Submission to TGA re: TGO 110 Standard for Vaporiser Nicotine consultation via online survey

Respondent contact information

1. What is your name?

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3. Name of your organisation?

The Society of Hospital Pharmacists of Australia

Part 1: Proposed scope of TGO 110

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

Yes

5. Why/Why not?

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA members believe that export only vaporiser nicotine products must comply with TGO 110. Given the decision by TGA to regulate vaporiser nicotine products as prescription medicines from 1 October 2021, vaporiser nicotine products must meet minimum Australian safety and quality standards regarding manufacturing, impurities and safety of excipients in line with other scheduled medicines dispensed by pharmacists.

The need for improved regulation in this area is clear, as quoted by the Federal government, the Victorian Poisons Centre reported a near doubling of nicotine poisons between 2018 (21 cases) and 2019 (41 cases), largely due to imported nicotine products of questionable safety and quality.

SHPA believes the role of the regulator is to ensure the safety of all therapeutic products being used in Australia, especially for substances as potentially harmful as liquid-nicotine containing products. Clinicians need to be confident that the manufacturing, excipients and packaging of liquid-nicotine containing products, meet minimum safety and quality standards outlined in the TGO 110, as with any other medication prescribed and dispensed in their practice.

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

No

7. Why/Why not?

SHPA believes that vaporiser nicotine clinical trial products should not be required to comply with TGO 110.

SHPA convenes a Clinical Trials Speciality Practice Group who are leading pharmacists in clinical trials pharmacy practice. Our members have advised that vaporiser nicotine clinical trial products should comply with all current regulations for clinical trials with no additional requirements in TGO 110, as this would add unnecessary additional regulatory burden to a sufficiently and highly regulated area.

Introducing unnecessary complexity to the regulatory environment for clinical trials may hinder the conduct of clinical trials, as well as reduce the attractiveness of the Australian setting for clinical trials investment. The treatment of vaporiser nicotine products in clinical trials should remain consistent with the Australian clinical trial landscape, especially as the risk of harm in this setting is mitigated within the controlled conditions and clinician-led patient monitoring associated with clinical trials.

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)?

No

9. Why/Why not?

SHPA believes that the proposed regulatory model in Australia from 1 October 2021 where they are treated as prescription medicines, is vastly different from international models for vaporiser nicotine products which are treated and regulated as consumer products, and not prescription medicines.

Automatically deeming products from these counties as compliant with TGO 110 would mean that the Australian regulator has no influence over changes to paraments and cannot guarantee the safety of vaporiser nicotine products exported from these countries.

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

Hospital pharmacists may be expected to source and/or supply these unapproved Schedule 4 products and therefore must trust that the regulator has ensured all permitted vaporiser nicotine products are deemed to comply with TGO 110 minimum safety and quality requirements.

SHPA would support Option 2 outlined in the discussion paper '*As per Option 1, but TGO 110 NOT to cover clinical trial products*' as this will not hinder clinical trials in Australia which would certainly impact on SHPA members who are clinical trial hospital pharmacists.

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

<u>Electronic Nicotine Delivery Systems</u>

The TGO 110, or a different therapeutic goods order, must specify requirements for vaping devices to ensure a precise and safe dosage is administered to patients. This is even more imperative when the substance is as harmful and addictive as nicotine. SHPA is concerned that the TGA does not intend to apply minimum quality and safety standards to Electronic Nicotine Delivery Systems (ENDS) and believes this position is inconsistent with its role as the regulator, especially as it regulates other medical and therapeutic devices.

The lack of regulation for ENDS with a TGO and necessitating patients to source these devices themselves from unauthorised local and international suppliers, means prescribers and pharmacists will have no confidence of the accuracy of the treatments they are prescribing and dispensing. Different ENDS will produce different results with respect to the actual quantity of nicotine delivered per dose. This represents a risk to clinical practice standards, professional pharmacy practice standards and may raise medicolegal concerns.

The TGA has stringent regulations for the delivery of substances that pose significantly less risk to patients than nicotine. For example, the TGA regulates devices used for inhaled medicines, such as

budesonide/formoterol delivered via Turbuhaler and Rapihaler devices, and so much so that both the metered and delivered doses require display on the packaging due to their difference. Regulation of these devices ensures a clear understanding of the actual dose delivered via the device. The treatment of ENDS should be no different to other devices used for inhaled medicines. Medical prescribers and dispensers must have certainty of the maximum dose of liquid nicotine being administered via the different ENDS used by patients and the safety of these devices.

Personal Importation Scheme

In the consultation paper, the TGA notes that it cannot take action to enforce TGO 110 against overseas manufacturers and suppliers of unapproved vaporiser nicotine products imported via the Personal Importation Scheme. It stipulates that the TGA strongly encourages individuals to check whether the products meet the TGO 110 requirements before purchasing. SHPA believes this is an unrealistic expectation on the consumer and that importation of unapproved products must be prohibited, or at the very least included in a prohibited products list for consumers to refer to.

Part 2: Labelling – Ingredient Lists

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

SHPA supports Option 1. Information regarding all active and excipient ingredients, including components of flavours, must be available both on the label and the information sheet, at the time of prescribing and dispensing, to assist health professionals in making informed and safe decisions.

Consumers with allergies to food and/or intolerances to flavour ingredients must have a way of identifying appropriate and safe products. On the other hand, if a flavouring ingredient triggers a hospital admission, hospital staff must have access to the ingredients in the product in order to best manage the patient's condition.

Listing all active and excipient ingredients, including components of flavours, would also assist with safety recalls in the event of emerging evidence on a certain ingredient. SHPA believes that eliminating flavour ingredients from the information provided at the time of prescribing and/or dispensing poses significant medication safety risks.

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

Pharmacists are medication experts and play a crucial role in medication safety. They utilise all available clinical information to ensure patient safety and safe and quality use of medications. If pertinent information regarding active and excipient ingredients, including components of flavours, are not accessible to them at the time of dispensing, this compromises their ability to make informed and safe clinical decisions that mitigate the risks of patient harm.

Part 2: Labelling – Nicotine Concentration

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

SHPA recommends *stating nicotine concentration in a standardised manner (mg/ml)*.

Stating concentrations in a non-standardised way will result in medication errors. Using mg/ml will remove the need for health professionals to perform dosage and conversion calculations which can introduce manual errors, causing dosing and dispensing errors that contribute to patient harm. It also aids health professionals by enabling simple comparison of concentrations across various products. In the event of accidental poisoning, nicotine concentration information must be clearly accessibly on the product label in order to allow for timely and appropriate treatment.

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

It is not sufficient to state nicotine concentration or content on the label and/or the information sheet if it is not presented in a standardised manner. SHPA recommends *stating nicotine concentration in a standardised manner (mg/ml)*.

Part 2: Labelling – Warning Statements

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

SHPA supports Option 1 with the inclusion of an additional statement indicating that the product is for inhalation only and not for drinking.

It is essential that all warning are included on the label as well as the information sheet, to protect individuals sharing or children 'borrowing' their parents' vaporisers.

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

Insufficient warning statements on product labels and information sheets will impact on medication safety place patients at greater risk of misuse.

Part 2: Ingredients – Prohibiting Certain Ingredients

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

SHPA supports Option 1 with an additional caveat that this list of ingredients is kept up-to-date based on latest evidence as it is impractical for health professionals to review. If the onus is on the health professional to actively monitor emerging research literature on ingredients, this will likely impact the practitioners' preparedness to prescribe or dispense vaporiser nicotine products.

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

Pharmacists need to be certain that the TGA is keeping abreast the safety of ingredients in vaporiser nicotine products in order to satisfy their own professional obligations and have the confidence to dispense these products to patients.

Part 2: Ingredients - Flavours

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

SHPA supports Option 1.

Compliance is necessary in nicotine cessation therapy therefore, acceptable flavouring is important. There is a risk that individuals will seek to add other flavouring agents to their vaporiser nicotine products if flavouring is prohibited, compromising the quality and safety of the product. However, the parameters of use must be in the context of cessation therapy therefore, SHPA believes a limited range of flavouring options (e.g. tobacco and mint) is sufficient. This will also work to reduce the risk of naïve people accessing liquid nicotine products for their flavour allure.

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

Not applicable.

Part 2: Packaging – Child-Resistant Packaging

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

SHPA supports Option 2. However, the use of child-resistant packaging on the liquid nicotine will not protect children who access the liquid through a device that does not have child-resistant packaging. Therefore, as discussed earlier, SHPA urges the TGA to consider regulating ENDS.

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

Not applicable.

Part 2: Packaging –Tamper-proof/evident Packaging

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

SHPA supports Option 1.

Vaporiser nicotine products imported through the Personal Importation Scheme must have tamper-proof packaging to provide assurance that the product has not been tampered with during transportation.

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

Not applicable.

Part 2: Nicotine concentration

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

SHPA supports Option 1.

Therapeutic products must have recommended maximum concentrations to guide health practitioners. Whilst there may be insufficient evidence to guide the most appropriate maximum concentration, it would be reasonable to utilise the experience of other countries and set a maximum concentration of 20mg/ml. Liquid nicotine is not a product that health professionals have any experience prescribing and dispensing, therefore defining a maximum concentration is essential to ensure safe access, and reduce the risks of accidental overdose and misuse.

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

As mentioned above, health professionals do not have any experience prescribing and dispensing liquid nicotine products. The lack of a defined maximum concentration will impact on their confidence and compromise the likelihood that they will provide these products to individuals seeking to cease smoking.

Part 2: Volume

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

SHPA suggests a maximum volume sufficient for 30 days' (one month) supply should be specified, in line with most other Schedule 4 therapeutic medications. Setting no limits to the volume provided may result in individuals receiving large e volumes and therefore, delay clinical review with their health professional, a significant component of successful smoking cessation therapy.

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

Nil

Part 2: Other Questions/ Comments

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

SHPA believes that general labelling reequipments as outlined in TGO 91 are appropriate for vaporiser nicotine products for example, expiry date, batch number, storage conditions, and sponsor details.

SHPA also notes the importance of ensuring nicotine vaporiser labels include a minimum space for dispensing labels to be attached without obscuring other information.

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

Yes

Part 3: Related Matters

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

SHPA supports Option 1.

Nicotine liquid products must comply with pharmacopeial quality standards, including microbial quality and labelling requirements. It is fundamental that Australians can continue to trust that products prescribed and dispensed by their health professionals are deemed safe and meet basic quality standards.

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

Pharmacists need to be certain that the liquid nicotine products they are providing meet minimum safety and quality standards in order to feel confident in dispensing them.

Part 3: Compounding

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

No.

Consent to publish

35. Do you consent to your answers being published

Yes