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# AMA submission to the Therapeutic Goods Administration – Potential reforms to the regulation of nicotine vaping products

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**Survey response**

The AMA supports strong, strictly enforced regulation of nicotine vaping products (NVPs). Australia is losing the public health battle on vaping and improving safety and removing loopholes in their regulation is essential to reversing this.

The aim of regulating NVPs must be to limit their use only for the intended purpose of smoking cessation, and to ensure these unproven products pose as little harm as possible. Due to the associated harms and lack of evidence as an effective nicotine cessation tool, it is the AMA's view that the prescription of NVPs should be a last resort, prescribed by a patient's doctor who has a strong understanding of their patient's health and history.

The AMA supported the government's proposal to make all NVPs Schedule 4 on 1 October 2021, however we raised serious concerns that the regulations were too weak. The AMA has repeatedly advocated for the following amendments:

1. Reduce the concentration limit allowed under Therapeutic Goods Order 110 from 100mg/ml to 20mg/ml, and introduce limits on the flavours and volume of nicotine that can be prescribed or ordered,
2. Ban the importation of NVPs through the Personal Importation Scheme,
3. Work with State and Territory Governments to add NVPs to Real Time Prescription Monitoring programs to reduce the risk of doctor shopping,
4. Amend MBS telehealth smoking cessation items so that only a patient's usual doctor may prescribe NVPs as a smoking cessation tool.
5. Work with State and Territory governments to deal with this issue more consistently and strategically, including better enforcement of vaping product laws to prevent the illegal sale of these products, especially to young people.

The TGA consultation paper provides a range of options to address many issues in the current regulatory framework which the AMA has repeatedly raised in recent years. In terms of the options presented in the consultation paper, the AMA's preferred options are as follows:

- **Border controls: option 4**, Introduce controls on the importation of all vaping products through the Customs Regulations. The AMA also supports **option 5**.
- **Pre-market TGA assessment of NVPs: option 3**, require registration the ARTG.
- **Minimum quality and safety standards: option 7**, significant adjustments to TGO 110.

Finally, the AMA strongly supports the proposal to regulate NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework with appropriate penalties and seizure.

**Border controls**

The AMA's preference is for option 4, *Introduce controls on the importation of all vaping products through the Customs (Prohibited Imports) Regulations 1956 (the Customs Regulations), to assist with the enforcement of the controls on NVPs (rather than with the aim of limiting access to non-nicotine vaping products)*. The AMA also strongly supports option 5. Whichever option is ultimately pursued, the Personal Importation Scheme must cease.

The Personal Importation Scheme bypasses many of the product standards outlined in Therapeutic Goods Order 110, such as labelling, packaging, and record-keeping requirements. For example, there are no warning statements or child-resistant packaging requirements. The AMA remains alarmed by the challenges with enforcing this scheme adequately, especially in context of the types of NVPs currently increasing in popularity amongst children and younger people.

The benefit of pursuing option 4 is that this would begin to address public health challenge of vaping as a whole rather than separating NVPs from non-nicotine vaping products. Vaping product use acts as a gateway to smoking and that young people are increasingly vaping.[1] The proportion of people who have 'ever' used vaping products increased from 8.8% to 11.3% from 2016-2019. The use of vaping products in young adults (18-24) is particularly concerning; 21.7% tried a vaping product device in 2020-21. Conversely, 83.3% have never tried tobacco.[2]

There are also significant risks from the substances themselves which warrant much stronger regulation, testing and enforcement. For example, vaping product liquids regularly contain products that are dangerous or are not correctly identified on the label. Non-nicotine vaping products contain nicotine,[3] 31% of vaping products registered in Australia contained prohibited ingredients in chemical concentrations that exceeded the legal limit.[4] These prohibited chemicals include vitamin E acetate and diacetyl, which is linked to the condition called bronchiolitis obliterans which can cause significant damage to the lungs.[5] There are increasing reports and established evidence of the harmful effects of vaping products, particularly in

[1] Banks et al. (2020) *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context.* Australian National University.
[2] Australian Bureau of Statistics (2022) *Smoking*.
[3] Therapeutic Goods Administration (2022) *Nicotine vaping products: news and updates.*
[4] Therapeutic Goods Administration (2022) *Testing of nicotine vaping products - TGA Laboratories testing report*
[5] Queensland Health (2021) *What's really in vape juice?*

children, such as nicotine poisoning, "popcorn lung"[6] and vaping product Associated Lung Injury (EVALI).[7,8]

The consultation paper notes that this may create problems for visitors to Australia, however this could easily be addressed through customs processes as might be done with other regulated medications. The main focus must be on preventing mass importation of liquids or devices, and Australians returning from overseas who should be made aware of the laws and regulations.

**Pre-market TGA assessment of NVPs**

The AMA's preference is for option 3, *Establish a regulated source of quality NVPs by requiring registration in the ARTG, following successful evaluation of quality, safety and efficacy (for smoking cessation)*. Medicines registered on the Australian Register of Therapeutic Goods (ARTG) give doctors more confidence that they are prescribing a product that has passed the robust safety, quality, and efficacy assessments of the TGA. There are challenges with this approach as there are currently no NVPs registered on the ARTG and vaping manufacturers have resisted registration of their products globally. Australia should choose to be a world leader in this space through a process that is known to identify risks and concerns prior to registration.

We expect that this change would lead to strong rejection by the industry and as such may create an environment where there are no NVPs registered on the ARTG leaving some people unable to lawfully obtain NVPs. This could lead them to pursue black market options or return to tobacco. As such, there will need to be interim measures put in place or a significant lead time.

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

The AMA does not support option 2, Establish a regulated source of quality NVPs by requiring pre-market assessment of NVPs by the TGA against a quality and safety standard. We share concerns with other stakeholders that this may be perceived by the community as safe, that the industry will use this to further obfuscate public health messaging about the risks of vaping, and that it would create an international precedent that the industry could use in other jurisdictions push their products as safe, therapeutic goods.

[6] Bosma and Landman (2019) *Popcorn lung: teen first case of life-threatening injury.*
[7] Centers for Disease Control and Prevention (2020) *Outbreak of lung injury associated with the use of e-cigarette, or vaping, products.*
[8] Department of Health (2021) *About e-cigarettes.*

While the AMA supports the current arrangements where NVPs are prescription only, there remains limited evidence for the use of NVPs as an effective nicotine cessation aid.[9] The safety and efficacy of these products has not been adequately proven, and therefore they should remain strictly regulated and access to them controlled. However, there are situations where NVPs are the best options for patients seeking to manage tobacco addiction.

Doctors and patients must have access to a range of therapeutic options, and through discussion and in consideration of the whole person, it may be concluded NVPs may be used as a last resort tool where other, more evidence-based, nicotine cessation methods have failed. . Ensuring that doctors know that NVPs have met the TGA's safety, quality, and efficacy assessments will support them to make this decision.

**Minimum quality and safety standards for NVPs**

The AMA supports option 7, *Options 2, 3, 4, 5 and 6 together. (Except for the option to require additional warning statements, preferred option)*. These proposals are excellent and we see no reason why these changes could not be implemented immediately. Enforcement issues will remain challenging, and the TGA must be supported in these efforts.

Flavour

The AMA believes that flavours for all vaping products should be restricted to stop flavour being an attractive quality of vapes for younger people. As noted in the discussion paper, flavour and taste was the most important characteristic for 14-17 year old users under the Generation Vape study.[10] The vaping product (i.e tobacco) industry heavily market these products to younger people.[11] Tobacco companies have a vested interest in keeping consumers addicted to vaping products and have invested considerable resources in undermining clear evidence and health advice.

Labelling or packaging requirements

The AMA supports plain pharmaceutical packaging for all NVPs which are only intended to be used as smoking cessation tools. There should be warning statements on NVPs that highlight they contain an addictive product. The AMA also supports warning labels being attached to non-nicotine vaping products.

Reducing maximum concentration

The AMA strongly supports reducing the dangerously high nicotine concentration limit of 100mg/mL to 20mg/mL. The trials studying NVP nicotine cessation used nicotine concentrations

[9] Royal Australian College of General Practitioners (2021) *Supporting smoking cessation: a guide for health professionals.*
[10] Watts, C et al (2022) *Vaping product access and use among 14-17 year olds in New South Wales: a cross sectional study*. Australian and New Zealand Journal of Public Health.
[11] Allem, J (2022) *E-cigarette maker Juul settled a lawsuit over its practice of targeting teens through social media, parties and models – here's why the company is paying $438.5 million to dozens of states.*

of less than 20mg/mL.[12] The current high concentration limit increases the risk of poisoning, particularly in children who may ingest the liquid, and dependence.

The AMA supports limiting the maximum volume of liquid NVPs and removing access to disposable NVPs.

**Clarifying the status of NVPs as 'therapeutic goods'**

The AMA strongly supports *the Secretary or a senior executive of the TGA making an order under Section 7 of the Therapeutic Goods Act to declare vaping products to be classed as therapeutic goods*. We agree that this "would ensure that the TGA is able to take regulatory action in relation to NVPs that contain nicotine, but are not labelled as such, under the therapeutic goods laws framework", as stated on page 25 of the consultation paper.

The majority of 'non-nicotine' vaping products contain nicotine, and these are available in shops and online, which undermines the TGA regulatory framework and misleads customers into purchasing an addictive product. Further, non-nicotine vaping products also contain a range of harmful chemicals and are an immediate public health concern.[13] These factors complicate and blur the line between regulation for nicotine/non-nicotine vapes, and therefore vaping regulation needs to be considered holistically.

In addition to NVP regulation reform outlined in this submission, the AMA demands enhanced regulatory measures to curb the proliferation of recreational non-nicotine vaping products, which include but are not limited to:

- Implementing similar regulation to tobacco products, such as health warnings, better labelling, plain packaging and tobacco licences
- A targeted Federal response to monitor and act on illegal advertising and promotion of vaping products, particularly online and on social media
- Better enforcement of existing State and Territory regulation to help block illegal vape sales both online and through shopfronts

Regulation of non-nicotine vaping products are the responsibility of the States and Territories.[14] However, laws, regulation, enforcement, and compliance vary between jurisdictions. Across Australia, it is illegal to sell non-nicotine vaping products to people under the age of 18, though it is widely reported that it is easy for under 18s to access them.[15] Queensland and Victoria do not have tobacco retail licences, which would assist in compliance measures. Some jurisdictions have been focusing more on enforcement recently, such as NSW Health who have seized $3 million-worth of illegal vaping products since July 2020 and currently have an education campaign.[16]

[12] Banks, E et al (2022) *Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health*. National Centre for Epidemiology and Population Health, Canberra.
[13] National Health and Medical Research Council (2022) *CEO statement on electronic cigarettes.*
[14] Department of Health and Aged Care (2021) *Smoking and tobacco laws in Australia.*
[15] Watts, C et al. (2022) *Vaping product access and use among 14-17 year olds in New South Wales: a cross sectional study*. Australian and New Zealand Journal of Public Health.
[16] NSW Health (2022) *NSW Health seizes more than $1 million of illegal nicotine vapes.*

**General Comment**

The AMA commends the TGA on preparing a well-researched consultation paper which presents a clear picture of an escalating public health issue in need of a strong policy response. We understand that the TGA is limited in its regulatory role to therapeutic goods and devices, however we would strongly encourage the TGA to present the Minister for Health and Aged Care with the broader feedback from stakeholders on options to address vaping.

For example, the AMA is concerned that the distinction between NVPs and other vaping devices implies that there are no risks associated with using non-nicotine vapes. We know that there are multiple risks including the high likelihood of consuming nicotine, vaping leading to deliberate consumption of nicotine through NVPs or cigarettes, and the health risks of consuming a poorly regulated substance such as "popcorn lung".

Last year, the AMA lodged a submission to the Department of Health for their consultation on the draft National Tobacco Strategy 2022-2030. The AMA stated that vaping products should be given more weight in the Strategy. The outcomes of this consultation should be considered and incorporated into the Strategy.

The AMA also remains frustrated and perplexed by the structure of the smoking cessation MBS telehealth items. These items do not require the patient to have an "existing relationship" with the GP as almost all other telehealth items do. This not only fragments care and undermines the therapeutic relationship between patient and GP, it has also led to numerous businesses offering scripts for NVPs after a short phone call. Many of these services do not meet the basic standards of telehealth.[17]

The AMA is one of is one of many public health voices calling for stronger action on vaping. The proposals within the consultation paper are an important first step and we stand ready to support the Government and the TGA in enacting them.

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[17] AMA (2021) *10 Minimum Standards of Telemedicine*.