ATTACHMENT 1

Consumer Healthcare Products Australia

Response to Consultation: TGO 110 Standard for Vaporiser Nicotine

Executive Summary

Thank you for the opportunity to provide comment on the above consultation.

CHP Australia is of the view that vaporiser nicotine should be required to comply with an appropriate standard, as proposed by the TGA, and we would also like to provide some additional key points relating to this consultation.

Tobacco control requires a comprehensive, evidence-based, population-wide approach, and an appropriate regulatory environment that ensures Australians have access to high quality, safe and effective smoking cessation products.

It is CHP Australia's firm view that any product seeking to make therapeutic claims, including smoking cessation, must be regulated as a therapeutic good. Currently available nicotine replacement therapy (NRT) products have undergone evaluation and approval by the TGA to ensure their quality, safety, and efficacy prior to supply.

In general terms, while emerging literature suggests that there may be a potential role for e-cigarettes/vaporisers containing nicotine in smoking cessation that is encouraging, more research is required to determine the effectiveness of these products as a cessation treatment, and the practical risk of uptake amongst non-smokers, particularly young Australians is concerning.

In re-scheduling vaporiser nicotine as a prescription only medicine, the TGA has effectively endorsed the role of these products as a smoking cessation treatment without the products having undergone any form of pre-market assessment for quality, safety and efficacy.

In the interests of public health and safety, CHP Australia believes that:

- Since smoking cessation is a therapeutic claim in Australia, vaporiser nicotine products such as e-cigarettes that make claims of efficacy in smoking cessation should require the same rigorous assessment as existing prescription and non-prescription medicines indicated for smoking cessation.

- Since the TGA has enabled pathways for unapproved smoking cessation products to be made available to consumers with a doctor's prescription, these products should as a minimum be required to comply with a standard such as TGO 110.

Compliance and enforcement activities are also important for ensuring that the products being supplied to consumers meet minimum standards of purity, quality and safety. The existence of a standard is a mechanism for setting appropriate standards and this must be followed up with appropriate compliance checks and enforcement activities, by the TGA as well as States and Territories who give effect to the Poisons Standard requirements.

Prescription only scheduling of vaporiser nicotine can mitigate against some risks by controlling who can access the product, however it will not eliminate all risk once the

products are in the hands of the user. For this reason, and due to the highly toxic and addictive nature of nicotine, CHP Australia requests the TGA to consider concentration and volume limits, especially if these are adopted by comparable overseas regulators. Australian consumers deserve similar levels of protection.

The medical practitioners who will be prescribing these products after the 1st October 2021 should also be appropriately trained on the use of these products and counselling patients on how to use these products safely and correctly, with a view to cutting down on use of nicotine altogether rather than using vaporiser nicotine as a substitute for cigarette smoking indefinitely.

We would like to thank the Nicotine Standards Team for considering our submission.

Please see attached CHP's responses to the consultation question, in the same order as they appear in the consultation paper.

ATTACHMENT 1 – CHP RESPONSES TO CONSULTATION QUESTIONS

Part 1: Proposed scope of TGO 110

Questions:

1. **Do you think that export only vaporiser nicotine should be required to comply with TGO 110? Why or why not?**

CHP believes that vaporiser nicotine products that are intended for export should comply with TGO 110 and be listed on the ARTG as export only therapeutic goods, irrespective of whether these products are sold as consumer goods in their respective export markets.

This will ensure that any vaporiser nicotine products exported from Australia will comply with a set of minimum quality and safety requirements.

2. **Do you think clinical trial products should be required to comply with TGO 110? Why or why not?**

CHP believes that the TGA has standards and processes in place for the conduct of clinical trials, and any vaporiser nicotine products used in clinical trials should follow the existing TGA legislative requirements, guidance and processes for the approval and conduct of clinical trials, e.g. the CTN and CTA schemes.

3. **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)? Why or why not?**

CHP is of the view that any therapeutic goods (or other products) intended for supply in Australia should comply with Australian standards.

Since vaporiser nicotine will be supplied in Australia with a doctor's prescription, these products should comply with TGO 110.

The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for purpose.[1] Vaporiser nicotine is no different; it will be supplied as a prescription only medicine and will in effect be a therapeutic good and should be regulated as such and meet minimum standards in order to be supplied in Australia.

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

N/A

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

[1] https://www.tga.gov.au/what-tga-regulates

We note that the TGA consultation paper states that TGO 110 cannot specify quality or safety requirements for vaping devices, and that for unapproved nicotine vaporiser products supplied via the SAS or the APS pathways, the TGA does not assess the devices.

CHP Australia is concerned at the lack of any regulatory standards or oversight of the vaporiser devices. In the UK, concerns have been raised regarding the safety of the devices themselves, and the risk of overheating, fire, battery explosion and ingestion of the nicotine liquid and poisoning[2]. These are not harmless devices.

We therefore encourage the TGA to consider quality and safety standards that should be applied to the devices, as well as the vaporiser nicotine liquid.

Part 2: Potential requirements for unapproved vaporiser nicotine products

Labelling – Ingredient Lists

Questions:

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

CHP agrees with the TGA's proposal to require all active and excipient ingredients (except ingredients of flavours) to be listed on labels or on information sheets.

This is an approach that is consistent with the requirements for therapeutic goods. Consumers and the medical practitioners who prescribe these products should be able to access this important information, to make informed decisions on safety and product comparisons.

Suppliers of these products should be encouraged to provide this information on the label of the product, because leaflets can be lost or damaged – however we also appreciate that this may not be practical in all cases and the option of a leaflet should be available.

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

N/A

Labelling – Nicotine concentration

Questions:

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

CHP agrees with the TGA's proposal to require a statement of nicotine concentration or content on the label or product leaflet.

This is an approach that is consistent with the requirements for therapeutic goods. Medical practitioners who prescribe these products and consumers who use them should be able to

[2] https://www.rospa.com/home-safety/advice/product/vaping

access this important information, to make informed decisions on safety and product comparisons.

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

N/A

Labelling – Warning statements

Questions:

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

CHP agrees with the TGA's proposed option, which is to rely on State/Territory requirements for warning statements and safety directions. Since vaporiser nicotine will only be available by prescription, we would expect that the prescribing doctor will convey important information on the risks and benefits of these products. The warning statements that will be included in Appendix F are adequate for a prescription only medicine.

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

N/A

Ingredients – prohibiting certain ingredients

Questions:

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

CHP agrees with the TGA's preferred approach, which is to prohibit active ingredients other than nicotine (including vitamins, caffeine) as well as ethylene glycol, diethylene glycol, diacetyl, 2,3-pentanedione, vitamin E acetate.

Unlike therapeutic goods that are entered in the ARTG, the TGA cannot evaluate quality data for these unapproved therapeutic goods. There are valid concerns regarding safety of some of these ingredients when inhaled into the lungs in vaporised form. We therefore believe that TGO 110 provides a mechanism for the TGA to prohibit certain ingredients that are known to carry risks to human health.

We also believe that compliance and enforcement are key and also recommend a mechanism whereby the TGA or States and Territories can audit for compliance.

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

N/A

Ingredients – flavours

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

CHP believes that the guiding principle in a decision on whether or not to allow certain flavours should be determined by the safety of the ingredients when used for inhalation, rather than the flavour per se.

Many flavours used in vaporiser nicotine are food grade, and the safety profile of the ingredients in these flavours when used for inhalation has not been properly evaluated, especially since these products may be used for prolonged periods.

It is therefore important that suppliers of these products in Australia should be aware of the inactive ingredients in the vaporiser liquids, including the ingredients used in flavours.

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

N/A

Packaging – child-resistant packaging

Questions:

1. **Which option (whether listed above or not) do you prefer?**

CHP believes that regulatory oversight is necessary to mitigate the risks associated with the potential ingestion of nicotine liquids used in vaporisers. Like other therapeutic goods that can be harmful when ingested, nicotine should be no exception and child resistant packaging should be a regulatory requirement. The TGA's proposal that nicotine vaporiser liquids comply with CRP requirements of the country of origin (for UK, EU, Canada, US, NZ products) or with requirements equivalent to TGO 95 for all other products, is a reasonable approach.

2. **Would any of these options, particularly the TGA's proposed option, have an impact on you? How? No comment**

N/A

Packaging – Tamper proof/evident packaging

Questions:

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

CHP understands the challenges that would exist if TEP were to be made mandatory for vaporiser nicotine products, and for this reason we do not oppose the TGA's preferred approach given that TEP is not mandatory for prescription medicines.

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

N/A

Nicotine concentration

Questions:

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

CHP believes that the prescription only scheduling of nicotine vaporisers can mitigate some of the risks of harm associated with nicotine, mainly by restricting who can be prescribed the product.

However, the prescription only status does not mitigate against all risks, with the greatest risk being how the product is used by the consumer, how it is stored and whether it can be accessed by other people, including children and adolescents.

The ingestion of a small quantity of nicotine can be lethal (120 mg for a smoking adult; 30-60 mg for a non-smoking adult; 10 mg for a child). CHP therefore is of the view that in the interests of consumer safety, the TGA should consider placing some restriction on concentration and volume, as other key comparable regulators are considering.

Currently, insufficient data exists to determine whether e-cigarettes, containing nicotine and/or other substances, can be considered safe, therefore some degree of regulatory oversight is appropriate and this should extend to limits on concentration and volume of containers.

2. **Would any of these options, particularly the TGA's proposed option, have an impact on you? How? No comment**

N/A

Volume

Questions:

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

As outlined in the previous section on concentration of nicotine, CHP believes that the TGA should consider some degree of regulatory oversight or limits on the allowable volume of containers.

Prescription only scheduling can assist in ensuring that the products are prescribed appropriately, however the usage of the nicotine vaporiser will essentially be uncontrolled after supply has taken place and consumers can be careless with how the products are stored and accessed in the home or other settings where the products may be used.

Given the toxicity of nicotine, CHP believes that the TGA should take a precautionary approach and consider aligning with limits being set by other comparable regulators.

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

N/A

Part 3 – Related matters

Default standards and nicotine purity

Questions:

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

CHP Australia does not object to the TGA's proposal to exempt unapproved vaporiser nicotine products covered by TGO 110 from complying with product default standards. Our interpretation of this section is that API default standards will apply. We also support the TGA's recommendations that sponsors and others considering commercial supply of vaporiser nicotine products should seek a Certificate of Analysis for the product and its active and inactive ingredients.

Medical practitioners who prescribe these products and the consumers who will be using them as prescription only medicines will have an expectation that the ingredients in these products meet basic requirements of purity and be free of contamination. This is especially important given that the vapour is inhaled into the lungs frequently and for prolonged periods.

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

N/A

Compounding

Questions:

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

No