AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission to the Therapeutic Goods Administration – Standard for vaporiser nicotine

nicotine.standard@Health.gov.au

Introduction

In considering this submission, it is important to note that the AMA still opposes the use of nicotine vaping products, including for therapeutic purposes[1]. There is a lack of high-quality evidence that vaping is an effective cessation aid and there is strong high-quality evidence that vaping causes harm[2].

While the AMA opposes the use of all vaping products, the AMA recognises that the medicine scheduling decision made in 2020 closes an existing loophole and will prevent access to nicotine vaping products for those previously accessing them for non-therapeutic use. The AMA regards this as an important move to ensure that patients see their doctor for advice on the most reliable and safe smoking cessation methods, creating an additional barrier for people to take up vaping.

The AMA believes that regulation around these products should be restrictive to limit their use for the intended purpose of smoking cessation, and to ensure these unproven products are as safe as possible. It is the AMA's view that the prescription of nicotine vaping products should be infrequent, due to their associated harms and lack of evidence of effectiveness, and so limits on availability is not perceived to be a great risk by the AMA.

The AMA believes these standards should be reviewed once the National Health and Medical Research Council review on e-cigarette safety and efficacy is available in late 2021[3]. These standards should be based on reliable evidence on how safe and efficacious nicotine vaping products are, including the safety and efficacy of different concentrations and volumes.

While several TGA proposals leave restrictions on dose and volume to the discretion of the prescriber, as this is a new product with little evidence of smoking cessation effectiveness, prescribing doctors will rely on guidance from the TGA, their medical college, and other reputable clinical guidelines. The TGA in taking a flexible approach by not restricting certain product aspects through TGO 110 might be perceived by the public that there are no safety, quality, or efficacy concerns.

[1] Australian Medical Association (2020) *AMA submission to the TGA – interim decision on amendments to the Poisons Standard – nicotine.*
[2] National Health and Medical Research Council (2021) *Electronic cigarettes.*
[3] Ibid.

In addition, the TGA will need to take care in finding the balance between ensuring doctors and patients understand and are aware of the medicine scheduling change and what it means for them, while not misleading patients into thinking that nicotine vaping products are TGA-approved. The AMA believes there is a risk that patients may perceive nicotine vaping products as being assessed to the same high level of standards as other products registered on the Australian Register of Therapeutic Goods (ARTG).

The AMA refers to vaporiser nicotine products as nicotine vaping products in this submission. The term vaporiser is easily confused with a medical product that produces steam to loosen congestion in infants and children who have colds, upper respiratory tract infections or other breathing problems. There should be no confusion between these evidence-based therapeutic products and vaping products that mimic tobacco smoking, cause harm, and have little evidence of therapeutic benefit. The TGA should also use one term consistently to avoid confusion.

The AMA considers the Therapeutic Goods Order 110 (TGO 110) proposed nicotine standards from the perspective of potential prescribers of nicotine vaping products, and patient safety.

Proposed scope of TGO 110

The AMA has no objections to the proposed scope outlined in the consultation paper.

Ingredients

The AMA agrees that a nicotine vaping product must contain nicotine as the only active ingredient. As this discussion paper outlines, nicotine vaping products exist that contain several active ingredients, such as caffeine, cannabinoids, or vitamins and minerals. These active ingredients are not required for the nicotine vaping product's intended therapeutic use – smoking cessation. Cannabinoids in particular would be a concerning addition given the evidence of its therapeutic uses is still emerging and not conclusive.

The AMA supports that these products must not contain an ingredient that is specified in Schedule 1. Nicotine vaping products should not contain additional ingredients that are known risks to human health, and medical practitioners will not prescribe these products if they perceive a significant risk to human health.

The AMA opposes the TGA proposal to have no limits on flavours. Flavours such as confectionary and dessert are attractive to younger people[4,5,6] and while there are child proof packaging requirements, young adults could easily bypass these. As the consultation paper outlines, there are also potential safety risks with ingredients of flavours. While patients may purchase non-nicotine flavoured products from a vape shop, flavours do not serve a therapeutic purpose and so should not be prescribed. From the AMA's perspective, the impact of flavouring nicotine vaping products would be to make them more desirable, or to send a harmful message that these

[4] Leventhal, A et al (2019) *Flavored e-cigarette use and progression of vaping in adolescents.* Pediatrics
[5] Harrel, M et al (2017) *Flavored e-cigarette use: characterizing youth, young adult, and adult users*. Preventive medicine reports.
[6] Pepper, J et al (2016) *Adolescents' interest in trying flavoured e-cigarettes.*

products are 'healthy', or at the very least, innocuous. The AMA proposes only flavourless nicotine vaping products should be permitted.

Labelling

Ingredients list

Active ingredients plus all excipient ingredients should be listed on nicotine vaping product labels and information sheets. However, the exemption for flavours would be obsolete under the AMA's recommendation to exclude nicotine flavours (see ingredient section above). The AMA understands that vaporiser nicotine products can include several excipient ingredients that may not fit on the label. The TGA should include in TGO 110 that if the number of excipient ingredients exceeds a certain number, they should be included in the information sheet (with a link to the information sheet online and also provided with the product). Most medical practitioners do not prescribe nicotine vaping products currently and so the more information provided about the ingredients, the more they will be able to make an informed decision on whether the product is right for their patient. This will also prevent the risk of prescribing a product with potential allergens.

This information should also be available online for prescribers to consider before purchasing each product. Where to find this information should be included in prescriber guidelines.

Nicotine concentration

The AMA supports the requirement for nicotine concentration or content to be included on the label of the product and on the product information sheet. International studies have demonstrated wide variations in nicotine concentration across vaping products, along with inconsistent labelling terminology and vague terms such as low, medium and high, rather than quantitative measurements[7]. It is essential that prescribers have accurate and consistent information about nicotine concentration as this will assist prescribers in determining the right concentration for their patient, and how this should decrease over time. The AMA also expects nicotine concentration to be a topic in updated prescribing guidelines. Existing nicotine replacement therapy (NRT) products have requirements around dosing and so it is reasonable to expect nicotine vaping products to follow suit. Consistency in how the concentration is expressed (e.g. mg/mL, percentage, total content) is preferable in order to simplify the prescription process.

Warning statements

The AMA believes that warning statements should be included on nicotine vaping products. In addition to the warning statements and safety directions as required under Appendix L and F of the Poisons Standard, pregnancy and nicotine addictiveness warnings should also be applied. While doctors do consider these risks when prescribing a product, a patient may become pregnant without the doctor knowing until the patient has come in for a consultation. A warning statement may prompt a patient to seek a consultation with their doctor to discuss safety concerns. AMA members report experiences of this occurring in their practice where they were

[7] National Academies of Sciences, Engineering and Medicine (2018) *Public Health Consequences of E-Cigarettes*.

able to transition the pregnant patient on to a NRT that was safe for them. Including a pregnancy warning would promote patient awareness of the risks. Further, patients should be aware that nicotine is addictive and while the doctor would communicate this risk, the warning statement would serve as a reminder to the patient to be careful with the product and use it only as prescribed. Similar warning statements about addictiveness now appear in prescription opioid products[8] without the same concern that it would undermine an individual's treatment plan and so the logic that this would occur in smoking cessation is inconsistent.

Packaging

Child-resistant packaging

The AMA believes that child-resistant packaging (CRP) in Australia should be as consistent as possible and CRP requirements should be equivalent to the high standards already set in Australia. For that reason, the AMA would recommend keeping the requirements in the Poisons Standard. As stated in the consultation paper, this includes:

- *The product must have at least **one** of the following:*
  - *A CRC compliant with Australian Standard AS 1928-2007.*
  - *Packaging compliant with a Ministerial standard made under section 10 of the Act, such as Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines (**TGO 95**) or TGO 110 (once made).*
  - *If it is in a can fitted with a press-on lid, a 'double tight' or 'triple tight' lid.*
- *Packages must retain child-resistant properties for the expected life of the medicine and the CRC must be appropriate for the container (Part 2, Section 2.4(2) of the Poisons Standard).*

Further, consistency in CRP requirements will give prescribers more certainty that their patient's nicotine vaping product will not be accidentally opened by a child.

Tamper-proof/evident packaging

The AMA believes that vaporiser nicotine products should have tamper-proof/-evident packaging. This would provide an additional level of security for patients trying a product that may be new to them and that could be easily accessible to their young adult children.

Nicotine concentration

The AMA opposes the TGA's proposal to have no limits on nicotine concentration for nicotine vaping products. The risk of at home mixing is the same risk as a patient taking extra doses of other prescription medication not advised by their doctor. As the consultation paper states, there are toxicity and fatality concerns around nicotine and this needs to be reflected in the concentration limits. Further, there have been reports of nicotine concentration varying significantly between manufacturing batches[9] and this needs to be controlled so prescribers are certain their patient is receiving the intended dose and there is reduced risk of harmful effects.

[8] Therapeutic Goods Administration (2019) *Opioids: boxed warning and class statements.*
[9] National Health and Medical Research Council (2017) *CEO statement: electronic cigarettes.*

The TGA should determine the safety profile of different nicotine concentrations and determine the limit from those results.

Volume

The AMA opposes the proposal to have no limit on the volume of a nicotine vaping product. The AMA in its submission to the interim decision for nicotine recommended a time limit for patients to trial nicotine vaping for smoking cessation. This is because there is a lack of evidence around its effectiveness for smoking cessation and therefore its use would require regular monitoring by the prescribing doctor. Volume limits would act as a method to ensure patients come back to the doctor for review. As there is potential to cause harm when using these products, patients should be using them for as little time as possible. Vaping mimics the act of smoking which may make it more difficult to quit entirely. Since prescribing nicotine vaping products is a new concept, clinical guidelines need to be developed that determine how long a patient should be on a nicotine vaping regime before this method should be abandoned. The TGO 110 requirements around volume should be determined by a review into how long the duration of therapy should be, taking into account safety and efficacy.

Default standards and nicotine purity

Medical practitioners expect that any therapeutic good being prescribed in Australia would meet high default standards. The AMA understands that some products created as consumer goods may not meet default standards, however this is not a reason to lower Australia's standards. Prescribing nicotine vaping products is going to be a last resort for smoking cessation, and doctors need assurance that pharmacopeial-grade nicotine is available for their patients. These products need to be as safe as possible if they are not going through the process to be on the ARTG. Active pharmaceutical ingredient (API) and product default standards should be retained.

Compounding

The AMA supports TGO 110 applying to compounded unapproved nicotine vaping products.

Conclusion

The AMA opposes the use of nicotine vaping products for all purposes, including for therapeutic use, due to the evidence that it causes harm and lack of evidence that it is an effective smoking cessation tool. Therefore, the AMA believes that the TGA should take a restrictive approach to the proposed nicotine standards outlined in TGO 110 to ensure these products are as safe as possible and provide as much information as possible to the patient and prescriber. The TGO 110 requirements need to be determined by the results of reviews into the safety and efficacy of nicotine vaping products, including volume and concentration limits.

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Contact
Hannah Wigley
Senior Policy Adviser
hwigley@ama.com.au