying the nicotine concentration on the label of vaporiser nicotine products. This requirement should extend to all product types, including heat-not-burn products, liquid nicotine-containing products and nicotine salt-containing products.

The concentration should be expressed as mg/mL of total nicotine base equivalent, rather than a percentage from which it is hard to derive a dose.

15. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Inadequate and ambiguous labelling in terms of nicotine concentration may diminish the capacity of the consumer to make an informed decision about whether to use these products and their choice of products. In turn, this may compromise the health and safety of people choosing to use these products.

- **Labelling – Warning Statements**

16. Which option (whether listed above or not) do you prefer? Why?

The proposal to rely on State and Territory requirements for warning statements and safety directions in the Poisons Standard is appropriate as it will avoid regulatory overlap and avoid products needing to be repackaged or relabelled. However, there are opportunities to enhance warning statements. In addition to the warning - KEEP OUT OF REACH OF CHILDREN on Appendix L of the Poisons Standard, there is merit in considering additional warnings, particularly warnings related to the addictiveness of nicotine (option one). In

accordance with the Select Committee's recommendation 12, consideration should also be given to health warnings on product packaging, such as 'Electronic cigarettes should be used with caution. Effects on human health are unknown'. These warnings enhance consumer awareness of the potential risks they take in using these products.

This approach is also consistent with the World Health Organization's (WHO) Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report[4].

In addition, in accordance with the Select Committee recommendation, consideration should be given to including the Quitline number/logo, or other smoking cessation tools or services, on product packaging.

17. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Inadequate communication of health warnings associated with the use of these products may diminish the capacity of the consumer to make an informed decision about whether to use these products. In turn, this may compromise the health and safety of people choosing to use these products.

- **Ingredients – Prohibiting Certain Ingredients**

18. Which option (whether listed above or not) do you prefer? Why?

Option one is the preferred option. This would enable the prohibition of other active ingredients, excipient ingredients, and other ingredients such as flavourings which carry known health risks. Additionally, nicotine should be the only active ingredient permitted to be included in these products, and any other active ingredients should be prohibited.

In line with the consultation that New Zealand is conducting, all colourants should be prohibited, where feasible, as they are not considered necessary in most cases for product consumption, and there is very limited data on colourant safety to assess their risk.

To ensure that this prohibited ingredient listing remains up to date, a mechanism should be put in place to monitor the emergence and evidence of harm for ingredients in the future, and update the prohibited ingredients accordingly, including those that could be present in flavours.

19. Would any of these options, particularly the TGA's proposed options, have an impact on you? How?

Accessibility of the community to certain ingredients that pose a danger to human health may threaten the health and safety of the community.

[4] Who.int. 2016. *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report*, [online] Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1 [Accessed 9 March 2021].

- **Ingredients – Flavours**

20. Which option (whether listed above or not) do you prefer? Why?

In accordance with the Recommendation three of the South Australian Select Committee on E-Cigarettes[5] and the WHO ENDS/ENNDS Report[6], the Standard would be strengthened with the prohibition of certain flavours (option two), particularly those that may appeal to minors, such as sweet and confectionery flavours. This will reduce the attractiveness of these products to children and young people and is consistent with the ban on fruit and confectionary flavoured tobacco products in South Australian legislation. The national application of TGO 110 will ensure a nationally consistent approach to this issue.

21. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Accessibility of the consumer to certain flavours may pose an unacceptable risk in terms of youth uptake, thereby posing a potential threat to the health and safety of the community.

- **Packaging – Child Resistant Packaging**

22. Which option (whether listed above or not) do you prefer? Why?

Option two is the preferred option. Child resistant packaging for e-liquids has been recommended by the WHO[7] to reduce the risk of accidental poisoning. In addition, Recommendation 11 of the South Australian Select Committee on E-Cigarettes[8] also recommended this requirement, acknowledging that leak-proof caps and temper-evident packaging is a standard and accepted practice when managing risks associated with poisonous or toxic substances such as nicotine.

Allowing CRP requirements overseas to apply to products in Australia must be accompanied by a process for ensuring that the applicable overseas requirements are equivalent, or comparable, to the TGO 95. This includes establishing an ongoing mechanism in Australia for monitoring the requirements in place overseas in order to assess their equivalence and remove the 'automatic' compliance with TGO 95 where necessary.

23. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Access to nicotine vaporiser products with inadequate child resistant packaging, may pose an unacceptable poisoning risk, particularly to children and young people which, in turn, would be a health and safety risk to the public.

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[5] Catalogue.nla.gov.au. 2016. *Final report of the South Australian Select Committee on E-Cigarettes*, February 2016, *National Library of Australia,* [online] Available at: https://catalogue.nla.gov.au/Record/7386277 [Accessed 9 March 2021].

[6] Who.int. 2016. *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report*, [online] Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1 [Accessed 9 March 2021].

[7] Who.int. 2016. *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report*, [online] Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1 [Accessed 9 March 2021].

[8] Catalogue.nla.gov.au. 2016. *Final report of the South Australian Select Committee on E-Cigarettes*, February 2016, *National Library of Australia,* [online] Available at: https://catalogue.nla.gov.au/Record/7386277 [Accessed 9 March 2021].

- **Packaging – Tamper-proof/evident Packaging**

24. Which option (whether listed above or not) do you prefer? Why?

The WHO[9] recommends reducing the risk of accidental acute nicotine intoxication by requiring tamper-evident/child resistant packaging for e-liquids and leak-proof containers for devices and e-liquids to minimise health risks to non-users, particularly to children. In line with the WHO recommendation, SA Health supports option one. This is also consistent with Recommendation 11 of the South Australian Select Committee on E-Cigarettes[10]. This measure would reduce the risk of child poisoning from the swallowing of these products.

25. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Accessibility of the consumer to nicotine-containing products with inadequate packaging may pose an unacceptable risk in terms of poisoning, particularly to young people. Inadequate regulation in this regard may pose a risk to the health and safety of the community.

- **Nicotine concentration**

26. Which option (whether listed above or not) do you prefer? Why?

The WHO Report on ENDS/ENNDS[11] encouraged Parties that have not banned these products to consider limiting the nicotine concentration and total nicotine amount in devices and e-liquids to minimise the health risks to non-users. In line with the WHO recommendation, consideration should be given to prescribing a nicotine concentration limit in vaporiser products (option one). The concentration limit for nicotine should be determined by the TGA based on a comprehensive analysis of public safety, particularly poisoning risk from ingestion, and prescribed as a free base total concentration in mg/mL.

27. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

Accessibility of consumers to dangerous concentrations would pose an unacceptable risk in terms of poisoning, particularly to young people. Inadequate regulation of nicotine concentrations may pose a risk to the health and safety of the community.

- **Volume**

28. Which option (whether listed above or not) do you prefer? Why?

Consideration should be given to prescribing a nicotine volume limit, given the potential for the importation of large volumes beyond the quantity needed for personal use. While it is acknowledged that, in terms of the Personal Importation Scheme, importation volume is

[9] Who.int. 2016. *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report*, [online] Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1 [Accessed 9 March 2021].

[10] Catalogue.nla.gov.au. 2016. *Final report of the South Australian Select Committee on E-Cigarettes*, February 2016, *National Library of Australia,* [online] Available at: https://catalogue.nla.gov.au/Record/7386277 [Accessed 9 March 2021].

[11] Who.int. 2016. *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report*, [online] Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1 [Accessed 9 March 2021].

limited to a three month supply, the lack of a volume limit may pose an enforcement challenge. In particular, Australian Border Force personnel may find it difficult to determine whether the volume in question equates to the volume needed for the purpose of a medical script over three months. A volume limit may address this enforcement challenge.

Further assessment of options one and two may be required to determine the most appropriate approach in terms of enforcement feasibility, as well as upholding health and safety considerations.

29. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

The absence of a volume restriction in the Standards may pose a risk to the health and safety of the community by allowing importation of large volumes beyond that needed for personal use and enabling unofficial domestic supply chains.

- **Other Questions/Comments**

30. Are there any other potential minimum requirements for unapproved vaporiser nicotine products the TGA should consider including in TGO 110?

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31. Would you like to be consulted on any draft guidance prepared for TGO 110?

SA Health would appreciate the opportunity to be informed and consulted on any draft guidance prepared for TGO 110 in relation to vaporiser nicotine products.

Part 3: Related Matters

- **Default standards and nicotine purity**

32. Which option (whether listed above or not) do you prefer? Why?

While no specific option is nominated, the approach taken by the TGA should uphold the protection of the health and safety of the community.

33. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

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34. Do you have any comments on the application of TGO 110 to compounded vaporiser nicotine products?

No specific comments. However, the approach taken by the TGA should uphold the protection of the health and safety of the community.

Consent to publish

35. Do you consent to your answers being published?

Yes