Response to TGA Consultation paper: Proposed reforms to the regulation of nicotine vaping products

The Heart Foundation welcomes the Australian Government's renewed focus on tobacco control and the decision to undertake a TGA consultation on the regulation of vaping and e-cigarette products, as a step toward protecting the cardiovascular health of all people living in Australia[1,2].

Cardiovascular disease claims the lives of more than any other disease group in Australia. Each day approximately 110 Australian lives are lost due to cardiovascular disease.[3] Around 600,000 Australians are hospitalised due to cardiovascular disease each year, costing the health system almost $12 billion p.a.[4]

There is unequivocal evidence surrounding the impacts of tobacco smoking on cardiovascular health[5]. People who smoke are two times more likely to have a heart attack, three times more likely to have a stroke, and five times more likely to develop peripheral arterial disease. The risk of dying from heart disease or sudden cardiac death in people who smoke is 4 and 3-fold higher than non-smokers respectively.

With increasing evidence that e-cigarette use by young people can be a gateway to smoking and nicotine addiction[6], the Heart Foundation supports the commitment of all Australian governments to maintaining a precautionary approach to e-cigarettes[7].

At this time, the Heart Foundation views increased control of e-cigarettes, nicotine vaping products (NVPs) and non-nicotine NVPs as one of the most important areas for policy and regulatory reform by the Australian and state and territory governments. From 2016 to 2019 there was a doubling in 18–24-year-old Australians using e-cigarettes, and approximately 230,000 people aged 14 and older reporting daily e-cigarette use (2019).[6] This dramatic increase in vaping, particularly amongst Australian children over the last 5 years, is of significant concern and should be addressed as a high priority.

The Heart Foundation shares the concerns of the TGA that existing regulations for NVPs are not meeting the aim of the 2021 reforms, that is, 'to prevent children and adolescents from accessing NVPs, whilst allowing smokers to access these products for smoking cessation with a doctor's prescription'[8]. Across Australia:

- children and adolescents are continuing to obtain NVPs in higher numbers; and
- adults are accessing NVPs without a prescription, rather than through lawful supply channels with a prescription from an Australian doctor.

A sizeable black market supplying NVPs has emerged and is openly selling vaping products without fear of prosecution owing to a lack of enforcement action. Rather than NVPs being used as a therapeutic device to aid those looking to cease smoking, they are being routinely supplied to adults and children. This is directly contributing to a new generation becoming addicted to nicotine, a chemical which is known to cause increased blood pressure, heart rate, flow of blood to the heart and a narrowing of the arteries.[9] Without action Australia is sleepwalking into a potential health catastrophe.

The Heart Foundation agrees that refinements to the existing requirements for NVPs should be introduced to better support the intent of the 2021 reforms. We are pleased to provide this submission which outlines the views of the Heart Foundation in response to the four sections of the consultation paper.

Overview

With respect to each of the four sections outlined in the consultation paper the Heart Foundation recommends the following:

- Section 1 – Option 4
- Section 2 – Option 3 (or option 1 if option 3 is not considered feasible)
- Section 3 – Option 7
- Section 4 – Yes

Maximum effectiveness of each of the options will only be achieved if all the preferred options are implemented in unison with each other.

The TGA consultation paper does not consider potential changes to the regulation of vaping products that do not contain nicotine, nor vaping devices. However, to have maximum impact in addressing the concerning increase in vaping and to protect the community, and in particular children and adolescents, the Heart Foundation recommends the Australian Government regulates and/or bans non-NVPs in conjunction with the reforms proposed through this consultation. Non-NVPs serve no constructive purpose, but their continued sale is being used to legitimise vaping as a practice, and to mask the sale of under the counter NVPs.

In addition, the Heart Foundation recommends the Australian Government utilises a whole of government approach, working with State/Territory Governments, to control importation and supply around the sale of NVPs across the country.

Section 1 – Border Controls

Options outlined in consultation paper:

1. Make no legislative changes to current border controls.
2. Prevent NVPs being imported under the Personal Importation Scheme exemption under the Therapeutic Goods Regulations 1990.
3. Impose tighter controls on the importation of NVPs by requiring an import permit.

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).
5. Options 2 and 3 together (preferred option).

The Heart Foundation supports Option 4

Position - The Heart Foundation supports the introduction of controls on the importation of all vaping products (NVPs and non-nicotine products and devices) through an amendment of the *Customs (Prohibited Imports) Regulations 1956* by declaring all vaping products are included as 'prohibited imports'. An import permit could be sought and would be required for permissible imports. This would be for individuals to access NVPs for smoking cessation purposes under medical supervision via the Authorised Prescriber (AP) scheme or Special Access scheme (SAS).

Rationale - As outlined in the consultation paper, the Heart Foundation recognises that NVPs are readily accessible across Australia by non-smokers without a prescription. This is of serious concern, and the mislabelling of NVPs is central to the problem with many products containing nicotine despite their labelling stating otherwise. The detection of mislabelled NVPs at the border is incredibly difficult since liquid nicotine cannot be identified by sight or smell. Therefore, the Heart Foundation recommends that all vaping products (NVPs and non-nicotine products and devices) be prohibited. Non-nicotine products serve no constructive purpose and have no place in the general retail market. The Heart Foundation believes the community health benefits from this would be significant as these actions would:

- Complement existing requirements for prescriptions for NVPs to be sourced from a medical practitioner with approvals under the AP scheme or SAS.
- Ensure NVPs would be accessed through local pharmacies (online or physical) ensuring that patients receive pharmacists' advice; and
- Close a loophole that may be exploited through the allowance of 15 months NVPs supply.

To strengthen this, the Heart Foundation supports therapeutic goods controls to deal with the domestic manufacture and supply of NVPs. This would require Federal, State and Territory government coordination to ban and enforce prohibition of the importation, manufacturing and supply of all vaping products.

Section 2 - Pre-market TGA Assessment of NVPs

Options outlined in consultation paper:

1. Make no changes.
2. Establish a regulated source of quality NVPs by requiring pre-market assessment of NVPs by the TGA against a quality and safety standard (rather than requiring all the requirements for registration in the ARTG to be met), with or without an assessment fee. Any safety evaluation would relate only to the safety of the ingredients and

would not involve a full safety analysis of the product. There would be no evaluation of efficacy under this pathway.

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).
4. Options 2 and 3 together - which would enable supplies of both unapproved NVPs that meet a quality and safety standard and of TGA-approved.

The Heart Foundation supports Option 3

Position - The Heart Foundation supports Option 3, that is, to require registration in the Australian Register of Therapeutic Goods, as the optimal model for access to nicotine vaping products in Australia. However, if option 3 is considered to pose a threat to the current prescription pathway, the Heart Foundation supports option 1 (that is, make no changes).

Rationale - The Heart Foundation supports this option because it would establish a regulated source of NVPs through the evaluation of quality, safety, and efficacy for smoking cessation. In addition, the Heart Foundation believes:

- the pre-market assessment process proposed in Option 2 would undermine important efficacy and product safety considerations and lower the bar for TGA regulation.
- NVP quality, safety and efficacy is an expectation of Australian consumers. It is likely that a pathway that did not undertake a full safety analysis of products or evaluation of efficacy could be misunderstood by consumers and/or misrepresented by the tobacco/vaping industry as an "endorsement by the TGA".

Section 3 - Minimum Quality and Safety Standards for NVPs

Options outlined in consultation paper:

1. Make no changes to minimum safety and quality requirements.
2. Prohibit all flavours (except tobacco) and additional ingredients.
3. Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements.
4. Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent).
5. Limit the maximum volume of liquid NVPs.
6. Remove access to disposable NVPs.
7. Options 2, 3, 4, 5 and 6 together. (Except for the option to require additional warning statements, preferred option).

The Heart Foundation supports Option 7

Position - The Heart Foundation supports option 7 to strengthen the TGO 110. We recommend that this should coincide with a ban on the importation of vaping products and devices, and not as a standalone option as this would be ineffective in curbing illegal access to NVPs.

Rationale - The Heart Foundation supports strengthening the TGO 110 to reduce appeal, improve safety, increase doctors' confidence to prescribe them and pharmacists' confidence to stock them. However, the Heart Foundation cautions the TGA that if amendments to TGO 110 be used as a standalone measure, it would be ineffective in addressing the challenges with the current regulatory framework. Addressing the illegal importation of NVPs is crucial for protecting children and non-smokers from the harms of vaping. Any amendments to TGO 110 should be made in addition to the recommended changes to border controls as described (Section 1).

Section 4 - Clarifying the Status of NVPs as 'therapeutic goods'

Question - Do you support regulating NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework?

Yes – The Heart Foundation supports classifying NVPs as therapeutic goods.

The Heart Foundation supports the proposal to clarify the status of NVPs as therapeutic goods. This could enable the TGA to take regulatory action in relation to NVPs that contain nicotine, but are not labelled as such, under the therapeutic goods legal framework. However, currently, there appears to be some uncertainty as to whether NVPs that are not labelled as containing nicotine are able to be considered "therapeutic goods" under the therapeutic goods legislation. This may hamper the TGA's ability to take enforcement action and should therefore be clarified.

References

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