Pharmaceutical Society of Australia

Consultation: TGO 110 – Standard for vaporiser nicotine

MAR 2021

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission in response to the Therapeutic Goods Administration (TGA) consultation paper, *TGO 110 – Standard for Vaporiser Nicotine* (Version 1.0, February 2021), which presents and explains the requirements proposed in a legal instrument, the *Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021*.

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 34,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Comments on TGA's proposals and options

Part 1: Proposed scope of TGO 110

- PSA welcomes the proposal to establish a standard which would assist in clarifying and ensuring safety and quality requirements for unapproved vaporiser nicotine products in Australia. However, PSA is concerned that the justifications used as the basis for proposed details contained in TGO 110 appear to be inconsistent in several places. In some instances, pre-market approval processes of overseas jurisdictions are seen to be an appropriate option for adoption in Australia while in other instances, there appears to be a preference to consider arrangements that exist under consumer law in similar jurisdictions. The TGO being established will be given effect under Australian law, even if they apply to products not approved in this country. Therefore PSA believes TGO 110 should encompass requirements that are acceptable

by Australian standards and there should be no dilution of requirements based on the origins or source of the unapproved products.

- PSA notes that the proposal to exclude from the scope of TGO 110, ARTG-listed export only vaporiser nicotine products, is to ensure the possibility of lawful export of those products to countries where they are regulated as consumer goods is not excluded. However, PSA believes export only products must also meet certain standards to warrant listing on the ARTG, and hence would query how they might compare with TGO 110 requirements. The rationale given appears to suggest that different, and possibly lower, standards are appropriate for therapeutic products if they are to be exported for supply in other countries. This could result in negative perceptions about the reputation and high standards upheld by the TGA and products subject to the Australian regulatory arrangements.

- PSA supports the proposal to require compliance with TGO 110 for unapproved vaporiser nicotine products which are imported/supplied for clinical trial purposes. PSA notes this will ensure some minimum safety and quality requirements are met, and also believes it would be appropriate to consent to non-compliance on a case-by-case basis provided these are based on reasonable criteria.

- PSA supports the rationale to deem consumer products from overseas markets to be compliant with TGO 110 provided they have been subjected to pre-market assessment by a comparable overseas regulator.

- PSA understands TGO 110 will not apply to vaping devices. This does not seem logical given devices are an essential component and mechanism for the delivery of nicotine doses which exert physiological effect.

- In addition, PSA is aware that the *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021* outlines that most vaping devices are not regulated as therapeutic goods unless they are to be used exclusively for the vaporisation and administration of a medicine. This means that “the therapeutic goods regulatory framework applies to vaporiser nicotine medicines and the vaping devices designed (exclusively) to deliver such medicines”. Thus, if TGO 110 applies to unapproved vaporiser nicotine, the unapproved vaping devices designed to deliver the nicotine should also be included in TGO 110, if not captured elsewhere.

- Further to the previous dot point, the Determination mentioned above states that devices not regulated as therapeutic goods include “vaping devices intended to vaporise and administer a medicine in conjunction with another substance, such as a flavour that is not an ingredient of the medicine”. PSA is concerned that this suggests the addition of a flavouring substance or compound to vaporiser nicotine could determine whether or not that nicotine product is regulated as a therapeutic good.

- Finally, while it is clear that the proposed scope of the consultation does not include “clinical guidelines and recommended dosage regimes for nicotine-containing products for smoking cessation”, the regulator must consider implementation aspects. PSA strongly re-iterates its position that pharmacists must be supported with resources such as clinical guidelines and practice support tools. Such resources are particularly important given the therapeutic decision-making and access arrangements involving unapproved products are not routine practice for many health practitioners as well as patients. PSA will partner with the TGA to ensure pharmacists can work seamlessly with prescribers and patients in the delivery of care including the provision of safe and quality therapeutic products containing nicotine.

Part 2: Potential requirements for unapproved vaporiser nicotine products

Labelling – ingredient lists

- PSA supports the inclusion of names of active and excipient ingredients on the labels of unapproved vaporiser nicotine products, as well as the word “flavour” (if used) but not the component ingredients. PSA also regards the inclusion of allergen information on the labels to be important for patients.

- PSA believes a list of ingredients presented in a document (e.g. information sheet) should only be permitted to be used in addition to the list being presented on the product label. Sole use of a document/sheet is associated with greater risk of ingredient information not being available to the patient or practitioner as it would be not be difficult to become separated from the product.

- PSA believes ingredient information must be presented in English language.

Labelling – nicotine concentration

- PSA supports the proposed requirement to state the nicotine concentration or content on the label of the product.

- For the same reasons mentioned above, PSA does not support the use of a separate document or information sheet as the sole means of providing nicotine concentration or content information of the product.

Labelling – warning statements

- In order to avoid duplication and promote uniformity, PSA recommends the application of warning statement requirements for unapproved vaporiser nicotine products to be as consistent as possible with current arrangements for registered products.

- For reasons outlined above, PSA does not support the use of a separate information sheet as the sole means of communicating warning statements relating to the product.

- As indicated in the consultation paper, the application of relevant and appropriate cautionary advisory labels will also be professional practice considerations of pharmacists when dispensing and counselling on a therapeutic product. Thus, clear information will need to be linked to clinical guidelines for pharmacists.

Ingredients – prohibiting certain ingredients

- Consistent with the objectives of the making of TGO 110, PSA supports the proposal to prohibit active ingredients other than nicotine and to explicitly specify the prohibition of other ingredients which carry known health and safety risks. These must include, as indicated in the consultation paper, substances such as vitamin E acetate which have been shown to cause harm through inhalation.

- PSA suggests it is also important that there is a process or mechanism to effect ongoing active monitoring around the safety of substances inhaled through unapproved vaporiser nicotine products. This may include substances used as excipients, diluents, flavours or colourings. The

scientific and clinical information base of these substances when (super)heated, vaporised and inhaled (including those which may be regarded to be safe when ingested) is still maturing and must continue to be monitored and analysed.

- PSA is aware that, in New Zealand, manufacturers and importers of vaping products must report any adverse reactions to the Vaping Regulatory Authority via the New Zealand Pharmacovigilance Centre (NZPC). Distributors and retailers must also report adverse reactions to the supplier and the NZPC.

- To support pharmacists in the procurement of unapproved products for patients, PSA seeks the advice of TGA on recommended minimum information requirements for a 'certificate of analysis' for imported vaporiser nicotine products.

Ingredients – flavours

- PSA firmly opposes the TGA's proposal to have "no limits on flavours". As products for therapeutic use, there should not be any scope for product characteristics, such as flavours, to intentionally or unintentionally portray them as items of commerce, especially as this may encourage inappropriate use or take-up. Some of the cited examples of flavours (including cannabis, soft drink, bubblegum and candy) are particularly concerning.

- PSA also notes that the current TGA proposal is inconsistent with the concerns expressed[1] previously by the delegate with regards to flavoured electronic cigarettes, viz.:

  > *Flavoured e-cigarettes (e.g. bubble gum, fruit and confectionary flavours), with or without nicotine content, could appeal to adolescents (leading to rapid uptake of tobacco smoking) and to children (leading to toxicity).*

- While PSA is opposed to the use of flavours in ways described above, flavours have a legitimate role in therapeutic products, for example, to improve product acceptability and medication adherence. PSA considers it appropriate to allow the use of flavours in vaporiser nicotine products that are found in registered therapeutic products.

Packaging – child-resistant packaging

- PSA supports the requirement for unapproved vaporiser nicotine products to be supplied in child-resistant packaging (CRP) given the potential risk of significant harm from accidental exposure to and/or ingestion of vaporiser nicotine products by children.

- PSA has no objections with the following proposals:

  - Products packaged for supply within the United Kingdom, Member States of the European Union, Canada, the United States and New Zealand must either comply with CRP requirements imposed in that country OR the requirements applicable to all other products.

[1] Therapeutic Goods Administration. Interim decisions & reasons for decisions by delegates of the Secretary to the Department of Health. 2 Feb 2017. At: **www.tga.gov.au/sites/default/files/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-november-2016.pdf**

- All other products must meet requirements equivalent to TGO 95 (CRP requirements for medicines), excluding the requirement to provide directions for opening/closing.

Packaging – tamper-proof/evident packaging

- PSA notes the TGA does not propose any mandatory tamper-proof/evident packaging for unapproved vaporiser nicotine products on the basis of several factors. As stated earlier in this submission, PSA supports the implementation of requirements that are acceptable by Australian standards and there should be no dilution of requirements based on the origins or source of the unapproved products.

- PSA provides comment on several issues canvassed or summarised in the consultation paper:

  - *Overseas jurisdictions require (or one is proposed to require) tamper-proof/evident closures or packaging. In all cases, vaporiser nicotine products are sold as consumer goods. On the other hand, these products will not be accessible to the general public in Australia as they will be regarded as Prescription Only medicines.*

    PSA is aware that there are other Prescription Only medicines that carry tamper-proof/evident packaging based on level of risk and therefore unapproved vaporiser nicotine products should not be exempted from this requirement based on its scheduling.

  - *Products currently without tamper-proof/evident packaging would need to be repackaged prior to supply in Australia. It is possible that public and patient confidence would be greater by having vaporiser nicotine products with tamper-proof/evident packaging. However, the impost on manufacturers of this requirement is likely to be significant.*

    PSA disagrees with the assessment that tamper-proof/evident closures or packaging requirements would have significant impost on manufacturers. The consultation paper indicates that most overseas jurisdictions require this already. It is also not appropriate to weaken this requirement given the risk of harm that unapproved vaporiser nicotine products pose.

  - *Mandatory tamper-proof/evident packaging requirements would not be enforceable against overseas suppliers of products imported via the Personal Importation Scheme.*

    PSA believes it is necessary for the TGA to invest in the communication of clear information on the types of features (such as tamper-proof/evident closures or packaging) that are regarded to demonstrate better safety provisions in unapproved vaporiser nicotine products. Consistent messaging around these topics can also be disseminated through pharmacists and prescribers.

- Thus PSA regards the implementation of requirements for tamper-proof/evident packaging for unapproved vaporiser nicotine products to be essential.

Nicotine concentration and volume

- PSA does not support the TGA's proposal to have "no limits" on nicotine concentration, active ingredient content and volume given the known chemical characteristics and physiological profile of nicotine.

- While the prescriber will determine the appropriate dose for each individual, it is nevertheless important to specify a limit on nicotine concentration (e.g. a maximum limit, or a specified range) and/or volume (in a single container) of vaporiser nicotine products. These measures are essential in helping to minimise the risks associated with accidental ingestion or exposure, and to appropriately manage the "high addiction potential"[2] that nicotine e-cigarettes possess.

- Where known, it is also recommended that the nicotine flow rate (or a reasonable range of expected flow rates) is considered and/or documented, given concerns around the potential for the delivery of variable or high levels of nicotine from electronic cigarettes.

- The volume limit could also be determined and based on pack sizes that may be regarded to provide for reasonable dosing regimens and continuity of therapy.

Part 3: Related matters

Default standards and nicotine purity

- PSA understands the rationale provided for the TGA's proposal to exempt unapproved vaporiser nicotine products covered by TGO 110 from complying with product default standards, as per the draft *Therapeutic Goods (Exempt Monographs) Determination 2021.* PSA supports this proposal in principle, provided greater clarity and emphasis are given on the parallel proposal of retaining the operation of the active pharmaceutical ingredient (API) default standards for unapproved vaporiser nicotine products. Currently the TGA's preferred proposal, as worded, does not mention the API default standard requirement even though this is stated under the 'justification' section.

- PSA notes that the TGA recommends sponsors and others supplying unapproved vaporiser nicotine products in Australia to "seek a certificate of analysis for the product, including for active and excipient ingredients". Similar to PSA's comment provided under the section on prohibiting certain ingredients, we seek TGA's advice on recommended minimum information requirements (e.g. nicotine purity, impurity limits) for a 'certificate of analysis' for imported unapproved vaporiser nicotine products. This type of advice will be critical in supporting pharmacists in the procurement of appropriate products for patients as intended by their prescriber, which may not currently be routine practice.

Compounding

- PSA notes the TGA's proposed requirement for compounding of unapproved vaporiser nicotine products is to be in accordance with existing requirements including the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990*, and the Pharmacy Board of Australia's *Guidelines on compounding of medicines.*

- PSA highlights that the *Good compounding practice* chapter has recently been updated and published in the 25th edition[3] of the Australian Pharmaceutical Formulary and Handbook (APF).

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[2] Therapeutic Goods Administration. Notice of final decision to amend the current Poisons Standard – Nicotine. 21 Dec 2020. At: **www.tga.gov.au/sites/default/files/notice-final-decision-amend-current-poisons-standard-nicotine.pdf**

[3] Sansom LN, ed. Australian pharmaceutical formulary and handbook. 25th edn. Canberra: Pharmaceutical Society of Australia; 2021.

The APF is a reference text listed in the Pharmacy Board of Australia's *Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists).*

Draft *Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021*

- **Schedule 1—Prohibited Ingredients**, p. 6: PSA believes the subsection reference in the note under the heading should be 7(2).

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