

Healthway Submission – Potential reforms to the regulation of nicotine vaping products

January 2023

The Western Australian Health Promotion Foundation (Healthway) welcomes the opportunity to comment on the proposed Therapeutic Goods Administration (TGA) reforms to the regulation of nicotine vaping products (NVPs) in Australia. The commitment of all Australian governments in maintaining a precautionary approach to e-cigarettes is strongly supported by Healthway given increasing evidence of the harms of e-cigarette use and as a gateway to smoking and nicotine addiction by young people.¹

Healthway is a state government health promotion agency dedicated to improving the health of all Western Australians. We work in partnership with sports, arts, racing, and community organisations, as well as health and research organisations to create a healthier Western Australia (WA).

Our current strategic priorities include creating a smoke-free WA and the Healthway Board has prioritised activities which aim to reduce the impact of vaping in the WA community, particularly for young people. This includes supporting research that explores; the impact of social media vaping advertising on young people; the level of vaping among year 7-12 students in WA; and legislation and regulatory frameworks to prevent young peoples' exposure to vaping advertising on social media. In addition, Healthway funds population-based education and advocacy initiatives relating to tobacco smoking and vaping, and recently funded the implementation of smoke and vape-free entertainment precincts in a metropolitan local government area. In total, Healthway has contributed close to \$2 million to initiatives that address vaping in WA.

The concerns of the TGA regarding existing requirements not preventing children and adolescents from accessing NVPs, are shared by Healthway. Of note is the increasing numbers of children and adolescents continuing to obtain NVPs, and adults accessing NVPs without a prescription, rather than through lawful supply channels with a prescription from an Australian doctor.

The reforms presented in the TGA consultation paper and options supported by Healthway provide for vaping products through a doctor's prescription if required however, children and young people will be better protected, reducing both illegal activity and nicotine addiction in this vulnerable group. Of paramount importance, is protecting public

¹ Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. 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: April 2022. <https://openresearch-repository.anu.edu.au/handle/1885/262914>

Healthway Submission – Potential reforms to the regulation of NVPs

health policies including these reforms, from the commercial and other vested interests of the tobacco industry and those of vaping products.

Healthway provides the following response to the TGA consultation.

Summary of recommendations

Summary of reform options and Healthway recommendations:

1. Border controls – Recommend Option 4 in conjunction with 2
2. Pre-market assessment of NVPs – Recommend Option 3
3. Minimum quality and safety standards for NVPs – Recommend Option 7
4. Clarifying the status of NVPs as therapeutic goods – Supported.

Healthway's stance on the proposed reform options

1. Border controls

Healthway supports Option 4 - *Introduce controls on the importation of all vaping products through the Customs Regulations to assist with the enforcement of the controls on NVPs in conjunction with Option 2* - *Prevent NVPs being imported under the Personal Importation Scheme exemption under the Therapeutic Goods Regulations 1990.*

Current NVP import restrictions are complex. As mentioned in the TGA consultation paper, large volumes of NVPs are being imported, and supplied unlawfully. Current regulatory requirements may be evaded by concealing nicotine in their products, and as a result of mislabelling and difficulties identifying nicotine based NVPs, Healthway recommends that the Federal Government amends current Customs Regulations to declare all vaping products as 'prohibited imports', regardless of if they contain nicotine or not.

In conjunction with option 4, Healthway also supports the implementation of option 2 to remove the Personal Importation Scheme (PIS) exemption. It is noted that as a stand-alone measure, this would likely be limited in effectiveness as it does not address other common sources of access. Therefore, it is recommended that Option 2 and Option 4 be implemented together.

For completeness, Option 3 is considered flawed given the current mislabelling of vaping products to bypass Custom Regulations. The requirement for all vaping products labelled as 'non-nicotine' to be tested and approved by the TGA before importation would be impractical and onerous for Australian Border Force and the TGA.

2. Pre-market TGA assessment of NVPs

Healthway 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).*

Requiring NVPs to be registered in the Australian Register of Therapeutic Goods (ARTG) will ensure that vaping products are lawfully imported and supplied, and that they have undergone a pre-market TGA assessment against a set of quality and safety criteria

Healthway Submission – Potential reforms to the regulation of NVPs

before they can be sold for smoking cessation purposes. ARTG registration should be considered the base standard, so as to not compromise the standards applied under Australia's therapeutic goods framework.

Noting issues regarding registered NVPs not being currently available, Option 1 would be the preferred if Option 3 is not feasible for implementation. Option 2 is not supported by Healthway as this could potentially set a dangerous precedent in lowering requirements for TGA regulation.

3. Minimum quality and safety standards for NVPs

Healthway supports Option 7, concurring with the TGA recommendation as the best opportunity to strengthen the TGO 110 and to reduce the harm and appeal of vaping products.

According to a small study by the Behaviour Change Collaborative (2022)², disposable vapes are most common among teenagers as they are easier to access and more affordable than refillable vapes, and vaping products without flavourings or nicotine are considered less attractive. Additionally, it was found that teenagers do assess product safety with consideration to health warnings and ingredient labelling.

Consequently, Healthway agrees with the suggested terms of the exemptions under which approved NVPs are imported:

- Prohibit all flavours (except tobacco) and additional ingredients
- Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements
- Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent)
- Limit the maximum volume of liquid NVPs
- Remove access to disposable NVPs.

While Healthway supports removing access to disposal NVPs, further consideration should be given to any potential unintended consequences resulting from a shift to larger volume devices that require dilution and mixing of liquid nicotine. This includes potential risks related to poisoning.

Overall, Healthway supports the suggested amendments to the TGO 110 however, reiterates the need to also address the problems with the current regulatory framework. Any amendments to TGO 110 should be made in addition to the recommended changes to border controls discussed previously.

² van Bueren D, van der Beeke L, Grainger A, Petrut R. Being Gen Vape - Exploratory research on the knowledge, perceptions, attitudes and influences on teen vaping in Western Australia. *The Behaviour Change Collaborative*. [Online] July 2022. <https://thebcc.org.au/wp-content/uploads/2022/08/Being-Gen-Vape-Exploratory-Research-Report-Final.pdf>.

Healthway Submission – Potential reforms to the regulation of NVPs

4. Clarifying the status of NVPs as therapeutic goods

Healthway supports the proposal to clarify the status of NVPs as therapeutic goods.

Clarification of the status of NVPs will enable the TGA to take regulatory action on all vaping products, including those that are mislabelled as not containing nicotine.