TGA CONSULTATION

POTENTIAL REFORMS TO THE REGULATION OF NICOTINE VAPING PRODUCTS

OPTIONS FOR BORDER CONTROL

1. Which border control option for regulating NVPs do you prefer? Why?

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)
6. Any other option (please explain)

Please provide details here (Required):

We prefer options 3 and 4.

Unless prescribed by a Medical Practitioner, it is illegal to use, sell or buy nicotine for use in e-cigarettes in Australia.

Nicotine has been found in e-cigarette liquids claiming to be nicotine-free – with recent testing undertaken by the TGA finding that 168 products of 296 products tested (57%) contained undeclared nicotine.

The safety of e-cigarettes is hard to assess due to the variety of devices and liquids available, incomplete or inaccurate labelling, user ability to modify the device or liquids, and because many diseases take a long time to develop.

The use of e-cigarettes is expected to have adverse effects on the health of the oral cavity including higher risk of transformation of premalignant lesions and development of cancers comparable to those of non-smokers, and a higher risk of fungal infections than non-smokers.

2. Would any of these options have an impact on you? How?

(Required)

- Yes
- No

Please provide details here (Required):

No direct impact to the ADA is anticipated.

Reducing access to, and resulting uptake of NVPs, can be expected to decrease associated public oral health risks.

3. In relation to options 2, 3 and 4, how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary, before the reforms come into effect?

Time required before reforms come into effect (in months): (Required)

Not applicable to the ADA or its members.

Please provide details here:

Not applicable to the ADA or its members.

OPTIONS FOR PRE-MARKET ASSESSMENT OF NVPS BY TGA

1. Which option (for pre-market assessment of NVPs) do you prefer? Why?

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 NVPs that have been assessed for quality, safety and efficacy (preferred option)
5. Any other option (please explain)

Please provide details here (Required):

We support Option 3 – presuming border control initiatives described earlier would prevent import of NVPs not intended for smoking cessation.

A transition period for patients currently undergoing smoking cessation therapy that utilises NVPs, where they could maintain access while suppliers undergo relevant approval processes, is important to consider.

Currently, insufficient evidence exists to support the use of e-cigarettes in support of smoking cessation.

There is limited research on health effects of long-term use of, or exposure to, e-cigarettes.

Further research could examine the impact of the use of, and exposure, to e-cigarettes and the role of e-cigarettes in supporting smoking cessation.

Given the lack of evidence, pre-market assessment by the TGA against a set of quality and safety criteria appears appropriate.

2. Would any of these options have an impact on you? How?

(Required)

- Yes
- No

Please provide details here (Required):

No direct impact is foreseen to the ADA or its members.

Reducing access to, and resulting uptake of NVPs, can be expected to decrease associated public oral health risks.

3. In relation to options 2, 3 and 4, how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary before the reforms come into effect? What impact would any requirement to pay a fee have on you?

Time required before reforms come into effect (in months): (Required)

Not applicable to the ADA or its members.

Please provide details here (including any impact of a fee requirement):

Required

Not applicable to the ADA or its members.

MINIMUM QUALITY AND SAFETY STANDARDS FOR NVPS

1. Do you support restricting or prohibiting the inclusion of flavours in NVPs? If so, which flavours would you like to see restricted? Should all flavours be prohibited or should tobacco flavour still be permitted? Which option to restrict flavours in NVPs do you prefer? Why?

- Make no change to the list of currently restricted flavouring agents in NVPs
- Prohibit all flavours in NVPs
- Prohibit all flavours except Nicotine flavour in NVPs
- Include additional flavours in the list of prohibited flavours (please provide details)

We support the option of prohibiting all flavours in NVPs.

Evidence suggests that flavours increase the attractiveness of NVPs for young adults and adolescents by improving the flavour and reducing the harshness and bitterness, also increasing consumption.

The health effects of flavours are currently unknown and should be examined.

The World Health Organization (WHO) recommends prohibiting or restricting ingredients that may be used to increase the palatability of tobacco products.[1]

The U.S. Food and Drug Administration (FDA) recommends banning all characterising flavours in tobacco products, to help save lives.[2]

We believe that flavours of NVPs should not be made to appeal to children and teenagers.

2. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?

Any known carcinogens should be prohibited in NVPs

We support restricting colouring agents because evidence suggests that these increase the attractiveness of NVPs for children and young adults.

e-cigarette use has a potential gateway effect that leads to cigarette smoking and normalising nicotine use, particularly among young people.

[1] WHO Framework Convention on Tobacco Control. Guidelines for implementation, 2013. *p.40* Accessed 11 Jan 2023. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/80510/9789241505185_eng.pdf;jsessionid=2C8EE4FE9E795677996C3B0B1183BD4C?sequence=1

[2] FDA News release. FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers. Accessed 11 Jan 2023. Retrieved from https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers

3. Do you support introducing plain packaging requirements for NVPs? If so, should this entail packaging similar to other prescription only medicines, or should additional measures be considered?

Yes.

Packaging similar to other prescription only medicines seems appropriate.

Packaging or design materials likely to appeal to children or teenagers is inappropriate.

4. Do you support introducing additional warning statements for NVPs? If so, which warning statements should be included? How would this align with the treatment of NVPs as prescription-only medicines?

We support introducing additional warning statements for NVPs including but not limited to:

- nicotine is an addictive substance
- not for use by children
- prescription only
- pregnancy warnings
- disclosure relating to unknown health risks of vaping
- only to be used under the direction of a health professional

5. Do you support restricting nicotine concentrations in NVPs to 20mg/mL (or base form equivalent concentration for nicotine salt products)? If not, what alternative do you support?

We're not in a position to comment, but believe health evidence should inform this.

6. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?

Details of effective therapeutic dosages and frequency of usage should be informed by health evidence.

7. Do you support preventing access to disposable NVPs?

Yes, in the interest of reducing environmental impacts, we support preventing access to disposable NVPs.

8. Would any of these options have an impact on you? How?

No direct impact is expected for the ADA or its members.

Reducing access to, and resulting uptake of NVPs, can be expected to decrease associated public oral health risks.

9. If new restrictions were to be introduced how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary, before the reforms come into effect?

Not applicable.

10. Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?

We don’t support unregistered NVPs.

CLARIFYING THE STATUS OF NVPS AS 'THERAPEUTIC GOODS'

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

Yes.