Asthma Australia Submission to the Therapeutic Goods Administration's consultation on potential reforms to the regulation of nicotine vaping products

January 2023

BACKGROUND

Asthma Australia welcomes the opportunity to comment on the Therapeutic Goods Administration's (TGA's) review of potential reforms to the regulation of nicotine vaping products (NVPs). We are deeply concerned about the adverse health impacts of NVPs given the conclusive evidence e-cigarette use causes a range of adverse health impacts, including respiratory disease.[1] Beyond these known harms, the long-term health impacts of these novel products are not yet understood. Asthma Australia urges adherence to the precautionary principle in regulating NVPs and welcomes the restatement of the importance of this principle by the TGA in its consultation paper on this topic. Asthma Australia strongly agrees with the position articulated by the Thoracic Society of Australia and New Zealand (TSANZ) that vaping products should not be used by non-smokers or children because of the known short- and mid-term adverse health impacts and risk of development of chronic lung disease.[2] We further agree with TSANZ that smokers should have access to behavioural support for smoking cessation in conjunction with therapeutic smoking cessation products approved through stringent regulatory processes.[3]

The current regulatory approach to NVPs is not working. While NVPs can only be legally obtained by adults with a doctor's prescription, the TGA's consultation paper recognises NVPs are being illegally accessed by children, adolescents and adults. The resulting public health crisis must be addressed urgently. Asthma Australia supports reforms to address the illegal importation of NVPs within the

context of this consultation. We additionally urge the TGA to look beyond the scope of these reforms to further measures necessary to effectively deal with this crisis.

Asthma Australia has consulted with leading health peak bodies in formulating our responses to the consultation questions. We acknowledge and support the submissions from our fellow members of the Lung Health Alliance, TSANZ and Lung Foundation Australia (LFA).

Overview

Asthma Australia's responses to each section of the TGA's review are as follows:

Border Controls: Option 4

Pre-market assessment of NVPs: Option 3

Minimum quality and safety standards for NVPs: Option 7 (with consideration of the role of plain packaging and warning statements)

Clarifying the status of NVPs as therapeutic goods: Yes

Border Controls

Asthma Australia supports 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).

Asthma Australia supports amending the *Customs (Prohibited Imports) Regulations 1956* to include all vaping products as a 'prohibited import' (regardless of whether they contain nicotine). Asthma Australia would support an exemption to this prohibition for access under medical supervision to NVPs that have undergone stringent regulatory approval processes, such as the processes required for registration on the Australian Register of Therapeutic Goods (ARTG), as discussed below. This would mean the products have successfully demonstrated quality, safety and efficacy.

Asthma Australia is deeply concerned by the current accessibility of NVPs to children, adolescents and adults without a prescription. Mislabelled NVPs, which wrongly state that nicotine-containing

products do not contain nicotine, contribute to this problem by adding to the difficulties faced by enforcement agencies in detecting these products. We therefore support prohibiting the importation of vaping products which do not contain nicotine. These products have no valid purpose and prohibiting their importation would greatly assist enforcement agencies currently struggling to identify and control mislabelled NVPs. This reform is critical if Australia is to address the public health crisis of NVP use.

If our recommendation of Option 4 combined with an exception for access under medical supervision to NVPs that have undergone stringent regulatory approval processes is not implemented, Asthma Australia would support combining Options 2 and 3, which would remove the Personal Importation Scheme exemption for NVPs and introduce an import permit requirement for NVPs.

Pre-market TGA Assessment of NVPs

> **Asthma Australia supports 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).**

Asthma Australia supports Option 3 because it would ensure NVPs are only available if they are successfully evaluated for quality, safety and efficacy in smoking cessation. Requiring registration in Australian Register of Therapeutic Goods (ARTG) is the optimal model for access to nicotine vaping products and would regulate NVPs, which can only be legally obtained with a prescription, using the standard practice applied to prescription products.

Asthma Australia does not support Option 2 because it would introduce a weak approval pathway for a class of products for which there is limited evidence of efficacy and strong evidence of health harms.[4] Option 2 represents a lower standard than ARTG registration because it would remove evaluation of efficacy for smoking cessation. Further, safety checking would be limited to the safety of the ingredients rather than a full safety analysis. Finally, Asthma Australia is concerned that consumers would not understand the difference between pre-market approval and ARTG registration and may mistakenly believe pre-approved products have been endorsed by the TGA as safe and efficacious.

Minimum Quality and Safety Standards for NVPs

Asthma Australia in principle supports Option 7, which encompasses 5 amendments that would strengthen the TGO 110, with consideration of the role of plain packaging and warning statements.

In principle, Asthma Australia supports strengthening the standards applicable to NVPs to reduce their harms and appeal to consumers. However, these changes will not be effective if action is not taken to end the illegal importation of NVPs, including products incorrectly labelled as not containing nicotine. Any efforts to strengthen TGO 110 should be made *in addition* to the changes to border controls recommended above.

Clarifying the Status of NVPs as 'therapeutic goods'

Asthma Australia supports the proposal to declare NVPs as a class of therapeutic goods, regardless of whether they are labelled as containing nicotine.

The TGA should be able to regulate all NVPs, regardless of whether they are correctly labelled as containing nicotine. The Consultation Paper recognises the increasing practice of hiding the presence of nicotine in NVPs. This incorrect labelling should not prevent the TGA from taking regulatory and enforcement action.

[1] Banks E, Yazidjoglou A, Brown S, 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.
[2] McDonald CF, Jones S, Beckert L, et al. 2020. Electronic cigarettes: A position statement from the Thoracic Society of Australia and New Zealand. *Respirology.* 25: 1082– 1089. https://doi-org.ezproxy.library.sydney.edu.au/10.1111/resp.13904
[3] Ibid.
[4] Banks E, Yazidjoglou A, Brown S, et al. 2022.