



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Potential reforms to the regulation of nicotine vaping products

Consultation paper

November 2022

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Overview

Purpose

The Therapeutic Goods Administration (TGA) is seeking comments on potential reforms to the regulation of nicotine vaping products (NVPs) in Australia.

NVPs are nicotine-containing products intended to be used in vaping devices such as e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs). This includes vape liquids, e-liquids and e-juices that contain nicotine and/or nicotine salts. NVPs do not include other nicotine replacement therapies (NRTs) for smoking cessation containing nicotine, such as patches, gum, lozenges, mouth spray and inhalators nor nicotine-containing products that are not intended for use in ENDs, such as chewing tobacco and snuff.

The regulatory requirements for NVPs changed on 1 October 2021, when a TGA decision to classify NVPs as prescription medicines (Schedule 4 to the [Standard for the Uniform Scheduling of Medicines and Poisons](#) (Poisons Standard)) took effect, meaning that NVPs are subject to the regulatory controls for prescription medicines (the 2021 reforms).

The aim of the 2021 reforms was to prevent children and adolescents from accessing NVPs, whilst allowing smokers to access these products for smoking cessation with a doctor's prescription. However, evidence is emerging that the reforms are not meeting these aims. Children and adolescents are continuing to obtain NVPs in higher numbers. Commonwealth law prevents the importation, and State and Territory laws prevent the domestic supply, of NVPs without a prescription. However, there is evidence that many adults are accessing NVPs without a prescription, rather than through lawful supply channels with a prescription from an Australian doctor.

The TGA, as the regulator of NVPs, is considering whether refinements to the existing requirements for NVPs could be introduced to better support the intent of the 2021 reforms, namely preventing children and adolescents from accessing NVPs while supporting access to products of known composition and quality for smoking cessation with a doctor's prescription.

This consultation paper does not consider potential changes to the regulation of vaping products that do not contain nicotine, nor vaping devices; the former do not fall under TGA's regulatory remit while the latter are only regulated by the TGA if their sole use is the delivery of medicine, such as nicotine. Over the coming months, the Commonwealth, in conjunction with State and Territory governments, is considering whether the regulation of these products requires any change.

Scope

This consultation covers the following topics:

- Part 1: Background
- Part 2: Emerging Issues
- Part 3: Reform options
 1. Changes to border controls for NVPs.

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2. Pre-market TGA assessment of NVPs against minimum quality and safety standards.
 3. Minimum quality and safety standards for NVPs.
 4. Clarifying the status of NVPs as ‘therapeutic goods’.

The following topics are **not** within the scope of this consultation:

- The classification of NVPs as prescription medicines under the [Poisons Standard](#) and the regulatory controls stemming from this classification.
- The regulation of vaping devices. Vaping devices are not regulated by the TGA except where they are intended, by the person under whose name they are or are to be supplied, to be used exclusively for the vaporisation and administration of a medicine.¹
- The regulation of products containing nicotine that are not NVPs, except where such regulation might support the enforcement of the regulatory scheme for NVPs.
- Clinical guidelines and recommended dosage regimes for nicotine-containing products for smoking cessation.

Providing feedback

We invite you to provide your feedback by completing our online survey on the [TGA Consultation Hub](#). We welcome feedback on the options presented in this paper and encourage alternative suggestions that may assist.

By providing a submission through this process, you are consenting to having your submission published by the TGA in full. However, we retain the right to not make publicly available any submissions, such as those that contain offensive or defamatory comments, or which are outside the scope of the consultation.

Submissions will be published to comply with Australia’s obligations under Article 5.3 of the World Health Organization [Framework Convention on Tobacco Control](#) (WHO FCTC), which requires Australia to protect its public health policies from all commercial and other vested interests of the tobacco industry. Those interests may be related to tobacco products and electronic nicotine delivery systems, including, for example, NVPs. The [Guidelines for implementation of Article 5.3](#) require that the Australian Government ensures that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent.

On request, we will remove personal information from submissions, such as personal email addresses, telephone numbers and home addresses, before publication.

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the TGA.

The closing date for providing feedback is **16 January 2023**.

¹ Unless intended to be used exclusively for the vaporisation or administration of a medicine, devices either do not meet the definition of ‘therapeutic goods’ in the TG Act or are an excluded good under the [Therapeutic Goods \(Excluded Goods\) Determination 2018](#) and/or are declared not to be a medical device under the [Therapeutic Goods \(Articles that are not Medical Devices\) Order No. 1 of 2010](#).

Part 1: Background

Accessing NVPs in Australia

NVPs are currently regulated through a combination of Commonwealth and State and Territory laws. The laws are designed to prevent the importation and supply of NVPs, while allowing current smokers to obtain these products solely for smoking cessation following a consultation with a medical practitioner and a prescription from a medical practitioner.

NVPs can only be lawfully supplied by pharmacies in Australia. It is illegal for other Australian retailers (such as tobacconists, 'vape' shops and convenience stores) to sell NVPs to consumers, even where the consumer has a valid doctor's prescription.

Commonwealth laws

At the Commonwealth level, NVPs are regulated as medicines under the [Therapeutic Goods Act 1989](#) (the TG Act). This means that they cannot be imported into, manufactured in, or in some cases supplied in, Australia, unless they are registered in the Australian Register of Therapeutic Goods (the ARTG) or an exception to registration applies. Retail supply is not generally regulated by the TG Act.

There are currently no TGA-approved NVPs registered in the ARTG, and the current lack of import controls on NVPs has been emphasised as a disincentive to companies obtaining the necessary evidence and applying to TGA to register an NVP on the ARTG. However, NVPs can be accessed with a prescription via 3 main² established access pathways for unapproved medicines:

- [Personal Importation Scheme](#): This scheme allows a person with a prescription from an Australian medical practitioner to directly import up to 3 months' supply of NVPs per order for their own personal use. A person can also import NVPs for immediate family members who have a prescription.
- [Authorised Prescriber Scheme](#) (AP scheme): Under this scheme, a medical practitioner can apply to the TGA for approval to supply NVPs to their patients as an aid to stop smoking.
- [Special Access Scheme B](#) (SAS B): Under this scheme, a medical practitioner can apply to the TGA to supply NVPs to a single patient on a case-by-case basis.

Consumers can purchase NVPs from Australian pharmacies if they have a prescription from a medical practitioner approved under the AP or SAS B schemes.

The legislation permits the importation (e.g. by commercial suppliers or pharmacists) of NVPs for supply under the AP and SAS schemes in advance of an AP or SAS approval being granted, provided the importer reasonably believes the NVPs will be supplied to the ultimate consumer under one of these schemes.

However, while NVPs can be accessed through established pathways for unapproved goods, they must meet minimum safety requirements set out in a product standard that came into

² There are also some other pathways to access unapproved goods that could be utilised to access NVPs, including through extemporaneous compounding or the clinical trial notification scheme. However, the TGA is not aware of significant supplies through these pathways.

force on 1 October 2021, [Therapeutic Goods \(Standard for Nicotine Vaping Product\) \(TGO 110\) Order 2021](#) (TGO 110). TGO 110 includes rules about:

- product labelling (including mandatory warning statements);
- child-resistant packaging;
- maximum nicotine concentration (although, people can still only access nicotine in the concentration specified in their prescription);
- requiring actual nicotine concentration/content to reflect what the product's label states;
- prohibited ingredients;
- records that need to be kept by the Australian sponsor for the product.

Australian State and Territory laws

Responsibility for the regulation of all prescription medicines (including NVPs) is shared between the Commonwealth and the States/Territories.

The States and Territories have, for many years, restricted the supply and, in many cases, use of NVPs. Prior to the scheduling decision mentioned above, NVPs could only be accessed with a relevant approval, such as a prescription. The scheduling decision did not change this.

It is an offence in all States and Territories to supply an NVP to a consumer who does not have a prescription. In most Australian jurisdictions, it is also an offence to either possess or use an NVP without a prescription.

Retail and wholesale supply of NVPs is also strictly controlled. NVPs can be supplied by pharmacists to consumers who have a prescription, but cannot be supplied by vape shops, convenience stores etc. NVPs can also generally only be sold by wholesale by a person with a wholesale licence.

In addition, some States and Territories restrict the supply of NVPs and vaping products that do not contain nicotine through their tobacco control laws. For example, in Western Australia, the [Tobacco Products Control Act 1986](#) (WA) makes it an offence to sell any food, toy or other product that is designed to resemble a tobacco product or package, or is in packaging that is designed to resemble a tobacco product or package, regardless of whether it contains nicotine.

Part 2: Emerging issues

The TGA and its State and Territory counterparts have engaged in a substantial education and compliance campaign to implement the 2021 reforms.

This has met with some success. Patients and health practitioners are increasingly using the access pathways in the therapeutic goods legislation to obtain NVPs. As at 23 November 2022, 447 medical practitioners had been approved to access an NVP under the SAS B pathway and 2,204 patients are estimated to have accessed an NVP under that pathway. As at the same date, there were 1,513 Authorised Prescribers (up from 113 at 30 September 2021 and 655 at 28 February 2022), and 373 Authorised Prescribers had consented to TGA publication of the name and surgery from which they practice.

However, any of Australia's almost 100,000 registered medical practitioners can legally write a prescription to enable a patient to import an NVP through the Personal Importation Scheme. Neither the TGA nor any other government authority has records on the extent of use of this pathway, although anecdotally we have been advised that personal importation is a major source of access to NVPs.

Nevertheless, it is apparent that the regulations are not achieving their intended purpose. It is clear that a black market of NVPs exists, and that NVPs are being readily accessed unlawfully by children and adolescents, and by adults for 'recreational' purposes (i.e. not for smoking cessation), without a prescription.

This is of serious concern. As outlined in the reasons for the scheduling decision,³ and in more recent research referred to below, there is evidence that NVP use by young people can be a gateway to smoking and nicotine addiction. Further, given that NVPs are relatively new products, 'the effect on most clinical outcomes is unknown'.⁴ In these circumstances, a precautionary approach to NVPs is warranted, and all Australian governments have committed to maintaining a precautionary approach.⁵

Recent evidence

Research published since 1 October 2021 supports the approach to the regulation of NVPs reflected in the scheduling decision and indicates that aims of the 2021 reforms are not being met.

There is no nationally published data on NVP usage after 1 October 2021. However, studies published in 2022 suggest that NVPs are being accessed by children and adults without a prescription.

In September 2022, the Generation Vape study published the results of a study of use of vaping products by 14 to 17 year-olds in New South Wales that was conducted in September 2021 (before the 2021 reforms took effect). The study found (amongst other things) that:

- 32% of 14- to 17-year-olds in the survey group had used vaping products;
- more than half of that group had used a vape that they knew contained nicotine;

³ See [Notice of final decision to amend the current Poisons Standard - nicotine | Therapeutic Goods Administration \(TGA\)](#).

⁴ National Health and Medical Research Council – 2022 CEO Statement on Electronic Cigarettes (2022). Available from: <https://www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement>.

⁵ See [Policy and regulatory approach to electronic cigarettes \(e-cigarettes\) in Australia | Australian Government Department of Health and Aged Care](#).

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- most of the teenage vapers who were surveyed for the study found it easy to access vapes - the majority did not buy them but obtained them from friends or, to a lesser extent, family.⁶

Since this time, another Generation Vape study on vaping by children has been conducted. Although the results of this second study have not yet been published, its findings corroborate the findings in the first Generation Vape study. In addition, media reports which quote some unpublished studies on vaping by children suggest that children's and young adults' use of vapes has increased very significantly over the last 1-2 years.

The Cancer Council Victoria released a report in October 2022 which summarised findings from two surveys of e-cigarette use in Victorian adults in 2018-19 and 2022. Key findings include that:

- The use of e-cigarettes by Victorian adults has significantly increased, particularly among young women and those under 30, and that:
 - ever use increased from 17% to 22%;
 - current use doubled from 3.0% to 6.1%;
 - regular use more than doubled from 1.6% to 3.5%;
 - of the estimated 308,827 current users in 2022, more than half were under 30 years old and more than 30% were aged 18-24 years.
- The proportion of never smokers who currently use e-cigarettes increased 4.5-fold from 2018-19 to 2022. This represents approximately 77,200 never smokers who reported currently vaping, of which 44,534 (more than half; 57.7%) were under the age of 25 years.
- 80.6% of regular e-cigarette users in 2022 (and 58.3% of all 2022 users) stated that they usually vaped nicotine.
- Almost 9% of e-cigarette users in 2022 stated that they had a prescription for nicotine.
- Shops such as tobacconists and vaping shops were the most common place of purchase (75.1%) compared to online vendors.
- 47.1% of 2022 users stated that they only ever used other people's devices. This was particularly the case with never smokers (73.8%) and those aged 18-24 (60.9%).⁷

In terms of the health risks of NVPs, a review of global evidence published by the Australian National University in April 2022 found (amongst other things) that:

- There is strong evidence that never-smokers who use e-cigarettes are about 3 times more likely to take up cigarette smoking than those who do not use e-cigarettes.
- There is substantial evidence that e-cigarette use by non-smokers results in dependence.

⁶ Watts, C, Egger, S, Dessaix, A, Brooks, A, Jenkinson, E, Grogan, P and Freeman, B (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*. <https://doi.org/10.1111/1753-6405.13316>

⁷ Bayly M, Mitsopoulos E, Durkin S, Scollo M. [E-cigarette use and purchasing behaviour among Victorian adults: Findings from the 2018-19 and 2022 Victorian Smoking and Health Surveys](#). Prepared for: Quit Victoria. Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia, October 2022.

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- Whilst there is insufficient or no evidence linking the use of e-cigarettes with many adverse health outcomes, there is conclusive evidence that their use can cause respiratory disease, severe burns, nicotine poisoning and seizures.⁸

In June 2022, the National Health and Medical Research Council (NHMRC) published a CEO Statement providing public health advice on the safety and impacts of e-cigarettes. The NHMRC CEO Statement was based on a review of the current evidence and broadly concluded that there are health and safety risks associated with e-cigarette use.⁹ The NHMRC CEO Statement advises, amongst other things:

- E-cigarettes can be harmful. All e-cigarette users are exposed to chemicals and toxins that can harm your health.
- Use of e-cigarettes can result in serious burns and injuries. In some cases, these burns and injuries have resulted in death. Poor-quality e-cigarette batteries or high-power devices increase the risk of explosions. Use of e-cigarettes can result in seizures in some users.
- Exposure to e-liquids that contain nicotine can result in poisoning for some users which, although it may not happen to everyone, can be severe and cause death.
- E-cigarette-related calls to Australian Poisons Information Centres have increased over the past 5 years. Most poisonings occur in toddlers and adults.
- Use of e-cigarettes can result in a serious and sometimes fatal lung condition known as E-cigarette or Vaping Associated Lung Injury (EVALI) in some users. Most cases of EVALI reported in the United States of America were linked to cannabis oils and vitamin E acetate, but other chemicals may also contribute to this condition.
- Use of e-cigarettes that contain nicotine probably results in throat irritation, cough, dizziness, headaches and nausea.
- There is not enough information from human research studies to know about the potential impacts of e-cigarette use on conditions such as cancer and cardiovascular disease, reproductive health, respiratory conditions (e.g. asthma) and mental illness.
- Lack of information does not mean that e-cigarettes are safe. More information is needed to know if long-term e-cigarette use is safe or may be harmful to health.

In terms of the use of NVPs for smoking cessation, the ANU report noted that there was:

limited evidence that, in the clinical context, freebase nicotine e-cigarettes may be more efficacious for smoking cessation than existing NRT, and that nicotine e-cigarettes may be more efficacious than no intervention or usual care.¹⁰

The NHMRC CEO Statement cautioned tobacco smokers about the utility of e-cigarette use for smoking cessation and stated '[f]or some smokers, using nicotine e-cigarettes may assist

⁸ 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. Available from: [Open Research: Electronic cigarettes and health outcomes: systematic review of global evidence \(anu.edu.au\)](https://openresearch.anu.edu.au)

⁹ National Health and Medical Research Council – 2022 CEO Statement on Electronic Cigarettes (2022). Available from: <https://www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement>

¹⁰ Banks E, et al, op cit., p xiii.

them to quit; however, more research is needed to confirm the harms and benefits of using them for this purpose’.

A more recent report by the Institute of Psychiatry, Psychology & Neuroscience at King’s College London (commissioned by the UK Department of Health and Social Care) was published on 29 September 2022¹¹ and found that:

- Vaping products remain the most common aid used by people in England to help them stop smoking.
- In stop smoking services in 2020 to 2021, quit attempts involving a vaping product were associated with the highest self-reported short-term success rates (64.9% compared with 58.6% for attempts not involving a vaping product).
- Using vaping products rather than smoking leads to a substantial reduction in exposure to toxicants that promote cancer, lung disease and cardiovascular disease.
- While vaping is not risk free (particularly for people who have never smoked), it poses a small fraction of the health risks of smoking in the short to medium term.

The Cochrane Collaboration is an international non-profit organisation formed to organise medical research findings to facilitate evidence-based choices about health interventions. A Cochrane Review is a systematic review of research in health care and health policy.

A very recently updated Cochrane Review (November 2022) compared the effects of NVPs with other ways of delivering nicotine, such as NRTs like patches and chewing gum, e-cigarettes without nicotine, and behavioural support only/no support.¹² The review included 78 studies (22,052 participants), including 40 randomised controlled trials, and studies had to report abstinence from smoking cigarettes at six months.¹³ Of the included studies, 10 (all but 1 contributing to the authors’ main comparisons) were rated at low risk of bias overall, 50 at high risk overall (including all non-randomized studies), and the remainder at unclear risk.¹⁴

In relation to the quit rates:

- There was high certainty that quit rates were higher in people randomized to NVP than in those randomized to NRT (risk ratio RR 1.63, 95% CI 1.30 to 2.04; 6 studies, 2378 participants). In absolute terms, this might translate to an additional 4 quitters per 100 using NVPs.
- There was moderate-certainty evidence that quit rates were higher in people randomized to NVPs than to non-nicotine vaping products (RR 1.94, 95% CI 1.21 to 3.13; 5 studies, 1447 participants). In absolute terms, this might lead to an additional 7 quitters per 100 using NVPs.

¹¹ McNeill, A, Simonavičius, E, Brose, LS, Taylor, E, East, K, Zúikova, E, Calder, R and Robson, D (2022). Nicotine vaping in England: an evidence update including health risks and perceptions, September 2022. A report commissioned by the Office for Health Improvement and Disparities. London: *Office for Health Improvement and Disparities*. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1107701/Nicotine-vaping-in-England-2022-report.pdf

¹² Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2022, Issue 11. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7. Available from: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full>

¹³ *ibid.*

¹⁴ *ibid.*

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- Compared to behavioural support only/no support, quit rates were higher for participants randomized to NVPs (RR 2.66, 95% CI 1.52 to 4.65; 7 studies, 3126 participants). In absolute terms, this represents an additional 2 quitters per 100 using NVPs. However, this finding was of very low certainty, due to issues with imprecision and risk of bias.¹⁵

An August 2021 analysis from the University of Queensland¹⁶ provided similar results. The study found that participants randomised to receive NVPs were 49% more likely to remain abstinent from smoking than those who received other NRTs (risk ratio RR = 1.49, 9 trials with 6080 participants). Those randomised to receive NVPs were 109% more likely to remain abstinent from smoking than those in control conditions where no nicotine was supplied (risk ratio RR = 2.08, 7 trials with 5674 participants). However, it concluded that more high-quality studies are required to ascertain the effect of NVPs on smoking cessation due to risk of bias in the included studies.

Another recent (September 2021) study from the Australian National University¹⁷ also demonstrated a small benefit in smoking cessation for freebase NVPs compared to approved NRT, in the clinical context and based on low certainty evidence. Significantly greater quit rates for participants randomised to freebase NVP were found compared to no intervention or usual care; evidence was also of low certainty.

Implementation issues

A key to achieving the intent of the 2021 reforms is for governments at all levels to continue to work together to focus on effective ways of reducing demand, and practical ways of limiting unlawful supply.

However, it is critical to consider whether the existing regulatory parameters could be refined to better limit children's and adolescents' access to NVPs, and better confine adults' use of NVPs to smoking cessation, with a doctor's prescription.

Several aspects of the regulatory framework are hampering the effectiveness of compliance and enforcement efforts:

- Because NVPs do not undergo any pre-market assessment by the TGA (as prescription medicines ordinarily would) a number of health professionals are reporting that they do not feel confident prescribing and supplying NVPs.¹⁸
- It appears that large volumes of NVPs are being imported, and supplied, unlawfully. It is possible that the breadth of the current exceptions to registration that allow unapproved NVPs to be imported into Australia, including the lack of systematic checks on either commercially or personally imported products, are contributing to the problem. The emergence of a large black market raises a question as to whether current importation controls should be tightened.

¹⁵ *ibid.*

¹⁶ Chan G, Stjepanović D, Lim C, Sun T, Anandan A, Connor J, Gartner C, Hall W, Leung J. A systematic review of randomized controlled trials and network meta-analysis of e-cigarettes for smoking cessation. *Addict. Behav.* Aug 2021. Electronic publication 15 March 2021. Available from: <https://pubmed.ncbi.nlm.nih.gov/33798919/>

¹⁷ Yazidjoglou A, Ford L, Baenziger O, Brown S, Martin M, Zulfiqar T, Joshy G, Beckwith K, Banks E. Efficacy of e-cigarettes as aids to cessation of combustible tobacco smoking: updated evidence review. Final report prepared for the Australian Government Department of Health: online version, September 2021. Available from: <http://hdl.handle.net/1885/247864>

¹⁸ Attwooll, J (2022), Study highlights vaping harms – and evidence gaps. *Royal Australian College of General Practitioners*. Available from: <https://www1.racgp.org.au/newsgp/clinical/study-highlights-vaping-harms-and-evidence-gaps>

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- Products imported via the Personal Importation Scheme cannot be lawfully supplied to others (sold or given away). However, the Personal Importation Scheme allows sizeable quantities of NVPs to be imported (up to 3 months' supply in any one order and a maximum of 15 months' supply in a year). It is impossible to ensure that the annual limit on the maximum quantity that can be imported is observed. It may be that some NVPs imported under this scheme are being sold on the black-market rather than personally used by importers with a prescription. In addition, it is very hard to police the requirement for a prescription, as overseas websites selling NVPs often do not ask for evidence of a prescription prior to supply.
 - The exemption for imports of commercial supplies prior to TGA approvals under SAS or AP being in place permit unlimited quantities of NVPs to be imported prior to such approvals being in place.
 - The traveller exemption (which is part of the Personal Importation Scheme) does not require a person who is bringing the goods into Australia (accompanied with them on an incoming aeroplane or ship) to hold a prescription, notwithstanding the status of NVPs as prescription medicines in Australia.
 - There is very significant evidence that companies and individuals are seeking to evade the new regulatory requirements by concealing the presence of nicotine in their products. Recent testing undertaken by the TGA found that 168 products of 296 products tested (57%) contained undeclared nicotine. This is creating enforcement issues at all levels of government. Similar results have been obtained in testing programs conducted by universities and state governments. Further, vaping devices are increasingly designed to look like other objects (e.g. watches, USB drives, pens), which further impedes detection efforts.
 - The current import restrictions for NVPs are complex, which means that enforcement at the Australian border is difficult. Under the current controls, which derive from NVPs being classified as a prescription-only medicine, NVPs detected at the border must be held by the Australian Border Force (ABF) and referred to the TGA. The TGA must then consider if the importation is lawful under the TG Act and provide advice to the ABF. If TGA advises the ABF that the importation is unlawful, the ABF will treat the imports as prohibited under their own legislation. Because of the growing trend to conceal the presence of nicotine NVPs, the TGA may need to test the products before providing advice to the ABF. The complexity of the importation requirements under the therapeutic goods legislation also means that it can take time for the TGA to assess whether an importation is lawful (sometimes it is necessary to ask the importer questions, or obtain legal advice to determine this).
 - TGA standards relating to labelling and packaging cannot be enforced at the border. This is because it is not an offence under the TG Act to import a medicine that does not comply with labelling and packaging standards, such as those in TGO 110. Rather, it is only an offence for the importer to supply products that do not comply with labelling and packaging standards such as those in TGO 110, but this does not prevent the entry of such goods into Australia. It also means that there is no requirement for NVPs imported under the Personal Importation Scheme to comply with the labelling and packaging and requirements in TGO 110.

Part 3: Reform options

Reforms are proposed for consultation in 4 main areas:

1. changes to border controls for NVPs;

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2. pre-market TGA assessment of NVPs against a product standard;
 3. strengthening of the product standard regarding minimum quality and safety standards for NVPs; and
 4. clarifying the status of NVPs as 'therapeutic goods'.

Border controls

We seek your feedback on whether some of the issues identified above might be addressed, or partially addressed, through changes to the border controls for NVPs.

Options

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).**

Issues

Option 1 – no legislative changes, but increase enforcement action at the border

It seems unlikely that changes to the import controls would eliminate all unlawful importation of NVPs.

It is also possible that tightening import restrictions could result in more extensive efforts to evade detection (e.g., increased changes to presentation and labelling to disguise products).

The detection of NVPs can be difficult at the Australian border due to the physical properties of the goods. Unlike some other products, such as tobacco, liquid nicotine cannot be identified by sight and smell.

However, specific import controls could limit the black-market supply of NVPs (especially commercial supply), deter non-compliance or make enforcement at the border easier.

Option 2 – Remove Personal Importation Scheme exemption for NVPs

Option 2 has 2 potential benefits:

- It would prevent the Personal Importation Scheme being abused to obtain NVPs to sell on the black market. There is anecdotal evidence that at least some NVPs imported under this scheme are being on-supplied, rather than used personally. Both the Generation Vape and Victorian Cancer Council surveys reported that significant usage of vaping products occurs through sharing of products or obtaining them from friends or family.

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- It would close a regulatory gap that prevents the TGA imposing standards in relation to the labelling and packing of NVPs imported through the Personal Importation Scheme.

However, it would not make the enforcement of the other importation requirements at the border simpler, or assist with the enforcement issues associated with identifying whether vaping products contain nicotine.

Preventing travellers from importing NVPs when arriving by ship or aeroplane may in some cases result in NVPs that are being accessed for bona fide smoking cessation reasons being seized at the border. This would then require travellers to consult a local doctor to be prescribed alternative NVPs.

A consequence of tightening personal importation controls is that quitting smokers would need to obtain NVPs dispensed from an Australian physical pharmacy or Australian online pharmacy. With appropriate transition periods, it should be possible to ensure continuity of supply for lawful purposes through such means, even with tighter import controls.

Option 3 Impose tighter controls on the importation of NVPs by requiring an import permit

Option 3 has all the benefits of option 2, but could be designed in a way to make the enforcement of the import restrictions more straightforward, and might act as a better deterrent against non-compliance.

Customs Regulations were made to implement this option in 2020, but these regulations never commenced. In broad terms, the [Customs \(Prohibited Imports\) Amendment \(Vaporiser Nicotine\) Regulations 2020](#) would have:

- imposed an absolute ban on the importation of NVPs by post (mail); and
- generally imposed a ban on the importation of NVPs by any other means without permission (but would have allowed travellers arriving by ship or aeroplane to import NVPs prescribed by a medical practitioner).

Under the scheme, a permission could only have been granted to:

- a medical practitioner with approvals under the AP or SAS schemes; or
- an importer who declared they were importing the goods under specific therapeutic goods requirements and who undertook to comply with those requirements.

The features of any new permit system would depend on other decisions made about regulatory controls. If a decision is made to require a form of pre-market assessment by TGA of NVPs, then permits would only be granted in relation to the importation of NVPs that had undergone that assessment.

Introducing a requirement that a person must hold an import permission before importing a NVP would also be simpler to enforce than the current scheme. If the goods are clearly labelled as being NVPs, it would only be necessary for the ABF to check if a person held the required import permit, rather than referring the goods to the TGA for assessment.

Tighter import controls may also act as a deterrent to non-compliance, and requiring an import permit would give the TGA greater visibility over who is lawfully importing NVPs. Further, it would ensure that requirements for TGA product standards relating to labelling and packaging could be enforced at the border.

A limitation of this option is that it may not assist with the enforcement issues that have arisen due to the concealment of nicotine in products. If a vaping product is imported, but is

not labelled as containing nicotine, the ABF would still need to refer the product to the TGA for testing to determine its regulatory status. It is possible to test for nicotine in a non-laboratory situation such as an airport or postal exchange, but this would require resources.

Further, even if Customs Regulations are introduced, it would still also be necessary to retain therapeutic goods controls to deal with the domestic manufacture and supply of NVPs.

Options 2 and 3 could be considered together.

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

Option 4 has all the benefits of option 3, but could also regulate non-nicotine vaping products for the purpose of facilitating the effective regulation of NVPs.

As already mentioned, a number of importers and suppliers are seeking to evade the regulatory requirements for NVPs by not labelling their products as containing nicotine. It would be possible to introduce Customs Regulations to combat this practice. For instance, the importation of any vaporiser products that do not contain nicotine could be prohibited unless the imported goods are accompanied by testing results from a certified, accredited laboratory demonstrating that the product does not contain nicotine and the products are labelled as containing 0% nicotine. This would set out simple and clear rules that would be easy to enforce by the ABF.

However, it would also increase compliance costs (for both industry and government) and would not regulate domestic manufacturing and supply of non-nicotine NVPs. Non-nicotine vaping products are not therapeutic goods and cannot be regulated under the therapeutic goods framework (which regulates domestic manufacturing and supply of therapeutic goods).

It may instead be better for any further regulation of non-nicotine vaping products to be considered as part of a comprehensive review of these products and in the meantime explore whether issues with the content of non-nicotine vaping products would be regulated through other existing legal frameworks, such as consumer protection laws.

Questions

1. Which option (whether listed above or not) do you prefer? Why?
2. Would any of these options have an impact on you? How?
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?

Pre-market TGA assessment of NVPs

Options

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).**

Issues

At present, there are no NVPs registered in the ARTG, but they can be lawfully imported under a number of established exemptions to the requirement for registration.

If regulated sources of quality NVPs were available, this may increase the confidence of medical practitioners to prescribe NVPs and dispensing pharmacists to stock and dispense them. The lack of healthcare professional confidence in the quality and safety of the currently available NVPs has restricted willingness to prescribe and stock these products.

If consumers had a clear choice between a product checked against a quality and safety standard and one that had not, consumers might be more inclined to purchase a TGA-assessed product through a lawful route, rather than a non-assessed product through an unlawful route.

Under Option 3, it would be necessary for NVPs to be registered in the ARTG to be lawfully imported and supplied (rather than permitting import and supply through the current pathways for unapproved goods). However, this option may not be feasible in the short to medium term, and could result in NVPs ceasing to be available in Australia. While several companies have had early-stage discussions with the TGA about registering NVPs, it is unclear whether there will be any applications to the TGA to register NVPs in the coming years and, if there are, whether such applications would meet the regulatory requirements for registration.

Under Option 3, NVPs could only be imported or supplied if they had undergone a pre-market TGA assessment against a set of quality and safety criteria specified in legislation (such as an amended version of the current product standard, TGO 110, or another product standard introduced for this purpose).

The effort required by the TGA for pre-market assessment against a product standard would be significantly less than that required for evaluation for potential registration of a prescription medicine. If this approach was adopted, a decision by government would be required to determine whether a fee should be charged to the applicant or whether, to encourage products to be assessed, a fee would not be required and the costs borne by government, at least for a limited period.

Questions

1. Which option (whether listed above or not) do you prefer? Why?
2. Would any of these options have an impact on you? How?
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?

Minimum quality and safety standards for NVPs

Currently, TGO 110 sets out minimum safety requirements for unapproved NVPs. There is scope to adjust these requirements, either through amendments to TGO 110 or by changing the terms of the exemptions under which unapproved NVPs are currently imported.

Options

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).**

Make no changes to minimum safety and quality requirements

The existing terms of TGO 110 were specified after extensive public consultation and were designed to ensure that a broad range of products were available for smoking cessation, with the oversight of a prescribing medical practitioner.

Certain limits to nicotine concentrations or volumes were not originally pursued, to allow medical practitioners flexibility to prescribe products appropriate for their patients and because medical practitioners could, in effect, include additional limits for each patient through the prescription process. There was also a concern that inclusion of detailed Australian requirements could limit access to products already being used for smoking cessation or increase the costs of NVPs in Australia, due to the need to comply with bespoke Australian requirements.

Further, the current problems relating to NVPs are associated with the supply of these products through the non-prescription (i.e. unlawful) market, and this seems to be the dominant market in 2022.

However, not all products that are supplied unlawfully are necessarily imported unlawfully. It is possible for products to meet the importation requirements, but then be subsequently supplied unlawfully (e.g. to persons without a prescription). The recent Generation Vape and Victorian Cancer Council research reports significant incidence of people accessing NVPs from friends or associates.

Further, some changes to minimum quality and safety standards (particularly around visible features of products) would assist law enforcement officers to better distinguish lawful from unlawful products. In addition, some changes to the minimum safety and quality requirements could make the products much less attractive to children and adolescents.

Prohibit or restrict flavours and additional ingredients

TGO 110 currently prohibits the inclusion of any active ingredient other than nicotine in NVPs, and prohibits the inclusion of substances that are specified in Schedule 1 of TGO 110 in NVPs. These prohibited ingredients include solvents or carriers (diethylene glycol and ethylene glycol), a vitamin (dl-alpha-tocopheryl acetate) and flavours (2-3-pentanedione, acetoin, benzaldehyde, cinnamaldehyde and diacetyl).

Flavours

TGO 110 prohibits the use of a number of specified flavouring agents - 2-3-pentanedione, acetoin, benzaldehyde, cinnamaldehyde and diacetyl. However, vapes are sold in hundreds of different flavours, and the range of flavours is constantly increasing.

There is growing evidence that flavours are an important factor in the attractiveness of e-cigarettes and the initiation of vaping in young adults and adolescents. The Generation Vape study recently found that 'flavourings and taste' were rated as *the* most important characteristic of vapes for users in the 14-17 year age group.¹⁹ Flavours and sweeteners are also associated with a decreased perception of harm and an increased intention to try these products.²⁰

The long-term effects of flavour inhalation are largely unknown. Vaping products can contain flavours that were originally intended for use, at low concentrations, in food/beverages that are ingested. In an overwhelming number of cases, the inhalation toxicity of flavours (and other ingredients) is unknown.

Prohibiting or limiting the inclusion of flavours of NVPs may reduce their attractiveness to children and young people, and guard against the unknown long-term health effects of flavours.

At least nine other international regulators have restricted or indicated an intention to restrict flavours. For example, confectionary, dessert, cannabis, soft drink and energy drink flavours are prohibited from use in NVPs in Canada. Canada is considering further limiting the flavours available to tobacco, mint and menthol.²¹ From 11 August 2021, New Zealand has restricted retailers to selling only tobacco, mint and menthol flavoured NVPs. Specialist retailers can sell other flavours.²²

It is important to note that a flavour may itself include ingredients, including potentially more than 20 such ingredients, and that the same flavour from different companies is unlikely to contain the same mixture of flavouring agents. This makes it difficult to regulate flavours by restricting them individually. If some flavours are to be permitted, it may be more workable to allow selected flavours only.

Cooling ingredients

A common ingredient used in tobacco-based cigarettes is menthol. This ingredient has been included in tobacco-based cigarettes for many years. Menthol imparts a 'cooling' sensation when inhaling tobacco smoke by soothing the irritation to the throat and airways caused by tobacco smoke and nicotine vapours. This sensation allows smokers to take easier and deeper inhalations, thereby increasing the dose of nicotine to the body. Menthol also reduces

¹⁹ Watts, C, et al, op cit.

²⁰ Banks E, et al, op cit.

²¹ See, for example, [Forward Regulatory Plan 2022-2024: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act \(Flavours\) and Standards for Vaping Products' Sensory Attributes Regulations](#), Government of Canada, 2022.

²² Ministry of Health, [Vaping information for all industry](#), Government of New Zealand, 2021.

the metabolism of nicotine, thereby increasing the presence of nicotine in the body. In a similar manner, the presence of menthol (and other 'cooling' ingredients) in e-cigarette/vaping solutions may increase the appeal of nicotine-based vaping solutions.

Other 'cooling' ingredients include WS-3 (N-ethyl, 2-sopropyl-5-methylcyclohexane carboxamide; CAS No. 39711-79-0) and WS-23 (2-isopropyl-N,2,3-trimethyl butyramide; CAS No. 51115-67-4). Both are used as food additives but are becoming popular in 'ice' labelled vaping solutions. The flavour of these ingredients has been described as having a mentholic, cooling, minty, eucalyptus and camphorous taste/effect. Recent scientific literature has raised concerns about their inhalation toxicity when used in vaping solutions.²³

Colouring agents

The United Kingdom, European Union and Canada also prohibit colouring agents (e.g. food grade colouring additives that create coloured emissions) in NVPs sold as consumer goods.²⁴ Colouring agents have been banned in New Zealand since 11 August 2021.²⁵

As with flavours, colouring agents may encourage youth uptake, and there is limited evidence regarding the inhalational safety of these types of ingredients. Prohibiting or limiting the inclusion of colouring agents in NVPs may reduce their attractiveness to children and young people, and guard against unknown long-term health effects.

Labelling and packaging

Plain packaging

There is currently no requirement in TGO 110 for plain packaging for NVPs. However, some other countries (e.g. Israel) mandate plain packaging for these products.

Plain packaging of NVPs may help to discourage youth and other non-smokers from taking up vaping, similar to the impact Tobacco Plain Packaging legislation had on tobacco usage in Australia. For NVPs, "plain packaging" could mean packaging like other prescription-only medicines, with packaging in a monotone colour and labelling specifying the product name, nicotine content and Australian sponsor only. Consideration would need to be given as to whether the product standard should also require pre-approval of the name of the, so that NVP names that appeal to children and adolescents are not permitted. So in this case "plain packaging" could mean packaging similar to any other prescription medicine.

While "plain packaging" for cigarettes and smoking products is generally accompanied by graphic warnings, in the cases of NVPs this may be incompatible with their intended use as prescription medicines, and such warnings could deter from their valid use in smoking cessation.

²³ See, for example, Leventhal AM, Tackett AP, Whitted L, Jordt SE, Jabba SV. *Ice flavours and non-menthol synthetic cooling agents in e-cigarette products: a review*. Tobacco Control. April 2022.

²⁴ See, for example, in the UK: [E-cigarettes: regulations for consumer products - GOV.UK](#), Government of the United Kingdom, 2022; in the EU: [Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC](#); and in Canada: [Backgrounder: Regulation of vaping products in Canada](#), Government of Canada, 2019.

²⁵ Ministry of Health, [Vaping information for all industry](#), Government of New Zealand, 2021.

Warning statements

TGO 110 requires that the following warning statements must be on or attached to the container or the primary pack of an NVP, or supplied with the container or the primary pack of an NVP:

- “KEEP OUT OF REACH OF CHILDREN”;
- “Avoid contact with eyes”;
- “Avoid contact with skin”.

Warning label requirements for NVPs sold as consumer goods in other countries include:

- nicotine addictiveness warnings (the United Kingdom, the European Union, Canada and the United States of America, New Zealand);
- ‘keep out of reach of children’ (the United Kingdom and New Zealand); and
- toxicity and first aid treatment statement (Canada and New Zealand).

Several additional warning statements could be included on NVP labels under TGO 110, along with a requirement to affix the label on the primary packaging of the product. Such additional warning statements could include:

- pregnancy warnings;
- nicotine addictiveness warnings (e.g. ‘Nicotine is addictive’);
- warnings about the health risks of nicotine including accidental consumption by children;
- warnings about the unknown health risks of vaping.

The inclusion of new warning messages could assist with discouraging the uptake of NVPs by children and non-smokers.

However, potential inclusion of such warnings on the packaging of NVPs could also be highly incompatible with their regulatory status as prescription only medicines. Other prescription only medicines, even opioids such as tramadol, do not require warnings about addictiveness, pregnancy and consumption by children. Furthermore, even controlled (Schedule 8) drugs with known addiction potential do not require a long list of on-pack warnings. Such warnings could also potentially discourage bona fide use by patients who have been prescribed a product for smoking cessation.

Location of mandated labelling

TGO 110 currently requires mandated labelling to be:

- on or attached to the container or the primary pack of an NVP; or
- supplied with the container or the primary pack of an NVP.

There is scope to change this requirement, to make mandated labelling more prominent and enduring (e.g. by requiring mandated labelling to be displayed on the primary pack and/or the NVP itself).

Reducing nicotine concentration

TGO 110 specifies a maximum nicotine concentration of 100 mg/mL in its base form or base form equivalent.

This concentration is higher than that permitted by other national regulators. There are at least 34 other national regulators (including the United Kingdom, Canada, Israel, Saudi Arabia, and European Union countries) that have set a maximum nicotine concentration of 20 mg/mL in NVPs (though this is not in the context of a prescription-only scheme).

The nicotine concentration of NVPs sold as consumer goods is limited to 20 mg/mL in the United Kingdom, European Union and Canada. Canada recently lowered its limit from 66 mg/mL to 20 mg/mL. These limits do not apply to therapeutic goods. New Zealand has also limited base form nicotine concentration to 20 mg/mL and nicotine salt concentration to 50 mg/mL in NVPs sold as consumer goods.

Although a concentration of up to 100 mg/mL of nicotine in e-liquids provides flexibility to the prescriber to prescribe an NVP to suit a patient's needs, e-liquids with nicotine concentration of over 20 mg/mL generally require "at home" dilution prior to use in devices. These dilutions can be complex and may lead to titration errors.

In the Australian context, where NVPs are available by prescription only, the illicit use or diversion through dilution and distribution of products obtained via a prescription may be more likely with higher concentration nicotine products.

With higher concentration NVPs, there is also a higher risk of acute poisoning in users (particularly in children) from intentional or accidental ingestion. For example, a 10 kg toddler would experience potentially lethal effects by ingesting as little as 0.5 mL of a 100 mg/mL NVP.

Reducing nicotine concentrations would lower the risk of titration errors caused by "at-home" dilution and mitigate the risk of acute poisoning in users from intentional or accidental ingestion.

It is likely that any limit applied to the nicotine concentration will continue to be expressed as base form or base form equivalent, rather than having a separate limit on the concentration of the nicotine salt. It is noted, however, that in New Zealand upper limits are applied to both the free-base nicotine of 20 mg/mL and the nicotine salt of 50 mg/mL.

Limit volume of liquid NVPs

The form of NVPs is constantly changing, and the volume of available products is ever increasing. For example, it is possible to buy devices that deliver over 10,000 puffs. These products are considerably cheaper than the equivalent amount of tobacco, and may entrench nicotine addiction. Large volume devices are also easier to share (e.g. amongst groups of children) and increase children's potential exposure to nicotine once they obtain the products (as compared to lower volume devices).

It would be possible to limit the maximum volume of liquid NVPs that can be lawfully accessed under the therapeutic goods legislation through amendments to TGO 110.

Preventing access to disposable NVPs

Recent evidence suggests that children who use vaping products usually use disposable products (i.e. where the entire device is disposable). These products are also relatively cheap (the Generation Vape survey reported they could be purchased for as little as \$5).

It would be possible to prevent disposable NVPs being lawfully accessed under the therapeutic goods regulatory framework.

Restricting access to disposable NVPs may reduce children's access to these products. However, disposable products may be most suitable for smoking cessation for some categories of users (e.g. people with disabilities) and restricting this product may lead people

to purchase larger volume devices that require dilution and mixing of liquid nicotine (which carries its own risks, including poisoning).

Questions

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?
2. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?
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?
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?
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?
6. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?
7. Do you support preventing access to disposable NVPs?
8. Would any of these options have an impact on you? How?
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?
10. Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?

Clarifying the status of NVPs as ‘therapeutic goods’

Section 7 of the TG Act permits the Secretary (in practice, a senior executive of the TGA) to declare classes of goods to be therapeutic goods. In light of the increasing practice of concealing the presence of nicotine in NVPs, it is desirable to utilise this power and clarify the regulatory status of these products. Making an order under s 7 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.

Question

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

Next steps

The responses will be analysed and any proposed reforms will be taken forward in discussion with the Government. If changes to the regulatory framework are made, suitable transition periods will be implemented to enable the development of a strong, responsible, local medical products-only industry of suppliers of prescription-only NVPs.