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Department of Health and Aged Care
Therapeutic Goods Administration

Proposed reforms to the regulation of vapes
Impact Analysis

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Contents

Glossary

Australian Register of Therapeutic Goods (ARTG): the public database of therapeutic goods that can be legally supplied in Australia. The ARTG is the main pathway for consumers to access prescription medicines and medical devices in Australia.

Authorised Prescriber (AP) Scheme: allows authorised medical practitioners to prescribe medicines or medical devices that are not included in the ARTG to a class of patients with a particular medical condition.

Contaminant: a chemical in the e-liquid (and sometimes the vaping device) that is not intended as an ingredient.

Convenience Stores: small, local, easily accessed store carrying limited selection of household goods.

Customs Regulations: *Customs (Prohibited Imports) Regulations 1956* (Cth).

Device component (of a vape): a device, or element of a device, designed to generate or release (or assist), by electronic means, an aerosol or vapour (i.e., mist or emission) for inhalation. Device components include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes, vape pens. Device components can include a battery, a liquid cartridge and an atomiser. Devices components are either disposable or refillable/reusable.

Disposable vape: a vape that is pre-filled with an e-liquid that cannot be refilled and is disposed of once the vaping substance runs out. Disposable vapes refer only to closed system (sealed unit) vaping devices.

E-liquid (component of a vape): means the substance (usually, but not always, a liquid) consumed in a vape. E-liquids usually contain propylene glycol, glycerol, and flavourings, and may or may not contain nicotine.

Ingredient: a chemical that is intended to be in an e-liquid (e.g. a flavour).

Medical Device (per TG Act): includes a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, and x-ray equipment. They differ from medicines as they generally have a physical or mechanical effect on the body or are used to measure (or monitor) the body and its functions.

Medicines (per TG Act): includes a wide range of goods, such as prescription medicines, complementary medicines, and over the counter medicines. They differ from medical devices or biologicals as they generally have a pharmacological, chemical, immunological or metabolic effect on the body.

Nicotine Vaping Product (NVP): a therapeutic vape that contains nicotine. A term defined in the Therapeutic Goods Regulations.

Nicotine Replacement Therapy (NRT) products: a range of products included on the ARTG that are used to support smoking cessation, including mouth spray, gum, lozenges, inhalators and patches.

Pharmaceutical Benefits Scheme (PBS): provides timely, reliable, and affordable access to necessary medicines for Australians.

Poisons Standard: Standard for the Uniform Scheduling of Medicines and Poisons, which is a legislative instrument consisting of decisions on the classification of medicines and chemicals into Schedules according to risk.

Prescription-only medicines: medicines listed under Schedule 4 of the Poisons Standard.

Reaction product: a chemical produced when the chemicals present in e-liquids and emissions react with light, heat or other chemicals (produced when e-cigarette devices are heated to produce the inhalable emission).

Refillable/reusable vape: a vape that can be refilled and/or reused multiple times, often with various e-liquids or pods sold separately to the device and can be recharged.

Therapeutic vape: a nicotine vape and a vape that makes a therapeutic claim (irrespective of nicotine content). Therapeutic vapes are regulated under the TG Act.

TGA: Therapeutic Goods Administration.

TG Act: *Therapeutic Goods Act 1989* (Cth).

TGO 110: *Therapeutic Goods (Standard for Nicotine Vaping Product) (TGO 110) Order 2021*, the product standard made under section 10 of the TG Act which sets out minimum safety and quality requirements for vapes that are not registered in the ARTG and that are imported into, supplied in, or exported from Australia. All therapeutic vapes currently available in Australia are unregistered.

Tobacconist Stores: retail business whose primary purpose is the sale of tobacco products and accessories.

Unapproved therapeutic goods: therapeutic goods that are not included in the ARTG and have not met the quality, safety and efficacy requirements for ARTG registration. There are established pathways under the TG Act that allow access to unapproved therapeutic goods in certain circumstances, including the Special Access Scheme and the AP Scheme.

Vaping device: see *device component*.

Vape: comprises both e-liquid and device components which, when used together, are designed or intended to vaporise and administer the e-liquid component by inhalation generally in a manner that replicates, or produces an experience similar to, smoking.

Vape Specialist Store: retail business focusing on the selling of vapes.

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Executive Summary

The public health problem

In view of the risks posed by vapes to tobacco control and population health, to date Australian governments have taken a precautionary approach to their marketing and use. Broadly, this approach is underpinned by the current state of evidence regarding the direct harms vapes pose to human health, their impacts on smoking initiation, continuation and cessation, their uptake among youth and young adults, and their dual use with conventional tobacco products.

Vaping – or the use of e-cigarettes – is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as use at least once in the month prior to being surveyed, increased from 2.5% to 7.5% between 2020 and 2022. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 21.4% in 2022.[1] These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes, and in particular the use of vapes by youth and young adults.

Vapes are widely marketed, available and accessible to youth and young adults in Australia, and many products have a very low purchase price compared to many consumer goods and tobacco products. Advertising and promotion occur across a range of media channels that have broad reach among youth and young adults, including websites, social media, in print and in retail stores. Evidence also suggests that exposure to these advertisements increases the likelihood that youth and young adults will try vaping. Direct exposure to vaping promotions has been found to lead to decreased risk perceptions for vaping. Some vape marketing is also emulating successful tobacco advertising, asserting an independent identity and a lifestyle choice, aligning the products with celebrities and influencers, and fashionable and youthful places and activities. Evidence further suggests that specific product features designed by the vaping industry, such as colours and flavours, are further contributing to their appeal and uptake among youth and young adults.

On 1 October 2021, the Australian Government introduced regulatory changes to clarify that consumers require a valid prescription from an Australian registered doctor for all purchases of nicotine vaping products, such as nicotine e-cigarettes, nicotine pods and liquid nicotine. This included purchases from overseas as well as in Australia. These changes were made to prevent youth and young adults from taking up nicotine e-cigarettes, while allowing current smokers to access these products to use for smoking cessation with appropriate medical advice. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found substantial evidence that vaping by non-smokers results in dependence and conclusive evidence that vape use can cause respiratory disease, severe burns, poisoning and seizures.[2]

[1] Wakefield, M et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Data collected from the Roy Morgan Research company and analysed by Cancer Council Victoria for the Department of Health and Aged Care. This data is not nationally representative. It should be considered preliminary until more comprehensive national data is published in 2023-24. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

[2] Banks, E et al, 'Electronic cigarettes and health outcomes: systematic review of global evidence' (2022) Australian National University, National Centre for Epidemiology and Population Health. Available at: https://openresearch-repository.anu.edu.au/bitstream/1885/262914/1/Electronic%20cigarettes%20health%20outcomes%20review_2022_WCAG.pdf

Vapes contain harmful chemicals, including flavourings, that are known to cause irreversible lung damage, and may also have chronic long-term effects. In addition, it appears that the majority of products on the domestic market contain, or are likely to be used in conjunction with, nicotine. This is the case even where no nicotine is indicated on the label of the product, if any label exists.

Further, even where vapes are being used for smoking cessation, the majority of vapes are not being sourced under medical supervision or from a pharmacy. This undermines the role of the Therapeutic Goods Administration (TGA) in safeguarding the health of Australians through effective and timely regulation of therapeutic goods.

All users of vapes are exposed to chemicals and toxins that have the potential to cause adverse health effects. However, vaping is of particular concern among youth and young adults. The prevalence of vaping is highest among youth and young adults, and the adverse health effects may be greater among this cohort when compared to the general population. Most vapes are used with nicotine, and there is evidence that nicotine use is addictive and can harm the young brain, which continues developing until about age 25.[3] Evidence also suggests that youth who are exposed to nicotine can become addicted at lower or more intermittent levels of consumption compared to adults.[4]

As vapes have only been widely used globally for about 10–15 years, many of the health risks specific to vaping are not yet widely known. However, this does not mean vapes are safe for widespread use in the general population. Notably, the use of conventional tobacco products rapidly increased at the beginning of the 20th century, but tobacco-caused diseases were not identified in large numbers until 30–40 years later. There is also evidence that vaping is a strong predictor of future tobacco use, particularly among youth and young adults. There is strong and consistent evidence that young and young adults who vape are up to 3 times as likely to take up smoking, compared to those who don't.

Dual use of vapes and tobacco products is also common and harmful, even if some people report using vapes to cut down on the number of cigarettes they are consuming. This is problematic as in addition to any independent health risks introduced by vapes, even light smoking still poses serious health risks.

A range of 'first line' smoking cessation products such as nicotine gums and patches are available, and these do not have the same health risks as vapes. These products have been rigorously assessed by the TGA and have established safety and efficacy profiles. These products are generally less addictive than vapes and many are widely available in supermarkets and other retail settings.

As no vapes have been approved or assessed by the TGA, the safety, quality, and efficacy of specific vapes remains uncertain. However, there are several ways that consumers can lawfully gain access to products in Australia, through the TGA's 'unapproved goods' pathways. In the case of nicotine vapes, access is governed through a prescription-only framework. Ensuring that vapes are only accessed with medical supervision provides an opportunity for consumers to receive appropriate advice from a health professional on the risks associated with their use and the benefits of smoking cessation. Medical supervision also enables close monitoring of emerging and ongoing health harms that may be associated with vaping. Under this framework, access controls, including the requirement for a prescription, can be modified in light of new public health evidence.

Some people may be successful in quitting tobacco smoking using vapes, but the overall evidence of the effectiveness of these products as a smoking cessation aid remains limited. The prescription model in Australia recognises that for certain people nicotine vapes may be an appropriate intervention, complemented by other supports. The Royal Australian College of General Practitioners advises that for people that have tried first line smoking cessation treatment options and supports, but

[3] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-Cigarette Use Among Youth and Young Adults; A Report of the Surgeon General' (2016) US Department of Health and Human Services, CDC: Atlanta, GA. Available at: https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf

[4] Doubeni C, Reed G, and Difranza J, 'Early course of nicotine dependence in adolescent smokers,' (2010) *Pediatrics* 125(6) 1127. Available at: https://doi.org/10.1542/peds.2009-0238

been unsuccessful in quitting, nicotine vaping products may be an intervention they wish to consider in combination with behavioural supports. However, this decision should be made with advice and support from their health professional, which includes consideration of the risks involved.

Collectively, this evidence highlights that the existing controls governing the marketing and use of vapes should be strengthened.

Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation (2022 Consultation) on potential reforms to nicotine vaping product regulation in Australia, to identify if refinements to existing requirements could better support the intent of the 2021 reforms. The consultation canvassed comments on potential reforms in four main areas:

- changes to border controls
- pre-market assessment against a quality and safety standard
- strengthening minimum safety and quality requirements in the applicable product standard, and
- clarifying that all vaping products containing nicotine are therapeutic goods and subject to regulation under Australia's therapeutic goods framework.

Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, retailers, patient groups and suppliers. There were over 3,500 submissions from private individuals.

In May 2023, based on the initial IA and on the feedback from the 2022 Consultation and advice provided by public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the Minister for Health and Aged Care announced, subject to consultation with the states and territories and other stakeholders, an intention to strengthen the regulation of all vapes and ban the import and supply of non-therapeutic vapes.

Consultations with the states and territories took place principally through Health Ministers' Meeting and its subordinate E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023 which conveyed Ministers' collective commitment to enhancing regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 (2023 Consultation) to consult on the proposals developed in consultation with states and territories and to further develop this IA. Submissions for this consultation closed on 21 September 2023.

Stakeholders were asked to comment from their particular viewpoint on:

- restrictions on importation, manufacture and supply of all vapes, other than therapeutic vapes
- changes to market accessibility requirements for therapeutic vapes
- heightened quality and safety standards for therapeutic vapes
- strengthening domestic compliance and enforcement mechanisms.

The consultation received 289 responses, including submissions from government agencies, consumer groups and associations, health professional peak bodies, school related groups, academic experts, pharmacy wholesalers, vape importers, vape manufacturers, vape retailers and others. Although not specifically solicited, over 120 of these were responses from individuals.

The TGA has developed this IA to examine options, including evidence, data and analysis of the broader costs and benefits, to address the public health problem. In April 2023, a draft IA was provided to OIA. It was found to be compliant with Australian Government IA requirements for that

stage of policy development and suitable to inform early policy development. Consideration of this draft IA and feedback from OIA informed the 2023 Consultation and questions asked.

In addition, the OIA was engaged throughout the policy development process, including receiving informal drafts of the updated IA. The IA is to be considered by the Australian Government in making the final decision on the reform approach.

The development of this IA has been done in line with and informed by:

- Australian Government guidance
- consultations with states and territories
- two sets of formal consultations with the general public and targeted stakeholders
- other consultations with key stakeholders concerning the proposed regulatory reforms, international best practice and the evidence base.

The 4 options put forward in this IA are:

- maintain the status quo (no change)
- regulate vapes under a consumer model
- increase regulation of vapes through the TG Act and Customs Regulations
- ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods and not available as ‘unapproved’ therapeutic goods.

In assessing the impact of the proposed options, compliance costs to industry were estimated for the purposes of this IA using a Regulatory Burden Measurement Framework that follows the guidelines provided by the OIA.

Through considering all options, Option 3 has been identified as the option that would deliver on the public health objectives to:

- arrest the uptake of vapes, other than for therapeutic purposes, especially in youth and young adults (aged below 25 years)
- counteract the marketing of vapes to youth and young adults, especially through product features such as flavours and packaging
- prevent nicotine addiction and reduce the risk of future tobacco use
- safeguard public health, increase confidence of consumers and prescribers, and minimise the short-term and long-term adverse health effects of vapes by ensuring vapes meet appropriate quality and safety standards.

Introduction

What is a vape?

The term “vape” is intended to have its ordinary meaning. It comprises both substance and device components, however they are manufactured, assembled, or presented. When used together, these components will be designed or intended to vaporise and administer the substance by inhalation, generally in a manner that replicates or produces an experience similar to smoking.

The substance is vaporised for administration by inhalation. The device component supports the vaporisation and inhalation. On occasion, the device component may simply comprise a housing unit and battery. The substance and device components may be sold individually, pre-assembled or as a combination kit. For simplicity, all components of a vape are referred to as a **vape** throughout this document.

The consumed substance, which may also be known as e-liquids, vape liquids or e-juices, will be referred to as **e-liquids** throughout this document, as they are generally, but not always, a liquid. An e-liquid may or may not contain nicotine. All vapes require e-liquids to enable vaping to occur. The e-liquid component can be added to a device component as a pod or cartridge, or as a refillable liquid. Some vapes, such as disposable vapes, are purchased with the e-liquids already present in the device component rather than needing to be added and are not designed to be refilled or reused.

The **device** component is a device, or element of a device, designed to generate, release or assist, by electronic means, an aerosol or vapour for inhalation.

Vapes come in two main configurations:

> A **disposable single use** (closed system) vape that is pre-filled with an e-liquid, cannot be refilled and is disposed of once the vaping substance runs out.
>
> A **refillable/reusable**[5] vape that may be refilled or reused multiple times, with various e-liquids pods, cartridges or solutions sold separately to the device; these vapes are intended to be recharged and reused.

For the purposes of this paper**,** references will also be made to **therapeutic vapes**. **Therapeutic vapes** are those that have, or are claimed to have, a therapeutic use, such as smoking cessation or treatment of nicotine addiction, irrespective of nicotine content.

A vape does not include **nicotine replacement therapy (NRT) products**, such as patches, gum, lozenges, mouth spray and inhalators, and these will not be covered in this document. Nor does it include other nicotine-containing products not intended for use with a vape, such as cigarettes, chewing tobacco, nicotine pouches or snuff.

Accessing vapes in Australia

The regulation of vapes is shared between the Commonwealth, state and territory governments and draws on laws that apply to poisons, therapeutic goods, tobacco products, consumer goods and industrial chemicals.

Current legislation relating to nicotine vapes is designed to prevent their importation, manufacture, and supply other than for the purpose of smoking cessation under medical supervision with a prescription.

[5]Refillable vapes when referenced in this document refer to vapes with tanks, pods or other systems that are designed to be refilled with e-liquid components; while reusable vapes refer to those with pre-filled disposable pods or cartridges.

Nicotine vapes must only be lawfully dispensed in Australia by pharmacists. It is illegal for retailers such as tobacconists, vape shops and convenience stores to sell nicotine vapes to consumers, even with a prescription.

Vapes that do not contain nicotine are generally subject to limited regulation. Outside the Australian Consumer Law, these goods are not generally regulated at the Commonwealth level unless represented to be for therapeutic use. At the state and territory level, there is some regulation of vapes through tobacco laws, but this is limited and inconsistent. The device components of vapes are also currently subject to limited regulation.

Commonwealth legislation

At the Commonwealth level, nicotine vapes are regulated as medicines under the *Therapeutic Goods Act 1989* (**TG Act**). This means that vapes cannot be imported into, manufactured in or supplied in Australia, unless registered in the Australian Register of Therapeutic Goods (**ARTG**), or a lawful exception to registration applies.

There are no nicotine vapes currently registered on the ARTG. Instead, nicotine vapes can be supplied to patients with a prescription as '**unapproved therapeutic goods**'. This means that nicotine vapes sold for a therapeutic purpose have not been assessed for safety, quality and efficacy by the TGA. Nevertheless, such nicotine vapes must still currently meet minimum quality and safety requirements specified under the standard that came into force on 1 October 2021, *Therapeutic Goods (Standard for Nicotine Vaping Product) (TGO 110) Order 2021* (**TGO 110**). There is, however, no pre-market notification or assessment process to certify or verify compliance with TGO 110.

Nicotine (and other therapeutic) vapes may be accessed with a prescription provided via three main[6] established access pathways for unapproved goods under the TG Act. Under these pathways, unregistered vapes can be supplied:

- **Personal Importation Scheme**: under this scheme, a person with a prescription from an Australian medical practitioner can directly import up to 3 months' supply of nicotine vapes for their own personal use. A person may also import nicotine vapes for immediate family members who have a prescription.
- **Authorised Prescriber Scheme (AP scheme):** under this scheme, a medical practitioner may apply to the TGA for approval to supply nicotine vapes to certain patients as an aid to stop smoking.
- **Special Access Scheme – Category B** (SAS B): under this scheme, a health practitioner may apply to the TGA to supply nicotine vapes to a single patient on a case-by-case basis.

Zero-nicotine vapes are not currently regulated under the TG Act, unless represented to be for therapeutic use.

Vaping devices are currently excluded from regulation under the TG Act unless they are intended exclusively for the vaporisation and administration by inhalation of a medicine.

State and territory legislation

For many years, the states and territories have restricted the supply and/or use of nicotine vapes. It is an offence in all states and territories to supply nicotine vapes to consumers without a prescription. In most Australian jurisdictions, it is similarly an offence to either possess or use a nicotine vape without a prescription.

Retail and wholesale supply of nicotine vapes is currently controlled by state and territory legislation. Nicotine vapes contain Schedule 4 substances and may therefore only be lawfully supplied by pharmacists to patients with a prescription. Nicotine vapes cannot be supplied by vape shops,

[6] There are also some other pathways to access unapproved goods that could be utilised to access nicotine vapes, including through extemporaneous compounding or the clinical trial notification scheme.

convenience stores and the like. Licensing requirements also apply to the wholesale supply of nicotine vapes.

All states and territories restrict the supply of vapes that do not contain nicotine, through tobacco control laws and/or public health laws. All ban the supply of vapes to minors and the use of vapes in smokefree areas. All regulate the advertising, display and marketing of vapes. Most states and territories (except Victoria and Queensland) require either a licence or a retailer identification number for retail sale. The controls in Western Australia are more extensive than other jurisdictions. 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. Western Australia also permits registered pharmacists to supply nicotine vapes as part of a medically supervised smoking cessation program.

Overview of the market for vapes

In Australia, the supply of vapes is complex, but only a low percentage of the supply of nicotine vapes is lawful. The supply pathways can be broadly simplified into the following categories:

1. Legal supply of nicotine vapes with a prescription – with a prescription dispensed through lawful avenues such as pharmacies in Australia or imported through the Personal Importation Scheme.
2. Illegal supply of nicotine vapes – with or without a prescription through a vape store, convenience store or an online store in Australia that is not a pharmacy, or supply without a prescription from an Australian pharmacy or overseas online retailer.
3. Supply of zero-nicotine vapes from within Australia or through importation.

There is very limited data available on the relative proportions and volumes of vapes being supplied through each of these categories. This is partially due to the concealment of nicotine in a large proportion of vapes currently supplied in Australia, confounding the ability to separate the supply levels of nicotine and zero-nicotine vapes.

The scale of the problem is highlighted in recent surveys:

- Roy Morgan survey (2023) found there are now an estimated 1.3 million adult users of vapes in Australia, and only 8% of all Australian vapers have a prescription, implying 92% of vapes fall within categories 2 and 3 above.[7]
- The National Illicit Drug Reporting System survey in 2022 reported even lower proportions in category 1, with only 3% of vapers having a nicotine prescription.[8]
- The Australian Association of Convenience Stores (AACS) survey in June 2022[9] reported up to 12% of vape users obtained a prescription to make their vape purchase.
- The Generation Vape Research Project found that nearly 80% of surveyed 14–17-year-old ever-vapers (people who have vaped once) found it very easy, easy or quite easy to access

[7] Wakefield M. et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

[8] Sutherland, R et al., 'Australian Drug Trends 2022: Key findings from the National Illicit Drug Reporting System (IDRS) Interviews,' (2022), National Drug and Alcohol Research Centre: UNSW Sydney, Sydney. Available at: https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/National_IDRS_2022_Report_16.01.23.pdf

[9] AACS, 'Nicotine Vaping Product Usage & Change' (June 2022). Available at: https://aacs.org.au/wp-content/uploads/2022/08/AACS-CMA-Research-Attachment.pdf. Please note that this survey has not been peer-reviewed. The AACS may also be perceived to have a private interest in this matter, given the commercial value of vapes to the convenience store industry.

vapes. Of the 70% who did not purchase their last vape, 80% reported getting it from friends. Of the 30% who did purchase their last vape, 49% bought it from a friend or an individual selling them, 31% purchased it from a retailer, 9% from social media, 7% from a website and 1% from a vape store.

Further, anecdotal evidence provided by vaping manufacturers, compliance officers and academics support these figures, or that the true proportion could be significantly lower than the 8% as estimated through the Roy Morgan survey.

The only published data estimating the volume of vapes sold in Australia estimated that in 2019 sales of e-cigarettes in Australia amounted to approximately US$125.14 million and represented an increase from 2018 with continued year on year growth.[10] Together with statistics regarding usage increases since 2018 (at least 4 fold), it is reasonable to estimate that the market for vapes supplied without a prescription, comprising illegal nicotine and legal/illegal zero-nicotine vapes, is worth well over $400 million annually. One Australian vape manufacturer estimated that the black market sells 30 million units, with each unit equivalent to a 1 mL pod, per month.[11]

Levels of legal nicotine vape supply

As highlighted above, the best estimates from surveys conducted over recent years conclude that there has been poor uptake by prescribers and consumers of legal supply pathways for nicotine vapes, likely ranging between 3–12%. This is despite the Commonwealth Department of Health and Aged Care and its state and territory counterparts engaging in a substantial education and compliance campaign to implement the 2021 reforms.

Regarding supply under prescription, approval is granted through either a practitioner authorised under the Special Access Scheme Category B (SAS B) scheme, or by an AP. The SAS B scheme provides for a medical or other health practitioner to apply for access to unapproved products for an individual patient, where the patient is not seriously ill, and the product is not on the established history of use list. An AP can access unapproved products for multiple patients.

As of 31 August 2023 and since the introduction of the 2021 reforms (1 October 2021), the TGA has approved 2,987 SAS B applications for nicotine vapes for 641 medical practitioners and 17 nurse practitioners. As at the same date, there were 2,333 **active** APs (up from 113 on 30 September 2021, 655 at 28 February 2022, 1,513 at 23 November 2022 and 2,088 at 18 April 2023), and 636 of the **active** APs had consented to TGA publication of the name and surgery from which they practise. This is still only a fraction of the estimated 100,000 medical practitioners eligible to be APs.

Further, noting the last reporting period was for 1 January to 30 June 2023, it is estimated that at least 69,987 unique prescriptions had been issued to patients for nicotine vapes.[12] In the context of the estimated 1.3 million adult users of vapes, only a very small proportion seek prescriptions.

There is currently no data available on the volume of vapes supplied against each script, those being obtained legally through pharmacies, those being imported legally through the Personal Importation Scheme, or indeed those being supplied through other sources. However, studies have reported on where consumers are usually obtaining their vapes. As reported by the Australian Association of Convenience Stores (AACS) in June 2022,[13] 12% of vapes were sourced with a script, 9% of vapes were sourced legally, 2% vapes supplied through a pharmacy with a script and 7% sourced online overseas with a script.

[10] Statista, 'Electronic cigarette and vaping sales value in Australia from 2014 to 2019,' (November 2020). Available at: https://www.statista.com/statistics/1189066/australia-electronic-cigarette-and-vaping-sales-value/

[11] Stakeholder response to the 2023 Consultation on vaping reforms.

[12] The TGA publishes a list of APs for nicotine vapes who have consented to have their names and consulting location published. Approximately 16% of published APs are online only with some of their listed online business names suggesting that they specialise in the provision of nicotine vape prescriptions.

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Levels of illegal nicotine vape supply

Evidence suggests that many Australians are accessing nicotine vapes without a prescription, rather than through lawful supply channels. As summarised above, with such a low level of vapes sourced with a prescription, it is estimated that illegal supply represents a significant portion of the supply of vapes in Australia.

Illegal supply is occurring through physical specialist retailers such as vape stores and tobacconists, general retailers such as convenience stores and petrol stations, and online retailers including websites and social media both in Australia and overseas. The current scope of the retail sector for vapes is covered in greater detail below. The ease of access to, and low cost of, illegal supply can make this a preferred option, even if an adult has obtained a legitimate prescription.

According to the Australian Association of Convenience Stores (AACS) in June 2022,[14] consumers preferred locations to purchase illegal (without a script) vapes were vape store (53%), online overseas without a script (17%), tobacconist (9%), independent supermarket (5%), social media (4%), friend/acquaintance /family (2%), petrol & convenience store (1%) and milk bar/local store (1%).

Youth appear to be readily accessing nicotine vapes, which are often disposable and flavoured, through both social and commercial channels. Of a survey of 14–17-year-olds, nearly 80% of ever-vapers found it very easy, easy or quite easy to access vapes (n=179), while less than 10% of ever-vapers found it quite hard, hard or very hard (n=20).

Concealment of nicotine in vapes is a significant issue, with manufacturers not declaring nicotine on the label to avoid being captured by the Commonwealth and state and territory regulation of nicotine vapes. As an example, as part of a TGA operation targeting prohibited sales of nicotine vapes, a large number of vapes were removed from three Canberra businesses in October 2022. Testing on samples of the seized vapes showed that all were found to contain nicotine, but two thirds of the products were not labelled as containing nicotine.[15] There is no data available on the overall level of the concealment of nicotine in vapes supplied in Australia, and therefore no data on the proportion of nicotine vapes supplied illegally versus zero-nicotine vapes supplied legally. More than half of ever-vapers had used a vape that they knew contained nicotine (53%, n=123), while 20% (n=47) said they had not used a nicotine-containing vape and 27% (n=63) did not know whether they had used a vape containing nicotine.

Overall, the supply of illegal vapes is undermining current policy objectives and the viability of legal supply pathways.

Levels of supply of zero-nicotine vapes

The supply of zero-nicotine vapes to adults, provided no therapeutic claims are made, is currently legal in most states and territories. The supply to minors is banned in all states and territories, and in WA the sale of any products that are designed to resemble tobacco products is prohibited.

The true size of the zero-nicotine vape market is largely unknown, given the concealment of nicotine in a large proportion of zero-nicotine vapes supplied in Australia. Short of laboratory analysis, it is not possible to determine whether vapes contain nicotine. This facilitates concealment and hampers

[14] AACS, 'Nicotine Vaping Product Usage & Change' (June 2022). Available at: https://aacs.org.au/wp-content/uploads/2022/08/AACS-CMA-Research-Attachment.pdf. Please note that this survey has not been peer-reviewed. The AACS may also be perceived to have a private interest in this matter, given the commercial value of vapes to the convenience store industry.

[15] Department of Health and Aged Care, 'Large numbers of illegal nicotine vaping products seized in a joint TGA-ACT Health operation,' (7 December 2021). Available at: https://www.tga.gov.au/news/media-releases/large-numbers-illegal-nicotine-vaping-products-seized-joint-tga-act-health-operation

enforcement, both at the border and once products are being by sold.[16] The concealment of nicotine in vapes is widely recognised.

The scale of the problem has not been clearly quantified or reported, but evidence of these practices has existed for some time:

- Scientific testing of e-liquid samples collected by NSW Health in 2013 showed that 70% of the samples contained high levels of nicotine even though the label did not state nicotine as an ingredient.
- Between November 2015 and April 2018, NSW Health inspectors visited 227 retailers selling e-liquids and found that 63% of e-liquids labelled "nicotine-free" did contain nicotine.[17]
- Research conducted in 2023 by the University of Wollongong on behalf of NSW Health (428 vapes seized from retailers, 322 surrendered by children at Sydney schools) found about 98% of vapes contained nicotine, despite most not listing it as an active ingredient.[18]
- Samples seized from ACT stores in 2021 and tested by the TGA were all found to contain nicotine, even though two thirds of the vapes were not labelled as containing it.[19]
- Researchers in 2019 investigating the potentially harmful ingredients in e-cigarettes tested 10 "nicotine-free" e-liquids and found that six contained nicotine.[20]
- Researchers from Curtin University in 2021 tested the chemicals and toxicity of 52 e-liquids available from retailers in Australia and found 100% were inaccurately labelled and 21% contained nicotine.[21]

Actual consumer usage data is typically poorly reported. A 2022 survey summary from Cancer Council Victoria found that 58.3% of past-year e-cigarette users usually vaped nicotine.[22] This figure increases to 80.6% when surveying regular e-cigarette users, with the remaining 19.4% reporting that they did not know or couldn't say if they usually vape nicotine. There are several reasons to believe that a high proportion of that 19.4% do vape nicotine – respondents may not have wished to disclose that they are engaging in illegal activity, or may legitimately be unsure, given the practice of mislabelling vapes or the difficulty for someone to correctly determine whether nicotine has been added.

A 2021 survey conducted by Cancer Institute NSW provides an estimate for respondents 18 years and older. For those who had ever used vapes, two thirds (65%) indicated that their last vape

[16] Dessaix, A, Jardine, E, Freeman, B and Kameron, C, 'Undermining Australian Controls on electronic nicotine delivery systems: illicit imports and illegal sales,' (2022) *Tob Control* 31(6). Available at: https://tobaccocontrol.bmj.com/content/tobaccocontrol/31/6/689.full.pdf

[17] Duxfield, F, 'NSW Health Department finds not all e-juices are as nicotine free as they claim,' (12 June 2018) *ABC News.* Available at: https://www.abc.net.au/news/2018-06-12/not-all-e-juices-are-as-nicotine-free-as-they-claim/9857540

[18] Messenger, A, 'Toxic chemicals found in vapes seized from NSW schools and retailers,' (25 September 2023) *The Guardian.* Available at: https://www.theguardian.com/australia-news/2023/sep/25/toxic-chemicals-found-in-vapes-seized-from-nsw-schools-and-retailers

[19] Department of Health and Aged Care, 'Large numbers of illegal nicotine vaping products seized in a joint TGA-ACT Health operation,' (7 December 2021). Available at: https://www.tga.gov.au/news/media-releases/large-numbers-illegal-nicotine-vaping-products-seized-joint-tga-act-health-operation

[20] Chivers, E et al., 'Nicotine and other potentially harmful compounds in "nicotine-free" e-cigarette liquids in Australia,' (2019) *The Medical Journal of Australia* 210(3). Available at: https://onlinelibrary.wiley.com/doi/full/10.5694/mja2.12059

[21] Larcombe, A et al., 'Chemical analysis of fresh and aged Australian e-cigarette liquids,' (2021) *The Medical Journal of Australia* 216(1). Available at: https://onlinelibrary.wiley.com/doi/10.5694/mja2.51280

[22] Bayly, M et al., 'E-cigarette use and purchasing behaviour among Victorian adults: Findings from the 2018-19 and 2022 Victorian Smoking and Health Surveys,' (2022) Centre for Behavioural Research in Cancer, Cancer Council Victoria. Available at: https://www.quit.org.au/facts-evidence/research-evaluation

contained nicotine, while 18% indicated that it did not.[23] Similarly, a 2023 study of 15–30-year-olds found that a large majority (86%) of current e-cigarette users reported using nicotine e-cigarettes.[24]

A number of companies currently manufacture, and supply zero-nicotine vapes. The current scope of the retail sector for vapes, including zero-nicotine vapes, is covered in greater detail below.

In summary, it is understood that a high proportion of vapes in Australia do contain nicotine, even when the label does not alert consumers to its presence, but quantification of the volumes and therefore the size of the zero-nicotine vape sector is not possible.

Retail landscape for illegal nicotine vapes and legal/illegal zero-nicotine vapes in Australia

The Australian vaping retail landscape has been on a growth trajectory to meet the surging demand for both legal and illegal vapes, as reflected in the increase in sales of vapes in Australia from 2018 with continued year-on-year growth. Generally, vapes are sold by retailers such as vape specialist, tobacconist and convenience stores adopting either physical and/or online business models across Australia.

Currently, it is estimated that there are **7,171** Australian business entities across vape specialist, tobacconist and convenience store types and **8,775** physical stores with the ability to sell vapes in Australia.[25] 'Super Vape Store' is the largest Vape Specialist Store identified. Their 'click and mortar' business model comprises one online storefront and 61 physical retail stores selling a range of vapes across Australia.

Of the numbers above, convenience stores make up the largest retail store type with almost 7,000 stores across Australia, as indicated in *Figure 1*. It is broadly expressed and understood in the vaping community that some retail stores, including some online stores, service stations, convenience stores, local tobacconists and corner stores, do sell 'under the counter' vapes that contain nicotine, that sometimes are not labelled as having nicotine, and that can only be purchased with cash to reduce traceability of the transaction.

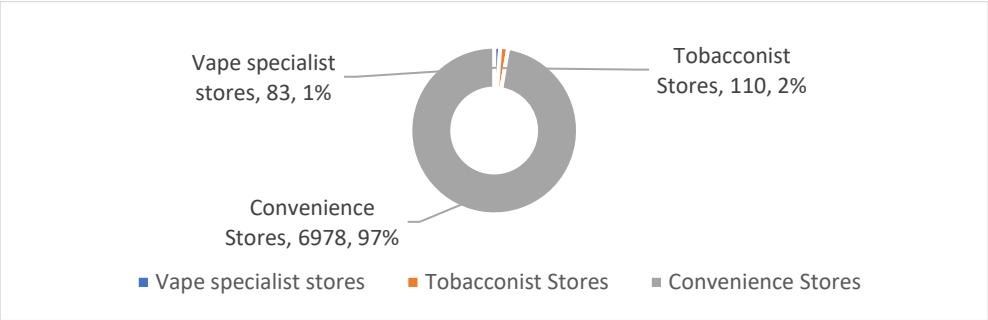
In some cases, Australian businesses operate overseas websites to facilitate sale of nicotine products to Australian consumers. There have been instances where, following compliance action by the TGA, Australian businesses have established overseas websites to circumvent the restrictions on the advertising and supply of nicotine vapes in Australia.

[23] Cancer Institute NSW, 'NSW Smoking and Health Survey' (2021) Available from: https://www.cancer.nsw.gov.au/about-cancer/document-library/nsw-smoking-health-survey-2021.

[24] Pettigrew S et al, 'E-cigarette attitudes and use in a sample of Australians aged 15-30 years' (2023) *Australian and New Zealand Journal of Public Health* 47(2):100035. Available from: https://www.ncbi.nlm.nih.gov/pubmed/36977623

[25] Figures in relation to vape specialist stores were sourced through obtaining business trading names on the member directory for the Australian Vaping Association followed by search engine use to investigate information such as, primary operating location via Australian Business Number look up online, physical store locations and online store functions via business online website.

Figure 1. Overall view of Australian e-cigarette retail business entities by store types

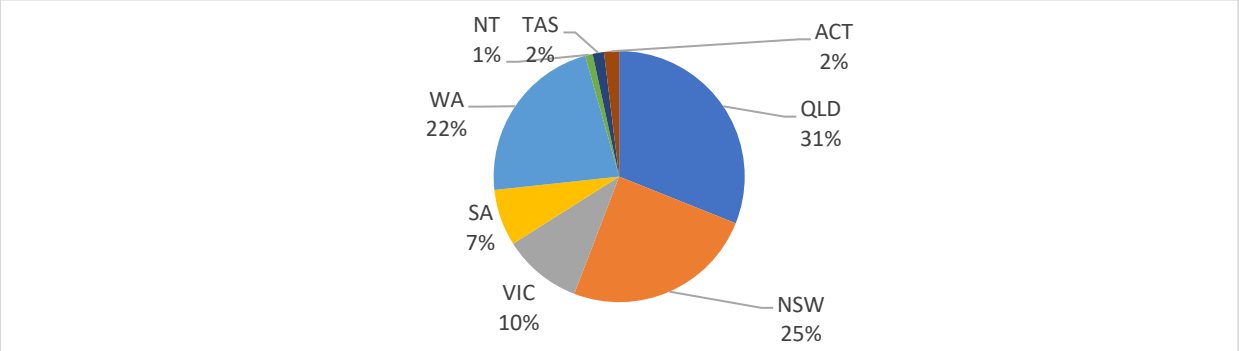


Source: Data sourced from initial desktop research.

Vaping Specialist Stores

There are an estimated **205** physical vaping specialist stores in Australian states and territories, with **78%** of these stores in Queensland, New South Wales and Western Australia (Figure 3).

Figure 2. Number of physical vaping specialist stores across Australian states and territories



While vape specialist stores make up only 1% of the retail vaping industry, 91% of vape specialist stores also have online stores providing nationwide shipping services.[26] There are **73** online vape specialist stores in Australia providing delivery and pick up options and a range of services including on-the-day order processing, order tracking, loyalty programs and referral code programs.

Around 10.9% of vaping specialist stores are solely eCommerce businesses and do not have a physical storefront.[27] Some online specialist vaping stores, and small businesses with up to one physical storefront, advertise the development and sale of a small batch of zero-nicotine e-liquids manufactured by Australian companies such as CV Labs.

During consultation, the majority of vape retailers indicated that vapes made up 90–100% of their sales.

Tobacconists

It is estimated that there are **1,592** tobacconist retail stores across Australia, primarily comprising major Australian-owned tobacconists such as Tobacco Station Group (TSG), Smokemart, Free choice

[26] Figure drawn from desktop research exercise conducted July 2023, capturing 84 separate online stores (owned by separate entities) out of 92 vaping specialist business entities.

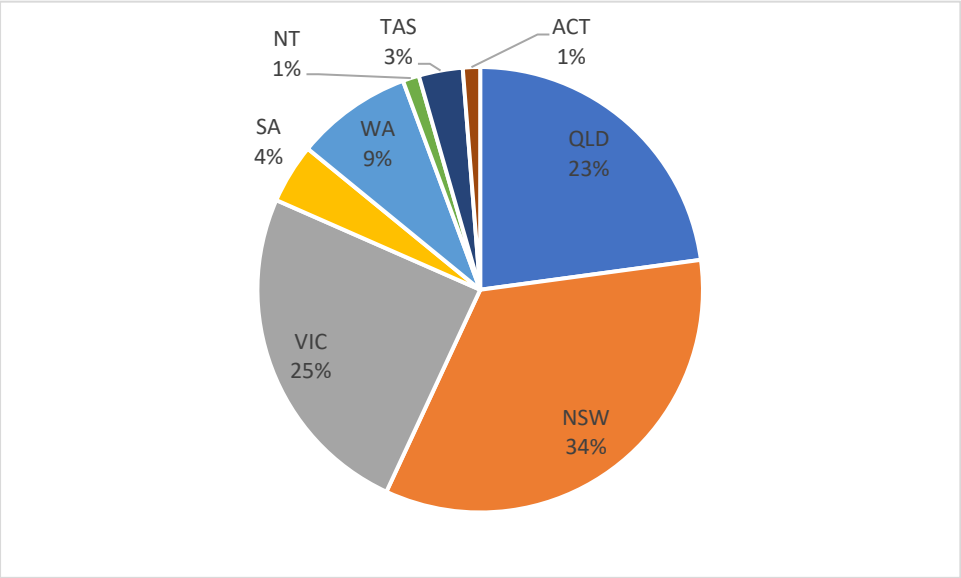
[27] Businesses in these industry segments adopt a range of business models:

- Brick-and-mortar Stores: refers to a business with a physical presence in a building or infrastructure.
- Click-and-mortar Stores: refers to a business that combines both online and physical channels for business operations
- Pure Play eCommerce Stores: refers to a business that only make sales via online storefront. Location of these type of stores are determined by primary location of operation as indicated on the Australian Business Register, available to the public.

tobacconist, Cignall and King of the Pack, which constitute approximately **82**% of domestic tobacconist stores. Tobacconist type entities primarily adopt brick-and-mortar business models. Most of these tobacconist stores advertise the retail sale of vapes.[28]

One tobacconist stakeholder indicated in response to the 2023 Consultation that 1–2% of their sales are vapes.

Figure 3. Number of physical tobacconist stores across Australian states and territories



Convenience Stores

Most convenience stores are brick-and-mortar businesses, focusing on providing customers ease of physical access to everyday household items. Convenience stores do not typically advertise vapes in their online catalogues.

Online vaping community forums have alluded to the retailing of vapes at multinational chain convenience retail stores with over **3,505** physical retail stores across Australia.

[28] One tobacconist stakeholder indicated in response to the 2023 Consultation that 1-2% of their sales are vapes.

Question One: What is the problem you are trying to solve and what data is available?

Despite regulatory reforms in 2021, vape marketing and use in Australia has increased in recent years, particularly among youth and young adults. This growth in vaping and the unknown quality and safety of vapes represent an unacceptable population health risk, particularly in light of the unfortunate lessons we have learnt from tobacco use.

Increasing vaping prevalence also has the potential to disrupt the significant achievements Australia has made to date in tobacco control. There is already emerging evidence that, alongside the increasing use of vapes, there has been an increase in youth and young adults using tobacco products.[29]

However, as discussed below under "Access to vapes is appropriate in some circumstances", some vapes should remain available as an option to assist a cohort of smokers to give up smoking and, where clinically appropriate, nicotine addiction. There is evidence that vaping, in the right context and as part of a coordinated program including behavioural support, can assist some people to give up smoking. Tobacco use remains one of the leading causes of preventable death and disability among Australians. While vape use also carries risks, vapes do not produce the tar produced by conventional cigarettes, which is the main cause of lung cancer. Nonetheless, while there is no tar in vapes, the long-term impacts of vaping are yet to be fully understood and some immediate and early health impacts are already being seen.

The 2021 reforms need refinement

Regulatory requirements for therapeutic vapes containing nicotine changed on 1 October 2021 (the 2021 reforms), when a TGA decision resulted in nicotine being scheduled as a Schedule 4 substance under the Poisons Standard, except in certain circumstances. The change meant that vapes containing nicotine were subject to regulatory controls under state and territory legislation relating to prescription medicines.

The intention of the 2021 reforms was to prevent access to vapes that contain nicotine, except for the purpose of smoking cessation under medical supervision with a prescription. These reforms also make it unlawful to import vapes containing nicotine without a valid prescription from a medical practitioner.

Recent evidence (as outlined above) suggests that the 2021 reforms are not meeting these objectives.

Increasing prevalence and attractiveness of vaping in Australia, particularly among youth and young adults

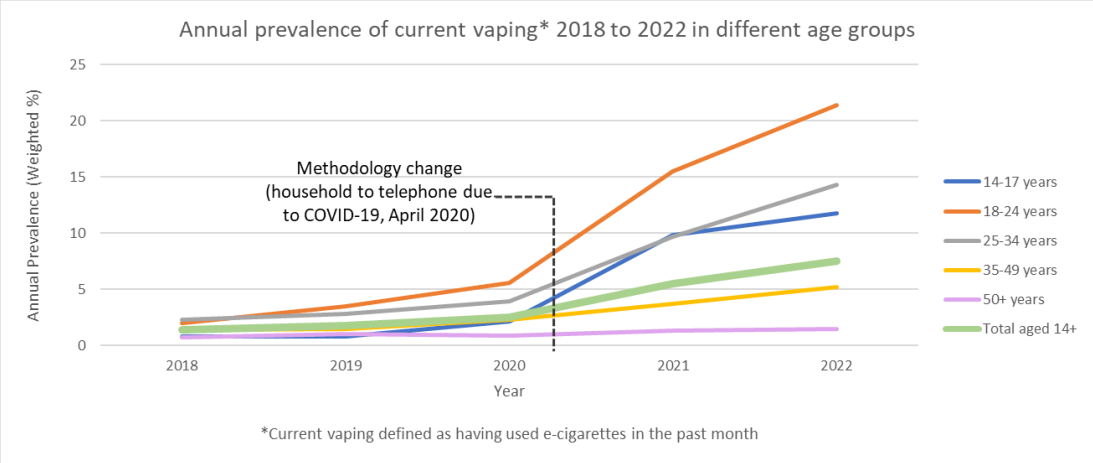
The prevalence of vaping in Australia is increasing and represents an unacceptable risk to public health. Of particular concern is the attractiveness of these products to and the recent rapid increase in

[29] Wakefield, M et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Data collected from the Roy Morgan Research company and analysed by Cancer Council Victoria for the Department of Health and Aged Care. This data is not nationally representative. It should be considered preliminary until more comprehensive national data is published in 2023-24. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

their use by youth and young adults.[30,31,32,33,34,35] Further, the nicotine component is highly addictive and levels of addiction are providing a gateway to tobacco smoking.

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data aligns with other prevalence data, summarised below, in showing that among people aged 14 years and over current use of an e-cigarette (defined as use at least once in the last month of being surveyed) increased from 2.5% to 7.5% between 2020 and 2022.[36] The increase was particularly marked among people aged 18–24 years old, with a concerning 4-fold increase from 5.6% in 2020 to 21.4% in 2022.

Figure 4. Annual prevalence of current vaping in different age groups



While no national statistics on vaping since 2019 are available, results from the 2022–23 National Drug Strategy Household Survey are expected to be available in early 2024. There have been several localised studies which all suggest that vaping rates continue to rise, especially among youth and young adults, even following the 2021 reforms. The key findings from these prevalence studies are outlined below.

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

[30] Conti CR, 'Clinical trials and the cost of medical care' (1999) *Clinical Cardiology* 22(9):549-50. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6655516/

[31] European Commission, 'Scientific Committees.' Available at: https://health.ec.europa.eu/scientific-committees_en

[32] Jankowski M et al, 'E-Cigarettes are More Addictive than Traditional Cigarettes—A Study in Highly Educated Young People' (2019) *International Journal of Environmental Research and Public Health* 16(13): 2279. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6651627/

[33] Wood N, 'Charlotte's accessible web: how West Australian children and adolescents can access e-cigarettes online' Australian and New Zealand Journal of Public Health, 45: 81-82. Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/1753-6405.13056

[34] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (Drug Statistics series no. 32 2020) 8. Available at: https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents/table-of-contents

[35] World Health Organisation, 'Summary results of the global youth tobacco survey in selected countries of the WHO European Region' (2021). Available at: https://www.who.int/europe/publications/i/item/WHO-EURO-2020-1513-41263-56157

[36] Wakefield, M et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Data collected from the Roy Morgan Research company and analysed by Cancer Council Victoria for the Department of Health and Aged Care. This data is not nationally representative. It should be considered preliminary until more comprehensive national data is published in 2023-24. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

- the use of e-cigarettes by Victorian adults has significantly increased, particularly among young women and those under 30, also showing 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.

Preliminary data analysed by Cancer Council Victoria[37] shows that, in the first quarter of 2023:

- 8.9% of people aged 14+ reported current use of an e-cigarette (i.e., use at least once in the last month of being surveyed). In particular, the reported current use of an e-cigarette in defined age groups was:
    - 14.5% for ages 14-17
    - 19.8% for ages 18-24 (highest prevalence)
    - 17.4% for ages 25-34
    - 6.6% for ages 35-49
    - 2.5% for those aged 50+.

The 2019 National Drug Strategy Household Survey (NDSHS) shows lifetime use of e-cigarettes (containing nicotine and zero-nicotine e-liquids) among all age groups increased significantly from 8.8% in 2016 to 11.3% in 2019. [38]

As reported by the AIHW[39] in 2019, for those people aged 14 and over:

- almost 2 in 5 (39%) smokers had tried e-cigarettes in their lifetime, a significant increase since 2016 (31%)
- there was a significant increase in the proportion of non-smokers who had tried e-cigarettes in their lifetime (from 4.9% to 6.9%)
- 3.2% of current smokers used e-cigarettes daily, a significant increase since 2016 (1.5%)
- 2.2% of ex-smokers used e-cigarettes daily, a significant increase since 2016 (0.8%)
- there were significant increases in the lifetime use of e-cigarettes across most age groups between 2016 and 2019, particularly for those aged 18–24 (from 19.2% to 26%) and 25–29 (from 14.8% to 20%)
- more than two-thirds (69%) of e-cigarette users were current smokers when they first tried an e-cigarette. Nearly 1 in 4 (23%) considered themselves to be a 'never smoker' at that time

[37] Wakefield M. et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

[38] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (2020) Drug Statistics series no. 32 2020, 8. Available at: https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents/table-of-contents

[39] Australian Institute of Health and Welfare, 'Alcohol, tobacco & other drugs in Australia', updated 14 December 2022. Available at: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/about

- higher proportions of younger people reported being a 'never smoker' (65% of 14–17-year-olds and 39% of 18–24-year-olds) compared with proportions lower than 10% for people in age categories for those 40 and over.

Collectively, all studies demonstrate the rapid and still rising rates of vaping in Australia, with the most significant increases worryingly in youth aged 14 years and over. There have been significant increases in all age groups, with the 2021 reforms having no obvious impact, and projections imply the uptake of vapes is still increasing.

With respect to behaviour and attractiveness, the most common reason for trying e-cigarettes was curiosity (54%), but people's reasons varied by age.[40] People aged under 30 were more likely to nominate curiosity while people aged 50 or older were more likely to use e-cigarettes as a cessation device. Almost 1 in 4 (23%) used e-cigarettes because they thought they were less harmful than regular cigarettes.

Other research also suggests that youth and young adults see vaping as socially acceptable and distinct from smoking. The most important factors driving youth uptake of vapes include flavours and taste, price (of disposable vapes), and the inconspicuous nature of devices.[41] The most common reason found in one study for e-cigarette use amongst Australians aged 18–25 years was enjoyment.[42]

In 2022, the Generation Vape group published the results of a study of vape use by 14-17 year-olds in New South Wales, conducted in September 2021 (before the October 2021 reforms).[43] The study found that disposable vapes are favoured among youth as they are marketed as easy for beginners to use, do not require liquid refilling, and are simply activated by inhaling on the mouthpiece.[44]

Since then, Generation Vape has conducted another study on vaping by children. Although the results of this second study have not yet been published, the new data corroborates the findings in the first Generation Vape study and demonstrates that vaping prevalence is still increasing, and the 2021 reforms are not having the intended effect.

In summary, the uptake and continued use of vapes has increased to concerning levels in all age groups over recent years. The largest increases were seen in the 18–24 age group, but the increasing use in youth aged 14 years and over is a key statistic that reforms should target. It is already illegal to provide nicotine vapes to this age group, so the appeal of vapes and the relative ease of access needs to be addressed. Finally, the high rates of vaping are giving vaping a level of social acceptability.

[40] Wakefield M. et al, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.' (2023) Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia. Available at: https://www.health.gov.au/resources/publications/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023?language=en

[41] Jongenelis MI, 'E-cigarette product preferences of Australian adolescent and adult users: a 2022 study' (2023) *BMC Public Health* 23:220. Available at: https://doi.org/10.1186/s12889-023-15142-8

[42] Jongenelis MI and Brennan E et al, 'Differences in use of electronic nicotine delivery systems by smoking status and demographic characteristics among Australian young adults' (2019) *Health Promotion Journal of Australia*, 30(2):207-211. Available at: https://doi.org/10.1002/hpja.202

[43] Watts C et al, 'Vaping product access and use among 14–17-year-olds in New South Wales: a cross-sectional study' (2022) *Australian and New Zealand Journal of Public Health* 46(6): 814-20. Available at: https://doi.org/10.1111/1753-6405.13316

[44] Watts C et al, 'Vaping product access and use among 14–17-year-olds in New South Wales: a cross-sectional study' (2022) *Australian and New Zealand Journal of Public Health* 46(6): 814-20. Available at: https://doi.org/10.1111/1753-6405.13316. Submissions to the TGA November 2022 consultation paper noted that disposable vaping products are preferred by youth because of their very low cost and ease of concealment from parental or teacher detection.

Vaping is not healthy and many of the health effects are unknown

Vaping is known to cause serious health issues, with the short-term risks well established but the long-term risks largely yet unknown. There is also evidence that vaping can be a gateway to tobacco smoking.

It is young adults who vape who will experience the most significant health effects in later life. The highly addictive nature of nicotine, and the fact that vapes are inhaled into the lungs, mean the population-wide health risks of these products are more severe than many other consumer goods. Much like the young Australians who smoked cigarettes in the mid-twentieth century, Australian teenagers who vape today are at risk of life-long addiction and are likely to feel the health effects of vaping in their later lives, with many of these effects as yet unknown. Further, nicotine use during adolescence can cause addiction and harm parts of the brain that control attention, learning, memory, mood, and impulse control.

The current regulatory settings that distinguish regulations applying to nicotine and zero-nicotine vapes is exacerbating the health risks. This approach has led to the widespread practice of concealing nicotine content in vapes to avoid regulatory controls, which is especially damaging for consumers, including youths, who are unwittingly becoming addicted to nicotine and more likely to take up tobacco smoking as a result.

Several international reports outline the evidence of harm from vapes in detail:

- The Irish Health Research Board systematic reviews (which will be collectively referred to as the 'Irish HRB reports'):
    - Electronic cigarette use and tobacco cigarette smoking initiation in adolescents. An evidence review (12 October 2020)
    - Electronic cigarette and smoking cessation. An evidence review (12 October 2020)
    - Harms and benefits of e-cigarettes and heat-not-burn tobacco products. A literature map (12 October 2020).
- The European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) report, Final opinion on electronic cigarettes (16 April 2021).
- The Australian National University (ANU) report by Banks, E. *et. Al.*, Electronic cigarettes and health outcomes: systematic review of global evidence (April 2022).
- The 2022 National Health and Medical Research Council (NHMRC) CEO Statement on Electronic Cigarettes.

Significant short-term health risks caused by vaping

Vaping of both nicotine and zero-nicotine liquids can cause significant harm to users. Nicotine vapes have particular harms, in addition to their addictive nature and gateway to smoking, which are listed explicitly under the 'Harms of nicotine' below. All other potential range of harms summarised here can apply to the vaping of zero-nicotine e-liquids.

Evidence shows that the use of vapes exposes users to chemicals that are known to or may cause harm. Some of the safety risks also relate to the operation of the vaping device. The safety of vapes was well summarised in the 2022 NHMRC *CEO Statement on Electronic Cigarettes,* based on a review of the current evidence.[45] The CEO Statement advises, among other things, that:

- e-cigarettes can be harmful. All e-cigarette users are exposed to chemicals and toxins that can harm your health.

[45] National Health and Medical Research Council, '2022 CEO Statement on Electronic Cigarettes,' (2022). Available at: https://www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement

- 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 explosion. Use of e-cigarettes can lead to seizures in some users.
- use of e-cigarettes can result in a serious and sometimes fatal lung condition in some users, known as "E-cigarette or Vaping Associated Lung Injury" (EVALI). Most cases of EVALI reported in the US were linked to cannabis oils and vitamin E acetate, but other chemicals may also contribute to this condition.

The National Academy of Sciences[46] review also found conclusive evidence that vaping devices can explode and cause burns and projectile injuries. It noted that while the true rate of these events is not known, when they do occur, they have the potential to cause great harm. The most frequent cause of burns is from overheating and exploding lithium-ion batteries in vapes. The quality and design of the vape may influence the likelihood of malfunction and explosions. The majority of case reports or case series reviewed by the committee involved burns to the thigh, with other injuries occurring to the face, chest, abdomen and genitalia. There have also been reports of injuries caused by projectiles vape explosions.

Similarly, a review of global evidence published by the Australian National University in April 2022[47] found (among other things):

1. conclusive evidence that:
    - intentional or accidental exposure to nicotine e-liquids can lead to poisoning, which can be severe and can result in death
    - use of e-cigarettes can result in nicotine toxicity
    - the use of e-cigarettes can lead to seizures
    - e-cigarettes can cause burns and injuries, which can be severe and can result in death
    - e-cigarette use results in increased airborne particulate matter in indoor environments
    - the use of e-cigarettes can cause respiratory disease among smokers and non-smokers (however mainly in e-cigarettes delivering THC and vitamin E).
2. substantial evidence that:
    - e-cigarette use by non-smokers results in [nicotine] dependence.
3. moderate evidence that:
    - less serious adverse events- such as throat irritation, cough, dizziness, headache, and nausea- occur with use of nicotine e-cigarettes
    - among smokers, use of e-cigarettes increases heart rate, systolic blood pressure, diastolic blood pressure and arterial stiffness acutely after use.
4. limited evidence that:
    - in non-smokers, e-cigarettes have acute (up to two hours post-exposure) effects on spirometry parameters
    - e-cigarette use increases respiratory resistance and impedance in healthy and asthmatic smokers up to 30 minutes post-exposure
    - e-cigarette use results in increased concentrations of airborne nicotine and of nicotine and cotinine on indoor surfaces

[46] National Academies of Sciences, Engineering, and Medicine, 'Public Health Consequences of E-Cigarettes,' (2018) The National Academies Press: Washington, DC,. Available at: https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes

[47] Banks E, et al., 'Electronic cigarettes and health outcomes: systematic review of global evidence.' (April 2022) National Centre for Epidemiology and Population Health: Canberra. Report for the Australian Department of Health. Available at: https://openresearch-repository.anu.edu.au/handle/1885/262914

- injuries due to e-cigarette explosions can lead to nerve damage
- e-cigarette use can lead to contact dermatitis.

Risks from nicotine

The ANU's National Centre for Epidemiology and Population Health has recently reported that 'Almost all e-cigarettes deliver nicotine, which is extremely addictive. Addiction is common in people using vapes and youth and young adults are especially vulnerable to addiction as their brains are still developing'.[48]

There are specific health concerns related to nicotine including acute toxicity, cardiovascular effects and effects on foetal and adolescent brain development.[49] Depending on dose, dose duration and frequency, route of exposure, formulation of the nicotine product and interpersonal variability, acute nicotine toxicity can lead to a broad range of physiological effects.[50] Mild symptoms can include nausea and vomiting. Greater exposure leading to cholinergic syndrome including diarrhoea, increased salivation, increased respiratory secretions, and bradycardia. Severe poisonings may progress further to seizures and respiratory depression, which can be fatal. Using nicotine in adolescence can harm the developing parts of the brain that control attention, learning, mood, and impulse control.

In 2018, the National Academy of Sciences[51] conducted a scientific review of the public health impact of nicotine containing vapes. The review found conclusive evidence that:

- exposure to e-liquids from drinking, eye contact, or dermal contact can result in adverse health effects including but not limited to seizures, anoxic brain injury, vomiting, and lactic acidosis, assumed to be a result of acute nicotine toxicity
- drinking or injecting e-liquids can be fatal, assumed to be a result of acute nicotine toxicity.

In June 2022, the National Health and Medical Research Council (NHMRC) published a CEO Statement[52] which summarised findings on the harms of e-cigarettes:

- 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 five years. Most poisonings occur in toddlers and adults. It is difficult to determine whether the poisonings are solely a result of nicotine
- use of e-cigarettes containing nicotine probably results in throat irritation, cough, dizziness, headaches and nausea.

In addition, higher concentration nicotine e-liquids present a higher risk of acute poisoning in users through intentional or accidental ingestion, particularly in young children. For example, an average 2-year-old child would experience potentially lethal effects by ingesting as little as 0.8 ml of a 100 mg/ml

[48] National Centre for Epidemiology and Population Health, 'Vaping increasing among young Australians, as risks confirmed', (21 March 2023). Available at: https://www.anu.edu.au/news/all-news/vaping-increasing-among-young-aussies-as-risks-confirmed

[49] National Industrial Chemicals Notification and Assessment Scheme (NICNAS), 'Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns report', (2019) Australian Government Department of Health. Available at: https://www.health.nsw.gov.au/tobacco/Pages/vaping-evidence-summary.aspx

[50] Banks E, et al., 'Electronic cigarettes and health outcomes: systematic review of global evidence.' (April 2022) National Centre for Epidemiology and Population Health: Canberra. Report for the Australian Department of Health. Available at: https://openresearch-repository.anu.edu.au/handle/1885/262914

[51] National Academies of Sciences, Engineering, and Medicine, 'Public Health Consequences of E-Cigarettes,' (2018) The National Academies Press: Washington, DC, p. 774. Available at: https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes

[52] 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

nicotine e-liquid.[53] Reducing nicotine concentrations would also 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.[54] Further, the fact that nicotine is highly addictive means that people using vapes are at risk of life-long dependence to a product that is known to cause some short-term harms and whose long-term effects are as yet poorly quantified.

Risks from known harmful chemicals (other than nicotine)

E-liquids contain chemicals that are known to be harmful. E-liquids, vaping devices and their inhaled emissions contain ingredients, contaminants and reaction products. Known carcinogens have also been found in e-cigarette aerosols, although the extent to which e-cigarette use increases the risk of cancer remains unknown.[55]

The Australian Government's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 2019 Report[56] researched the chemistry of liquids used in e-cigarettes in Australia and found the following:

- A number of chemicals used as flavouring ingredients are of concern to human health, such as diketone flavourings, which have (rarely) been linked to irreversible lung damage known as bronchiolitis obliterans or 'popcorn lung'.
- Emissions from e-cigarette devices contain reaction products such as carbonyl compounds that may pose a risk to human health- known cancer-causing agents such as acetaldehyde, acrolein and formaldehyde were the most common carbonyl compounds identified and were present in emissions from all devices and e-liquids tested.
- E-cigarette emissions contain contaminants derived from e-liquids such as volatile organic compounds, phthalates, pesticides and tobacco-specific nitrosamines. At a sufficient concentration and exposure, the contaminants identified in e-cigarette emissions may have the potential to adversely affect human health.
- E-cigarette emissions may contain metal contaminants derived from vaping devices, such as arsenic, chromium, lead, mercury and nickel, which pose health concerns even at low exposure levels.

The findings above are even more concerning given the small fraction of e-liquids analysed in the report. Many more, predominantly flavouring, chemicals remain to be identified as e-liquid ingredients which may pose additional health concerns.

Quality of vapes

The risks associated with known chemicals in vapes highlight the importance of ensuring the minimum quality and safety of any vapes supplied. There are currently no vapes registered on the ARTG, which means that there are no therapeutic vapes available in Australia that have been fully assessed by the TGA for quality, safety and efficacy.

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[53] Morgan J and Kelso C, 'Nicotine Vaping Product Analysis: Evidence from the University of Wollongong' (September 2021). Available at: https://www.tga.gov.au/sites/default/files/2022-11/nicotine-vaping-products-analysis-evidence-university-wollongong.pdf

[54] S National Industrial Chemicals Notification and Assessment Scheme: Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns. 2 October 2019. Available at: https://www.industrialchemicals.gov.au/sites/default/files/2020-08/Non-nicotine%20liquids%20for%20e-cigarette%20devices%20in%20Australia%20chemistry%20and%20health%20concerns%20%5BPDF%201.21%20MB%5D.pdf

[55] Bozier, J et al, 'The evolving landscape of Electronic Cigarettes: A systematic review of recent evidence,' (2020) *Chest* 157(5) 1362. Available at: https://pubmed.ncbi.nlm.nih.gov/32006591/

[56] National Industrial Chemicals Notification and Assessment Scheme (NICNAS), 'Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns report', (2019) Australian Government Department of Health. Available at: https://www.health.nsw.gov.au/tobacco/Pages/vaping-evidence-summary.aspx

While nicotine vapes must meet the minimum requirements in a TGA quality standard, these requirements are relatively low. This leaves risks for consumers and undermines medical professionals' trust in prescribing these products.

In addition, there is no requirement for nicotine vapes currently imported under the Personal Importation Scheme to comply with all of the quality and labelling requirements outlined in TGO 110, and there is abundant evidence, as previously discussed, of poor quality of vapes available in Australia. As a result, consumers of products imported under this scheme may not be in possession of accurate information about the products they are purchasing. Further, the other requirements of TGO 110 are very difficult to enforce, due to the difficulty of intercepting and testing small consignments of products imported through the mail.

There is even less regulation of the quality of zero-nicotine vapes, whether or not they are marketed for a therapeutic purpose. There is no product standard that applies to these goods. This means, for example, that there is no legislation that expressly prevents these products containing prohibited ingredients with known health effects that are outlawed for nicotine vapes.

Largely unknown long-term impacts of vaping

The chronic, long-term effects of vaping on health are still unknown, as these products have not yet been used for an extended period of time and many diseases, including cancer, take a long time to develop.[57,58]

In addition to outlining the short-term impacts of vaping, the NHMRC CEO Statement[59] published in June 2022 provided public health advice on the long-term safety and impacts of e-cigarettes. This statement advises that:

- 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 and mental illness
- lack of information does not mean that e-cigarettes are safe. More information is needed to understand the long-term impacts of e-cigarette use.

Similarly, the review of global evidence published by the Australian National University in April 2022 noted that "the impact of nicotine and zero-nicotine e-cigarettes on important clinical health outcomes- including those related to cardiovascular disease, cancer, mental health, development in children and adolescents, reproduction, sleep, wound healing, neurological disease and endocrine, olfactory, optical, allergic and haematological conditions- is not known, as reliable evidence is lacking." [60]

The National Academy of Sciences review[61] also found substantial evidence that:

- e-cigarette aerosols can induce acute endothelial cell dysfunction, although the consequences and outcomes on these parameters with long-term exposure to e-cigarette aerosol are uncertain.

[57] Ibid.

[58] Australian Government Department of Health and Aged Care, 'About e-cigarettes,' (13 April 2023). Available at: https://www.health.gov.au/topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes.

[59] National Health and Medical Research Council, '2022 CEO Statement on Electronic Cigarettes,' (2022). Available at: https://www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement

[60] Banks E, et al., 'Electronic cigarettes and health outcomes: systematic review of global evidence.' (April 2022) National Centre for Epidemiology and Population Health: Canberra. Report for the Australian Department of Health. Available at: https://openresearch-repository.anu.edu.au/handle/1885/262914

[61] National Academies of Sciences, Engineering, and Medicine, 'Public Health Consequences of E-Cigarettes,' (2018) The National Academies Press: Washington, DC, p. 774. Available at: https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes

- components of e-cigarette aerosols can promote formation of reactive oxygen species/oxidative stress. This supports the biological plausibility of tissue injury and disease from long-term exposure to e-cigarette aerosols.
- some chemicals present in e-cigarette aerosols, such as formaldehyde and acrolein, can cause DNA damage and mutagenesis. This supports the biological plausibility that long-term exposure to e-cigarette aerosols could increase risk of cancer and adverse reproductive outcomes. Whether or not the levels of exposure are high enough to contribute to human carcinogenesis remains to be determined.

In addition to the well-established risks of first-and second-hand smoking, recent evidence has emerged in relation to the risk of 'third-hand' exposure. Third hand exposure relates to the transfer of chemicals from surfaces. This research has shown that residues from vaping, including nicotine, can be left on surfaces and passed on to others, including children, through touch. The effect 'is like putting a nicotine patch on their skin'.[62]

Vaping is a strong predictor of tobacco smoking initiation

There has been widespread expansion of e-cigarette use internationally. A strong and consistent body of evidence shows that vaping by people who never smoked increases the risk of uptake in tobacco smoking, particularly among youth and young adults.

Vaping is a strong predictor of future tobacco use for youth and young adults, including for those who would otherwise be unlikely to take up conventional smoking.[63] Vaping also mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely.[64]

The Irish HRB, SCHEER and ANU reports discussed above provide strong evidence that e-cigarettes are a gateway to smoking for youth and young adults. The ANU systematic review indicates that there is strong evidence that never smokers who use e-cigarettes are around three times as likely than those who do not use e-cigarettes to initiate cigarette smoking.[65]

There are also concerns about direct health harms associated with e-cigarette use, concurrent use of e-cigarettes and tobacco products, and the potential for their use to further contribute to nicotine addiction and tobacco use, particularly among youth.[66]

[62] Professor Brian Oliver, 'Navigating the hazards', (12 September 2023) University of Technology Sydney. Available at: https://www.uts.edu.au/news/health-science/navigating-hazards

[63] Department of Health and Aged Care, 'Notice of final decision to amend the current Poisons Standard – nicotine' (2020) Australian Government. Available at: https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-current-poisons-standard-nicotine#:~:text=Pursuant%20to%20regulation%2042ZCZR%20of,to%20be%20fitted%20in%20liquid

[64] Baenziger ON et al. 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,' (2021) *BMJ Open* 11(3). Available at: https://pubmed.ncbi.nlm.nih.gov/33785493/

[65] Banks E, et al., 'Electronic cigarettes and health outcomes: systematic review of global evidence.' (April 2022) National Centre for Epidemiology and Population Health: Canberra. Report for the Australian Department of Health. Available at: https://openresearch-repository.anu.edu.au/handle/1885/262914

[66] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-Cigarette Use Among Youth and Young Adults; A Report of the Surgeon General' (2016) US Department of Health and Human Services. Available at: E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General—Executive Summary; E Banks, K Beckwith and G Joshy, 'Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context' (2020) Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health. Available at: https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf

Tobacco use remains one of the leading causes of preventable death and disability among Australians. This risk is identified as a priority area in the National Tobacco Strategy 2023–2030, and any reform measures need to align with those Government objectives.

Access to vapes is appropriate in specific circumstances

Following an extensive review of the evidence available in 2020 and thousands of consultation submissions, the decision maker for the scheduling of nicotine in Schedule 4 of the Poisons Standard concluded that there is a powerful argument that reducing the ease of with which nicotine e-cigarettes can be accessed by youth will act to safeguard current and future generations from nicotine addiction.[67]

The Poisons Standard classifies medicines and poisons into schedules depending on their risk, with access controls for products vary depending on the schedule in which they are included. In making any decision, the scheduling delegate carefully considers all the available evidence about the risks of a particular substance to determine what schedule it should be included in.

In making the December 2020 scheduling decision, the delegate carefully considered all the available evidence about the risks of vaping and the use of nicotine vapes for smoking cessation, including advice from an expert advisory committee, published scientific studies and approximately 2,500 submissions including from medical and scientific experts.

In making the decision, the scheduling delegate considered, among other things:

- evidence of the harms of tobacco use – the delegate noted that at that stage this was a leading cause of preventable disease and death among Australians
- evidence of the harms of vaping, including on youth and young adults – the delegate broadly noted evidence of the harms already described above
- evidence of the effectiveness of nicotine vaping for smoking cessation – the delegate concluded while, at that time, there were promising signs that that nicotine e-cigarettes may be of value in smoking cessation, the evidence was not sufficiently strong to make a firm conclusion.

There was a 3-stage decision-making process, involving an initial request for public submissions on scheduling proposals, advice from the Joint Meeting of the Advisory Committees on Medicines Scheduling and Chemical Scheduling, and an interim decision that was publicly consulted on. After carefully weighing all the evidence, the delegate concluded that restricted access to nicotine vapes for smoking cessation should be available under medical supervision to a cohort of smokers who had been unable to give up smoking by other means. The delegate considered that restricted access to nicotine vapes under medical supervision for smoking cessation would appropriately balance the risks presented. It would prevent access for youth and non-smokers, and a practitioner could make a clinical judgement about whether a vape would be clinically suitable for a particular patient based on their particular circumstances and clinical history.

The evidence has not significantly changed since the scheduling decision was made, although there is more evidence that vaping may be an effective smoking cessation aid and some evidence it may be more effective than traditional NRTs.

Tobacco use remains a leading cause of preventable disease and death among Australians. It is estimated to have killed 1,280,000 Australians between 1960 and 2020. In 2018 alone, tobacco use

[67] Department of Health and Aged Care, 'Notice of final decision to amend the current Poisons Standard – nicotine' (2020) Australian Government. Available at: https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-current-poisons-standard-nicotine#:~:text=Pursuant%20to%20regulation%2042ZCZR%20of,to%20be%20fitted%20in%20liquid .

was estimated to have killed almost 20,500 people.[68] While vaping carries significant health risks, the known health risks (at least for regulated vapes) are, at this stage, lower than for smoking. Unlike cigarettes, vapes do not generally contain tar which is known to cause lung cancer.

The recently updated Cochrane Review, Electronic cigarettes for smoking cessation (November 2022)[69],compared the effects of nicotine vapes with other ways of delivering nicotine, such as NRTs including patches and chewing gum, e-cigarettes without nicotine, and behavioural support only or no support.[51] 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.[52] Of the included studies, 10 (all but one contributing to the authors' main comparisons) were rated at low risk of bias overall, and 50 at high risk.[70] In relation to quit rates:

- there was high certainty that quit rates were higher in people randomised to nicotine vapes than in those randomised to NRT (risk ratio RR 1.63, 95% CI 1.30 to 2.04; 6 studies, 2,378 participants). In absolute terms, this might translate to an additional 4 quitters per 100 using nicotine vapes.
- there was moderate-certainty evidence that quit rates were higher in people randomised to nicotine vapes than to zero-nicotine vapes (RR 1.94, 95% CI 1.21 to 3.13; 5 studies, 1,447 participants). In absolute terms, this might lead to an additional 7 quitters per 100 using nicotine vapes.
- compared to behavioural support only/no support, quit rates were higher for participants randomised to nicotine vapes (RR 2.66, 95% CI 1.52 to 4.65; 7 studies, 3,126 participants). In absolute terms, this represents an additional 2 quitters per 100 using nicotine vapes. However, this finding was of very low certainty, due to issues with imprecision and risk of bias.[71]

Supporting the use of vapes for treating current smokers, UK smokers have been actively urged to swap cigarettes for vapes under a 'swap to stop' scheme.[72] The scheme was based on findings from an independent review on ways to be smokefree by 2030,[73] which found that vapes continue to be the most popular and effective aid used by people trying to quit smoking. In 2020, 27.2% of people had used a vape in a quit attempt in the previous 12 months. The review recommended accelerating the path to prescribed vapes through medicinal licensing to complement the swap to stop packs and give hesitant professionals (and the public) more confidence in their safety and effectiveness.[74]

The requirement for a prescription for access to any vapes is key to ensure patients are obtaining and benefiting from evidence-based advice on smoking cessation or nicotine addiction from their doctor. A doctor can facilitate the use of multi-session behavioural interventions such as smoking cessation counselling, combined with clinically appropriate pharmacotherapy, to maximise the likelihood of successful long-term cessation.[75]

[68] Australian Institute of Health and Welfare, 'Australian Burden of Disease Study 2018: Interactive data on risk factor burden,' updated 24 November 2021. Available at: https://www.aihw.gov.au/reports/burden-of-disease/abds-2018-interactive-data-risk-factors

[69] Hartmann-Boyce J et al., 'Electronic cigarettes for smoking cessation,' (2022) *Cochrane Database of Systematic Reviews* 11. Available at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full

[70] Ibid.

[71] Ibid.

[72] UK Department of Health and Social Care, 'Smokers urged to swap cigarettes for vapes in world first scheme,' (11 April 2023). Available at: https://www.gov.uk/government/news/smokers-urged-to-swap-cigarettes-for-vapes-in-world-first-scheme

[73] Khan, J, 'The Khan review: making smoking obsolete,' (9 June 2022) Available at: https://www.gov.uk/government/publications/the-khan-review-making-smoking-obsolete

[74] Ibid.

[75] Jongenelis, MI, and White, S, 'The pros and cons of prescription-only liquid nicotine,' (28 September 2021). Available at: https://findanexpert.unimelb.edu.au/news/31387-the-pros-and-cons-of-prescription-only-liquid-nicotine

Improving the safety profile of vapes, such as imposing additional quality and safety standards, will continue to increase the benefit-risk profile for the use of vapes as a tool for smoking cessation.

Individual experiences of using vapes to quit smoking

Individuals responding to the First and Second Consultations by the TGA (see Question 5) provided anecdotal evidence of the assistance that vaping gave them in quitting smoking. Note all quotes are verbatim and therefore may contain spelling, grammatical and typographic idiosyncrasies which have not been corrected:

- Was a smoker for 40 yrs – Vaping saved my life.
- I have given up cigarette many years ago 10 at least and the only way I could do it was by using a ecig and slowly reducing nicotine.
- I used to smoke about 40 cigarettes per day. Then I tried vaping. It has been 3 years since I smoked a cigarette. I started vaping with 18mg of nicotine. Now I'm down to 2mg.
- Helped quit smoking.

Similarly, although the Second Consultation was not targeted at individuals and there were no questions within the survey to elicit the individual's experience with vaping, some individuals took the opportunity to state strongly that they did not support a ban on vapes and explained the effect of banning vapes might have on them. Note all quotes are verbatim and therefore may contain spelling, grammatical and typographic idiosyncrasies which have not been corrected:

- I successfully quit smoking after 16 years. I have been cigarette free for 2 years.
- Many failed attempts prior to this, the only success I have had is with vaping.
- If you're going to continue to offer nicotine in any form, it's hypocritical to take away a method of harm reduction.
- No I do not. I am a personal user of nicotine vapes. With the assistance of the vape i have not had a cigarette in 5 years. health issues and my fitness have improved from the change. when the changes came last year i had a lot of issues.
- I'm a long term vaper and successfully stopped smoking cigrarettes within 3 weeks, so it works as an option for me and feel so much better about it.
- As someone who has used vapes to stop smoking I know this will hamper my road to recovery as no doctors I have spoken with are willing to supply me with a prescription.
- I wont be able to calm nicotiene cravings & i will be at risk of going back to tobacco smoking which has been proven to be far more dangerous than vaping. Ban all vaping product would leave the government open to a class action lawsuit if people have been forced back on smoking cigarettes which is clearly what the government secretly wants due to massive yearly tax revenues streams cigarrettes & combustable Tobacco products it brings in when you could tax nicotiene vapes reasonably & abolish the need for a doctor prescriptions likein the good old days Cannabis should also be available in vaping products like in Canada & othercopuntries that are forwarding thinking while Australia keeps going backwards due to narrow minded, opressive Nanny state medeling scumbags! We the people want these draconian prohibition laws on Cannabis abolished & any plans of vape ban abandoned!You can still make massive multi billion dollar a year tax revenue streams by taxing vapes & taxing Cannabis instead of wasting billions in tax payer money wrongfully prosecuting & wrongfully jailing people because of opressive Nanny state draconian prohibtion laws & as people are getting smarter in hiding money so less & less is seized in raids. Eventually a defendant will selected a jury that supports legalization & succesfully argue in a not guilty court trial for jury nullification & fight back against these oppressive draconian drug prohibtion laws!
- Almost 3 years of hard work potentially down the drain with not using tobacco.

- I would no longer be able to access a safer smoking cessation device and liquids. This would be detrimental to my personal health as it has greatly improved by the use of vaping products this would mean going back to smoking cigarettes. The ban of flavours etc would greatly Impact this as the variety of choice is what sustains the healthier choice.
- As a 42 year chronic tobacco smoker I have been using vapes on and off for over 10 years. In recent times I have been using them more and more.
- The first thing I would like to be noted is that my chronic cough disappears when I use vapes consistently. I have had a chronic cough for close to 30 years from using tobacco products. But using a vape clears my lungs within a matter of a day.
- It would have serious consequences to my health if I were not able to use vapes.
- It will remove access to life saving alternatives to cigarettes.
- I have completely quit smoking for just over three (3) years now, thanks to Vaping. Since we cannot purchase/get Nicotine here in Australia, the Personal Importation Scheme is an important factor to us vapers.
- I started out with vaping at 6mg nicotine and currently I can only vape at 4mg due to the fact that 6mg has become too strong. Even with my Pod kits I vape 4 mg. Therefore, I am of the opinion that in another 5 or 6 years, I will be totally nicotine and vape free. Therefore, it is safe to say that it is not addictive (in my case) and does actually wean off dependency gradually and a very effective tool to quit smoking cigarettes.

Use of vapes versus approved Nicotine Replacement Therapies

Careful consideration needs to be given to the issuing of a prescription for a vape to assist with smoking cessation. A range of smoking cessation products are already available that do not have the same health risks (known and unknown) as vapes. These products are known as ‘’first line' smoking cessation medications as they have been rigorously assessed by the TGA and have an established safety and efficacy profile. These products are generally less addictive than vapes and many are widely available in supermarkets and other retail settings. Many of these products (such as nicotine gums, patches and lozenges) are subsidised on the Pharmaceutical Benefits Scheme (PBS).

As no vapes have yet been evaluated by the TGA, the quality, safety and efficacy of these products in assisting with smoking cessation cannot be assured. A decision to prescribe an unapproved therapeutic good is a benefit-risk decision made on clinical grounds by a health practitioner in consultation with their patient. The RACGP currently advises that for people who have failed to achieve smoking cessation with first-line therapy and are still motivated to quit smoking, nicotine vapes may be a reasonable intervention to complement behavioural support. However, this needs to be preceded by an evidence-informed shared decision-making process, wherein the patient is aware of the appropriate caveats:

- Due to the lack of available evidence, the long-term health effects of nicotine vapes are unknown
- Nicotine vapes are not registered therapeutic goods in Australia and therefore their quality, safety and efficacy have not been established
- There is a lack of uniformity in nicotine vapes and the device components, which increases the uncertainties associated with their use
- To maximise possible benefit and minimise risk of harms, dual use (vapes and cigarettes) should be avoided and long-term use of vapes should be minimised
- It is important that the patient returns for regular review and monitoring.

The TGA has approved many other products such as patches, gum, lozenges, mouth spray and inhalators as quitting aids that are safe to use and are demonstrated to increase likelihood of quitting

smoking. It follows that nicotine e-cigarettes are not first-line treatments for smoking cessation.[76] Taking into account the current body of evidence, and consistent with the Royal Australian College of General Practitioners Supporting smoking cessation – A guide for health professionals (last revised September 2021) (RACGP guidelines), a consultation with a doctor will ensure:

- patients have the opportunity to discuss with their doctor whether approved pharmacotherapy interventions and NRT products would be suitable. If approved pharmacotherapy interventions or NRT are not appropriate, then the option to use nicotine e-cigarettes may be explored
- greater likelihood of using a quality nicotine e-cigarette product with reduced risk of injury and the provision of advice on appropriate use
- close monitoring and management of long-term side effects and health complications from the use of nicotine e-cigarettes
- greater chance of stopping smoking and relapse prevention through behavioural and advice-based support.[77]

When there may be clinical justification to supply nicotine e-cigarettes to a patient, the doctor's clinical decision-making process should be guided by the RACGP guidelines. These guidelines provide that nicotine vapes may be a reasonable intervention for individuals who have failed to achieve smoking cessation with approved pharmacotherapies but remain motivated to quit smoking and have raised vape usage with their healthcare practitioner.

Marketing of vapes targets youth and young adults

The sale of vapes to minors is banned by state and territory legislation. While the advertising of nicotine vapes to consumers is generally prohibited under the TG Act, there is ample evidence to suggest that youth and young adults can still obtain both nicotine and zero-nicotine products. The intentional marketing of vapes to youth and young adults contributes to the increasing prevalence of use and risks the health of youth and young adults.

Vape marketing intentionally targets youth and young adults through its promotional activities and product features. Vapes are aggressively promoted via online advertising and other youth-focused media channels. In 2015, one vape company reportedly bought online advertisements on teen-focused websites for Nickelodeon, Cartoon Network and Seventeen magazine. Promotional spending for vapes varies year-on-year, but in 2014 it was found that US$91 million (AU$143 million) was spent on vape advertising in the United States. This spending is often focused on social media promotion, allowing for lower costs and wider reach, particularly to youth and young adults. The marketing messages promote perceptions among youth and young adults that e-cigarettes are fun, cool, healthier and safer than tobacco cigarettes, and often focus on the appeal of flavours.

Even though advertising of vapes is restricted in Australia – as is advertising of combustible cigarettes- online retailers are not subject to the same point-of-sale marketing restrictions as brick-and-mortar stores. This has led to a growing trend of vape promotion and purchases in Australia taking place online. Youth and young adults exposed to vape advertising on social media are more likely to try vapes compared with young people not exposed to these advertisements.

Studies also show that vapes are marketed on a range of online platforms that typically appeal to younger audiences such as Twitter, Instagram, YouTube, TikTok, Facebook, Pinterest, internet search engines, and banner/video advertisements. Due to the borderless nature of social media,

[76] Department of Health and Aged Care, 'Notice of final decision to amend the current Poisons Standard – nicotine,' (21 December 2020). Available at: https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-current-poisons-standard-nicotine

[77] Royal Australian College of General Practitioners, 'Supporting Smoking cessation: A guide for health professionals – About this Guideline,' (29 September 2021). Available at: https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation

posts from any country can be viewed in Australia on these platforms. New research from VicHealth and Quit has identified the subversive and unethical ways the vaping industry uses social media to promote and sell vapes to young Australians. The research found the vaping industry and pro-vaping influencers are flooding social media platforms including TikTok and Instagram with videos and photos normalising and promoting vaping. Specifically, the research identified that TikTok is home to more than 18.1 billion posts with the hashtag #vape. On Instagram, 16.4 million posts were tagged #VapeLife- the majority of this content promotes e-cigarette use, and worryingly suggests to underage social media users that vaping is a normal part of life.[78]

Vape product features such as flavours, product design and packaging are designed to appeal to youth and young adults. The wide range of sweet flavours is a common reason for youth and young adults trying e-cigarettes. In 2017, almost 20,000 different e-liquid products with unique flavour and nicotine combinations were available. Further, e-cigarette product packaging often includes graphics and colours aimed to appeal to youth and young adults. Moreover, the packaging of e-liquids often resembles food and beverage products – such as juice boxes, lollies, or cookies – which makes them more appealing to youth and also increases the risk of poisoning for younger children. The design of these products often facilitates inconspicuous use to conceal the product and/or exhaled vapour to avoid detection by parents and teachers.

Vaping results in a significant amount of waste and disposal is complex

In addition to the public health risks outlined above, the increased prevalence of vapes has raised questions about appropriate and effective disposal of these products. According to Clean Up Australia's *Rubbish Report 2022*, vapes appear to be more damaging to the environment than cigarette butts.[79] Vapes contain poisonous material and lithium batteries meaning, they should not be disposed of through kerbside bins.[80] Vapes present a 'triple-threat' to the environment- plastic waste, electronic waste and hazardous waste.[81] Recent media reporting has indicated that disposal of vape cartridges is 'complex, expensive and confusing' and that vapes are being sold without any clear disposal or reprocessing pathways.[82]

When non-compliant, unlawfully imported or supplied nicotine vapes are intercepted by Australian regulators, these are seized and eventually disposed of using specialist commercial providers. These providers can safely dismantle and dispose of vape components through appropriate waste streams to ensure the risks to human and environmental health are mitigated. Given the complexity of this process, the costs associated with the appropriate disposal of unlawful vapes are significant and are generally borne by the regulator, as there are limited means in most jurisdictions for regulators to require that the costs are borne by the importer or supplier.

[78] VicHealth, 'Bad Vapefluence Teaching kids to hide vapes from parents & making vaping glamorous,' (25 September 2023). Available at: https://www.vichealth.vic.gov.au/news-publications/media-releases/bad-vapefluence

[79] Clean Up Australia, 'Rubbish Report 2022.' Available at: https://www.cleanup.org.au/rubbish-report

[80] Mellet, GB, 'Waste experts tip Clean Up Australia Day will be 'overwhelmed by plastic' including vapes and e-cigarettes,' (2 March 2023) *PerthNow*. Available at: https://www.perthnow.com.au/local-news/experts-tip-what-this-years-clean-up-australia-day-waste-will-look-like-and-how-to-dispose-of-it-c-9860153

[81] Erdiaw-Kwasie, MO, and Abunyewah, M, 'E-cigarettes pose a 'triple threat' to the environment, says Clean Up Australia waste report,' (28 February 2023) *Australian Geographic*. Available at: https://www.australiangeographic.com.au/news/2023/02/e-cigarettes-pose-a-triple-threat-to-the-environment-says-clean-up-australia-waste-report/

[82] Leaver, K, 'Growing volume of vape waste a challenge with recycling costly and dangerous,' (19 March 2023) *ABC Online*. Available at: https://www.abc.net.au/news/2023-03-19/vape-disposal-waste-environment/102104946

Question Two: What are the objectives, why is government intervention needed to achieve them, and how will success be measured?

Objectives of Government Action

The objectives of the Government's action are to:

1. Arrest the uptake of vapes (other than for therapeutic purposes) especially in youth and young adults (aged below 25 years).
2. Counteract the marketing of vapes to youth and young adults (especially through product features such as flavours and packaging).
3. Prevent nicotine addiction and reduce the risk of future tobacco use:
    a. by mitigating the increased risk of uptake in cigarette use that occurs as a result of vaping, especially for youth and young adults
    b. by ensuring vapes are available under medical supervision and through therapeutic pathways only, as opposed to black market pathways, so that smokers receive advice from medical professionals on the most appropriate pathways for smoking cessation and the risks and benefits of different treatment options.
4. Safeguard consumer health, increase confidence of users and prescribers, and minimise the short-term and long-term adverse health effects of vapes by ensuring vapes meet appropriate quality and safety standards, including protecting consumers from harms such as:
    a. known harmful chemicals in the wide range of flavouring ingredients
    b. known harmful chemicals in the emissions of vapes, including contaminants and reaction products
    c. known harms of nicotine, including the risk of poisoning
    d. known harms of vapour delivery, including the risk of explosions and burns caused by device components of the vape
    e. still unknown long-term harms.

Need for Government intervention

Commonwealth law prevents the importation, and state and territory laws prevent the domestic supply, of nicotine vapes without a prescription. There is evidence, however, that many Australians are accessing such products without a prescription, rather than through lawful supply channels. It is apparent that current regulations are not achieving their intended purpose. An extensive illegal market of nicotine vapes exists and vapes are being readily accessed unlawfully without a prescription by youth and adults for non-therapeutic purposes. Further, despite state and territory laws restricting sale of vapes to people under 18, it is apparent that youth are readily accessing vapes of all kinds. Government intervention is needed to improve the effectiveness of regulation of vapes.

The ''Question One'' section above outlines evidence of the harm caused by vapes and that vaping is a gateway to smoking, as well as the growing prevalence of vaping and the intentional marketing of vapes to youth and young adults using online media, which circumvents advertising bans for these products. The absence of full scientific certainty about the harm caused by vapes is not a valid reason to postpone measures to protect public health. Despite the arguably limited information on the long-term effects of vaping to inform scientific opinions, the level of threat or potential for harm is sufficiently high that uncertainty does not justify inaction.

Due to the problems outlined in section ''Question One'' above, a precautionary approach to vapes is warranted, and all Australian governments have committed to implementing such an approach.

The prevention of potentially serious and permanent harm, particularly to youth and young adults, arising from the sale of vapes warrants strong government action. The Australian Government is well placed to lead and shape the regulation of vapes. Only the Australian Government can control border through restrictions in the *Customs Act 1901*. The reforms both support the National Tobacco Strategy 2023–2030 and enable a national coordinated approach through the therapeutic goods scheme. This scheme allows the Australian Government to legislate an approach which will be automatically adopted in all states and territories, other than Western Australia, through an existing and well-understood mechanism. It would be significantly slower and more complex to progress legislative reforms in all states and territories than to progress Commonwealth legislation, and it may be difficult to secure the passage of uniform legislation across all jurisdictions. Action by states and territories, particularly in relation to enforcement, will be key to the effectiveness of any vaping control measures.

While threats to public health must be balanced against other considerations, such as the economic interests of those involved in the vaping industry, it is clear that the risk of harm far outweighs those economic interests. The harm will be borne by the Australian people, in terms of their personal health, into the future, in the same way as the harms from smoking have been a significant burden on personal health. Further, the costs of future health care will be borne by Australian governments, and the Australian community, rather than the vaping industry.

The strong feedback to the November 2022 public consultation paper titled ‘Potential reforms to the regulation of nicotine vaping products’ from state and territory governments, health professional bodies, individual health professionals, public health associations and university researchers was that the status quo was not sustainable, and direct intervention by the Australian Government was required. Indeed, noting the difficulty encountered by enforcement officers and consumers in differentiating between nicotine vapes and purported zero-nicotine vapes, and noting the health risks of all vapes, many respondents submitted that regulatory controls should be placed on zero-nicotine vapes that went further than those proposed in the consultation paper.

Given the extent and rapid growth of vaping, it is unlikely that alternatives to government action would be sufficient. Awareness campaigns targeting health professionals and the public, conducted in accordance with the objectives of the National Tobacco Strategy 2023–2030 (‘NTS’), would likely have some success in arresting the uptake of vaping by youth and assisting smokers to cease smoking. Without additional regulatory changes, however, this is unlikely to significantly reduce access for non-therapeutic purposes, particularly among the youth. It is clear that strong marketing tactics are focused on encouraging youth to try vaping, and education alone will be insufficient. Actions by schools and public health entities, particularly in educating people on the risks of vaping, can usefully support government action. Due to its role in tobacco reform, the Australian Government is also well placed to coordinate these public education efforts.

Recent media reporting has continued to highlight the public’s concern about the dangers of vaping among youth. As an example, on 2 March 2023 the ABC reported that some schools were so concerned about the extent of vaping among their students that they have installed vape detectors in bathrooms to try and detect and deter this behaviour.

Reforms would support the National Tobacco Strategy 2023–2030

Proposed reform measures are designed to support and prioritise the objectives and targets in the National Tobacco Strategy, and complement other measures announced by the Australian Government to reduce rates to smoking and vaping. These include:

- New public health information campaigns to prevent and reduce the use of tobacco and vapes

- Expansion of specialised programs and services to support Australians to quit smoking and vaping
- Extension and expansion of the Tackling Indigenous Smoking program to reduce both vaping and smoking among First Nations people
- New tobacco control legislative reforms first announced in November 2022, to prevent uptake of e-cigarettes by youth and young adults and those who have never smoked.

Barriers to successful Government intervention

There are a number of potential barriers to government intervention to address the problems associated with vaping:

1. Requires a high degree of agreement and cooperation of all Australian governments and multiple agencies at each level of government.

   As discussed above, vapes are currently regulated through a combination of Commonwealth and state and territory laws. An effective national regulatory system requires jurisdictions to have a harmonised regulatory approach without legal gaps, and to cooperatively enforce the legal framework. Consistent public health messaging must promote the harms of vapes. Without cooperation, including in relation to roles and responsibilities, the arrangements could potentially lead to ineffective enforcement, inconsistent laws and inconsistent public health messaging, discussed further below.

2. Potential increase in black market sales of products that do not meet quality standards.

   There is a widespread black market in vapes that has to date proved difficult to combat. As noted above, the exploitation of loopholes and a lack of understanding of the current regulatory framework has allowed the black market to flourish. Any changes to regulatory settings have the potential to further increase black market activity. A multi-faceted approach will be required to manage this potential risk, including strengthening compliance action at all steps in the supply chain and for unlawful advertising of vapes, coordinated enforcement action between agencies and governments, and increased education to decrease demand for vapes and ensure people are aware of the legal requirements in relation to vapes.

3. Insufficient access to vapes for legitimate purposes.

   A range of factors could impact on whether consumers have sufficient access to vapes for therapeutic purposes:

   a. Strengthening of regulatory controls could lead to suppliers exiting the market because they are unable to comply with new requirements or because compliance burden would impact too greatly on profitability.

   b. The prescription model may be too restrictive in terms of types of vapes available and ease of access, compared with the current broad range of vapes available and ease of access.

   c. There may be insufficient prescribers to meet demand or inability to access prescribers.

   d. There may be insufficient pharmacies willing to stock vapes or the range of vapes being stocked by pharmacies is too limited to meet consumer wishes.

   e. Supply chain issues may exist with lawful vapes, including because there is insufficient information available to allow suppliers and pharmacists to gauge the likely demand.

   f. The cost of lawful vapes may rise, particularly with the potential for pharmacies to exploit a monopoly on supply to consumers.

   To mitigate these risks, market forces will need to be carefully considered and monitored, based on consultation feedback, with regulatory tools sufficiently responsive and adjustable to ensure sufficient supply can be maintained in the short and long-term.

4. Increase in tobacco use due to inability to source vapes.

If access to nicotine-containing vapes were to be significantly restricted there is a risk that Australians addicted to nicotine may seek alternative products to meet cravings, such as tobacco. However, as noted above in Question 1, vapes are currently regarded as a 'second tier' aid for smoking cessation. Other therapeutic goods, including some on the ARTG, are available to assist with smoking cessation. Further, these risks can be partially addressed by ensuring ease of supply for legitimate use and access. The risks can also be mitigated through additional measures, such as implementing preventive public health campaigns focused on vaping and smoking cessation and increasing and improving vaping and smoking cessation support. These are outlined in the Australian Government's Tobacco Strategy 2023–2030 and the Australian Government has provided additional funding to support public health campaigns and cessation support and information.

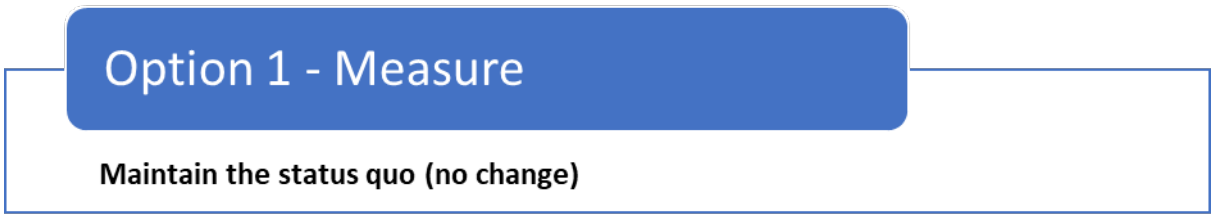
Question Three: What policy options are you considering?

There are four regulatory options proposed to address the vaping problem. The status quo (Option 1) provides the baseline for the determination of any changes to regulatory compliance costs for the other options under consideration.

Table 1. Policy options considered

Options	Elements
Option 1	Maintain the status quo (no change): • Australian consumers with a prescription will continue to be able to lawfully access nicotine vapes through pharmacies or by import via the Personal Importation Scheme. • Some minimum quality standards would apply to nicotine e-liquids. • Zero-nicotine vapes would remain widely accessible through domestic and international retailers and quality standards would not generally apply to these products. • Many vaping devices would not be subject to controls under the Therapeutic Goods Act. • Education campaigns and targeted tobacco and vape cessation support.
Option 2	Regulate vapes under a consumer model: • Adult consumers could access all vapes at retail outlets without a prescription or advice from a health professional. • Quality standards would be applied. • Retailers would be licensed to aid enforcement of regulatory controls.
Option 3	Increase regulation of vapes through the Therapeutic Goods Act and Customs Regulations: • Restrictions on importation, manufacture and supply of all vapes. • Changes to market accessibility requirements for therapeutic vapes. • Heightened quality and safety standards for therapeutic vapes, including better regulation of device components. • Strengthening import and domestic compliance and enforcement mechanisms.
Option 4	Ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods and not available as ‘unapproved’ therapeutic goods.

Option 1. Maintain the status quo (no change)



Under the status quo:

- Australian consumers with a prescription would continue to be able to lawfully access nicotine vapes through pharmacies or by import via the Personal Importation Scheme.
- Some minimum quality standards would apply to nicotine e-liquids. These are currently applied by TGO 110.
- Nicotine vapes sold in Australian pharmacies would continue to be supplied as unapproved goods as there are no nicotine vapes currently registered on the ARTG. Companies could apply to register therapeutic vapes.
- Many vaping devices would not be subject to controls under the TG Act.
- Illegal nicotine vapes will continue to be available with limited regulation. As examples, virtually unlimited colours and flavours would continue to be available, and permissible nicotine concentrations would remain at 100 mg/ml.
- Zero-nicotine vapes would continue to be sold by thousands of retailers through both physical and online stores.
- Despite the supply of vapes by retailers to people under 18 being illegal in all Australian states and territories, there would still be high and growing use of nicotine and zero-nicotine vapes among this cohort.
- At the state and territory level, there will continue to be some regulation of vapes through tobacco laws.

The Department of Health and Aged Care and its state and territory counterparts would continue to engage in substantial information and education activities to highlight the dangers of vaping and encourage and support individuals to quit. All jurisdictions would continue to undertake and increase enforcement efforts. Under this option – and all other options – parallel work would continue to be performed as follows:

- Development of targeted cessation support and resources for users of vapes and tobacco products, their support networks, and health professionals. This includes, but is not limited to, establishing an online quit support hub, redeveloping the My Quit Buddy app to include vapes, scaling up state and territory Quitline and other quit services, and updating clinical guidance and training resources to support the health workforce to provide cessation advice and support.
- Public health campaigns to denormalise vaping and disrupt and counter the influx of vape advertising and promotional activities. The Commonwealth is developing 2 campaigns:
    - A national Youth Vaping Education Campaign which will contribute to national efforts in educating youth and young adults, parents and carers, and the broader community on the harms of vaping.
    - A national Tobacco and E-Cigarette Campaign targeted towards adults, with a particular focus on priority and at-risk population groups. A key focus of this campaign will be to drive tobacco and vaping cessation among adults.
- An extension of the Tackling Indigenous Smoking Program to include vaping, while also maintaining the focus on reducing First Nations smoking prevalence, by funding local organisations to deliver grassroots-led activities to create generational behaviour change and prevent uptake of e-cigarette use.
- The continuation and heightening of enforcement activities.
- The Public Health (Tobacco and Other Products) Bill 2023, introduced into the House of Representatives on 13 September 2023, which includes prohibition of advertising and promotion of e-cigarettes.

How does the status quo meet the Government's objectives?

The status quo goes some way to meeting the Government's objectives as:

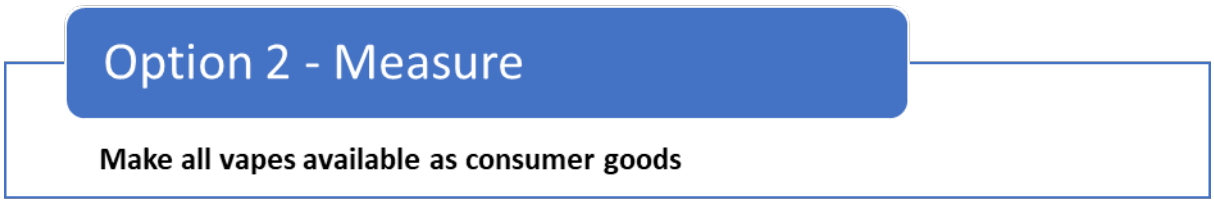
- the uptake of vapes by youth is partially addressed by restrictions on sale of zero-nicotine vapes to minors and the requirement for nicotine vapes to be supplied through pharmacies on prescription
- the marketing of vapes to youth and young adults would be countered by advertising restrictions that would come into effect through the Public Health (Tobacco and Other Products) Bill 2023 assuming it is enacted
- nicotine and smoking addiction are addressed through public health campaigns, quit services and by making nicotine vapes available on prescription
- safe-guarding consumer health is facilitated through product standards that apply to nicotine vapes (but not to zero-nicotine vapes or most devices) and the requirement for nicotine vapes to be prescribed.

While compliance and enforcement could be increased to better meet these objectives, recent compliance and enforcement efforts have demonstrated several deficiencies in the current compliance framework for nicotine vapes. These deficiencies are:

- The regulatory distinction between nicotine and zero-nicotine vapes would remain. This regulatory distinction has allowed unscrupulous importers and suppliers to evade regulatory controls by concealing the presence of nicotine in vapes, as demonstrated in TGA-published testing results.[83] The concealment of nicotine in vapes is especially damaging for consumers, including youths, who are unwittingly becoming addicted to nicotine. It has also significantly undermined the effectiveness of the 2021 reforms because it requires costly testing of vapes to determine whether they can be lawfully supplied. This practice makes enforcement difficult at both national and state and territory levels and reduces public confidence that the arrangements are effective and working.
- Under the status quo, nicotine vapes would continue to be able to be imported under the Personal Importation Scheme. Neither the TGA, nor any other government authority, has records on the extent of use of this pathway, although anecdotally the TGA has been advised that personal importation is a source of access to unlawful nicotine vapes for personal use or for unlawful supply. Further, the health risks seeking to be addressed by the TGA's product standard for nicotine e-liquids (TGO 110) are less likely to be applied to products imported under the Personal Importation Scheme when compared to those obtained from domestic community pharmacies.
- The TGA can only undertake compliance activity on nicotine e-liquids once they have been in the market for some time and potential non-compliance has been detected or reported to the TGA.

There are also several other deficiencies with the status quo, discussed below in Question 4.

Option 2: Regulate vapes under a consumer model



Option 2 would result in all vapes being available as consumer goods. This Option would result in vapes being available for purchase by consumers from a range of retail outlets, including supermarkets and convenience stores, provided appropriate regulatory requirements are met. There would not be a restriction on the intended use.

[83] Department of Health and Aged Care, 'Laboratory test results'. Available at: https://www.tga.gov.au/resources/lab-test-reports

Description of option

The main regulatory requirements would:

1. Require retailers to be licensed to sell vapes. Licensed vape shops and licensed general retail outlets would be permitted to sell vapes (including nicotine vapes) as consumer goods. A positive licensing system would require retailers to meet regulatory requirements for the supply of vapes, including those preventing sale of vapes to minors and requiring vapes to meet product standards. Non-compliance could be dealt with by including additional conditions in a licence or suspending or revoking a licence. The licensing system would ensure a range of regulatory levers are available to secure compliance with the regulatory controls, in addition to taking formal legal action for breach, such as prosecuting an offence.
2. Prevent the sale of vapes to under 18s. Retailers would be required to conduct age verification at the time of sale. This is currently required for the sale of cigarettes and so all retailers would already have processes in place to meet this increase in regulation. Most submitters to the 2 TGA consultations considered that an appropriate age limit would be 18.
3. Impose quality and safety standards. To ensure a level of quality and safety of the goods, vapes would need to comply with strict standards. The standards would be similar to those proposed under Option 3 but would not be as limiting in relation to flavours and colours. In both consultations, most people who advocated for this model submitted that a reasonable range of flavours should be available because they are important in encouraging smokers to take up vaping as a smoking cessation tool. Submitters suggested that people will source vapes from the black market or return to or continue smoking unless a reasonable flavour range continued to be available.
4. Require manufacturers to submit pre-market notification. Notification would include certification that confirms compliance with quality and safety standards and would be required before supply is permitted. This would be complemented by post market surveillance and reporting of adverse events.
5. Limit the advertising of vapes. This would include restricting advertising of vapes as already proposed in the Public Health (Tobacco and Other Products) Bill 2023.

Similar consumer models for supply of vapes are in place in other countries, such as in NZ and the UK. Their consumer models are summarised below.

- In NZ, legislation regulates sale to minors, advertising and sponsorship restrictions, smokefree and vape free areas, labelling and packaging, and product safety.[84] Further regulation of vapes was added in 2023, limiting flavour descriptions, packaging, approval requirements for specialist vape retailers and additional product safety requirements. The new laws require general retailers, as well as specialist vape retailers, to notify the NZ Government that they are selling vapes.[85] All vapes must also be notified before they can be sold.
- In the UK, vapes are regulated as both consumer and therapeutic products, but all supply is currently through the consumer market. Vapes are required to comply with a range of minimum safety and quality standards, packaging requirements, and advertising restrictions. Importers and manufacturers must also submit information to the regulator about their products.

[84] NZ Ministry of Health, 'About the Smokefree Environments and Regulated Products (Vaping) Amendment Act,' (7 September 2023). Available at: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/vaping-herbal-smoking-and-smokeless-tobacco-products-regulation/about-smokefree-environments-and-regulated-products-vaping-amendment-act

[85] NZ Ministry of Health, 'Obligations – Notifiable Products,' (22 September 2023). Available at: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/vaping-herbal-smoking-and-smokeless-tobacco-products-regulation/information-retailers-notifiable-products/obligations-notifiable-products

Change from the status quo

The main changes from the status quo would be:

- Nicotine and other therapeutic vapes would cease to be regulated as therapeutic goods and prescription medicines. This would mean that they could be imported by or supplied to consumers for any purpose and without medical supervision. It would also mean that wholesale licensing restrictions that currently apply to nicotine vape wholesalers would cease.
- Product standards would apply to all vapes, not just nicotine vapes and some devices.
- Pre-market processes would need to be observed to introduce vapes to the Australian market.
- Retail licences would be required in more jurisdictions than they currently are.

How does Option 2 meet the Government's objectives?

This option was advocated by some stakeholders during the 2022 and 2023 Consultations, mainly by individual vapers and retailers but also by some medical professionals. The overall view was that the benefits and risks of vapes could be appropriately managed in a consumer model.

This model could go some way to addressing the Government's objectives as:

- the uptake of vapes by youth could be addressed by preventing retailers from selling vapes to youth and applying product standards to vapes to reduce some features that are attractive to youth. A range of flavours that also appeal to youth would continue to be available, however. This model would not address uptake by young adults.
- the marketing of vapes to youth and young adults could be counteracted by introducing specific provisions limiting advertising of vapes, and by applying products standards to limit packaging appealing to youth and limit the flavours most appealing to youth.
- nicotine and smoking addiction could be addressed through public health campaigns and quit services, and by making vapes freely available for smoking cessation. Even though vapes would be widely available, quit services and education campaigns about the risks and appropriate use of vapes would mitigate the risk of non-therapeutic use of vapes and consequent nicotine addiction. They would also provide adults with information about how to effectively use vapes for smoking cessation.
- product standards would safeguard consumer health.

However, it would not fully address the objectives for a number of reasons as discussed further in Question 4.

Option 3: Increase regulation of vapes through the Therapeutic Goods Act

Option 3 - Measures

Measure 1. Restrictions on importation, manufacture and supply of all vapes

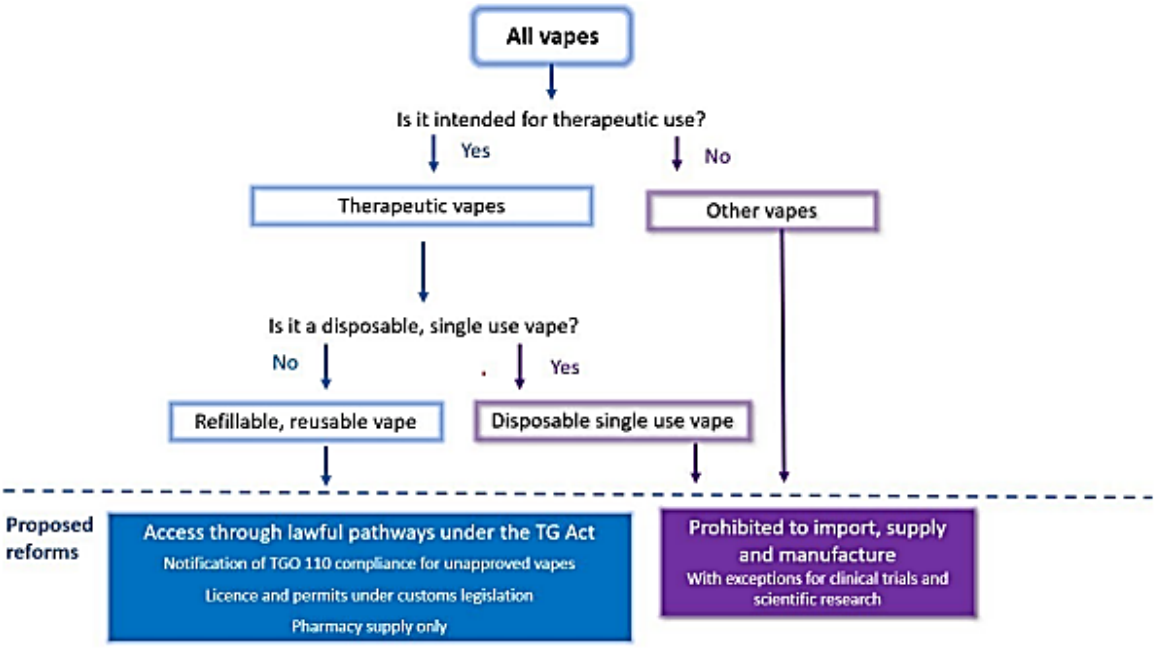
Measure 2. Changes to market accessibility requirements for therapeutic vapes

Measure 3. Heightened quality and safety standards for therapeutic vapes, including better regulation of device components

Measure 4. Strengthening import and domestic compliance and enforcement mechanisms

This option would strengthen the regulatory amendments made as part of the 2021 reforms to tightly restrict imports and sales of nicotine and zero-nicotine vapes. Under this option, vapes would be prohibited unless they are therapeutic vapes that meet TG Act requirements. The TG Act requirements for therapeutic vapes would be strengthened, as would compliance powers. Access to therapeutic vapes, depicted in Figure 5 below, would be facilitated by allowing all doctors to prescribe therapeutic vapes for smoking cessation or to treat nicotine addiction without needing to apply to the TGA for approval.

Figure 5. Access to vapes under Option 3

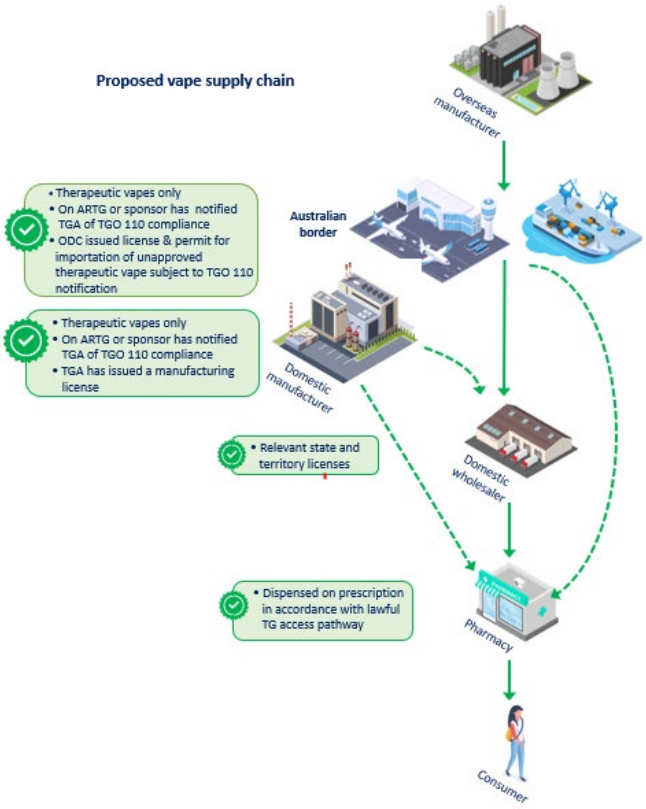


For importation of therapeutic reusable vapes to occur, the importer would need to have either registered the product on the ARTG or notified the TGA that the vape complies with TGO 110. Once the TGA has accepted the TGO 110 compliance notification, the Office of Drug Control may issue a customs licence and permit to the sponsor. Once a licence and permit has been received by ABF, the product could cross the Australian border and be supplied directly to pharmacies, or through wholesalers who may need to also hold state or territory licences.

Therapeutic reusable vapes could also be manufactured in Australia. Domestic manufacturers would need to comply with manufacturing controls under the TG Act. To manufacture therapeutic e-liquids, a manufacturing licence, or a relevant exemption, would be required. A manufacturer or sponsor would also need to have registered the product on the ARTG or notified the TGA that the therapeutic reusable vape complies with TGO 110. The vapes could then be supplied directly to pharmacies, or through wholesalers who may need to also hold state or territory licences.

Figure 6 outlines the steps described that are required to import vapes and for patients to gain access under this option.

Figure 6. Proposed lawful vape supply chain



Measure 1. Restrictions on importation, manufacture and supply of all vapes

Measure 1

- **Measure 1(a).** Limit the importation, manufacture and supply of all disposable vapes
- **Measure 1(b).** Limit the importation, manufacture and supply of all other vapes
- **Measure 1(c).** Prevent importation through the Personal Importation Scheme
- **Measure 1(d).** Preserve the traveller's exemption
- **Measure 1(e).** Prohibit the advertisement of vapes generally

Measure 1(a). Limit the importation, manufacture and supply of all disposable vapes

This measure would ban the importation, manufacture or supply of all disposable (closed system) vapes. This would be irrespective of nicotine content or therapeutic claims, with minor exceptions, such as for clinical trials and scientific research.

This approach was supported by most respondents to the 2022 consultation on the basis that disposable vapes are preferred by youth, due to their low cost and ease of concealment from parents and teachers, and because of the environmental impact of disposable vapes.

This measure alone, with effective enforcement, could go a long way to achieve the Government objectives of arresting the uptake of vapes and preventing nicotine addiction and risk of future tobacco use. It would also partially address the problems of ease of access and attractiveness to youth.

It would also address the environmental risks associated with disposable vapes, which are made predominantly of plastic and contain batteries that end up in landfill, requiring specialist disposal services.

Measure 1(b). Limit the importation, manufacture and supply of all other vapes

This measure would include a prohibition on the importation, manufacture and supply of all other vapes, except therapeutic vapes that comply with regulatory controls under the TG Act, including with licensing and notification requirements. This option seeks to significantly restrict the importation, manufacture and supply of vapes in Australia to legitimate therapeutic vapes, as illustrated in Figure 5 above.

Under this option, the importation of all vapes would be prohibited under the *Customs (Prohibited Imports) Regulations 1956* (Customs Regulations), unless a licence and permit are issued by the Office of Drug Control (ODC). Obtaining a licence would require the importer to demonstrate fitness and propriety. A permit would only be granted in relation to vapes that comply with TG Act requirements. The domestic manufacture and supply of non-therapeutic vapes would be prohibited under the TG Act.

These measures are intended to overcome the current challenge faced by the ABF, the TGA and state and territory officials, in distinguishing between lawful and unlawful vapes. Instead of having to refer vapes to the TGA to test for nicotine content, the ABF would be able to determine if a vape is lawful simply by ascertaining whether or not it is being imported by a person with a licence and a permit. In combination with pre-market notification controls, it would also assist domestic compliance officers to enforce controls as the TGA will be able to publish a list of lawful vapes. This would also assist consumer and prescribers to source lawful, and quality regulated, products.

Together with the ban on disposable vapes (Measure 1(a)), this proposal would tighten the regulatory controls for vapes and thereby ease compliance and enforcement efforts at the border and domestically. It would therefore facilitate the Government's objectives of arresting the uptake of vapes, preventing nicotine addiction and reducing the risks of future tobacco use.

Measure 1(c). Prevent importation through the Personal Importation Scheme

This measure would prevent the importation of all vapes into Australia through the Personal Importation Scheme, subject to the preservation of a traveller's exemption (Measure 1(d)). This measure would assist in the Government's objective of arresting the uptake of vapes and safeguarding consumer health.

The Personal Importation Scheme presently allows a person with a prescription from an Australian medical practitioner to directly import up to 3 months' supply of nicotine vapes for their personal use. There can be any number of repeat transactions on the same prescription. This makes the scheme subject to abuse and facilitates the diversion of vapes for illegitimate supply.

Further, it is extremely difficult to police regulatory controls, including the requirement for a prescription or compliance with the relevant quality standard, where goods are imported under the

Personal Importation Scheme. Retaining an exemption for personal importation would undermine the other elements of Option 3 designed to simplify enforcement, which will depend on compliance and enforcement officers being able to clearly identify the vapes that may be lawfully supplied on the basis of having a permit or being on a list of vapes notified to meet TGO 110.

Measure 1(d). Preserve the traveller's exemption

Despite the proposed cessation of the Personal Importation Scheme, Option 3 would preserve a limited traveller's exemption to recognise that persons arriving in Australia as a passenger on a ship or plane may need therapeutic vapes for their personal use.

The traveller's exemption would apply limits on the quantity of vapes for each passenger, to prevent this exemption becoming a pathway for domestic supply or allowing diversion of vapes.

Measure 1(e). Prohibit the advertisement of vapes generally

The current TG framework prohibits advertising prescription-only and certain pharmacist-only medicines to the public. Consistent with this prohibition, this measure would prohibit advertising vapes generally, with exceptions to allow:

- appropriate marketing of therapeutic vapes to health practitioners
- health practitioners to provide advice to patients about use of therapeutic vapes in a clinical setting
- limited advertising by pharmacies.

The proposal is intended to stop aggressive marketing to youth and young adults and the promotion of vapes outside the prescription pathway. This measure would interact with the proposed Public Health (Tobacco and Other Products) Bill 2023, and both measures would need to be aligned. It would support the objectives of arresting the uptake of vapes to youth and young adults and counteracting the marketing of vapes to youth and young adults.

Measure 2. Changes to market accessibility requirements for therapeutic vapes

Measure 2

- **Measure 2(a).** Pre-market notification of compliance with product standards
- **Measure 2(b).** Streamlined access under Special Access Scheme and Authorised Prescriber scheme

Measure 2(a). Pre-market notification of compliance with product standards

This measure would require those introducing vapes to the Australian market to provide a declaration and hold supporting evidence that e-liquids and/or associated device components meet the product standards such as TGO 110 and device standards. This measure complements Measure 4 in addressing the Government objective to ensure vapes, including both e-liquid and device components, meet appropriate quality and safety standards. It would also assist consumers, enforcement officers and practitioners to identify lawful vapes as it would enable the TGA to publish a list of vapes that can be lawfully supplied.

A pre-market notification process will require suppliers of vapes to consider the quality and safety requirements in the product standards and to declare that any vapes supplied are compliant with

these standards. It will also make it easier for the TGA to identify the person responsible for the supply of the goods, which is useful in the event of subsequent quality issues or compliance actions.

It is not intended that the sponsor will be required to provide evidence to the TGA, in relation to the formulation of the product, specifically with relation to the presence of only permitted ingredients or restricted ingredients less to or equal to the maximum permissible concentrations. However, the expectation is that appropriate product testing would occur on a per batch basis.

The notification would be required for each vape type to be supplied and would be enduring unless there were a change to the formulation.

It would be a legal requirement that the sponsor must produce upon demand by the TGA evidence to demonstrate how they have met the requirements specified in the TGA standards.

This is a similar regulatory requirement for notification schemes for nicotine vapes sold as consumer goods in the UK, EU and NZ. Notification would be a pre-condition for the granting of an import permit by the ODC under Customs Regulations.

Measure 2(b). Streamlined access under Special Access Scheme and Authorised Prescriber scheme

This measure would ensure that therapeutic vapes used for smoking cessation, treatment of nicotine addiction and other therapeutic purposes may continue to be lawfully accessed under the TG Act, subject to appropriate regulatory controls.

In the absence of any therapeutic vapes registered on the ARTG, therapeutic vapes are accessed in Australia through established pathways for 'unapproved' goods. Currently, these pathways require therapeutic vapes to be supplied to patients with a prescription from a health practitioner who has authority to prescribe under the AP and Special Access B (SAS B) schemes.

The fact that a limited number of health practitioners may currently prescribe therapeutic vapes is potentially a barrier to people accessing vapes for therapeutic purposes, which could impede the Government's objective that vapes be available for smoking cessation where clinically appropriate.

This measure would include enabling access to vapes through the Special Access Scheme Category C (SAS C) notification system in addition, or as an alternative, to the AP and SAS B schemes. Importantly, the approach would not require a prescriber to obtain pre-approval or authority under the TG Act but instead notify the TGA within 28 days after a therapeutic vape being supplied to a patient.

This change would enable more timely access to unapproved vapes for individual patients and reduce the regulatory burden on practitioners, while maintaining a level of regulation commensurate with the risk posed by unapproved therapeutic vapes.

Measure 3. Heightened quality and safety standards for therapeutic vapes, including better regulation of device components

Measure 3

- **Measure 3(a).** Heightened quality and safety standard for therapeutic vapes
  - i. Packaging and labelling changes
  - ii. Limiting flavours
  - iii. Lowering maximum nocotine concentration in e-liquids
  - iv. Other requirements for e-liquid components
- **Measure 3(b).** Requirements for device compenents

These measures would enhance requirements for vapes, including both e-liquid and device components, to achieve the Government objective for vapes to be of appropriate quality and safety to safeguard consumer health, minimise the attractiveness of vapes (especially for youth and young adults), increase confidence of users and prescribers, and minimise the potential short-term and long-term adverse health effects of vapes.

Measure 3(a). Heightened quality and safety standards for therapeutic vapes

Packaging and labelling changes

TGO 110 would outline requirements for therapeutic vapes to have 'pharmaceutical-like' packaging and presentation. This is appropriate where therapeutic vapes contain scheduled substances that are prescription medicines and supply is directed through pharmacies. The proposal would also facilitate detection of non-compliant or illicit nicotine vapes, such as any brightly coloured products with pictorial representations. Significantly, it would reduce attractiveness of vapes to youth and young adults and close off one avenue by which these products are being marketed to youth, as an example, no more yellow packaged 'Juicy Fruit' vapes.

The introduction of 'pharmaceutical' style plain packaging would reinforce that vapes are a therapeutic rather than a consumer product. These new requirements would include that therapeutic vapes must be predominantly white for the retail pack with only black and grey lettering permitted, bear mandatory prominent health warnings, observe prohibitions on certain product names, logos or brand names, and meet further labelling requirements in line with selective requirements applying to other prescription medicines under TGO 91 (Standard for labels of prescription and related medicines).

Limiting flavours

This measure would substantially limit flavours currently available for use in vapes, to reduce the attractiveness of vapes to youth and young adults and address a number of safety concerns with ingredients present in flavours.

During the 2022 consultation, the TGA consulted on restricting flavours in vapes. Many governments and public health organisations supported banning all flavours or limiting to only tobacco flavour, noting that nicotine alone vapes have an unpleasant taste and may deter use in smoking cessation.

Flavour restrictions guard against the unknown long-term health effects of ingredients found within flavours. However, given that nicotine-alone e-liquids have an unpleasant taste, providing limited flavour options for those using nicotine e-liquids for approved therapeutic purposes would support smoking cessation objectives.

Lowering maximum nicotine concentration in e-liquids

This measure would reduce the maximum allowable nicotine concentration from 100 mg/ml to a more appropriate level to limit safety concerns, while still allowing prescribers flexibility to prescribe appropriately.

A separate limit for nicotine salt has been considered but is not practicable. There are several different nicotine salt forms and salt form combinations used in vapes, which makes it challenging to have a standardised limit. However, an equivalent base form concentration would be standardised and could be efficiently enforced.

Other requirements for e-liquid components

This element of the measure would prescribe:

- a list of permitted ingredients – only 4 ingredients (plus permitted flavours) would be allowed to be mixed in the formulation of a vape and limits will be applied to the quantity of some ingredients. These permitted ingredients would be nicotine, propylene glycol, glycerine, and water.

- quality standards for ingredients (pharmacopeial grade) – all ingredients in e-liquid, except for flavours, would be required to comply with a pharmacopeial standard, derived from the European Pharmacopoeia, British Pharmacopoeia or United States Pharmacopoeia. Permitted flavours would likely be exempted from this requirement as pharmacopeial grade material is generally not available.
- a list of restricted substances – chemicals such as contaminants, degradation products, reaction products or residual compounds in the raw materials must remain below specified concentration. These chemical entities may include known harmful substances such as formaldehyde, heavy metals, and carbonyl compounds.
- the maximum volume of e-liquid for retail units – limiting the maximum amount of e-liquid sold for open system vapes and for closed system vapes (pods) would maximise safety and prevent misuse and unauthorised distribution. Currently, there is no restriction on the volume of e-liquid retail packs. Where possible, proposed limits would align with similar limits enforced in other jurisdictions such as the EU, UK and NZ.

Measure 3(b). Requirements for device components

Under this measure, requirements for the device component would be specified by legislative instrument to ensure minimum design and safety standards, including to:

- ensure vaporisation process and dosing controls
- ensure the device component conforms with minimum safety principles to reduce user risk, having regard to the generally acknowledged state of the art
- ensure the device component performs and operates safely during its expected lifetime (including storage)
- demonstrate device physical, thermal, material, and electrical safety, including battery safety
- minimise risks to the user associated with contaminants, residues, and leachable substances (and their degradation and reaction products)
- ensure any risks of fire or explosion occurring during normal use of the device are removed or minimised
- ensure programmed features or software perform appropriately and any resulting risks are minimised
- ensure suitable labelling of the device and instructions for use
- maintain certification of the manufacturer to international standards for Quality Management Systems (consistent with ISO9001, ISO13485).

Demonstrated compliance with relevant comparable overseas regulatory requirements would provide pathways for manufacturers to demonstrate compliance with most or all of these requirements. These include:

- US FDA guidance document – "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)"
- EU standard "CEN/TS 17287 – "Requirements and test methods for electronic cigarette devices"
- MHRA – "Guidance for licensing electronic cigarettes and other inhaled nicotine-containing products as medicines".

Measure 4. Strengthening import and domestic compliance and enforcement mechanisms

This measure seeks to strengthen the domestic compliance and enforcement mechanisms under the TG Act to support the broader policy intent of the vaping reforms, particularly Measure 1 of Option 3.

Commonwealth, state and territory officials agree that effective compliance and enforcement mechanisms are essential to ensure this option works as intended. Recent compliance and enforcement efforts, and discussions between Commonwealth, state and territory officials, have illustrated deficiencies in the current TG Act compliance framework for nicotine vapes and vaping devices, most notably the general need to test for the presence of nicotine before compliance and enforcement action may be confidently undertaken.

Measure 4(a). Enhanced compliance and enforcement measures

This measure includes enhanced compliance and enforcement measures needed to support the new restrictions outlined in Measure 1. Associated offences and civil penalties would prohibit:

- the importation, manufacture and supply of disposable vapes, irrespective of nicotine content or therapeutic claims
- the importation, manufacture and supply of all other vapes, irrespective of nicotine content, other than those included in the ARTG or subject to alternative regulatory controls under the TG Act such as including pre-market notification of compliance with the relevant quality standard
- the advertisement of vapes generally.

None of the new offences would be dependent on proving nicotine content before compliance and enforcement action may be undertaken. This would have the benefit of simplifying the compliance and enforcement effort at the border and domestically, and allow for the search, seizure and disposal of vapes without the requirement for laboratory testing.

Under this measure, reforms to the regulation of vapes in Australia would be supported by:

- New powers relating to forfeiture and destruction of unlawful therapeutic goods to prevent unlawful therapeutic goods and vapes being returned to the market.
- New criminal offence and civil penalties for supplying vapes to consumers outside a pharmacy and possession of unlawful vapes for supply – it is not proposed that such offences or penalties would apply to possession for personal use.
- New powers to make enforceable directions relating to importation, manufacture, supply, advertisement and possession.
- Increased powers to share information with states and territories and other compliance and enforcement bodies.
- Revised powers to release and otherwise publish information relating to enforcement and compliance.

Measure 4(b). Integrated Australia-wide enforcement

This measure complements those under Measure 1**,** to integrate into an Australia-wide enforcement framework by enabling state and territory officers to exercise compliance and enforcement powers and functions relating to the wholesale and retail supply of vapes.

Currently, state and territory officers may be authorised by the Secretary to undertake compliance and enforcement powers and functions, including investigative and monitoring activities. Under this measure, state and territory officials could support compliance and enforcement efforts by taking responsibility for issuing infringement notices, commencing civil penalty proceedings, and referring briefs of evidence to the Commonwealth Director of Public Prosecutions on behalf of the Secretary under the TG Act.

Measure 4(c). Expand regulation making powers for laboratory testing

This measure would allow regulations to be made to enable laboratory testing to play a critical role in supporting effective compliance and enforcement action in the interests of public health, such as through the detection of prohibited toxic substances in vapes.

Changes to the status quo

These measures involve an increase in regulatory requirements for importers, manufacturers, suppliers and retailers compared to Options 1 and 2.

The increase in regulation over Option 1 would be the following:

- Non-therapeutic vapes would be banned instead of being freely available from many retail premises.
- Importers and domestic manufacturers of therapeutic vapes would be required to ensure that therapeutic vapes meet new product standards and would be required to notify the TGA of this. Importers would also need to obtain customs licences and permits prior to importation.
- Zero-nicotine vapes that have a therapeutic use and more vaping devices would need to meet TGA product standards.
- Zero-nicotine vapes could only be supplied through pharmacies and pharmacists would be required to ensure that consumers have a prescription for zero-nicotine vapes. Doctors would not need to apply for SAS B or AP approvals to prescribe ‘unapproved’ therapeutic vapes but could instead prescribe under the SAS C scheme.

In addition, consumers will lose a currently lawful avenue for accessing vapes due to cessation of the Personal Importation Scheme. As a consequence, they will:

- experience a reduction in the range and availability of zero-nicotine vapes and devices
- require a prescription for therapeutic zero-nicotine vapes
- need to obtain their zero-nicotine vapes and devices through a pharmacy

Where vapes were supplied prior to the domestic ban on non-therapeutic vapes, there would be no requirement for consumers to dispose of products. Similarly, there would be no requirement for consumers to dispose of vapes which would not meet the increased product standards.

How does Option 3 meet the Government’s objectives?

All measures in combination could largely meet the Government’s objectives.

1. Restrictions on importation, manufacture and supply of all vapes. This would only allow certain therapeutic vapes to be supplied. Non-therapeutic vapes and disposable single use vapes would be banned. Import through the Personal Importation Scheme would be banned. This measure aims to address the uptake of vapes and counteract the marketing of vapes to

youth and young adults, and therefore works to prevent nicotine addiction and reduce the risk of future tobacco use.

2. Changes to market accessibility requirements for therapeutic vapes. Therapeutic vapes would be subject to pre-market access controls and streamlined access under the Special Access Scheme (SAS) and AP scheme. This measure aims to ensure that vapes are available for therapeutic purposes and therefore addresses nicotine addiction and reduces the risk of future tobacco use.
3. Heightened quality and safety standards for therapeutic vapes, including better regulation of device components. Labelling and packaging requirements would be restricted to minimise marketing and appeal to youth, the quality and safety requirements would increase, requirements for the device components would be introduced, and a notification of compliance to the new standards will be required. This measure aims to safeguard consumer health, increase confidence of users and prescribers, and minimise the short- and long-term adverse health effects of vapes. It will also counteract the marketing of vapes to youth and young adults, especially through product features such as flavours and packaging, and therefore arrest the uptake of vapes, especially in youth and young adults.
4. Strengthening import and domestic compliance and enforcement mechanisms. This measure aims to ensure that the benefits of the reforms are not undermined through the illegal importation, manufacture or supply of unlawful vapes. This measure is therefore relevant to all the Objectives of Government Action in Question 2.

While each regulatory measure could be enacted separately, each would be most effective if all are enacted together. For example, heightening quality and safety standards for therapeutic vapes alone will achieve little and could incentivise illegal-market efforts to evade detection. It is critical to heighten quality and safety standards for therapeutic vapes in conjunction with the other measures.

Option 4: Ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods, and not available as 'unapproved' therapeutic goods

Option 4 - Measure

Ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods, and not available as 'unapproved' therapeutic goods

This option imposes a higher level of regulation for vapes than Option 3. As with Option 3, it would involve banning all non-therapeutic vapes, but would add a requirement for any vape to be registered on the ARTG to be able to be lawfully supplied in Australia.

This model would provide confidence to prescribers on the quality, safety and appropriate use of approved vapes, ensure safety for consumers, and increase transparency and certainty for retailers and suppliers of approved vapes.

The ARTG is the public database of therapeutic goods that have been approved for the purpose of supply in Australia. It contains information such as the approved product name, list of ingredients, classification (in the case of medical devices), sponsor and manufacturer.

It would be necessary for a sponsor seeking to introduce a product to the Australian market to apply for the product to be registered. Application fees generally apply. The TGA would then assess the product for quality, safety, and efficacy, based on appropriate clinical trials and regulatory inspections and certifications.

The TGA enters therapeutic goods in the ARTG when it has:

- assessed higher risk therapeutic goods as meeting the requirements for quality, safety and (where appropriate) efficacy and/or performance; or
- validated lower risk medicine or medical device applications.

Every ARTG entry belongs to a sponsor who is responsible for applying for and maintaining the ARTG entry and the supply of the product. Only the registered sponsor, and no one else, can lawfully supply, import, or export that specific product to or from Australia.

The application, evaluation and registration of vapes on the ARTG can be managed via the TGA's standard application pathways. The amount of data considered necessary to support approval will depend on a range of factors including the extent to which the new therapeutic product is similar to already registered products.

It would also be necessary for products to meet manufacturing requirements. For therapeutic e-liquids, products would need to be manufactured by a licensed manufacturer in accordance with Good Manufacturing Practice principles. Imported products would also need to meet Good Manufacturing Practice requirements, and this would be considered as part of the application for registration. The sponsor is responsible for meeting the regulatory requirements of the therapeutic goods legislation, which includes post-market surveillance of their products. The TGA continually monitors the safety and, in some cases, the efficacy or performance of therapeutic goods that are available on the market. Risks associated with individual products can be managed in a number of ways, including by changes to product information, safety alerts and recalls, or compliance-based enforcement.

This option will require significant premarket data requirements be met by vape sponsors, as well as achieving GMP certification of all manufacturing sites. The time and costs involved in meeting these requirements suggests that it will take significant time, potentially years, before vape sponsors will be ready (or willing) to submit applications for ARTG registration.

However, there are no vapes currently registered on the ARTG. Further, the length of time required to undertake the clinical trials necessary to register a vape on the ARTG and to supply the market would result in a total absence of supply of vapes in Australia for greater than a year – and this is on the assumption that any sponsor would find it commercially attractive to seek registration on the ARTG, which is by no means assured.

As a result, this may mean that under this option no vapes, of any kind, are available in Australia, for an indefinite period.

Changes to the status quo

This option would have the effect that all vapes would be prohibited until a therapeutic vape has undergone full assessment and approved by TGA as a therapeutic good and entered in the ARTG.

This option involves an increase in regulatory requirements for importers, manufacturers, suppliers and retailers over Options 1 and 2.

The increase in regulation over Option 1 would be:

- People seeking to introduce therapeutic vapes to the Australian market would be required to apply for and meet the application requirements for registration
- Domestic manufacturers would be required to meet manufacturing requirements, including the requirement to obtain a licence to manufacture a therapeutic e-liquid
- All of the changes outlined for Option 3.

How does Option 4 meet the Government's objectives?

This would meet the Government's objectives in a similar way to Option 3. The crucial difference is that it would far better safeguard consumer health, increase confidence of users and prescribers, and minimise the short-term and long-term adverse health effects of vapes. This would come, however, at the cost of reducing the risk of future tobacco use by jeopardising the availability of vapes for smoking cessation where clinically appropriate. The practical effect of this option will be to ban all vapes until a product is registered.

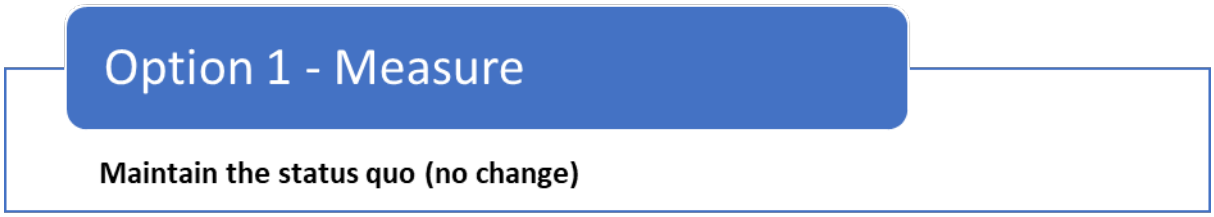
Question Four: What is the likely net benefit of each option?

This section outlines the benefits and costs for each of the four options proposed in this Impact Analysis.

A Regulatory Burden Measurement Framework (the Framework) has been applied to each option outlined in the Impact Analysis (see Annexure B).

The Framework follows the guidelines provided by the Office of Impact Analysis. The regulatory burden measurements are calculated on a ten-year basis. Costs are presented on an average per year basis, with one-tenth of the initial start-up costs added to the expected ongoing annual regulatory burden costs to provide the annual average cost that is expected for the first ten years of the proposed regulation. A range of assumptions have been used as model inputs. Many of the key assumptions are the same between the measures.

Option 1. Maintain the status quo (no change)



Overview

Under the status quo, the Commonwealth would not take any further action to strengthen the regulations for vapes. We would expect to see that the current trends outlined in Question 1 would continue.

While this option would minimise regulatory impost for industry stakeholders and consumers, the associated health impacts on users of vapes, and the impacts on the health system generally, overwhelm any actual benefit. In addition, the status quo is not tenable due to the risks of repeating the past lessons on the well-defined harms to consumers from tobacco use.

Who is affected and what are the economic, social and environmental costs and benefits?

Under the status quo, the trends and problems outlined under Question 1 would be expected to continue. This will have the biggest impact on the health of consumers, although it is also likely the vaping retail sector would continue to grow as a consequence of increasing demand.

Consumers

For consumers, a benefit of this option has been to continue to allow lawful access to a wide range of vapes, including nicotine vapes through prescription and at low cost for smoking cessation.

However, this option would expose consumers who vape regularly to the health risks outlined in Question 1.

In addition, as set out in Question 1, vaping is a gateway to smoking. Over time, and with an increasing proportion of the population vaping, the status quo option will result in increased numbers of people taking up smoking, with its associated known health risks.[86]

Product standards do not generally apply to zero-nicotine vapes, which exposes users to harm from potentially unsafe ingredients. As discussed in Question 1, while some ingredients are prohibited in therapeutic vapes under TGO 110 because of known health risks, these restrictions do not apply to non-therapeutic vapes. Further, due to the difficulties with policing whether vapes imported through the Personal Importation Scheme comply with the regulatory standards in TGO 110, the prescription vapes many people are obtaining may not meet this standard or any other regulatory requirements.

For smokers, ready access to zero-nicotine vapes without a valid prescription is likely to detract from, rather than maximise, chances of smoking cessation. It is well established that smoking cessation is most likely to be successful when delivered through or with behavioural support (see Question 1). The current regulatory settings allow smokers to self-medicate with zero-nicotine vapes, which is more risky than other treatment options and is not most likely to succeed. A medical practitioner can provide advice to patients on all of the options for smoking cessation, with their comparative risks and benefits, and provide the behavioural support which is important in smoking cessation. There are a range of smoking cessation aids that have been approved by the TGA whose quality, safety and efficacy for smoking cessation has been rigorously assessed, which is not the case with vapes. The status quo also legitimises dual use of vaping and tobacco products, which can have the counteractive effect of vaping enabling smokers to continue to smoke, rather than to quit.

Health practitioners

Medical practitioners will need to continue to apply to the TGA to prescribe ‘unapproved’ therapeutic vapes through the SAS B and AP schemes and report to the TGA under these schemes. They will also need to continue to supply their SAS B and AP approvals to pharmacists before prescriptions can be dispensed.

In the absence of any TGA pre-market controls for nicotine vapes, medical practitioners would need to continue to independently review product options for the purpose of prescribing.

Pharmacists

Competition from the continued growth of illegal supply would progressively undermine the current legal supply of nicotine vapes through pharmacies.

In the absence of any TGA pre-market controls for nicotine vapes, pharmacists would need to continue to independently review product options for the purpose of stocking and supplying lawful therapeutic vapes.

Manufacturers and suppliers

Option 1 is unlikely to impose any additional regulatory cost on any of these stakeholder groups, with the domestic manufacturers of zero-nicotine vapes allowed to continue to manufacture.

Retailers selling zero-nicotine vapes, and domestic manufacturers of these products, would have the benefit that their businesses can continue to operate. Over time, increasing enforcement activity has the capacity to impact supply of illegal nicotine vapes, which may undermine the viability of some specialist vape stores who may be unable to maintain a business relying solely on (legal) sales of zero-nicotine vapes.

There would also be no new impact on manufacturers and importers supplying therapeutic vapes to the pharmacy market. However, a number of suppliers to the pharmacy market have invested significant capital in developing nicotine vapes for supply in Australian pharmacies that comply with

[86] The evidence on the harms from smoking is outlined in the Impact Analysis for Review of Tobacco Control Legislative Framework (Thematic Review) 2023Available at: https://oia.pmc.gov.au/published-impact-analyses-and-reports/review-tobacco-control-legislative-framework-thematic-review

the regulatory requirements in the TG Act. The ability for people to readily access nicotine vapes, disguised as zero-nicotine vapes, on the black market means that this investment is not being realised. In the 2022 and 2023 Consultations, suppliers to the pharmacy market indicated that the black market is impacting on the viability of them continuing to supply lawful nicotine vapes.

Analysis of the net benefit of Option 1:

Economic costs and benefits

There is a net positive impact on manufacturers and retailers that supply zero-nicotine vapes.

However, over time, the continued growth of unlawful supply would risk undermining the viability of manufacturers, prescribers and pharmacists responsible for the legal supply of vapes in Australia.

Social costs and benefits

The status quo would continue to bring social benefits in relation to consumer choice and price.

However, failure to move from the status quo would mean that, over time, more consumers, particularly youth and young adults, would take up vaping, attracted by marketing that intentionally targets youth and young adults through product features such as flavours and packaging. Allowing access to zero-nicotine vapes for non-therapeutic purposes normalises these products and counteracts messaging to youth and young adults about the harms of vaping. An increasingly larger proportion of the population of Australia will be exposed to the unquantifiable short- and long-term harms that come from vaping, even when using zero-nicotine vapes.

While vapes are unavailable to youth and young adults under the current regulatory framework, youth and young adults appear to have ready access to all kinds of vapes despite these controls. As the Generation Vape study referred to in Question 1 has found, youth and young adults are accessing vapes from friends and family, individuals selling them, retailers and online. As outlined in Question 1, this problem is expected to grow over time.

Environmental costs and benefits

Disposable vapes would remain widely available, leading to environmental damage and the need to implement expensive cost disposal mechanisms – estimated costs per device vary. In the absence of reliable information relating to vaping usage, it is not currently possible to estimate how many disposals occur per year. In any case, the scale of the current problem is obscured by inappropriate dumping of vape waste in ordinary garbage.

Net benefit

There are very few additional benefits over time resulting from no intervention, aside from potentially maintaining consistency for industry.

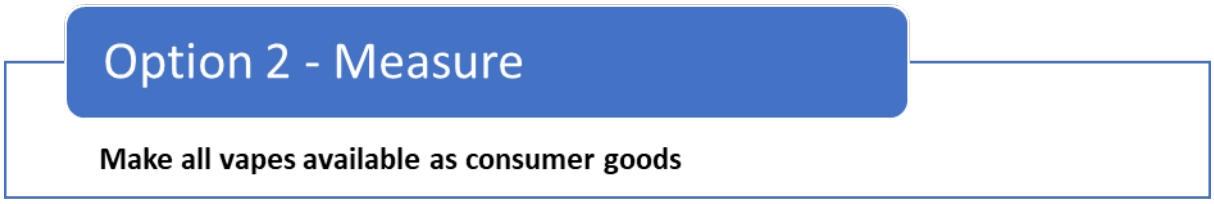
The status quo will not meet the objectives for Government action stated in Question 2 nor address the health costs of vaping. It will not arrest the future uptake of vapes, especially by youth and young adults. The trends identified under Question 1, “Increasing prevalence and attractiveness of vaping in Australia, particularly amongst youth and young adults”, will continue.

The status quo also does not adequately address the growing unlawful access to nicotine vapes. While theoretically nicotine vapes are only available to consumers with a prescription, surveys conclude that the legal supply of nicotine vapes is likely ranging between 3-12% of all nicotine vapes supplied in Australia (as outlined in Question 1). There is also anecdotal evidence that smokers buy zero-nicotine e-liquids from a retail or online store in Australia and then purchase nicotine to mix with this solution from an overseas website without a prescription.[87]

[87] Suppliers on the internet are abundant and are easy to find with a simple search in any website search engine.

It is difficult to police the requirement for a prescription for products imported for personal use through the mail. Access to nicotine products without a prescription has been exacerbated by the current regulatory settings that have allowed nicotine containing vapes to be disguised as zero-nicotine vapes. While many vapes sold in Australia are not labelled as containing nicotine, as outlined in Question 1, when tested these products are often shown to contain nicotine. This makes enforcement action difficult, as product testing is required to determine if it is a lawful or unlawful vape.

Option 2: Regulating vapes under a consumer model



Overview

Option 2 would result in vapes being available for purchase by consumers from a range of retail outlets, including supermarkets and convenience stores, provided appropriate regulatory requirements are met. There would not be a restriction on the intended use of vapes and prescription from a medical practitioner would not be required to access any form of vape.

As outlined in Question 3, this option represents a lower level of regulation than the status quo. The main regulatory requirements would be to:

- require retailers to be licensed to sell vapes
- prevent the sale of vapes to under 18s
- limit advertising of vapes
- impose quality and safety standards
- require manufacturers to submit pre-market notification.

This option would entail the repeal of the October 2021 reforms as prescriptions would no longer be required. State and territory legislation, relating to tobacco, medicines and poisons, would also require amendment. In practice, it may be difficult to achieve uniform reform in this area, leading to different regulatory practices throughout Australia.

Who is affected and what are the economic, social and environmental costs and benefits?

Consumers

Consumers would benefit through greater personal choice as to when to vape and the range of vapes used.

Consumers who wish to access vapes for smoking cessation would have easy access to a range of products for this purpose. A number of submissions to the 2022 and 2023 Consultations argued that flavour choice significantly contributes to the uptake of vaping for smoking cessation.

There would be cost savings for consumers in not being required to obtain a prescription to use vapes for smoking cessation.

Consumers would also benefit because the quality of lawful vapes would improve, with all vapes, not just nicotine vapes, subject to a minimum product standard. Quality standards on vapes have the

potential to lower some of the health risks associated with use of low quality vapes, both zero-nicotine and nicotine. As outlined in Question 1, a number of studies on vapes sampled from retailers and seized imports have shown the presence of a wide range of chemicals in vapes, including some listed on the prohibited ingredients list outlined in TGO 110. The introduction of quality standards for all vapes would have significant benefits to consumers in mitigating some health risks of vaping compared to the status quo.

However, these benefits come at the risk of even greater health impacts for individuals. A minimum product standard cannot protect consumers from the health risks of vapes. Consumers will be exposed to the known short-term risks of vaping outlined in Question 1. These include nicotine addiction, nicotine poisoning, exposure to toxins, and serious injuries and burns. Those vapers who have never smoked will be exposed to a significant risk of taking up smoking. As outlined in Question 1, vapers who have never smoked are 3 times more likely than non-vapers to take up smoking. They will also be exposed to the unknown long term health impacts of vaping that public health experts are concerned could be of a similar magnitude to those resulting from smoking.

A minimum product standard cannot provide the support that most assists smokers to quit. Use of vapes for smoking cessation without medical supervision does not provide the behavioural support and advice that is so often important in quitting. It can also result in prolonging smoking though with dual use of vapes and tobacco products. Vape use can support continued smoking because it is a cheap option to satisfy nicotine cravings in conjunction with cigarette use.

Health practitioners

Compared to the status quo, this option would remove the need for medical practitioners to prescribe vapes, and the need for vapes to be dispensed by pharmacies. Based on the costings in Annexure B, the savings to prescribers is expected to be $1.14m just for the Authorised Prescribers currently having to submit 6 monthly reports, and up to 140,000 visits to seek prescriptions per year (current users with a script). Savings for practitioners using SAS would also be achieved.

Pharmacists

While pharmacies would be able to sell vapes as consumer goods, it is difficult to see how this would be an economically viable option as consumers would be likely able to obtain a greater product range and at a cheaper price from domestic vaping retailers or online overseas retailers.

Manufacturers and suppliers

The main regulatory cost to manufacturers would be the need to change formulations to meet the quality requirements and in notifying compliant products to a regulator.

The true regulatory cost is difficult to estimate accurately without understanding the likely number of manufacturers and suppliers. The requirements imposed under a product standard would be broadly of the same kind as proposed under Option 3 for TGO 110, but with fewer limitations on flavours and somewhat less restrictive labelling packaging. For consumer products, it is expected that the cost per manufacturer would be approximately $500k per sponsor.

The notification process would be similar to that proposed under Option 3. On this basis, the regulatory impact would be similar to Measure 3 of Option 3 (calculated in Annexure B to be a one off $1,500,000 cost).

Retailers

There would be costs relating to applying for licensing and maintenance of licences but these are expected to be minor. Many retailers selling cigarettes are already required to comply with licensing requirements under tobacco regulation in most jurisdictions, though not all. There would be some additional costs in complying with licensing requirements in jurisdictions currently without those requirements.

It is possible that some retailers would come under more scrutiny to ensure supply to youth and young adults is limited and that only vapes that meet the quality requirements are supplied, but this is not considered a direct regulatory cost burden.

Analysis of the net benefit of Option 2:

Economic costs and benefits

The regulatory cost of the proposed regulatory reforms under Option 2 is substantially lower than the status quo. There is likely to be an overall regulatory cost saving due to the repeal of the October 2021 reforms. There would be cost savings to medical practitioners. Economic costs to consumers may also decrease.

There will be increased costs for manufacturers relating to introduction of product standards.

Social costs and benefits

While the uptake of vaping by youth and young adults could be counteracted by specific provisions limiting advertising of vapes, by applying products standards to limit packaging flavouring appealing to youth and young adults and through public health education, this option is highly unlikely to achieve the sought public health outcomes in Question 2. It would likely result in a continuation of the historical trend of increased vaping uptake by youth and young adults, with the attendant risk of vaping being a pathway to tobacco smoking.

The consumer model would normalise non-therapeutic vaping for adults and counteract public health messaging to youth and young adults about the harms of vapes. Nicotine vapes, which are highly addictive, would be widely available and likely easily accessible by youths despite age restrictions on sales and retailer licensing. The consumer model is, to a significant extent, the existing state and territory model for regulating zero-nicotine vapes, albeit with some enhancements. State and territory laws already prohibit the sale of vapes to youths and some jurisdictions already have licensing laws that apply to vape retailers. These measures have been proven ineffective in stemming the flow of vapes to youth and young adults and have proven ineffective at preventing retailers from selling nicotine vapes to youths.

Further, the equivalent model in place in NZ and the UK is not stemming the uptake of vaping by youth and young adults. In NZ, vaping rates of young people are continuing to rise. In 2021/22, young people aged 18–24 in New Zealand had the highest rate of daily vaping in (22.9%), up from 5.0% in 2019/20.[88] New Zealand is currently implementing further reforms to combat this trend.[89] In the UK, vaping rates among youth are continuing to rise, with a recent survey showing a sharp increase in vaping among 11 to 17 year olds from 4% in 2020, before the first COVID-19 lockdown, to 7% in 2022. As a result, the UK is reviewing the evidence about youth vaping with a view to pursing regulatory reforms.[90]

The deregulation in Option 2 would result in vapers seeking to self-medicate with vapes for smoking cessation and the treatment of nicotine addiction outside medical supervision. Further, it is likely to reduce the extent to which persons seeking to use vapes would be willing to access professional advice on the benefits, contraindications, and dangers of vapes.

[88] Ministry of Health New Zealand, 'Smoking status of daily vapers: New Zealand Health Survey 2017/18 to 2021/22,' (6 June 2023). Available at: https://www.health.govt.nz/publication/smoking-status-daily-vapers-new-zealand-health-survey-2017-18-2021-22

[89] Ministry of Health New Zealand, 'New polices will help reach Smokefree goal and address increase in youth vaping,' (6 June 2023. Available at: https://www.health.govt.nz/news-media/news-items/new-policies-will-help-reach-smokefree-goal-and-address-increase-youth-vaping

[90] Office for Health Improvement & Disparities United Kingdom, 'Youth vaping: call for evidence,' (4 October 2023). Available at: https://www.gov.uk/government/calls-for-evidence/youth-vaping-call-for-evidence/youth-vaping-call-for-evidence

It will also reduce the likelihood of the vaping industry progressively increasing standards relating to quality and safety of vapes over time. It will remove the emerging market for therapeutic nicotine vapes and essentially negate any investment made by companies in developing and bringing to market nicotine vapes that accord with the current TGO 110 specifications. There would be little or no perceived benefit for any company wishing to register vapes as therapeutic goods.

Vapes would fall outside the TG regulatory framework and therefore measures such as post-market surveillance and reporting of adverse events would rest solely in the province of the Australian Consumer Law.

Given this, the social costs from any increase in vaping far outweigh a reduction in economic and regulatory costs.

Environmental costs and benefits

As noted under Question 1, the environmental cost of vapes is high, as vaping results in a significant amount of waste and disposal is complex. These costs would increase under a consumer model, commensurate with the growth in vaping. Disposable vapes would remain widely available, leading to environmental damage and the need to implement expensive cost disposal mechanisms (estimated costs of safe disposal per device vary).

Net benefit

This option, combined with the advertising prohibitions for vapes, could conceivably provide some benefits in reducing the uptake of vaping, particularly among youth and young adults. However, this option does not address most of the problems outlined in Question 1. In particular, significant social costs outweigh any benefits from a consumer model, particularly where prevalence rates show that even the status quo is providing a youth gateway to smoking.

Option 3: Increased regulation of vapes through the Therapeutic Goods Act and Customs Regulations

Option 3 - Measures

Measure 1. Restrictions on importation, manufacture and supply of all vapes.

Measure 2. Changes to market accessibility requirements for therapeutic vapes.

Measure 3. Heightened quality and safety standards for therapeutic vapes, including better regulation of device components.

Measure 4. Strengthening import and domestic compliance and enforcement mechanisms.

This option would strengthen the regulatory amendments made as part of the 2021 reforms to tightly restrict imports and sales of nicotine and zero-nicotine vapes. Under this option, vapes would be prohibited unless they are therapeutic vapes that meet TG Act requirements. The TG Act requirements for therapeutic vapes would be strengthened, as would compliance powers. Access to therapeutic vapes would be facilitated by allowing all doctors to prescribe therapeutic vapes for smoking cessation or to treat nicotine addiction without needing to apply to the TGA for an approval.

This option represents a higher level of regulation than Option 1 (the status quo).

Who is affected and what are the economic, social and environmental costs and benefits?

Consumers

Measure 1

Measure 1 would impact consumer choice in relation to vapes as:

- consumers would cease to be able to purchase zero-nicotine vapes for non-therapeutic use
- those consumers who are using zero-nicotine vapes for smoking cessation would be required to obtain a prescription from a health practitioner to continue to access these products
- consumers would have far less choice as to vape flavours for therapeutic use, given the very large range of vape flavours currently available.

These changes would increase the costs of obtaining zero-nicotine vapes for smoking cessation. A prescription would be required from a health practitioner and the cost of purchasing regulated products through a pharmacy is likely to be greater than purchasing these products through retail outlets currently.

Legal importation of nicotine vapes would no longer be permitted via the Personal Importation Scheme using an online retail platform. However, with a valid prescription, purchase from a pharmacy would be available. The impact of this change on individual consumers would vary, with the greatest cost if consumers need to physically visit a doctor and a pharmacy to access vapes, to the least cost if both are conducted online. The need to fill the prescription monthly is also reflected in the increased cost in Annexure B, rather than receiving a 3-month supply through the Personal Importation Scheme. Closure of the Personal Importation Scheme is also likely to impact on product choice and could impact on cost.

The modelling detailed at Annexure B estimates that 450,000 additional consumers may seek a prescription under the proposed changes, equating to additional out-of-pocket costs for consumers of $42.55 (average) in FY2022–23 for a non-referred GP attendance. The number of consumers is expected to decline over time as consumers respond to public health messaging and advice from medical practitioners regarding the danger of vaping.

The prohibition on importing disposable vapes may further increase consumer costs, primarily by forcing consumers to use more expensive vapes. This prohibition is also likely to have some impact for disabled or older users, who may struggle with the greater complexities of using refillable/reusable vapes, though this could be minimised if they switched to a pod/cartridge vape rather than an open system requiring the application of a refill liquid.

There is also potential for higher costs for different groups of consumers. This cannot be quantified as it would vary depending on the location of the consumer. For example, costs would be greater for patients in ACT where bulk billing rates are lower than the national average. Other geographic areas, particularly rural areas, may have higher transport costs and/or consumer choice may be more limited.

However, consumers would also be positively impacted by this Option. The quality of lawful vapes would improve, with all vapes, not just nicotine vapes, being subject to a minimum product standard. Significantly, access arrangements under Option 3 would mean that consumers are not exposed to the significant health risks arising under the status quo as outlined above.

Measures 2 and 4

Measures 2 and 4 would not impact consumers in any direct way. The length of an appointment with a medical practitioner is unlikely to change as a result of Measure 2 (Changes to market accessibility requirements), so would be unlikely to impact on costs to consumers.

Measure 3

Compared to the status quo, the proposal to heighten TGA standards for therapeutic vapes would limit the choice of therapeutic vapes currently available to consumers, particularly to limit the flavours and nicotine concentrations available.

It is also expected that costs for consumers will increase from this regulatory reform. The nature of these costs cannot be quantified. Cost pressures include the inability to source cheaper disposable vapes, choice of vapes available that meet TGO 110, and the passing on to consumers of the cost of manufacturing a pharmaceutical grade vape.

A significant transition period for the withdrawal from sale of all non-TGO 110 compliant vapes would remove an additional regulatory cost arising from needing to purchase a new TGO 110 compliant vaping device, as consumers would most likely have needed to purchase a replacement vaping device anyway based on standard usage.

However, these changes also have health benefits for consumers.

Measure 3 - Heightened quality and safety standards for therapeutic vapes, would negate the pull factor of packaging, brand names and flavours, particularly for youth and young adults. It would also assist with combating the uptake of vaping and the consequential health risks.

A key benefit of Measure 3 is limiting the ingredients, including flavours of vapes, to mitigate the short and potential long-term health effects related to the vaporisation of ingredients. The risks associated with the inhalation of specific ingredients are largely unknown at this time and therefore this specific benefit to consumers cannot be quantified.

Reducing the maximum nicotine concentration from 100 mg/ml to a lower level has a number of benefits. It would reduce nicotine dependence and could reduce the instances of accidental poisoning through ingestion or dermal absorption, particularly among toddlers and young children.

The proposed product standard requirements for the device component will provide clear benefits for consumers by reducing the overall safety risk of operating the device, by removing or minimising design risks (such as the battery exploding), as well as user error by suitably labelling the device and providing clear instructions for use.

Most submitters to the two TGA Consultations on this issue recognised that nicotine concentrations could be significantly reduced without compromising the utility of vapes for smoking cessation. However, there is some debate amongst experts as to the appropriate level of reduction. Some recommend reducing concentrations to 20 mg/ml to align with some international regulators and because this amount should be clinically sufficient for smoking cessation. However, other experts argue that 20 mg/ml would reduce the utility of products for smoking cessation because a higher concentration would best replicate the hit of nicotine from smoking and because lower concentrations mean people will puff more and thereby inhale larger quantities of the other potentially harmful substances in vapes.

Health practitioners

Measure 1

Option 3 will bring a significant increase in the number of patients seeking a prescription for therapeutic vapes, due to stopping the illegal domestic supply of nicotine vapes, closing the Personal Importation Scheme, and prohibiting the supply of non-therapeutic vapes. As vapes are unapproved goods, currently the processes for prescribing vapes are more onerous than for registered therapeutic goods.

Measure 2

Changes to market accessibility requirements should benefit medical practitioners. However, unless reporting requirements for SAS C are changed or automated through prescribing software, the lower regulatory burden for reporting as an AP will mean that the AP pathway will likely continue to be the

most popular option for health practitioners to prescribe nicotine e-liquid. The regulatory burden in relation to becoming an AP will not change. Health practitioners currently prescribing under the SAS B pathway will simply switch to SAS C.

The publication of a compiled list of notified vapes will likely reduce the existing regulatory cost for health practitioners in ascertaining what products can be lawfully supplied and increase confidence in prescribing.

Measure 3

The heightened requirements around the quality and safety of vapes will have no direct regulatory impact on health practitioners. Some health practitioners may have greater confidence in prescribing unapproved vapes if the standards are increased, combined with the proposal to require notification to the TGA of compliance under Measure 2.

Pharmacists

Option 3 will bring a significant increase in the quantity of vapes purchased directly from domestic pharmacies, due to closing the illegal domestic supply of nicotine vapes and the Personal Importation Scheme for vapes, and the prohibition on the supply of non-therapeutic vapes.

In the absence of any TGA pre-market controls for nicotine vapes, pharmacists would need to continue to independently review product options for the purpose of stocking and supplying lawful therapeutic vapes.

There would be no additional cost associated with the need to dispose of non-compliant stock due to improved quality standards, as the transition period until TGO 110 commences will ensure time for pharmacies to turnover stock.

Manufacturers and suppliers

Measure 1 – those supplying to the pharmacy market

Option 3 would strengthen the economic viability of those manufacturing and supplying to the pharmacy market by reducing access of consumers to nicotine vapes outsides pharmacies.

Importers would require a licence and permit (issued by the ODC) to import any vapes into Australia, which will be an additional regulatory burden. The estimated number of sponsors who would seek to provide a therapeutic vape that accords with the revised TGO 110 specifications is estimated to be no more than five. Therefore, the overall regulatory burden in complying with import and permit requirements is estimated to be $2,362.36 per year.

There would be no additional cost associated with the need to dispose of non-compliant stock due to improved quality standards, as the transition period until TGO 110 commences will ensure time to turnover stock.

Measure 1 – those supplying to the retail market

The impact on this sector will be substantial. It is likely that there would be no legal market for domestic manufactured zero-nicotine e-liquids unless they could be reformulated as therapeutic goods. Manufacturers of these products (approximately 7 Australian manufacturers) could exit the market.

Depending on stock levels and transition times, some manufacturers and suppliers may need to dispose of non-compliant stock. However, this cost would be mitigated by the length of time between the Minister for Health and Aged Care's announcement of the proposal to pursue reforms on 2 May 2023 and implementation of the domestic ban. This period will be at least 12 months and should allow retailers and suppliers to run down their stocks.

Measure 2

The regulatory cost for manufacturers from notification requirements will be minimal and largely upfront, as notification of conformance with TGO 110 will be required for each different formulation in their product range. New notifications are only needed if the product range changes. This notification process is very simple to complete so the overall cost is minimal (as summarised in Annexure B).

Measure 3

The greater cost is associated with meeting TGO 110 and holding the data to demonstrate batch-specific compliance with TGO 110. Compliance costs for manufacturers are likely to be substantial, but the degree will vary greatly between companies. As outlined in Annexure B, based on the range of figures identified by likely sponsors in relation to the 2023 Consultation, this cost would be approximately $1.5m per sponsor (but there is a high degree of uncertainty about the accuracy of this costing due to the very limited data on which it is based).

The main risks to be balanced are the ability for manufacturers to absorb this cost, timeframes to meet the requirements, and the willingness to manufacture an Australian-specific vape. If all manufacturers considered the requirements to be too high, then the risk would be an absence of legal supply of vapes in Australia. To mitigate this risk a transition period will be observed and, where possible, the requirements will be aligned with the those in similar jurisdictions, including the UK, EU, Canada and NZ.

However, it is likely that there will be bespoke Australian requirements, including in relation to ingredients and packaging. Specific feedback was sought in the consultation on these risks and costs, but the actual risk of manufacturers leaving the market is considered low, as none exhibited an unwillingness to meet the requirements.

Measure 4

Manufacturers and suppliers who meet regulatory requirements would not be affected by Measure 4.

Retailers

The impact on retailers from restrictions on the importation and supply of non-therapeutic vapes will be significant in some cases. However, this is dependent on the extent of their product line and associated revenue provided by vapes.

As the sale of zero-nicotine vapes is generally legal it has been included in the costing impact. However, income or store viability dependent on the sale of nicotine vapes illegally is not included in the cost to retailers.

Speciality vaping stores will most likely close, as their income is exclusively funded from sale of vapes. There are estimated to be 205 specialist vape stores and it is expected that all will likely close. It is estimated that each business averaging 2–3 staff has various levels of investment in retail fixtures, development of an online marketplace, and long-term property leases. It is estimated that this equates to a financial loss of approximately $500,000 per vape specialist store. This is loosely based on cost impacts provided from vape stores in response to the 2023 Consultation.

Transition times will be crucial to minimise cost impact, by allowing most stock to be sold and minimise write offs. It would also be mitigated by the length of time between the announcement of the proposal to pursue reforms by the Minister for Health and Aged on 2 May 2023 and the likely implementation of these restrictions.

For tobacconists, revenue from the sale of vapes is likely to be a small proportion of their business compared to tobacco, so tobacconists would remain viable. The lowest impact is on convenience stores, for which sales of vapes would only make a very small proportion of their business.

The cost on retailers is acknowledged but not further quantified in Annexure B due to insufficient knowledge. Despite specifically seeking feedback from suppliers on the impact of the changes to their

businesses in the 2023 consultation, insufficient data was provided to assist accurate quantification of the impact.

Measure 2 would have no impact on vape retailers as opposed to pharmacies, due to changes in market accessibility requirements, as this measure relates specifically to the selling of therapeutic vapes through pharmacies.

There would be no direct regulatory cost on retailers due to improving quality standard for unapproved vapes.

Similarly, retailers who meet regulatory requirements would not be affected by strengthening import and domestic compliance and enforcement mechanism. However, there would be a direct impact of the compliance and enforcement mechanisms on current and future vape retailers who disregard the other measures detailed in this option.

Analysis of the net benefit of Option 3:

Economic and regulatory costs and benefits

This option will likely result in regulatory burden costs, as outlined in Annexure B, particularly for manufacturers and suppliers who are seeking to achieve compliance with the proposed requirements in TGO 110.

In addition, the implementation of this option will completely shut down the retail vaping sector in Australia, with the consequent economic loss for those who have invested in this sector, as well as associated job losses.

A significant regulatory cost of this option would be on manufacturers in complying with increased quality requirements under Measure 3, but most companies supplying through pharmacies at present seem prepared to meet these costs and supply vapes that comply with the increased quality requirements under this option. If the manufacturers are able to meet this significantly higher bar for product quality and safety, then significant benefits will be realised, such as increased confidence in prescribing and use, with fewer ingredients likely to cause adverse health outcomes.

Measure 4 – Strengthen import and domestic compliance and enforcement mechanisms, will facilitate effective enforcement of the regulatory reforms, including greater efficiency in enforcement activities and co-operation between Commonwealth, state and territory enforcement officials. Effective enforcement is key to achieving the anticipated health benefits of the reforms.

By enabling state and territory officials to exercise compliance and enforcement power and functions, more officials who are already distributed across the nation will be available to take appropriate action when unlawful activity in relation to vapes is suspected or detected. It will also lower the complexity in determining the appropriate officials with jurisdiction to take action and arrangements for multi-agency enforcement operations. This will increase overall efficiency in removing unlawful vapes from the supply chain.

The expansion of the existing regulation making power in relation to laboratory testing will remove gaps in the TGA laboratories being able to comprehensively test all vapes that fall under the new regime.

Social costs and benefits

This option will produce significant health outcomes and at a relatively low cost when compared to the overall impact of smoking and vaping-related conditions on both individuals and public health expenditure.

Measure 1 would remove from the market disposable devices, which the evidence suggests are particularly attractive to youth because of their very low cost and ease of concealment from parental or teacher detection (see Question 1). The restrictions on prohibition of the importation of all e-liquid, regardless of nicotine content, would remove the need for regulators to determine whether a product

contains nicotine, noting that evasion tactics would remain a concern. The implementation of a licensing and permit system would provide greater visibility and control of quantity and type of vapes imported and make unlawful vapes easier to detect.

It would also cut off a source of the supply of unlawful nicotine vapes and strengthen the economic viability of the market for regulated nicotine vapes by reducing consumer access to nicotine vapes outside of pharmacies.

Closing off the Personal Importation Scheme for vapes would remove a suspected source of black market vapes and address concerns that vapes imported by this means may not comply with any standards – noting that the preservation of the travellers' exemption will still allow the importation for personal use of a limited quantity of vapes. Advertising prohibitions on vapes will reduce their attractiveness to youth and young adults, noting that legal non-therapeutic use of vapes (for 18-year-olds and over) would be removed.

The requirement in Measure 2 for sponsors to notify the TGA, and hold evidence, of compliance with the relevant standard (TGO 110) may increase the confidence of some medical practitioners. This may assist them in prescribing vapes for smoking cessation and treatment of nicotine addiction purposes by strengthening compliance against the relevant product standard (TGO 110 as modified) and requiring sponsors to notify the TGA, and hold evidence, of compliance with the relevant standard (TGO 110). Further, enabling the SAS C pathway will decrease the administrative burden for prescribers compared to SAS B, albeit the AP pathway may remain the most popular pathway for prescribing vapes unless changes are made to reporting obligations or reporting obligations can be automated.

Measure 3 would directly target the attractiveness of vaping to youth and young adults for non-therapeutic purposes by prohibiting use of most colour and images designed to appeal to youth and by excluding fruit and other youth-attractive flavours. Measure 3 would result in overall improved health outcomes for all vapers due to the restriction of the number of ingredients (including flavours), some of which contain known harmful chemicals and whose long-term health impacts are unknown, as well as reducing the nicotine concentration. Health outcomes would also be improved by the introduction of safety and quality requirements for a greater range of vaping devices, which would specifically reduce the risk of product malfunction either by design fault or user error.

Environmental costs and benefits

There is the potential for significant environmental and disposal costs of vapes for manufacturers, retailers and suppliers (including wholesalers) relating to existing stocks of:

- therapeutic vapes and vaping devices being supplied to the pharmacy market which meet current regulatory requirements but will not meet the new product standards. This would be mitigated through a transition period of 6–12 months to allow selling down of these stocks.
- non-therapeutic vapes and non-therapeutic devices. This would be mitigated by the advance warning the industry has had of the proposed reforms, which should be at least 12 months by the time they would be implemented.

Net benefit

Each of the regulatory measures proposed in this option targets existing weaknesses in the regulatory framework introduced in 2021, which is not meeting its intended objectives. The regulatory burden under this option is significantly higher than the status quo but each of the measures alone has a clear cost benefit, and they collectively represent the highest benefit option.

Option 3 will address many of the underlying concerns about the population wide health risks of vaping, particularly for youth and young adults. This option targets existing weaknesses in the current regulatory framework that are enabling widespread access to vapes by the youth and for non-therapeutic purposes.

Substantial health benefits flow from preventing vape use in susceptible groups under Measure 1 – Restrict importation, manufacturing and supply of all vapes. These outweigh the economic costs to

the main impacted stakeholders, consumers and specific vape retailers. In the 2023 Consultation on these reforms, there was very strong support for these measures and clear benefits highlighted by Government agencies, health professional peak bodies, public health organisations and university research groups, who noted the positive impact these reforms would have on communities in curbing the illegal trade in nicotine vapes.

Measure 2 – Change market accessibility requirements for therapeutic vapes, is designed to complement Measure 1 by requiring manufacturers and importers to notify compliance with TGA standards prior to introducing a therapeutic vape to the Australian market. It will also make access through the legal pathway more attractive, particularly by streamlining the SAS and AP schemes to remove some of the burden on prescribers.

The regulatory cost of Measure 2 on stakeholders is minimal, but there are significant benefits in streamlining appropriate access to vapes through medical practitioners and introducing a level of responsibility on manufacturers to declare compliance with TGA standards. The notification scheme would also increase the level of transparency and assurance to consumers and prescribers of the quality and safety of prescribed vapes. For example, benefits of this regulatory measure would include:

- reducing the 'duty of care' checking undertaken by prescribers, wholesalers and pharmacists to determine if particular vapes can be lawfully supplied, as the TGA would provide a published list of vapes that are registered or that sponsors have declared meet the requirements outlined in TGA standards
- increasing the confidence of consumers and prescribers in the safety and quality of vapes, although it is recognised that some prescribers and consumers will never have confidence in unregistered products.

The health benefit of Measure 3 – Heightened quality and safety standards for therapeutic vapes, including better regulation of device components, is significant as it ensures that only vapes of a certain quality are supplied. This public health benefit would outweigh the cost to consumers of any price increases and reduction of choice, and the cost to manufacturers to meet these standards.

The regulatory costs to legitimate industry are minimal for changes under Measure 4 – Strengthening import and domestic compliance and enforcement mechanisms, but the benefit to achieving the intention of the reform measures and anticipated health benefits can be realised.

The overall annual regulatory cost of this option is estimated to be $59.46m (plus costs on vaping store closure). The benefits of quitting smoking were quantified in the recently published IA on the review of the Tobacco Control Legislative Framework.[91] The proportion of the 1.3 million Australian adult vapers who are never smokers cannot be determined at this time. However, the estimated regulatory burden of $59.46m for Option 3 would be justified if approximately 200 individuals never progressed to tobacco smoking by not taking up vaping in the first place/or by ceasing vaping before they started tobacco smoking. This figure (n=200) represents only 0.015% of the current population of Australian vapers (n=1.3m). Given this very low target there is a high likelihood that the benefits would outweigh the costs for this option.

[91] Department of the Prime Minister and Cabinet, 'Review of Tobacco Control Legislative Framework (Thematic Review) 2023,' (18 September 2023). Available at: https://oia.pmc.gov.au/published-impact-analyses-and-reports/review-tobacco-control-legislative-framework-thematic-reviewhttps://oia.pmc.gov.au/published-impact-analyses-and-reports/review-tobacco-control-legislative-framework-thematic-review

Option 4: Ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods, and not available as 'unapproved' therapeutic goods

Option 4 - Measure

Ban non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods, and not available as 'unapproved' therapeutic goods.

Overview

This option imposes a higher level of regulation for vapes than Option 3. As with Option 3, it would involve banning all non-therapeutic vapes, but would add a requirement for all vapes to be registered on the ARTG to be lawfully supplied in Australia. Only vapes that have been reviewed by TGA for quality, safety, and efficacy/performance can be included on the ARTG.

This option would meet the Government's objectives in a similar way to Option 3. The crucial difference is that it would far better safeguard consumer health, increase confidence of users and prescribers, and minimise the short-term and long-term adverse health effects of vapes.

However, this option would come with the practical effect to ban all vapes until a product is registered. This in turn risks losing the opportunity of reducing the risk of future tobacco use by threatening the availability of vapes for smoking cessation where clinically appropriate.

Who is affected and what are the economic, social and environmental costs and benefits?

Consumers

Option 4 has a very high level of public and individual health benefit compared to the status quo, as vapes would have been reviewed for quality, safety and efficacy/performance to the same level as any other approved therapeutic good. This would remove any doubt about the suitability for the intended clinical use and ensure the risk-benefit of the quality and safety of ingredients in the vape and components of the vape have been considered.

However, implementing this option in the short term would effectively result in a total ban on all vapes. There are currently no vapes on the ARTG and this option would prevent consumers using vapes as a tool for smoking cessation or any other purpose until such time as a product is added to the ARTG.

The price of vapes would also likely increase substantially, as the cost to manufacturers of seeking TGA approval are likely to be passed on. These costs are delayed until a vape is included on the register. Detailed costing is outlined in Annexure B but is expected to be $52.1m.

Health practitioners

Manufacturing vapes in accordance with strict standards in line with other approved therapeutic goods would remove concerns of health practitioners about prescribing them as regulated therapeutic goods. Likewise, any patient concerns about the quality, safety and efficacy of vapes would be greatly reduced.

Option 4 would remove any existing and future regulatory burden for health practitioners in complying with the requirements for AP and SAS prescription pathways for nicotine vapes, so there would be a reduction in costs over the status quo.

Pharmacists

There would be an increased number of consumers needing to seek a prescription and fill it through pharmacies. While this cost is already borne under the status quo in relation to nicotine vapes, it will be a new cost in relation to zero-nicotine vapes.

Detailed costing is outlined in Annexure B but is expected to be less than $6.57m.

Manufacturers and suppliers

The overall cost in obtaining full ARTG registration cannot be accurately quantified at this stage.

The regulatory costs will be higher than the status quo and include additional expenses imposed on manufacturers due to the need to seek TGA certification of all manufacturing sited to Good Manufacturing Practice (GMP) standards and generation of data (including through clinical trials) to support an application for ARTG registration.

Retailers

The impact on retailers selling will be significant with specialty vape retailers likely to close. It is estimated that the loss of sales of zero-nicotine vapes, and devices would equate to a financial loss of approximately $500,000 per vape specialist store.

Analysis of the net benefit of Option 4:

Economic and regulatory costs and benefits

There are currently no vapes registered on the ARTG. Implementing Option 4 would, in the short term, effectively result in a total ban on all vapes. The estimated cost would be the value of the lawful vape market.

Once a sponsor achieves ARTG registration they would receive an immediate market benefit as they would be the sole supplier of therapeutic vapes in Australia, which would effectively allow them to set the price. Therapeutic vapes are not likely, at least in the short term, to be subjected to the price control measures of the Pharmaceutical Benefits Scheme. This market monopoly would encourage other sponsors to enter the market (given the initial size of the market is estimated to be 520,000 individuals) but there might be additional delays in doing so.

In the meantime, the complete loss of the legal market for those sponsors who complied with the existing TGO 110 specifications and have indicated a willingness to meet the proposed revised specifications, would remove any related incomes streams, potentially resulting in them exiting the market as it is no longer economically viable. This factor would most likely result in further delays for a vapes achieving ARTG registration.

As comparable overseas regulators, and hence the markets serviced by likely international manufacturers, mostly regulate vapes as a consumer rather than a therapeutic good, any potential supplier is unlikely to be able to leverage previous clinical trials to demonstrate the safety and efficacy/performance of therapeutic vapes. They will therefore need to incur this cost largely to supply to the Australian market, although it may also assist to enter other markets which allow for vapes to be supplied as medicines, such as the UK.

The regulatory costs for the TGA in assessing and approving registered goods form part of the normal costs of business for the TGA. Internal compliance processes at the TGA would be simplified from the status quo as TGA would no longer be operating a parallel regulatory framework for vapes as unapproved goods by imposing quality standards through TGO 110.

Social costs and benefits

Option 4 is the most desirable option from a long-term population health perspective as vapes would only be available for therapeutic purpose where they had been assessed by the TGA for quality, safety and efficacy/performance. It would also require vapes to be manufactured in accordance with strict manufacturing standards. Having approved vapes on the ARTG removes concerns health practitioners currently have about prescribing vapes as unapproved medicines.

Likewise, any patient concerns about the quality, safety and efficacy of vapes would be greatly reduced, although it should be noted that any such concerns have failed to curtail the exponential growth of vaping in Australia under the status quo.

Environmental costs and benefits

All vapes being lawfully imported, manufactured or supplied in Australia would become unlawful and would require disposal. Depending on timing, including the length of any transition periods, there is the potential for significant environmental and disposal costs.

Net benefit

In order to be approved by TGA and placed on the ARTG, the health benefits arising from the use of vapes for smoking cessation and treatment of nicotine addiction must have been established and the full health benefits of this option can be realised.

However, implementing this option in the short term would effectively result in a total ban on all vapes as there are currently no vapes on the ARTG. There is interest by manufacturers to seek registration of vapes, but they have indicated that it might takes years, or may not be possible at all, to gather the necessary clinical evidence to support ARTG entry. In the meantime, there will be no legal mechanism for vapes to be accessed for therapeutic purposes and those seeking treatment for smoking cessation or nicotine addition will be dependent on existing behavioural and pharmacological products, such as NRT.

As a consequence, compared to the status quo, this option also has the greatest potential to incentivise the growth of the black market. Until a vape is registered on the ARTG, there will be no legal pathway to obtain a vape in Australia, with the exception of bringing relatively small volumes into Australia from overseas for personal use under the Traveller's Exemption. This aspect would likely increase the noted safety and health risks associated with the use of nicotine vapes that are completely non-regulated by the TGA.

The overall annual regulatory cost of this option is estimated to be $59.87m (plus costs on vaping store closure). The benefits of quitting smoking were quantified in the recently published IA on the review of the Tobacco Control Legislative Framework.[92] The proportion of the 1.3 million Australian adult vapers who are never smokers cannot be determined at this time. However, at an estimated regulatory burden of $59.87m for Option 4 would be justified if approximately 200 individuals never progressed to tobacco smoking by not taking up vaping in the first place/or by ceasing vaping before they started tobacco smoking. This figure (n=200) represents only 0.015% of the current population of Australian vapers (n=1.3m). Given this very low target there is a high likelihood that the benefits would outweigh the costs for this option.

[92] Department of the Prime Minister and Cabinet, 'Review of Tobacco Control Legislative Framework (Thematic Review) 2023,' (18 September 2023). Available at: https://oia.pmc.gov.au/published-impact-analyses-and-reports/review-tobacco-control-legislative-framework-thematic-reviewhttps://oia.pmc.gov.au/published-impact-analyses-and-reports/review-tobacco-control-legislative-framework-thematic-review

Question Five: Who did you consult with and how did you incorporate their feedback?

Consultations

In the last 12 months, the TGA has conducted 2 significant consultations on the potential reforms to the regulation of vapes. The first consultation, conducted between 30 November 2022 and 16 January 2023, was a public consultation on proposed reforms to nicotine vaping products (2022 Consultation).

In May 2023, based on the feedback from the 2022 Consultation and advice provided by public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the Minister for Health and Aged Care announced, subject to consultation with the states and territories and other stakeholders, an intention to strengthen the regulation of all vapes and ban the import and supply of non-therapeutic vapes.[93]

The TGA engaged in extensive discussions with the states and territories between June and August 2023 to assess the regulatory options and develop policy proposals. A second, targeted consultation, was undertaken with stakeholders between 7 September 2023 and 21 September 2023 (2023 Consultation) to consult on the proposals developed in consultation with states and territories.

In addition to the 2 formal consultation processes, the TGA has had, and continues to have, meetings with key stakeholders concerning the proposed regulatory reforms.

A summary of the 2022 and 2023 Consultations is outlined below.

2022 Consultation

On 30 November 2022, the TGA released a public consultation paper titled '*Potential reforms to the regulation of nicotine vaping products*' (the 2022 consultation paper), with the submission period closing on 16 January 2023.

The 2022 Consultation covered four reform options:

Reform option 1 – Border controls

Reform option 2 – Pre-market TGA assessment of nicotine vaping products (NVPs)

Reform option 3 – Minimum quality and safety standards for NVPs

Reform option 4 – Clarifying the status of NVPs as 'therapeutic goods'

The TGA received almost 4,000 submissions in response to the consultation. Respondents included:

- state and territory health and education departments
- health professional bodies
- public health associations
- university researchers
- pharmaceutical industry and peak bodies
- vaping manufacturers and importers
- vaping retailers, including convenience stores and petrol stations

[93] Minister for Health and Aged Care, 'Taking action on smoking and vaping' (2 May 2023), Australian Government. Available at: https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping

- pro-vaping associations
- individual healthcare professionals
- the general public, including individual vapers, smokers, and ex-smokers.

Of the almost 4,000 submissions, just under 100 came from state and territory government health and education departments, health care professional peak bodies, industry peak bodies and academics and advocacy groups involved in smoking harm reduction. Many of the general public submissions appeared to be campaign responses that advocated changing the current regulatory framework in which nicotine vapes are regulated as prescription medicines, which had been established in 2021 and was outside the scope of the consultation.

A thematic summary of the matters raised in the submissions for each reform option is outlined below.

1. Changes to border controls

The 2022 consultation paper proposed strengthening border controls by requiring importers to obtain an import permit and by closing off the Personal Importation Scheme.

All state and territory governments supported tightening border controls for nicotine vapes, with most also supporting closing the Personal Importation Scheme and requiring import permits. Health professional bodies, public health associations, individual health professionals, university researchers and companies marketing prescription nicotine vapes to Australian pharmacies showed overwhelming support for tightening border controls for nicotine vapes. Many, but not all, of these groups also submitted that border controls should be placed on zero-nicotine vapes, a suggestion that went further than the proposed options in the consultation paper. These groups submitted that stronger regulation of all vapes was required because of the known and unknown health risks of use, including the evidence that vaping can lead to smoking uptake. They were supportive of TGA-regulated vapes being available to assist with smoking cessation, but only under medical supervision. This feedback supported consideration of Options 3 and 4 (in the reforms proposed in the 2023 consultation), in which registration vapes are regulated as therapeutic goods, through registration on the ARTG or other regulatory controls.

By contrast, individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations did not generally support any import controls. These groups generally submitted that vapes should be regulated as consumer goods and available for supply in retail outlets. Common reasons advanced to support this view were that the prescription model is failing and creating a black market, restricts access to vapes for people who need then for smoking cessation, and interferes with personal liberty. These groups also generally considered that adequate regulatory controls could be imposed under a consumer model by, for example, preventing sales to youth, licensing retailers, and imposing a quality standard. This feedback supported consideration of Option 2, in which vapes are regulated through a consumer model.

2. Pre-market Therapeutic Goods Administration assessment of nicotine e-liquids against a product standard

The 2022 consultation paper proposed requiring pre-market TGA assessment of nicotine vapes against a product standard specifying certain quality and safety requirements. Companies supplying to the prescription pharmacy market supported this approach, as did about half of the state and territory governments, half of health professional bodies and nearly half of individual health professionals.

Nearly half of public health associations and health professional bodies proposed instead that all nicotine vapes should be registered in the ARTG and opposed any pre-market assessment mechanism as they were concerned it could be misinterpreted as TGA approval. This feedback supported consideration of Option 4, in which registration on the ARTG should be the only legitimate pathway to supply therapeutic vapes.

Many individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations supported at least some regulation to ensure nicotine vaping products' safety and quality but with nicotine vapes regulated as consumer goods, instead of as prescription medicines. This feedback also helped to inform consideration of Option 2 above to assess the risks and benefits of the consumer regulatory model. This led to further consideration of international developments, including in jurisdictions where the consumer model has been adopted in its various incarnations, to assess the appropriateness of this approach in resolving the vaping problem.

3. Strengthening quality standards for nicotine e-liquids

The 2022 consultation paper proposed strengthening TGO 110 to introduce warning statements, require pharmaceutical-like packaging, lower the maximum allowable nicotine concentrations, prohibit/restrict flavours and certain other ingredients, and limit nicotine vape volume and overall nicotine content. There was strong support for these proposed regulatory changes from state and territory governments, health professional bodies, individual health professionals, public health associations and university researchers. Many of these submissions also called for the imposition of similar controls on zero-nicotine vapes, which was outside the scope of the consultation.

Many individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations proposed abandoning the prescription model and regulation through TGO 110, which was also outside the scope of the consultation. Regardless, many in this category supported some regulation to ensure nicotine vapes quality and safety. There was significant support for import restrictions on disposable vapes from all categories of submitters, including individual vapers, but some opposed this due to concerns that such restrictions could affect accessibility for smoking cessation and because of the risks of using some alternative products.

4. Clarifying the status of nicotine vaping products as 'therapeutic goods'

The 2022 consultation paper discussed concerns in relation to the increasing practice of concealing the presence of nicotine in what are purported to be NVPs. On this basis, it was proposed to utilise the power in section 7 of the TG Act to clarify the regulatory status of vapes. On the proposal to clarify that all vaping products containing nicotine are therapeutic goods, there was general support for from all categories of submitters except individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations.

This feedback was carefully analysed in early 2023 and used to advise the Commonwealth Minister for Health and Aged Care about the policy options available. It was also discussed with state and territory officials in assessing the various policy options. It informed the preliminary announcement made by the Minister for Health and Aged Care on 2 May 2023 that, subject to further consultation, the Australian Government intended to take stronger action in relation to all vapes. It was also used to expand the policy options being considered to address the vaping problem, identify the impacts of different options on different stakeholder groups and assess the viability of options. The 2022 Consultation feedback was also used to refine proposals for further consultation and to identify issues that required further consideration in the policy development process. This included developing a notification scheme, the risks of the device components of vapes, the impact of the prescription model on doctors, management of the waste associated with vapes, necessary transition times for specific measures, and maintaining a viable supply of products for smoking cessation.

2023 Consultation

On 7 September 2023, the TGA released the consultation paper titled '*Proposed reforms to the regulation of vapes*' (the 2023 consultation paper) for targeted consultation, with the submission period closing on 21 September 2023.

The stakeholder groups targeted in the consultation were:

- government organisations
- consumer organisations and school related groups
- retailers
- retail associations
- vape importers/manufacturers/wholesalers/distributors
- health professional peak bodies
- public health peak bodies
- university researchers, including public health experts.

These groups were selected for these specific reasons:

- To obtain information from people who would be affected by the proposed restrictions on all vapes that were not consulted on as part of the 2022 Consultation, specifically consumer groups and school related groups, vaping retailers, vaping importers/manufacturers/ wholesalers/distributors and retail associations).
- The need to obtain information from people who would be affected by proposed refinements to TGA regulatory controls (specifically vaping importers/manufacturers/wholesalers/ distributors and health professional organisations).
- The need to obtain expert advice on measures from public health experts.

The consultation list was compiled from responses to the 2022 Consultation, complemented by stakeholder lists maintained by the TGA.

The purpose of the 2023 Consultation was to seek views from targeted stakeholders. This included matters not covered by the 2022 Consultation being:

- proposed restrictions on the importation and supply of non-prescription vapes
- a pre-market notification scheme, being a streamlined SAS and AP to address concerns about access to prescriptions
- modifications to quality and safety requirements for therapeutic vapes.

As such, it was intended to inform the assessment of the appropriate policy response to the vaping problem, including by understanding the specific impacts on particular groups.

The 2023 Consultation outlined 4 proposals:

Proposal 1 – Restrictions on importation, manufacture and supply of all vapes, other than therapeutic vapes.

Proposal 2 – Changes to market accessibility requirements for therapeutic vapes.

Proposal 3 – Heightened quality and safety standards for therapeutic vapes.

Proposal 4 – Strengthening domestic compliance and enforcement mechanisms.

Reform Option 4 from the 2022 Consultation, clarifying the status of NVPs as therapeutic goods, was not revisited as part of the 2023 Consultation. This reform option was no longer necessary because of the proposed reforms to regulate all vapes, irrespective of nicotine content.

Stakeholder feedback during the 2023 Consultation

The consultation received 289 responses, including submissions from the following stakeholder groups:

- 20 government agencies, including state and territory health and education departments

- 19 consumer groups and associations
- 11 health professional peak bodies
- 37 peak public health organisations
- 5 school related groups
- 19 with expertise and interests in smoking and effects of nicotine
- 3 pharmaceutical industry participants (not solely trading in vapes)
- 4 pharmacy wholesaler stakeholders
- 16 advocacy groups, from a range who self-identified as public health organisations, vape suppliers and education sector, and unsolicited submitters
- 5 vape importers
- 9 vape manufacturers
- 20 vape stores- retail outlets specialising in the selling of vapes
- 1 other retailer- tobacco and convenience stores and chains that sell vapes
- 120 ‘others’, consisting mainly of vape consumers (users).

Two late responses were received from one government agency and one health professional peak body. Due to time constraints, these were not included in the analysis outlined in the IA, but will be published on the TGA website.

The 120 responses from the ‘Other’ group were unsolicited by the TGA, coming from persons or bodies who were not directly the target of the consultation. The majority of these responses were from vape consumers. The views of consumers were specifically sought and comprehensively analysed under the 2022 Consultation, in questions specifically designed to elicit consumer responses. By comparison, the 2023 Consultation was designed to address specific areas of regulation which formed part of the Minister’s announcement on 2 May 2023, and which have been included in Option 3 (see Question 3 above).

Views raised by the ‘Other’ group in 2023 broadly reflected the views obtained through the 2022 Consultation, with strong opposition to the proposed reforms, concerns that the reforms would increase the black market, and concerns that the reforms would be counterproductive to those seeking to quit smoking. The ‘Other’ group also expressed views that while the local vape industry would cease, pharmaceutical and tobacco companies would benefit, resulting in an increase in costs and a reduction in consumer choice.

It should be noted that for some questions the feedback received from particular stakeholder groups was either not provided or was inadequate. For example, the TGA sought feedback around total sales and size of the current lawful market, but only 6 responses were received in relation to this particular issue. This has made data compilation and analysis difficult because it was not possible to develop information that would provide reliable estimates for further consideration in the development of policy options. There may be several reasons why this information was not disclosed to the TGA, including that the information was commercially sensitive, that it was not readily available, or that the data relates to, or cannot be separated from, sales of vapes that do not comply with the current regulatory requirements.

Proposal 1 – Restrictions on importation, manufacture and supply of all vapes, other than therapeutic vapes

The 2023 consultation paper sought feedback from stakeholders, including whether they supported a ban on the importation, manufacture, and supply of all vapes (excluding therapeutic vapes), removal of the Personal Importation Scheme exception, retention of the traveller’s exemption, and the prohibition of advertising in line with restrictions on advertising prescription medicines. The 2023

consultations also sought stakeholder views on how they anticipate industry and consumers would respond to implementation of the measures.

Banning vapes (other than therapeutic vapes)

Government agencies, health professional peak bodies, public health organisations and academic experts and vape manufacturers/importers supplying to the pharmacy market were all, or nearly all, in favour of the proposed ban on the manufacture, import and supply of disposable and non-therapeutic vapes, citing the positive impact this will have on communities and noting it would assist enforcement to curb the illegal trade.

Vape retailers and importers not part of the pharmacy supply chain strongly opposed the ban (90%), but some could see a point in banning disposables but not non-therapeutic vapes. This group argued it would lead to increase in black market sales and would be counterproductive for smoking cessation initiatives.

Consumer groups and associations expressed limited support for the proposal. Some youth welfare groups mistook this proposal as involving the criminalisation of the use of vapes, arguing it would be detrimental to the wellbeing of youth to be penalised for vape use. The ‘Others’ group, consisting mostly of consumers, were nearly 100% against the proposed ban.

Removing vapes from the Personal Importation Scheme

Government agencies, health professional peak bodies and public health organisations strongly supported (90 to 100%) the proposal to remove the Personal Importation Scheme, arguing that it is prone to abuse and allows unregulated product to enter the market. Academic experts and vape manufactures/importers supplying to the pharmacy market expressed mixed support (60-68%) for the removal of Personal Importation Scheme, while vape retailers and importers not part of the pharmacy supply chain were unsupportive of the removal of Personal Importation Scheme (nearly 75% opposing). Consumer groups and the 'Others’ group, mostly consisting of vape users, were also strongly against removal of Personal Importation Scheme, arguing that it will restrict personal choice and make it difficult for consumers to access vapes, especially in rural settings.

Retaining the traveller’s exemption

Government agencies, health professional peak bodies, public health organisations and academic experts expressed strong support (around 90%) for retaining the traveller’s exemption, although they raised concerns that the quantity proposed was too generous. They also sought further information on the kind of vapes that would be permitted under the exemption. All other major stakeholder groups showed support for retaining the traveller’s exemption, except vape retailers, manufacturers and importers, who were predominantly against retaining the traveller’s exemption.

***Restriction*s on advertising**

The majority of respondents (>60%) across all stakeholder groups supported the proposed restrictions on the advertisement of vapes. This included suggestions for a ban on all direct advertising to customers and restricting advertising or promotional activities directed to healthcare providers. Concerns were raised that the vaping industry may use corrupt practices to influence the use of vapes while promoting products to prescribers. Further concerns were raised that social media advertisements might use predatory practices to target young users. Stakeholders felt these should be the focus of enforcement agencies.

Proposal 2 - Changes to market accessibility requirements for therapeutic vapes

The 2023 consultation paper discussed the following proposed regulatory controls:

- Pre-market notification of compliance with TGO 110

- Streamlined access under the Special Access Scheme (SAS) and AP scheme.

Pre-market notification

Out of government agencies, health professional peak bodies and public health organisations, only one respondent was against the proposed pre-market notification program. Strong support (90-100%) was also received from academic experts and vape manufacturers/importers supplying to the pharmacy market. However, strong opposition was received from vape retailers and importers not part of the pharmacy supply chain (<25% in favour). Those from the 'Others' group, mostly consisting of vape users, were strongly against the proposal with more than 70% responding negatively. Although there was significant support for the proposal, some concerns were raised regarding the possibility of notified vapes being misinterpreted or misrepresented as products endorsed by the TGA. These stakeholders recommended severe penalty measures to stop such misinformation. A research institute also raised concerns about bringing devices on to a pre-notification program, stating that device technology changes too fast to regulate these using a notification scheme.

Streamlined access

Government agencies and public health organisations were highly supportive of the SAS C pathway for access to vapes (nearly 100% in favour), arguing it will reduce the burden on prescribers. Health professional peak bodies agreed with this reasoning but only 60% were supportive of SAS C. The RACGP noted that the availability of SAS C would streamline prescribing by removing the administrative step of requiring AP and SAS C approvals to be provided to pharmacies for the nicotine vapes to be dispensed.

Those who were opposed stated that AP and SAS B are adequate and that the introduction of SAS C will not improve accessibility, because the issue is the lack of trust from health practitioners that vapes are a safe and effective treatment. This group also felt that unapproved access pathways are inconsistent with other NRT access pathways and may disincentivise future product registration. As a consequence, this group felt the unapproved pathway should be implemented for a limited time only as a transitional mechanism, and sponsors should be encouraged to apply for ARTG registration.

University researchers were strongly in favour of the proposed SAS C pathway but raised concerns regarding the potential for abuse and the possibility for the regulation to be undermined (for example, by dedicated telehealth businesses providing prescriptions for vapes). There was a recommendation made to include nurses as prescribers to reduce the burden on medical practitioners. There was mixed support from consumer groups and the 'Other' group. Only 10% of vape retailers and importers were in favour, compared to 100% of vape manufacturers.

Proposal 3 - Heightened quality and safety standards for therapeutic vapes

The 2023 consultation paper proposed improving quality standards for unapproved (unregistered) vapes by:

- specifying new requirements for device components
- enhancing the requirements for vape components.

Device components

Registration of devices and compliance with relevant international standards

Importers, manufacturers and suppliers were asked whether they were familiar with relevant US FDA or MHRA guidance and/or EU standards covering vaping devices, and whether their vapes would currently comply with those standards. They were also asked whether their vapes were manufactured at facilities that meet relevant international standards for Quality Management Systems (QMS), such as ISO9001.

All vape manufacturers stated that they are familiar with international guidance and standards (FDA, MHRA and EU) for devices and all but one meet QMS requirements. Two vape manufacturers even said their devices already meet one or more of these standards. By contrast, only half of the retailers responded that they are familiar with overseas standards for devices and only just over half of those said their devices meet one or more comparable overseas standard or their facilities hold relevant QMS.

Suppliers were also asked whether they intended to apply for any vaping device to be included on the ARTG as an approved medical device. Three of the nine manufacturers indicated their interest in registering device(s), but others felt the cost of registration is prohibitive and devices technology change so fast that registration would quickly become redundant. All but two manufacturers are looking at registering their products in next 2 years. Some respondents indicated that at present, vape sales via prescriptions account for an extremely small part of the market and that the market share will need to increase significantly to justify a case for full therapeutic goods registration.

There was mixed support across the stakeholder groups for applying devices requirements under TGO 110. Concerns were raised over the complexity of devices, and their safety with different settings and batteries. Other concerns were raised regarding the lack of information available on the safety of vaping in terms of potentially toxic compounds migrating into the liquid from the device component or the packaging.

Regulation of combination device and medicine components

The proposed regulation of both vape and device components under the same part of the TG Act received mixed support amongst consumer groups and associations, with some arguing it would increase costs and cause a rise in the black market. In contrast, government agencies and health professional peak bodies were very supportive of device and medicine components being regulated together (100% and 80%, respectively), arguing that stronger regulation will help enforcement, and support welfare agencies to deal with youth addiction. A concern regarding the ability to control an ever-changing device market was raised. It was also highlighted that pharmacies will need sufficient time for education and information to prepare for this change.

Vape retailers and importers not part of the pharmacy supply chain strongly opposed the proposal (only 20% in favour). Vape manufacturers supplying to the pharmacy market gave strong support (80% in favour). Consumer groups were generally opposed to regulating the vape with the device as it would reduce personal choice, reduce accessibility, and only benefit pharmacies and tobacco companies. Manufacturers and consumers also urged Australia to follow a model similar to the UK and NZ.

Most stakeholders agreed that more than 12 months would be needed to adjust to the new regulation.

Enhanced requirements for vapes

Flavours

Overall, limiting flavours received strong support from government agencies, public health organisations, health professional peak bodies and schools related groups. These groups felt limited flavours would reduce some of the appeal of vapes to youth. University research groups were split, as some felt the definitions were not specific enough and would need to specify the chemicals that are to be permitted.

Support was low among consumer groups, ‘Others’ mostly consisting of consumers, and zero-nicotine vape manufacturers, vape retailers and manufacturers/retailers. Concerns were raised across several stakeholder groups that the restriction of flavour choice for patients may turn them back to cigarettes, or to the black market to get their preferred flavour. Many users were opposed to tobacco flavour as this may invoke memories of cigarettes and lead patients to relapse.

Some university research groups would prefer no flavours, arguing that this would be much less harmful. Vape retailers and manufacturers were concerned that limitation on permitted flavours would

significantly impact their industry. Vape manufacturers said that tobacco and mint only form a very small part of the market and therefore do not represent consumers' preferred choice. Vape manufacturers stated that significant re-formulation will be required, which means changing raw materials, stabilising the new formulations, and validating new processes. This significant investment may cost up to 2 million dollars and the industry would like to see how the market reacts and the black market controlled, before committing to such a financial investment.

Limits on menthol

There was mixed support for the upper limit of menthol in vapes. Government agencies, public health organisations and health professional peak bodies showed strong support (>80%). School related groups and university researchers showed less support (50–65%). Support among consumer groups, 'Others' mostly consisting of vape users, and vape retailers and manufacturers was even less (0–30%). They argued the limit was too low and that it limited personal choice. Health care professionals and public health organisations highlighted that menthol, and some isomers of menthol, are known for their pharmacological action causing lung injury. This led some to suggest that menthol should not be allowed at all.

Plain packaging requirements

Plain packaging was strongly supported by schools and education groups (80%), government agencies, university researchers, public health organisations and health professional peak bodies (all 90–100%), as it is seen as a step in reducing youth appeal. It was recommended by some that labels indicate whether the vape has been tested and/or evaluated by the TGA. Poison information centres would like more information on labels regarding nicotine salts and their equivalent concentration when responding to potential nicotine overdoses.

Consumer groups, 'Others' mostly consisting of vape users, and vape retailers and importers were less supportive (≤40%) of plain packaging as it was seen as unnecessary and not an effective way to reduce appeal. More vape manufacturers supported the plain packaging of vape products (60%).

Most vape retailers and manufacturers responded that it would take 3 to more than 12 months to comply with this requirement.

Permitted ingredients

Apart from the 'Others' mostly consisting of vape users, vape retailers, importers and manufacturers (20–45% support), there was strong support for a permitted ingredient list across the other stakeholder groups (70–100%).

Regulation of zero-nicotine vapes

Government agencies, public health organisations, university research groups, health professional peak bodies and vape manufacturers provided strong support (80–100%) for the same regulatory controls for zero-nicotine therapeutic vapes, as for nicotine therapeutic vapes. They argued it will make enforcement easier by eliminating the need to prove nicotine presence before compliance action can be taken. It was also noted that ingredients in zero-nicotine vapes may be harmful so should be regulated.

There was limited support amongst vape retailers and importers, consumer groups and 'Others' mostly consisting of vape users (10–36% support).

The business impact and the fact that overseas manufacturers will avoid Australia, further limiting product availability, were raised as arguments against this proposal.

Proposal 4 – Strengthening domestic compliance and enforcement mechanisms.

The paper proposed strengthening the domestic compliance and enforcement mechanisms under the TG Act to support the broader policy intent of the vaping reforms, particularly those measures included in Proposal 1. Feedback was sought to determine the effect of the proposed reforms on particular stakeholders. Stakeholders were also given an opportunity to provide any other comments in relation to the proposed reforms.

Government agencies welcomed tougher regulation with powers delegated to state and territory authorities. Government agencies, health professional peak bodies, public health organisations and university researchers were supportive of uniform application of regulations across states and territories and delegation of powers to state and territory authorities to help in enforcement. Tougher regulations with penalty measures were also supported as a deterrent.

While concerns were raised that the black market will continue to exist, the view was also put that the use of the legal pathway should increase with the proposed reforms. There were concerns that unapproved product pathways can be misused if not accompanied by monitoring, and this would heavily disincentivise the ARTG registration pathway.

It was further recommended that targeted educational and awareness programs will be required to stop demand as well as to support the young users who are already addicted to vapes.

General questions

Suppliers were asked to confirm if they intend to continue to supply therapeutic vapes under the proposed reforms and, if so, to provide an outline of their product range and the length of time it would take to meet the new requirements. Suppliers were also asked whether they intended to register therapeutic vapes in the next two years, as well as the nature of guidance and assistance required from the TGA.

There were mixed responses from suppliers as far as their ability to maintain supply under the proposed reforms, but a few indicated that their products already conform with TGO 110 or international guidance and/or standards and are manufactured in facilities that hold ISO and/or GMP certification. Some companies supplied commercial-in-confidence information regarding their current range of products and their standards. This information cannot be disclosed as part of this Impact Analysis but has been considered as part of the TGA's development of these reforms.

One stakeholder estimated that vape sales via prescription presently account for an extremely small part of the market for therapeutic goods to assist in the cessation of smoking. Suppliers indicated that market share would need to increase significantly to justify a case for registration on the ARTG. Vape manufacturers expressed concerns with the time and money required for GMP certification, compliance with standards for devices, the development of new flavours, and conducting safety studies.

How this feedback informed policy development

The process of policy development has involved extensive consultation with the sector, both directly and through two rounds of formal consultation.

The initial scope of these reforms followed emerging evidence that the intended objectives of the 2021 reforms were not being met.

In both consultations the feedback was generally split between the consumers calling for limited regulation, and most other stakeholder groups calling for urgent intervention by Government. Both significantly informed the options considered as part of the policy development process and assessment of the regulatory impact on the sector.

This 2022 Consultation feedback was carefully analysed in early 2023 and used to advise the Commonwealth Minister for Health and Aged Care on the policy options available. It was also discussed with state and territory officials in assessing the various policy options. It informed the preliminary announcement made by the Minister for Health and Aged Care on 2 May 2023 that, subject to further consultation, the Australian Government intended to take stronger action in relation to the regulation of all vapes.

It was also used to revise the policy options being considered to address the vaping problem, identify the impacts of different options on different stakeholder groups, assess the viability of options, and identify issues that required further consideration in the policy development process. For example, the 2022 Consultation feedback resulted in:

- a reconsideration of the scope of the vaping problem and consideration of whether regulation should cover all vapes, not just nicotine vapes.
- the revision of the proposal for TGA pre-market controls. While the initial proposal was for TGA to assess compliance of products with TGO 110 prior to market entry, this was revised to a proposal to notify compliant products following opposition to the proposal from public health stakeholders.
- Re-examination of the options for regulating of vapes as consumer goods (which was outside the scope of the 2022 Consultation).
- re-examination of the option of permitting only ARTG registered vapes, which received strong support from public health stakeholders in the 2022 Consultation.
- further consideration of the risks of the device components of vapes, the impact of the prescription model on doctors, management of the waste associated with vapes, necessary transition times for specific measures, and the regulatory parameters necessary to maintain a viable supply of products for smoking cessation.

The outcomes of the 2022 Consultation informed the design of the options outlined in the consultation published in September 2023. This consultation also provided an opportunity to for stakeholders to provide more specific industry input relating to the impacts on them.

Stakeholder feedback from the targeted consultation in September of 2023:

- has directly informed the implementation plan in this Impact Analysis and the transition periods necessary to mitigate costs to industry and ensure adequate supply of therapeutic vapes through pharmacies
- assisted with identifying the benefits and costs on key stakeholders to inform this Impact Analysis and compare the policy options.

The feedback has also signalled a need to carefully consider the precise terms of technical regulations that will be decided as part of the legislative development process, including:

- the need to carefully consider the final position on allowed flavours and nicotine concentration and volumes (noting there were contested health expert views on these points)
- the risks of allowing ‘open system’ devices and how to mitigate those risks.

Question Six: What is the best option from those you have considered and how will it be implemented?

What is the best option?

Of the four presented options, Option 3 most effectively delivers on the regulatory objectives concerning vapes. It is the option that best balances mitigating the health risks associated with vaping with maintaining access to vapes for smoking cessation and other genuine therapeutic purposes.

Option 1 – Maintain the status quo (no change)

Option 1, the status quo, fails to address the present problem concerning vapes and to deliver on the policy objectives of the regulation.

The widespread lawful availability of zero-nicotine vapes normalises vaping as a non-therapeutic activity and contradicts messaging about the harms of vaping. Safety standards do not apply to zero-nicotine vapes or most vaping devices, The quality and safety standards that apply to nicotine vapes are limited. The current regulatory distinction between nicotine and zero-nicotine vapes frustrates effective regulation of these products and enables businesses to easily evade the regulatory requirements for nicotine vapes through concealment actions. The ease of this evasion has encouraged businesses to risk unlawful sales of nicotine and vapes containing nicotine. Due to the impact of unlawful trading, the viability of the lawful vaping industry is compromised. Maintaining the status quo does not address these problems.

Option 1 will not directly address the uptake of vapes, nor counteract the marketing of vapes to youth and young adults through appealing packaging and flavours. Although it includes measures to safeguard consumer health through the existing TGO 110, these quality and safety standards are not sufficient to address the known and unknown harms from vaping and are difficult to police for personally imported goods. Due to the growth in vaping, particularly among youth and young adults, Option 1 would not succeed in preventing nicotine addiction, nor reduce the risk of future tobacco use. Consequently, Option 1 does not fully address the Objectives of Government Action (see Question 2 above).

Further, although the 2021 reforms sought to find a balance between allowing access to vapes for legitimate therapeutic purposes and protecting the community from the potential harms of vaping, maintaining the status quo will not address the problems that have been identified with the current approach. As noted above, these include difficulties with enforcement due to the lawful sale of zero-nicotine vapes.

The avoidance of an additional regulatory burden is not a reasonable basis for supporting the status quo where it is failing to address the objectives of government action and failing to protect public health.

Option 2 – Regulating vapes under a consumer model

Consultation with consumers in December 2022 strongly supported a significant reduction in regulation, citing the need for personal choice and for allowing a range of options in deciding how they should quit smoking.

This option could meet the Objectives of Government Action to a limited extent. The uptake of vapes by youth would be targeted by preventing retailers from selling vapes to youth and applying product standards to vapes to reduce some features that are attractive to youth. The marketing of vapes to

youth and young adults would be counteracted by specific provisions limiting advertising of vapes and by applying products standards to limit packaging and flavours most appealing to youth.

Nicotine and smoking addiction would be targeted through public health campaigns and quit services, and by making a range of vapes readily available for smoking cessation. Even though vapes would be widely available, education campaigns about the risks and appropriate use of vapes, and quit services, could mitigate the risk of non-therapeutic use of vapes and consequent risks of nicotine addiction and smoking uptake. They would also provide adults with information about how to effectively use vapes for smoking cessation.

The introduction of product standards would safeguard consumer health.

However, apart from the introduction of product standards and stricter advertising controls, this is the regulatory model that applies today for zero-nicotine vapes in states and territories. This model has proven ineffective in stemming the flow of vapes to youth and young adults for non-therapeutic purposes. Under this model, vaping rates for young adults are increasing.

It would also normalise vaping use and would likely fail to arrest vaping rates. Vaping is likely to increase with fewer access controls and a normalised environment, especially because this would make highly addictive nicotine vapes easier to access than under the status quo (or the other options). It would thereby fail to address the very real public health risks posed by vaping, including rising nicotine addiction rates with potentially life-long consequences for Australia's young. Such a normalisation of vaping would undercut the concurrent tobacco reforms being pursued by the Government which aim to reduce the overall use of tobacco and nicotine products in Australia.

It would also limit the effectiveness of vaping as a smoking cessation tool as users may self-medicate without accessing the professional advice and supervision that best facilitates quitting.

Option 2 would greatly reduce the regulatory burden and associated economic impact of the proposed regulatory reforms for many. The current retail vaping sector would continue to prosper, which is a key economic impact.

This, in itself, is not sufficient justification to consider this option further. Option 2 is highly unlikely to achieve the sought public health outcomes. It is likely to reverse public health gains in relation to tobacco control. Although changes in quality and safety standards may partially safeguard consumer health, Option 2 does not meet most of the Objectives of Government Action set out under Question 2.

Option 3 – Increased regulation of vapes through the Therapeutic Goods Act and Customs Regulations

Option 3 is the most likely of the options considered to address the underlying concerns about the existing regulatory controls for **all** vapes. This option targets existing weaknesses in the current regulatory framework that are enabling widespread access by youth to nicotine e-liquid, as well as decreasing the attractiveness of vaping to youth and young adults and improving overall health outcomes.

Option 3, however, would effectively close a currently legal market for zero-nicotine vapes and vaping devices for the retail sector, other than pharmacies. Closing down this market would cause significant economic impact on both the broader vaping sector and individual businesses.

Fears that extra regulation may incentivise growth in the black market for nicotine vapes must also be acknowledged. In response to the September 2023 consultation paper, close to a third of respondents,[94] spread across stakeholder categories, commented that a likely impact of the proposed

[94] 80 out of 283 responses (28%) that completed the consultation paper survey specifically mentioned the growth in the black market for vapes as likely result of the proposed regulatory changes.

reforms to vaping regulation was an increase in black market activities. These fears are equally relevant for the proposed reforms in both Option 3 and 4.

This is a legitimate risk as tighter regulation will often raise the risk of black-market sales. There are arguably fewer risks, however, associated with Option 3 than Option 4, as Option 3 provides lawful pathways to access vapes. This risk will be mitigated in two principal ways.

Firstly, strong messaging that non-therapeutic vapes are unlawful, unregulated, and unsafe is being explained to consumers through education campaigns about the harms of vaping. Investment in Quit services to assist people in giving up both smoking and vaping will also assist to reduce the demand for unlawful vapes.

Secondly, the investment in strong, nationally coordinated enforcement will go some way to addressing this risk. Option 3 is explicitly designed to simplify regulation and enforcement, and thus increase regulatory effectiveness. More extensive enforcement at the border, in retail settings and in relation to online sales will do much to stamp out the presently existing black market and prevent its future flourishing.

Unlike Option 2, this option will also limit consumer choice, in terms of the range of vapes available and the ease with which stakeholders can access those vapes. Stakeholders in both Consultations raised the risk that Options 3 and 4 could lead to increased smoking rates, as consumers could switch from vapes to tobacco products. Again, this is a legitimate risk. This risk will be mitigated through the Government's National Tobacco Strategy 2023–2030. It will also be mitigated through the changes to market accessibility for therapeutic vapes proposed under Measure 2 of Option 3, particularly streamlined access under the Special Access Scheme and AP arrangements (Measure 2(b) of Option 3).

Through both Consultations, consumers using their personal experience argued strongly for retention of vapes as a smoking cessation tool. By contrast, other stakeholders, particularly academics and public health bodies, argued that vapes were relatively ineffective as a smoking cessation tool and that they should only be available if registered on the ARTG (Option 4). The RACGP's view is that vapes have a legitimate role as a 'second tier' smoking cessation tool but more effective tools are available. Option 3 would provide a legitimate path for consumers to access vapes to assist in smoking cessation but not for non-therapeutic purposes. In doing so, this option recognises the need to place a high priority on maximising individual efforts to cease smoking to ensure good public health outcomes. It does not ignore or underestimate the public health risks from vaping.

In balancing economic impact against public health outcomes, public health must be given more weight. The regulatory changes envisaged under Option 3 would provide the response that best balances the health risks associated with vaping, while maintaining access to vapes for smoking cessation and other genuine therapeutic purposes. In finding this balance, Option 3 is also best suited to realise the goals of the Government's broader tobacco reforms. By restricting access to only therapeutic vapes, Option 3 provides a legitimate, and medically supervised, method to motivate Australians to combat tobacco/nicotine addiction, while also preventing the unsupervised vaping that encourages tobacco smoking. As such, Option 3 is well aligned with the Government's broader policy agenda concerning tobacco/nicotine regulation.

Option 4 – Ban on non-therapeutic vapes and require therapeutic vapes to be registered on the Australian Register of Therapeutic Goods and not available as 'unapproved' therapeutic goods

Option 4 would allow consumers to access vapes as a smoking cessation tool, but only where those vapes were registered on the ARTG. Like Option 3, this option places a high emphasis on maximising individual efforts to cease smoking to ensure good public health outcomes, notwithstanding the public health risks of vaping. Permitting only vapes registered on the ARTG would further reduce the public health risks of vaping. Option 4 is the most desirable option from a population health perspective as vapes would only be available for therapeutic purpose where they had been assessed for quality,

safety and efficacy or performance by the TGA. This will strongly safeguard consumer health, increase the confidence of users and prescribers, and minimise to the maximum extent possible the short- and long-term adverse health effects of vapes.

This approach was strongly supported by academic, government and public health stakeholders in both the December 2022 and September 2023 consultations.

It would simplify prescribing, as any GP could prescribe without the associated increased regulatory burden associated with the prescription of unapproved therapeutic goods. The impact at the border would be unchanged from Option 3, but the TGA's regulatory efficiency would increase due to the relative simplicity of enforcement – if the vape were unregistered, it could not be lawfully imported, manufactured or supplied. Once entered on the ARTG, the health benefits arising from their use for smoking cessation and treatment of nicotine addiction would accrue.

It would also arrest the uptake of vapes and counteract the marketing of vapes to youth and young adults, due to the strict access controls and regulation of advertising for goods registered on the ARTG.

However, Option 4 fails on the cost/benefit analysis as it would likely result in total failure of the therapeutic vaping market. In the current circumstances, Option 4 would effectively totally ban all vapes for an indefinite period, at least 2 years **–** until such time as a product is successfully registered on the ARTG.

Existing vaping manufacturers have indicated that it might takes years, if it is possible or commercially viable at all, to gather the necessary clinical evidence to support ARTG registration. Additionally, the removal of any current income streams for the sale of nicotine vapes in Australia as an 'unapproved' medicine is likely to delay ARTG registration. While existing manufacturers would be the most likely to progress to registration, if they are forced to exit the market now, it may not be economically viable for them to seek registration later.

In the meantime, there would be no legal mechanism for vapes to be accessed for therapeutic purposes. Persons seeking treatment for smoking cessation or nicotine addition will be dependent on existing behavioural and pharmacological products, such as NRT. As noted above, consumers and retailers argued strongly in both Consultations that vaping is the smoking cessation tool that some consumers find works for them. Removing legitimate therapeutic pathways to reduce tobacco and nicotine addiction could impede the Government's broader policy objective of reducing the use of tobacco and nicotine products.

The total absence of any lawful mechanism for accessing vapes would significantly increase the risks of black-market sales (see Option 3 above). Mitigation through education and Quit services will not be as effective as where there is legitimate access to these products. Mitigation would rely solely on effective enforcement at both the border and domestically.

Implementation approach

While arguably the most effective Option, Option 3 would take time to roll out in its entirety and would require significant government reform and investment.

To achieve success, the approach must be comprehensive and multi-faceted. The success of Option 3 will be influenced by programs delivered at all levels of government in Australia, through support programs, communication campaigns and compliance and enforcement.

Implementation of Option 3 will complement and align with other Australian Government measures including tobacco control reforms, the *Public Health (Tobacco and Other Products) Bill 2023*, the Tackling Indigenous Smoking program, targeted communication campaigns and support for cessation. The proposed measures outlined in this IA will complement the existing measures and the Australian Government will continue to consider future measures consistent with the National Tobacco Strategy 2023**–**2030 to reduce harms from e-cigarettes.

Who will be involved in the implementation of Option 3?

Implementation of the preferred Option 3 will require a coordinated effort between the Commonwealth and states and territories to be effective.

Health Ministers agreed on 1 September 2023 to pursue extending the operation of the TG Act to restrict the importation, manufacture and supply of all vapes. They further agreed the Commonwealth Government would lead the enforcement of new importation and manufacturing controls, advertising controls, and controls on therapeutic vapes, and that states and territories will lead the enforcement efforts at the point of wholesale and retail.

Within the Commonwealth, coordination is required across multiple agencies and departments. The TGA will lead and coordinate much of this activity and will coordinate with other areas within the Department of Health and Aged Care to ensure alignment with implementation of the National Tobacco Strategy 2023–2030.

Restrictions on importation will be implemented by the TGA and the Office of Drug Control from the Department of Health and Aged Care, and the Australian Border Force from the Department of Home Affairs. Restrictions on importation by mail will also need to be coordinated with the Department of Infrastructure, Transport, Regional Development, Communications and the Arts.

Enforcement will be coordinated with state and territory health departments and state and territory policing, as well as the TGA, Australian Federal Police, AUSTRAC and the Australian Competition and Consumer Commission. Measures restricting unlawful sales through the internet will require the assistance of the Department of Infrastructure, Transport, Regional Development, Communications and the Arts.

Environmental issues and disposal of vapes will need to be coordinated between Commonwealth and state/territory health departments and environment departments. For the Commonwealth, this is the Department of Climate Change, Energy, the Environment and Water.

Non-Government Organisations, such as the RACGP, will also play an important role in ensuring that health practitioners receive guidance about prescribing of vapes for smoking cessation and to treat nicotine addiction and are aware of, and willing to prescribe under, pathways to assist access to therapeutic vapes. The Australian Health Practitioner Regulation Agency will also play a role to monitor and respond to professional misconduct in prescribing.

What legislative amendments will be required for the implementation of Option 3?

It is proposed that Option 3 would be implemented through a number of legislative instruments, as well as amendments to the TG Act. Key proposed legislative changes are:

- amending the *Customs (Prohibited Imports) Regulations 1956* to make vapes, including devices, prohibited imports. An import licence and permit would be required to import any vapes and would generally only be granted for non-disposable therapeutic vapes that are registered or that have met the proposed new notification requirements
- amending regulations made under the TG Act to require sponsors to make a pre-market notification to the TGA that their product complies with the relevant product standard and modify some existing exemptions to registration for devices
- a new legislative instrument to allow vapes to be prescribed under the SAS C scheme to facilitate prescribing and reporting by health practitioners
- amending TGO 110 to heighten minimum safety and quality standards, including to restrict ingredients (including flavourings), restrict colourings, require pharmaceutical-like plain packaging, reduce maximum allowable nicotine concentrations, reduce permissible volumes of nicotine, and make commensurate changes to product standards for devices

- amending the TG Act to impose a domestic ban on the manufacture, supply and commercial possession of non-therapeutic vapes. This would enliven the existing cooperative scheme for therapeutic goods and ensure a uniform national approach (other than in WA).

Consequential amendments may be required to other legislation within the Commonwealth, including the *Industrial Chemicals Act 2019*.

Further, state and territory legislation may require amendment to ensure it is not inconsistent with amendments to the TG Act. However, these changes do not fall within the scope of this Impact Analysis.

What is the timing for implementation of Option 3?

As set out in Annexure A, the implementation of Option 3, and the above legislative amendments, can be broadly categorised into Stages 0–3, which build upon the policy agreement on the national approach with states and territories. In September 2022, the Commonwealth, states and territories began the initial efforts to gain national policy agreement on a cohesive and uniform approach to vape regulation across all Australian jurisdictions. Engagement between all jurisdictions will continue throughout implementation and beyond.

The four stages for implementation are:

Stage 0. Preparation for border requirements (October 2023 to December 2023).

Preventing the importation of unregulated / non-therapeutic vapes.

Facilitating access to prescriptions for consumers who require a lawful pathway.

Stage 1. Transition to new product standards (October 2023 to December 2024).

Stage 2. Preparation for the domestic ban on non-therapeutic goods (January 2024 to July 2024).

Stage 3. Commencement of a domestic ban on all non-therapeutic vapes, including primary legislative (dependent on Parliamentary timetable but possibly 1 July 2024).

Implementation issues and risks

Each implementation stage of Option 3 has associated implementation risks which are detailed in Annexure A, with repeating themes and categories of risk, and broad mitigation. Below are some of these implementation issues, repeating risks and associated mitigation strategies.

Tight timeframes

The health risks posed by the increase in vaping, and the need to discourage stockpiling of illegal products, indicate that all measures should be implemented as soon as possible. This means that the timeframes for development and implementation of vaping reforms will be very tight.

There is the risk that a lack of either time or agreement will prevent a uniform regulatory framework being successfully designed, and later implemented, across all Australian jurisdictions.

Of particular concern is the effect of the short time frames for implementation on the supply chain. These risks have been partially addressed through consultation with industry stakeholders[95] and will continue to be managed through provision of clear advice on the regulatory amendments to ensure early awareness of changes and required timeframes. Risks include:

- ensuring that the new notification system and the import controls are in place with sufficient time to allow importation of therapeutic vapes following the commencement of the import ban.

[95] Within the scope of Article 5.3 of the WHO Framework Convention on Tobacco Control.

This would be mitigated through a short transition period to allow sponsors to notify compliant products to the TGA, obtain customs permits and licences and deliver stock to pharmacies

- the ability of the e-cigarette industry to sell/dispose of all products that meet the requirements of the present TGO 110 and are currently lawful but will cease to be lawful when product standards are increased (see “Implementation Costs” below)
- the ability of overseas or domestic manufacturers to manufacture to new product standards. The risk of this is considered to be low as product standards frequently change.
- ensuring that there is a sufficient supply of therapeutic vapes available through to those consumers who might need them. This is being mitigated through consultation with pharmaceutical wholesalers and importers, to ensure there is sufficient stock available for pharmacies
- ensuring there will be sufficient health practitioners prepared to prescribe therapeutic vapes to meet consumer demand. This would be mitigated by streamlining access under the SAS C and AP schemes to encourage health practitioners to prescribe vapes for smoking cessation (as described in Measure 2(b) of Option 3) and through revision of the RACGP Guidelines.

Implementation costs

Retailers have had significant warning about the long-term viability of their sector and have witnessed regulatory reform of varying stringency in other countries. The broad policy approach of these reforms was first announced by the Minister for Health and Aged Care on 2 May 2023, in which the plan to ban all non-therapeutic vapes was expressly communicated. Several months will also be provided between when the importation of non-therapeutic vapes are banned and the domestic supply of such vapes becomes prohibited. This will provide time for retailers to sell their remaining stock.

Implementation costs for manufacturers, retailers and suppliers (including wholesalers) will include the disposal of existing stocks of therapeutic vapes and vaping devices being supplied to the pharmacy market which meet current regulatory requirements but will not meet the new product standards and will consequently become unlawful once these commence. This would be mitigated through a transition period of 6–12 months to allow selling down of these stocks.

Implementation costs for manufacturers, retailers and suppliers (including wholesalers) will also include disposal of existing stock of non-therapeutic vapes and devices. This stock is currently lawfully sold by retailers but would become unlawful when the domestic ban on supply of non-therapeutic vapes commences. The ban is proposed to commence soon after the passage of amendments to the TG Act, possibly towards the end of the second quarter of 2024. This cost would be mitigated by the length of time between the Minister for Health and Aged Care’s announcement of the reforms on 2 May 2023 and implementation of the domestic ban. This period will be at least 12 months and the costings in Annexure B are based on a 12-month transition. This lengthy period should have allowed retailers and suppliers to run down their stocks. Further, the TGA has been advised anecdotally that the rapid development of vapes means that stock is seldom more than six months old.

Implementation costs for retailers and suppliers will include the disposal of existing stocks of disposable vapes, which would manifest when the domestic ban on supply of vapes commences. This cost would be mitigated by the length of time between the Minister for Health and Aged Care’s announcement of the reforms on 2 May 2023 and implementation of the domestic ban. This period will be at least 12 months and the costings in Annexure B are based on a 12-month transition. This lengthy period should have allowed retailers and suppliers to run down their stocks. Further, it is likely that consumers will seek to stockpile disposable vapes as they will not be able to obtain them in the future. Therefore, it is unlikely that these costs will be high unless suppliers and retailers are deliberately increasing their stocks in the hope of obtaining compensation from the Government.

It is also envisaged that domestic manufacturers currently manufacturing lawful zero-nicotine e-liquids would be provided with a 12–18-month transition period for compliance with good manufacturing practice requirements for current products (not new products).

Disposal of unlawful vapes seized under compliance action

Disposal of unlawful vapes is not only an issue for manufacturers, suppliers and retailers holding products which become unlawful. The TGA, ABF and states and territories are in the process of increasing capacity to safely dispose of vapes seized by regulatory action. Options for disposal of vapes that become unlawful are currently being discussed with the states and territories. Commonwealth and state and territory health departments are liaising with their respective environmental departments regarding options for disposal.

Education Campaign

The TGA will publish guidance materials on the new legislative requirements that clearly identify the changes which have been made and their implications for various stakeholder groups. The webpage will provide guidance material and fact sheets educating stakeholders and the public of the requirements of the legislation.

Many of the identified implementation risks in Annexure A will be mitigated through preventive public health campaigns focused on vaping and smoking cessation and increasing and improving vaping and smoking cessation support. These are outlined in the Australian Government's Tobacco Strategy 2023–2030 and the Australian Government has provided additional funding to support public health campaigns and cessation support and information.

Ensuring regulation will meet its aims

As with any broad population health reform requiring behavioural change, there are a number of potential barriers to meeting the objectives of regulation. To achieve success, the approach must be comprehensive and multi-faceted.

The October 2021 reforms aimed the need to balance discouraging youth and young adults from nicotine vaping against the need to allow nicotine vaping for smoking cessation. It did not comprehensively capture all e-cigarette product types and was focussed only on e-cigarettes containing nicotine.

As noted in Question 1, evidence shows that the majority of e-cigarettes available contain nicotine, even if not labelled as such. The regulatory distinction between zero-nicotine and nicotine vapes has allowed the restrictions on nicotine vapes to be evaded. Further, there are health risks associated with all vaping. Therefore, a comprehensive approach to all types of e-cigarettes is required for the reforms to be implemented successfully. Option 3 would seek to regulate vapes, whether or not they contain nicotine.

The Australian Government works with state and territory governments, law enforcement agencies and relevant taskforces, such as the Illicit Tobacco Task Force, to investigate allegations of illegal tobacco and e-cigarette supply.

The success of stricter e-cigarette reforms will be influenced by programs delivered at all levels of Government in Australia, through public health organisations such as Cancer Councils, and through clinical guidelines, support programs and communication campaigns. Stakeholder engagement and collaboration is key to ensuring that all measures being implemented through Option 3 are appropriately adapted to complement the broader tobacco control environment. To mitigate any risk of e-cigarette industry influence on the implementation of the proposed e-cigarette control measures, consultation has been limited to that which is necessary to enact effective e-cigarette control measures and has been undertaken in line with Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC).

For individuals who use vapes, a key barrier to successfully reducing e-cigarette prevalence rates includes cognitive biases which distort perceptions, judgements or decision making. The e-cigarette and tobacco industry employs these biases to influence social norms, habits and routines to encourage tobacco and e-cigarette use. There is the potential for some individuals to seek alternate options to maintain nicotine consumption, rather than using the e-cigarette products through an approved prescription. This may include seeking new e-cigarette sources, such as vape products

being sold on the black market or transitioning to the use of tobacco products through either legal or illegal channels. These risks would be mitigated in a number of ways. The regulatory controls proposed in option 3 are designed to make enforcement easier and would be accompanied by increased resources for enforcement at the border by the ABF, regulatory requirements by the TGA, and retail and wholesale restrictions by the states and territories. A detailed compliance plan is being developed to better deter non-compliance, including the planned imposition of high penalties for egregious breaches and new strategies to close down internet sales. This would be accompanied by increased education and enhanced quit services to reduce demand.

Question Seven: How will you evaluate your chosen option against the success metrics?

Measurement of success

In relation to resolving the issues relating to vaping supply, usage and uptake, the Government's objectives would be met if, by 1 July 2026:

- vaping rates are significantly reduced in all age groups, but especially in youth and young adults (aged below 25 years), other than for therapeutic use
- the proportion of vapes being supplied through legal pathways, such as with a prescription and obtained from a pharmacy, significantly increases
- there is increased consumer and prescriber awareness of therapeutic vapes as an option for smoking cessation
- vapes for non-therapeutic use are considered to be less attractive to youth and young adults (aged below 25 years) compared to the current state
- strengthened border controls significantly reduce the quantities of unlawful vapes being imported into Australia
- strengthened domestic controls significantly reduce the quantities of unlawful vapes being supplied within Australia.

Monitoring and evaluation

Compliance with the proposed legislation and existing legislation relating to the sale of e-cigarettes and vaping devices will continue to be monitored under existing frameworks to limit the trade of vaping and e-cigarette devices or tobacco that does not comply with legislative requirements. Changes in smoking patterns and behaviours will also be monitored.

Should Option 3 be chosen, a monitoring and evaluation program for the reforms will be established. The program will be developed in line with the Commonwealth Evaluation Policy, which provides for a principles-based evaluation approach that is fit-for-purpose, useful, robust, ethical, culturally appropriate, credible, and transparent where appropriate.

The monitoring and evaluation program will include an evaluation framework, program logic and post-implementation review designed to measure a wide range of outcomes relevant to the marketing and use of vapes and their impacts on population health. The program will measure reduction in cessation rates of vaping and improvement in patient outcomes from the collective impact of these measures.

The evaluation framework will be targeted and adaptable to the specific aims and outcomes of the relevant measures contained in Option 3. It will incorporate both existing and to-be-developed datasets, information sources and international comparisons (where available), and will likely link into the measures implemented for tobacco control, due to the clear links between the two reforms, stakeholders and health outcomes.

The program would seek to track measures from their earliest stages to ensure implementation approaches are fit for purpose and can pivot as necessary during implementation. The monitoring activities and data collected as part of the program will provide Government with insights into uptake and utilisation trends of cessation supports, oversight of industry marketing activities, and compliance and enforcement activity. This will enable policy settings to adapt as needed to drive desired activities, behaviours, and outcomes.

Implementation will be supported by strengthened enforcement and monitoring activities that ensure compliance with new regulatory provisions at the border and in retail settings. Compliance with the new legislative requirements will be monitored by the TGA, ABF, state and territory health and police authorities, AUSTRAC and the ACCC. Instances of non-compliance will be considered in accordance with the TG Act to ensure that enforcement and any potential penalties are proportionate to the nature of the contravention. Through education and awareness materials, suppliers and retailers will be supported to understand their new obligations.

There is also the risk that the desired quality standards will be breached by sponsors who notify compliant products to the TGA. The TGA will be conducting post-market surveillance and testing of products being supplied to the pharmacy market to mitigate this risk.

Measuring Success

As with many areas of health reform, most indicators of success in the regulation of vaping are likely to be lag rather than lead indicators. As part of the National Drug Strategy, the National Drug Strategy Household Survey, began in 1985 and is conducted approximately every 3 years. The survey is commissioned by the Department and the Australian Institute of Health and Welfare. It draws upon data provided by survey responses from over 20,000 citizens aged 14 years and over. This survey provides the most comprehensive national data set on illicit drug, alcohol and tobacco consumption, including vaping. It would provide an evidence base for determining the impact of the proposed regulatory changes, after adjusting for the impact of broader tobacco control measures. Additional datapoints could be provided from longitudinal health studies undertaken by the state and territory health departments, such as the NSW Government's Generation Vape study detailed earlier in this document.

A reduction in the use of e-cigarettes is not a specific target in the National Tobacco Strategy 2023-2030,[96] though the listed actions specifically targeting e-cigarette use will contribute to achieving the listed national targets to reduce daily smoking prevalence.

Reporting by health practitioners prescribing under the Special Access Scheme and AP pathways will provide data relating to the lawful access to therapeutic vapes. This data will be supplemented through IQVIA data, which will assist with determining the supply of therapeutic vapes from wholesalers to pharmacies.

In addition to the National Drug Strategy Household Survey, other key data to determine consumer awareness and attitudes over time include Roy Morgan and ASSAD survey data.

Strengthened border controls may also enable an output measure of interceptions and seizures of vapes, which would be expected to decrease over time as the market for these products decreases and the risk of detection at the border increases. Less robust indicators of success might include a reduction in online marketing of vapes indicating a market contraction, though this will be dependent on the running down of domestic stockholdings.

Similarly, the level of interceptions and seizures of vape by state and territory health departments and police could be used as an output measure. These could be influenced, however, by the level of enforcement, rather than the level of unlawful products available.

In addition, state and territory governments, public health organisations and experts, smoking cessation services, and the research community will have valuable roles in contributing to the Government's impact evaluation through the contribution of aligned data and research. Reports outlining the findings from impact evaluation will be published, where possible.

[96] Stated targets are reduce Australia's daily smoking prevalence to below 10% by 2025 and 5% or less by 2030 and reduce the daily smoking rate among First Nations people to 27% or less by 2030. Department of Health and Aged Care, National Tobacco Strategy 2023-2030, p.39.

2026 Review

Further, it is proposed that in 2026 the TGA will undertake consideration of whether it is appropriate to continue to allow the continued importation, manufacture and supply of vapes as unapproved goods. If it is appropriate to continue to regulate vapes as unapproved goods, the TGA will also look to whether product standards should be further increased. This consideration will result in recommendations to Government.

Annexure A – Vaping Policy Implementation Plan

Step 0: Policy agreement on national approach with states and territories

Description:
- Health Ministers' meetings and E-Cigarette Working Group meetings prior October 2023 – considered policy approach for addressing vaping problem

Timeframes:
- Started September 2022. Finalised October 2023, noting conversations with states and territories will be ongoing throughout implementation of Commonwealth reforms

Objective:
- Achieve a national approach to vaping regulation to facilitate consistency in regulatory controls, enforcement and public health messaging

Commonwealth Government actions:
- Coordinate state and territory responses to vaping regulation and take primary responsibility for regulation of vaping products, including through regulation of therapeutic goods, border enforcement and advertising

Measure of success:
- Broadly uniform approach adopted and successfully implemented

Risks and mitigation:
- Lack of unity between states and territories would undermine the Commonwealth's regulatory approach because inconsistency of measures would create regulatory gaps and inconsistent public health messaging
- Mitigation – continued strong engagement with states and territories to promote consistent approach. Engagement with Police Ministers required to recognise potential for organised crime to exploit inconsistency across jurisdictions.

Step 1a: Preparation for border requirements – Preventing the importation of unregulated / non-therapeutic vapes

Description:
- Activities to enable commencement of Customs (Prohibited Imports) Regulations and related border arrangements

Timeframes:
- October 2023 to December 2023, Regulations to be made by the end of the year

Objectives:
- Ensure sector and government agencies are prepared to stop the importation of recreational and non-therapeutic vapes into Australia

Commonwealth Government action:
- Set up system for pre-notification of compliance with Therapeutic Goods Act requirements
- Set up system for permits, noting licencing is an existing system
- Educate consumers and importers of new border requirements
- Coordinate across Commonwealth agencies to establish mechanisms to identify non-compliant products
- Educate states and territories of new arrangements

Measure of success:
- When the Regulations are made, the sector and all government agencies are ready to observe/enforce new requirements

Risks and mitigation strategy:
- Risk of a large influx of permit applications. Mitigation - engagement with industry to forecast expected applications. Limit who might apply to ensure genuine applications received.
- Risk that quality of premarket notification may not be sufficient to attest that the product meets required standards. Mitigation - design of permit mechanism to ensure notifications are genuine and complete.
- Timeframes are very tight for substantial reform. May reduce ability of regulators to educate sector. Mitigation - planning for efficient communication activities.
- Stockpiling by consumers or suppliers may be an issue. Education may increase risk due to forewarning of border closure. Mitigation - education on risks of stockpiling.
- Potential for black market sales. Mitigation - intelligence gathering for targeted enforcement; coordinated enforcement across governments and agencies (including deterrent action); education on risks of non-compliance; education on risks of vaping and expansion of quit services to reduce demand.

Step 1b: Preparation for border requirements – Facilitating access to prescriptions for consumers who require a lawful pathway, and preparation for the closure of the personal importation scheme

Timeframes:
- October 2023 to December 2023

Objectives:
- Consumers who require lawful access to vapes will continue to have a pathway for access following commencement of border requirements
- Medical practitioners understand new arrangements and are ready to support consumers who require access

Commonwealth Government action:
- Implement SAS C pathway to increase doctors who can prescribe for domestic supply
- Liaise with RACGP and GPs to ensure GPs are aware of SAS B, SAS C and AP pathways, RACGP Guidance related to prescribing vapes and lawful product range that may be supplied
- Facilitate update of RACGP Guidance on smoking cessation (including potentially to include vaping cessation)
- Coordinate with pharmacists and industry to facilitate adequate supplies to meet expected demand
- Educate pharmacists on requirements for lawful supply of vapes and products that can lawfully be supplied
- Educate consumers regarding new requirements and closure of personal importation scheme
- Investigate/implement strategies to close-down purchasing websites

Measure of success:
- Sector readiness – no surprises for doctors, consumers, pharmacists

Risks and mitigation strategy:
- Insufficient lawful supply to meet demand. Mitigation – liaison with pharmacists and industry in relation to implementation and stock levels
- Insufficient practitioners willing to prescribe. Mitigation – education and monitoring of access issues
- Unlawful personal imports through mail continue. Mitigation – compliance activity (including engagement with overseas online suppliers and publication of action for deterrence); education on risks of non-compliance; education on risks of vaping and expansion of quit services to reduce demand.
- Potential for vapers to take up smoking if vaping becomes less accessible. Mitigation – education and quit services and accessibility to other 'first tier' smoking cessation products.

Step 2: Preparation for the domestic ban on non-therapeutic vapes

Timeframes:
- 1 January 2024 to 1 July 2024

Objectives:
- Ensure all affected stakeholders are well prepared for commencement of primary legislation:
    - Importers, manufacturers and suppliers/retailers understand the new requirements and phase out non-compliant business operations relating to vapes that will be banned
    - Consumers using zero-nicotine vapes understand new controls and seek support for smoking/vaping cessation in advance of ban commencing
    - Medical practitioners understand changes to lawful supply pathways for zero-nicotine vapes and devices and their role in prescribing unapproved goods
    - Pharmacists understand changes to lawful supply pathways for zero-nicotine vapes and devices and have implemented arrangements to source lawful products for supply

Commonwealth Government action:
- Prepare for tidy closure of the non-therapeutic vaping market through education about the new requirements and supporting business to pivot to a lawful therapeutic goods supply pathway where feasible
- Education/consultation with all affected stakeholders (including retailers, consumers, doctors and pharmacists)
- Continue coordination efforts with states and territories and Commonwealth agencies to ensure enforcement mechanisms are in place
- Engage with states and territories regarding implementation of environmentally sustainable disposal pathways for businesses and consumers for non-compliant vapes (noting waste disposal is generally undertaken at state and territory and local government level)
- Monitor supply pathways (including new SAS C pathway) and consult with suppliers, medical practitioners and consumers to identify/resolve any access issues

Measure of success
- Sector readiness for commencement
- Clear enforcement plan in place between Commonwealth and state and territory agencies
- Disposal pathways available to industry and consumers prior to commencement of legislation

Risks and mitigation strategy
- Significant disruption for sector. Mitigation – communicate new requirements clearly, facilitate disposal pathways and allow sector to sell down stocks prior to commencement of primary legislation.

Step 3: Transition to new product standards

Timeframes:
- Q3 2023-Q4 2024

Objectives:
- Smooth transition to new product standards, with sufficient compliant therapeutic vapes available to meet demand

Commonwealth Government action:
- Further consultation to refine precise terms of new standard and make new standard (Q4 2023)
- Allow manufacturers and suppliers to transition to new product standards - new requirements commence from Q4 2024 to allow compliant products to be developed and existing products that meet old standard to be sold
- Set up notification and permit systems to facilitate transition to new standards
- Education of sector on new requirements

Measure of success
- Upon commencement of new product standards, manufacturers and suppliers are ready to supply lawful products that meet new standards
- Better quality products available to consumers

Risks and mitigation strategy
- Suppliers exit market because unable, or not financially viable, to meet new standards and insufficient therapeutic vapes to meet therapeutic demand. Mitigation – careful design of standards in consultation with industry; appropriate transition times.
- Black market in products that do not meet standard. Mitigation - coordinated enforcement (including deterrent action); education on risks of using non-compliant products; education about purchasing compliant products; education on consequences of non-compliance; education on risks of vaping and expansion of quit services to reduce demand.

Step 4: Commencement of a domestic ban on all non-therapeutic vapes including primary legislative requirements, restrictions on advertising, creation of new offences, including possession of commercial quantities, and creation of new authority for state and territory enforcement officers

Timeframes:
- 1 July 2024 onwards

Objectives:
- Ensure sector and government agencies are prepared to stop the manufacture and supply of non-therapeutic vapes in Australia
- Unlawful and unsafe products no longer widely accessible

Government action
- Enforce new restrictions on possession and supply of of non-therapeutic vapes
- Enforce the restrictions on the manufacturing of non-therapeutic vapes
- Enforce the requirements on the manufacturing of therapeutic vapes
- Ensure consumers retain access to therapeutic vapes

Measure of success
- Non-therapeutic vapes no longer sold in Australia

Risks and mitigation strategy
- Timeframes are very tight for substantial reform. May reduce ability of regulators to educate sector. Mitigation - planning for efficient communication activities.
- Stockpiling may be an issue. Education may increase risk due to forewarning of ban. Mitigation - education on risks of stockpiling.
- Disruption for retail sector. Mitigation – more than a year between measure being announced and implemented.
- Insufficient lawful vapes to meet therapeutic demand. Mitigation - liaison with pharmacists and industry in relation to implementation and stock levels.
- Insufficient practitioners willing to prescribe. Mitigation – education and monitoring of access issues.
- Potential for black market sales – coordinated enforcement across governments and agencies (including deterrent action); education on risks of non-compliance; education on risks of vaping and expansion of quit services to reduce demand.
- Potential for vapers to take up smoking if vaping becomes less accessible. Mitigation – education and quit services and accessibility to other 'first tier' smoking cessation products

Annexure B – Regulatory Burden Estimate

Purpose of this annexure

This annexure provides a quantification of the regulatory burden of the proposed changes to the regulation of vapes.

Approach

The modelling detailed in this annexure was conducted in accordance with Office of Impact Analysis (OIA) guidance for the calculation of regulatory costs on businesses, community organisations and individuals. For the purposes of this regulatory burden estimate, stakeholder groups include medical practitioners, pharmacists, manufacturers, suppliers and vape retailers. Individuals, referred to collectively as consumers, comprises both patients of medical practitioners and consumers who purchase vaping devices.

The below activities were undertaken to inform the development of the regulatory costs:

- desktop research to understand the current regulations for vapes in Australia
- numerous workshops and meetings with departmental staff, both internal and external to the Department of Health and Aged Care, to clarify and refine the underpinning policy positions for the proposed regulatory changes, identify likely response pathways (including frequency and time required for each activity), and test and validate assumptions
- identification of regulatory touchpoints for the proposed regulatory changes (including second-order touch-points necessary to achieve the sought policy outcomes)
- determination of the respective populations impacted by identified touchpoints (i.e., consumers, medical practitioners, pharmacists, manufacturers and suppliers (sponsors) and vaping retailers) and mapped pathways and requirements
- review and analysis of responses to the September 2023 TGA consultation paper titled 'Proposed reforms to the regulation of vapes'
- utilisation of existing datasets to estimate current and future (growth) population numbers (where relevant).

Specifically, the regulatory costing considered the following options:

> Option 1 – Status Quo. Under the status quo, vapes would continue to be able to be imported under the Personal Importation Scheme and border enforcement activities would remain complicated by it being difficult to distinguish between unlawful and lawful imports of vapes. There would remain no import restrictions on zero-nicotine vapes and disposable vapes.
>
> Option 2 – Regulating vapes under a consumer model. This Option would result in vapes being available for purchase by consumers from a range of retail outlets, including supermarkets and convenience stores, provided appropriate regulatory requirements are met (including compliance with product standards and age restrictions for sale). There would not be a restriction on the intended use of vapes.
>
> Option 3 – Increased regulation of vapes through the Therapeutic Goods Act and Customs Regulations. Under this option, vapes would be prohibited unless they are therapeutic vapes that meet TG Act requirements. The TG Act requirements for therapeutic vapes would be strengthened, as would compliance powers. Access to therapeutic vapes would be facilitated by allowing all doctors to prescribe therapeutic vapes for smoking cessation or to treat nicotine addiction without needing to apply to the TGA for approval. **This option is the most**

likely to achieve the sought health outcomes and Government objectives, so the estimated regulatory burden arising from the option has been costed in detail.

Option 4 – Ban on non-therapeutic vapes and require vapes to be registered on the Australian Register of Therapeutic Goods and not available as 'unapproved' therapeutic goods. As with Option 3, it would involve banning all non-therapeutic vapes, but would add a requirement for any vape to be registered on the ARTG to be able to be lawfully supplied in Australia. This option provides all the desired benefits from Option 3 with the added advantage of removing any remaining hesitation from health practitioners to prescribe vapes for smoking cessation and the treatment of nicotine addiction purposes due to their status as unapproved medicines. However, by requiring vapes to be registered in the ARTG and given the low likelihood of a sponsor to seek to have a product approved, this would likely preclude access to such products by consumers for a period of at least a couple of years, which is counter to the Government's stated policy objectives to preserve access to vapes for therapeutic purposes. While the registration of vapes on the ARTG should remain the long-term objective of the vaping reforms, this option will not meet the Government's policy objectives. The regulatory burden variations between Option 4 and Option 3 have been estimated.

Within Option 3, the following summarises the regulatory impact of each of the reform measures on the key stakeholder groups:

Measure 1 – Restrictions on importation, manufacture and supply of all vapes.

Significant direct regulatory cost to consumers, manufacturers, suppliers and retailers.

Measure 2 – Changes to market accessibility requirements for therapeutic vapes.

Significant direct regulatory cost to consumers, and some impact on medical practitioners and pharmacists.

Measure 3 – Heightened quality and safety standards for therapeutic vapes, including better regulation of device components.

Significant direct regulatory cost to manufacturers and suppliers, and minor impact on consumers, manufacturers, suppliers and specialist vape retailers.

Measure 4 – Strengthening import and domestic compliance and enforcement mechanisms.

These result in no direct regulatory cost to any of the main stakeholder groups. As such they are not discussed further in the regulatory burden analysis. These changes are solely designed to ensure Commonwealth and state and territory officials have effective compliance and enforcement mechanisms available to them.

Costing model

Overview

The development of the regulatory costing model was undertaken in accordance with the OIA July 2023 Guidance Note, 'Regulatory Burden Measurement Framework' (the Guidance Note). Estimated regulatory costs were mainly administrative compliance costs,[97] with the assumption that the identified substantive compliance cost for consumers to purchase a new refillable/reusable vape via a pharmacy to replace an existing device purchased from a vape retailer will be substantially mitigated by a transition period for the withdrawal from sale of all non-TGO 110 compliant vapes. There will likely also be significant substantive compliance costs incurred by vape sponsors to meet the revised TGO 110 specifications.

The labour cost formula was used to determine these administrative compliance costs:

[97] While costs of professional services needed to meet regulatory requirements are classified as a substantive compliance cost, the costs of conducting tests, even though likely to be conducted by an accredited testing laboratory to demonstrate compliance against TGA product standards (TGO 110) are classified as an administrative cost.

price x quantity

In its more expanded version, this formula is:

(Time required × Labour cost) ×

(Times performed × Number of businesses or community organisations × Number of staff).

Direct estimates are provided for substantive costs. The paucity of data available to determine these substantive compliance costs gives these estimates a low confidence level. In most instances, they are likely an overestimation of the costs that will be incurred.

As detailed above in this report, various consultation activities with key stakeholders, supplemented by document reviews, have been undertaken to identify first- and second-order touchpoints for specified stakeholder groups to allow quantification of the arising regulatory burden.

Labour cost

As per the Guidance Note, the hourly work-related labour cost of $79.63 has been used for wholesalers and retailers, with the hourly non-work-related cost of $36 applied to vapers/patients.[98] The Australian Bureau of Statistics (ABS) semi-annually publishes 'Average Weekly Earnings' data. As of 26 September 2023, the latest dataset is May 2023.[99] Given that potential vape sponsors could be based in any state/territory, the national dataset was used. The relevant table is Table 10H ('Average Weekly Earnings, Industry, Australia (Dollars) - Original - Persons, Full Time Adult Total Earnings' (includes overtime)). The below Australian and New Zealand Standard Industrial Classification (ANZSIC) division was considered the most relevant to the particular activities being costed:

- Professional, Scientific and Technical Services (ANZSIC Division M). Industry subdivisions are: Professional, Scientific and Technical Services (Except Computer System Design and Related Services), and Computer System Design and Related Services. As identified in the most recent dataset (May 2023 dataset), the figure for weekly earnings is $2192.70.

It was assessed that Professional, Scientific and Technical Services was the most appropriate industry division because it is most likely to include the regulatory staff who would undertake the regulatory compliance activities required by the TGA.

Therefore, the figure for weekly earnings is $2,192.70. To determine the average hourly cost, this figure is divided by the average number of total hours worked (including overtime) for full-time non-managerial employees, using the 'All Industries' category- a figure of 39.40 hours.[100]

In accordance with OIA guidance, a multiplier of 1.75 was used to account for non-wage labour on-costs and overhead costs, giving an hourly rate of: ($2,192.70/39.40) *1.75 = $97.39.

A 50% loading has been added onto this base amount for General Practitioners (GPs) and Pharmacists, as explained below, giving $97.39 x 1.5 = $146.09.

While there are national awards for both Medical Practitioners (MA000031) and the Pharmacy Industry (MA000012), these set out minimum wages and conditions. Across Australia there is known to be a wide variance in the salaries of medical practitioners and pharmacists, due in part to private commercial and state-based variation. There is not a separate ANZSIC Division for these professions. The 50% loading on the ANZSIC Division M average hourly cost reflects that, on average, medical

[98] Labour rates are generally updated biennially. The next update is scheduled for February 2024.

[99] Australian Bureau of Statistics, '6302.0 - Average Weekly Earnings, Australia, May 2023,' (17 August 2023). Available at: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/latest-release

[100] Australian Bureau of Statistics,' 6306.0 - Employee Earnings and Hours, Australia, May 2021,' (19 January 2022). Available at: https://www.abs.gov.au/statistics/labour/earnings-and-work-hours/employee-earnings-and-hours-australia/latest-release#data-download

practitioners and pharmacists are assumed to receive higher wages than the average salary included in Division M.

Throughout this regulatory burden estimate, the upper limit for population modelling has been applied. This approach was taken to avoid underestimating the cost of the arising regulatory burden, particularly for consumers.

Impact on consumers

Overview

Most of the proposed regulatory measures under Option 3 will have a significant impact on consumers. In particular:

> **Measure 1.** The restrictions on importation, manufacture and supply of all vapes will indirectly impact on consumer choice, but consumers will still be able to source vapes for therapeutic use from pharmacies. Non-therapeutic vapes and disposable single-use vapes would be banned, but transition periods will assist consumers to change over to alternative vapes, where appropriate. Currently, consumers can readily source nicotine vapes through legal and illegal pathways, but under this option they will need to obtain a prescription to access vapes, and only for therapeutic purposes such as for smoking cessation or treatment of nicotine addiction. Consumers would then need to fill the prescription through pharmacies, as per other prescription medicines.
>
> **Measure 2.** This measure will not directly impact on consumers as it relates to activities undertaken by sponsors and medical practitioners.
>
> **Measure 3.** Most of these restrictions will not directly impact consumers, other than limiting choice of vapes available, which is not a regulatory cost. For example, while changes to labelling and quality of the e-liquid and device components of the vapes have no direct impact on consumers, restrictions to flavours and nicotine concentration will restrict choice.

There is considerable vaping stock present in Australia,[101] but a transition period will be applied for the withdrawal from sale of non-therapeutic vapes that will become illegal when the legislative changes are implemented. Therefore, the proposed regulatory changes are not expected to have an immediate impact on the availability of non-therapeutic vapes for consumers. It is expected that consumer choice will gradually decrease as domestic stockholdings of non-therapeutic vapes decrease with time.

Nicotine vapes are currently widely available, both through legal import using the Personal Importation Scheme or domestically through pharmacies, but also illegally through various means described in greater detail above. Under proposed reforms, closure of the Personal Importation Scheme for vapes will significantly impact the purchasing behaviour of consumers, with consumer access only through domestic pharmacies on presentation of a valid prescription, the product range significantly smaller, and supply only for narrowly defined therapeutic purposes. However, the timeframes for all consumers needing to move to seek a prescription and source all nicotine vapes legally will depend on the success of enforcement activities and prevention of illegal access.

The baseline for the regulatory burden estimate on consumers is the number that already access vapes via prescription through a pharmacy.

Obtaining and filling a nicotine vape prescription.

[101] Responses to the 2021 September consultation paper from vape retailers indicated that they held on average $1m - $2m in stock on hand (included zero-nicotine e-liquids, devices and accessories), Wholesalers reported significantly greater stockholdings, with some currently holding millions of stock units.

Patients can obtain therapeutic vapes (zero-nicotine and nicotine vapes) only if prescribed by a medical practitioner. This can be achieved through in-person, telehealth or online consultation:

- For an in-person consultation, it is estimated that the time taken to book a consultation is 2 minutes and this is usually completed over the phone or through an internet booking portal. To attend an in-person consultation, a patient will need to travel to and from their consultation. As there are many variables in how someone can travel to the doctor (walk, bus, drive themselves, ride share etc.), the monetary cost of the travel has not been included in the regulatory costing. It is estimated that, on average, patients will require 15 minutes each way to travel for their appointment, totalling 30 minutes.

  It is estimated, based on consumer behaviour survey data,[102] that individuals will spend an average of 30 minutes in a waiting room before being able to see their doctor. During the consultation activity the doctor and patient will need to discuss the severity of addiction, various cessation options, the need for a paper or electronic prescription. It is noted that if a doctor is an AP, they will also be required to provide the patient a copy of their AP authorisation for domestic prescription fulfillment.

- The average doctor's consultation time in Australia has been estimated to be 15 minutes per consultation. The total elapsed time for an in-person consultation is 77 minutes (2 minutes book + 30 minutes travel + 30 minutes wait + 15 minutes consult). From this total, 15 minutes needs to deducted for the regulatory baseline activity of obtaining a vape via the Personal Importation Scheme, giving a total of 62 minutes (77- 15 min).

- Nationally, 80% of GP consultations are bulk billed. Out of pocket costs (gap payment) to patients for non-bulk-billed standard (15 minute) GP consultations has been estimated to be $40.42 per GP visit.

- For the purpose of this costing activity, the estimates will assume that all consults will be in-person, which represents the greatest overall regulatory burden for consumers as a proportion of consults will be via telehealth or online, which involve less elapsed time.

- It should also be noted that this is an estimate for an initial consultation and plan development. Subsequent and follow-up consultations, which will likely be only to obtain a prescription, will likely be shorter, and more likely to be completed by electronic means. This estimate therefore will overestimate over the life of the treatment of the patient for these purposes.

- A person who attends a telehealth consultation (which involves direct interaction with a doctor) will not need to spend any time travelling as they can have the virtual consultation from any location (i.e., at home or work). Additionally, a patient who attends a virtual consultation will not have to spend any time waiting as they can go about their daily activities while they wait for the doctor to call them.

- Since the previous regulatory burden estimate was compiled (2021 reforms), there has been significant channel growth in 'vaping' prescriptions obtained via online means. This option entails considerably less regulatory burden than an in-person and slightly less than a telehealth consultation. The websites themselves estimate that the online process to provide the necessary details (including a smoking history) to obtain a prescription for nicotine vapes takes no longer than 10 minutes, with a simple internet search directing the consumer to such platforms.[103] To upload their prescription and order a nicotine vape from an online pharmacy is assessed to take no longer than 5 minutes, so a total of 15 minutes.

- From the estimated total number of GP consultations, it is estimated that the total number of consultations resulting in a prescription being written for therapeutic vapes is 50% (n=225,000), but this number may even be lower. This estimate is based on current RACGP guidelines, which highlight that vaping is second-line treatment for smoking cessation or nicotine addiction, so medical practitioners strongly direct patients to other primary

[102] World Self-Medication Industry, Consumer Behaviour Fact Book, March 2015..

[103] It is understood that the Australian Health Practitioner Regulation Agency (AHPRA) may be investigating some of the general practitioners providing these online 'vaping scripts' platforms but at the time of writing these platforms are still in operation.

pharmacotherapy, accompanied by behavioural support, and therefore would be less likely to prescribe a nicotine vape.

Prescribing behaviour by medical practitioners

There is a low likelihood of therapeutic vapes being included on the Pharmaceutical Benefits Scheme (PBS) Schedule, due to there being no approved vapes on the ARTG and little likelihood of a sponsor applying for such approval, and concerns regarding its cost-effectiveness for cessation.[104] It has therefore been assumed that vapes will be supplied over the duration of the regulatory costing (10 years) under private prescription. Therefore, there is no specified maximum number of repeats, nor is there a specified maximum quantity that can be prescribed at any one time. It is possible that medical practitioners may therefore prescribe a range of nicotine concentrations (higher potency) to cater for variance in addiction levels, but it is considered that the general prescribing conditions as for the PBS will be applied by medical practitioners, in that each prescription will provide approximately one month's therapy, which may be repeated to provide 6 months' therapy in total. This seems appropriate as it is assumed that doctors might only prescribe nicotine vapes over a shorter periods and schedule more frequent consultations to monitor progress towards the objective of successful smoking cessation.

Future population considerations (medical practitioners visits)

As detailed in the response to Question 1, there are an estimated 1.3 million adult users of vapes in Australia. It has been estimated that of this base number, 20% are exclusively zero-nicotine vapers (n=1.04m). of which 50% are occasional vapers who are unlikely to seek a prescription for smoking cessation or treatment of nicotine addiction (n=520,000). From this number the existing number of vapers who have already obtained a script and will likely continue to do so in the future (n=70,000) are removed, leaving n=450,000. Noting the likely prescribing behaviour detailed above, it is assessed that each patient will consult with a medical practitioner twice a year, meaning 900,000 GP visits.

In this costing, no year-on-year reduction in the rate of prescriptions sought is conservatively assumed. However, it is expected, in line with policy intent, that the population of vape users will decrease following implementation of the proposed regulatory changes, due in part to incidences of successful smoking cessation attempts and increased consumer awareness of the health risks of vaping. So too, then, will the number of GP visits to obtain a prescription. As such, it is estimated that the number of patients seeking a prescription for vapes could reduce by 10% per year, as per the table below.[105] As a result, the impact would be expected to be much lower, with the number of vapers seeking a prescription dropping to 349,000 by Year 10 (2034/35), However, as noted earlier, to avoid underestimation of the impact of the proposed regulatory changes, the unadjusted vaping population base (n=450,00) has been taken forward into subsequent modelling.

Table B1. Reduction in number of GP visits per year to obtain a prescription for vapes

	Year	Population growth	Reduction in those seeking a vaping prescription per year
Yearly Growth Factor		0.90	
Year 1	24/25	900,000	
Year 2	25/26	810,000	-90,000
Year 3	26/27	729,000	-81,000
Year 4	27/28	656,100	-72,900
Year 5	28/29	590,490	-65,610

[104] Advice from the TGA to Noetic on 21 October 2020 stated that although some future importers/wholesalers/sponsors may wish for e-cigarette nicotine to be included on the PBS, there is a high possibility that applications could be rejected.
[105] It has been assumed that there is not a meaningful correlation between the number of vapes and overall increases in the Australian population. Thus, the base population has not been adjusted to account for population increases over the 10-year default period for the regulatory costing.

	Year	Population growth	Reduction in those seeking a vaping prescription per year
Year 6	30/31	531,441	-59,049
Year 7	31/32	478,297	-53,144
Year 8	32/33	430,467	-47,830
Year 9	33/34	387,420	-43,047
Year 10	34/35	348,678	-38,742
	Totals	**5,861,893**	**-551,322**

Number of pharmacy visits

It has been assumed that most patients who obtain a prescription for a therapeutic vape will have it filled, therefore no reduction has been made to the population to account for non-presentation of prescriptions.

Once a consumer has obtained a prescription for a therapeutic vape, they are then required to visit a pharmacy (in person or online), noting that access to overseas retailers via the Personal Importation Scheme will cease under the proposed regulatory changes. Thus, the consumer has two options for obtaining nicotine vapes:

1. visit physical pharmacy to obtain nicotine vapes, or
2. order nicotine vapes from an online pharmacy (domestic only).

According to the Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines,*[106] while the supply of multiple quantities of a prescription at one time is permitted under the regulatory framework this should only occur at the specific direction of the prescriber on each occasion when exceptional circumstances exist to the satisfaction of the pharmacist. For this reason, it is assumed that each pharmacy interaction will provide a 1-month (30-day) supply of nicotine vapes, hence up to 12 pharmacy interactions in a year.

Note that this analysis has not incorporated the possible beneficial impact of the Government's 60-day dispensing reforms.

In terms of the additional regulatory burden associated with a physical pharmacy visit, it is noted that most GP clinics are likely to be collocated with or situated in close proximity to a pharmacy, and that many individuals are likely to incorporate a trip to the pharmacy into other personal activities such as shopping. The travel time associated with a physical pharmacy visit is therefore estimated to be minimal, of the order of 2 minutes. It is estimated that the time within the physical pharmacy would be 5 minutes, incorporating both the wait and consultation time with the pharmacist. Thus, the total time for a physical visit is 7 minutes.

For the purpose of this regulatory costing, the estimates will assume that all prescriptions will be filled by a physical visit to a pharmacy, which represents the greatest overall regulatory burden envelope. In reality, it is estimated that the burden will be substantially lower for the following reasons:

- Based on current practice that 70% of users will obtain their nicotine vapes via an online domestic pharmacy with the remaining 30% obtaining their vape from a physical pharmacy.
- Filling a prescription at an online pharmacy has a reduced regulatory timing cost as there are no associated travel or wait times.
- The ability to upload a script and have it 'on file' also reduces regulatory burden. This means consumers will not need to re-upload their script when getting a repeat filled.
- Consumers who are visiting an online pharmacy send their script to the online domestic pharmacy of their choice. This can be through the GP posting the physical copy of their script by mail with no postage cost to the patient, the GP providing an electronic script direct to the pharmacy, or the consumer uploading/sending the script to their pharmacy of choice. Once the script has been uploaded/provided (virtually or by mail) (estimated to be 4 minutes), the usual processes for online shopping are applicable. This generates no addition to the

[106] Pharmacy Board of Australia, *Guidelines for Dispensing a Medicines*, September 2015.

regulatory burden, compared to the current baseline activity for obtaining nicotine vapes via an online retailer under the Personal Importation Scheme.

- The National Drug Research Institute, Curtin University report 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16'[107] identified 46 medical conditions requiring treatment and care caused by active smoking. It is therefore likely that a portion of users seeking to obtain therapeutic vapes will already be visiting a pharmacy to obtain other therapeutic goods related to a range of medical conditions caused by smoking.

Other considerations

This regulatory burden estimate considers only the changes to legitimate activities under the current regulatory regime. The fundamental aspect of the previous regime, being that nicotine e-liquid is listed on Schedule 4 (prescription-only medicines) of the Poisons Standard and the arising downstream regulatory compliance activities, such as requiring a prescription from a medical practitioner, remain unchanged.

In relation to changes to consumer behaviour, the following points are made:

- All adult zero-nicotine vapers, after a transition period, will no longer have any legal access to zero-nicotine vapes. While this restricts their choice for vapes available as a consumer it does not result in any additional regulatory burden.
- A large proportion of vapers currently aged under 18-years-old would obtain their vapes illegally.
- Current nicotine vapers aged 18 years and over will be able to obtain a prescription for nicotine vapes online and order the product online (total elapsed time is assessed to be no longer than 15 minutes). This is comparable in time to having obtained their vape online using the Personal Importation Scheme so will not result in any additional regulatory burden. Even for those who were obtaining their nicotine vapes via the black market, the time taken to obtain a vape via an online therapeutic pathway is considered equitable and so there will be no additional regulatory burden arising from the proposed regulatory reforms – noting to avoid underestimating the regulatory burden on consumers, we have assumed that all vapers will obtain their therapeutic vapes via a physical visit to a pharmacy).
- There will be no change in regulatory burden for those vapers who are currently obtaining a vaping prescription from a GP, via in-person or telehealth consultation, and visiting a community pharmacy to have their prescription fulfilled.
- Some consumers will choose to discuss with their GP the use of vapes for smoking cessation or the treatment of nicotine addiction. Some would have been visiting their GP already to discuss other health matters, though others will make a specific appointment to do so. It is only for this latter category that an additional regulatory burden will be generated.
- A transition period of greater than 6 months for the withdrawal from sale of all non-TGO 110 compliant vapes would largely negate the costs of consumers needing to purchase a new vaping device, as they would most likely have needed to purchase a new vape anyway, based on an economic life of a vaping devices of approximately 6 months to a year. Conversely, an immediate ban on the sale of vapes outside a pharmacy on passage of the legislation might require consumers to purchase a new vaping device while they still had economic life in their existing vaping device. In the absence of a transition period the average cost of a new vaping device is $150 then the arising cost could be as high as $67.5m ($150 x 450,000 vapers switching to a therapeutic pathway in the first year).
- On average, the cost of vapes sourced solely through a pharmacy may be significantly higher than those sourced through most current means, but no data is available to quantify the impact readily or accurately. Any increased cost of therapeutic vapes is a direct reflection of the additional cost entailed in their manufacture to meet the TGO 110 specifications. Over

[107] National Drug Research Institute, Curtin University report titled 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16', 2019, < https://ndri.curtin.edu.au/NDRI/media/documents/publications/T273.pdf>.

time, as the market for therapeutic vapes increases, fixed production costs could be spread over large production runs, potentially resulting in decreased costs for consumers. This factor cannot be quantified at this time.

Changes to the regulatory burden

Key assumptions

- These estimates are considered the upper limit of expected regulatory costs. For example, it does not include patients seeing GPs for multiple issues.
- There are different routes through which a prescription can be obtained, but for the purpose of this regulatory costing the option generating the highest regulatory cost, in-person visits of 62 minutes additional time, is assumed- noting the caveats outlined above.
- Although under a private prescription a GP could potentially provide up to 12 months' supply, GPs may also choose to provide a lesser number of repeats to cater for more frequent monitoring of their patient's progress towards smoking cessation. It is assumed that on average, GPs will provide 6-months' supply of nicotine vapes per consultation and only one month of supply per filled prescription.
- Many individuals are likely to incorporate a trip to the pharmacy into other personal activities, such as shopping. The total time for a physical visit to a pharmacy is 7 minutes, incorporating travel and wait time, and consultation time with a pharmacist.
- 80% of vapers visiting to obtain a prescription for a therapeutic vape will be bulk billed. The remaining 20% will incur an out-of-pocket cost of $40.42 per consultation.

Inputs

- Number of vapers visiting a GP to obtain a prescription for a therapeutic vape= (450,000) x 2 GP visits per year = 900,000 additional GP consultations.
- Number of vapers visiting a GP to obtain a prescription for a therapeutic vape who will NOT be bulk billed (20%) = 900,000 x 0.2= 180,000.
- Out of pocket cost per non-bulk billed GP consultation = $40.42.
- Number of vapers who will obtain a prescription for a therapeutic vape and visit a physical pharmacy (50% of carry forward vaping population (n=450,000)) = 225,000.
- Number of pharmacy visits per year = 12 (Note: this is the top estimate, as it is not including possible impact of 60 day dispensing reforms or that these are private prescriptions and not subject to dispensing restrictions).
- Time spent by patients for a physical visit to a GP = 62 minutes.
- Time spent by consumers for a physical visit to a pharmacist = 7 minutes.
- Hourly non-work-related cost = $36.

Future population (consumers)

Note- while figures are shown as rounded, actual rounding occurs only in the final step.

Step 1. Calculate total time in minutes to fulfil regulatory requirement:

Annual activities:

- Physical visit to a GP to obtain a prescription for a therapeutic vape: 900,000 (additional GP consultations) x 62 minutes per consultation = 55,800,000 minutes.
- Physical visit to a pharmacy to fulfil a prescription for a therapeutic vape: 225,000 x 7 minutes per visit x 12 visits per year = 18,900,000 minutes.

Step 2. Calculate total time in hours to fulfil regulatory requirement:

Annual activities:

- GP visits = 930,000 hours (55,800,000/60).
- Pharmacy visits = 315,000 hours (18,900,000/60).

Step 3. Apply the hourly rate to determine overall regulatory compliance cost (average cost):

- GP visits: 930,000 hours x hourly rate ($36.00) = $33,480,000.
- Pharmacy visits: 315,000 hours x hourly rate ($36.00) = $11,340,000.
- Total: $33,480,000 (GP visits) + $11,340,000 (pharmacy visits) = $44,820,000.

Step 4: Calculate direct financial costs:

- Out of pocket expenses for visiting a GP to obtain a prescription for a therapeutic vape = 180,000 (900,000 consultations x 20%) x $40.42 = $7,275,600.

Step 5. Determine the average annual cost over the ten-year default period for regulatory changes:

- $44,820,000 (regulatory compliance costs) + $7,275,600 (direct financial costs) = $52,095,600.
- Average annual cost = $52,095,600 or $52.1m.

Average cost per year for consumers (GP & pharmacy visit) + system costs over the default ten-year period under the regulatory burden framework measurement = **$52.1m**

Impact on medical practitioners

Overview

While most of the proposed regulatory measures that comprise Option 3 would not have a direct regulatory impact on medical practitioners, indirectly the changes will lead to a significant shifting of consumer behaviour from illegal to legal channels and therefore increase demand for obtaining nicotine vapes for therapeutic purposes through a prescription. In particular:

> **Measure 1.** The restrictions on importation, manufacture, and supply of all vapes will significantly increase the demand for patients to have consults with medical practitioners to seek access to vapes for therapeutic purposes. As vapes are currently unapproved goods, the mechanisms to prescribe vapes is more onerous than for approved medicines.
>
> **Measure 2.** The only sub-measure to have an impact on medical practitioners will be the ability to utilise an additional supply pathway, SAS C, making prescribing easier than the current SAS B pathway used for therapeutic vapes.
>
> **Measure 3.** The heightened requirements around the quality and safety of vapes will have no direct regulatory impact on medical practitioners.

Although not a regulatory change *per se*, as it is an existing pathway for the provision of unapproved products under the TG regulatory framework, the TGA is seeking to make therapeutic vapes accessible via SAS C, which is permissible for products with established history of use. Currently, nicotine e-liquid can be accessed only via:

- the AP pathway – provide an unapproved product to multiple patients), or
- SAS B pathway[108] – provide an unapproved product to an individual patient on a case-by-case basis but pre-approval required.

[108] Special Access Scheme Category A (SAS A) is not applicable as this is limited to patients who are classified on the TGA website as 'seriously ill', defined as 'a condition that is reasonably likely to lead to a person's death within less than a year or, without early treatment, to the person's premature death'.

The baseline regulatory burden for medical practitioners is based on nicotine e-liquid as a prescription-only medicine (Schedule 4). The regulatory burden for this option reflects the projected increases compared to the current level of consults and prescriptions for therapeutic vapes.

Access through AP and SAS Schemes

Overview

To be able to prescribe nicotine e-liquid for domestic supply, medical practitioners must either be an AP or submit a SAS B submission.[109] The SAS B pathway generates a significantly higher "per transaction" administrative burden to doctors than the AP route, once the doctor is registered as an AP. There is also a delay between the doctor submitting the SAS B submission and receiving approval from the TGA, which will likely result in a patient having to collect their script from the doctor post consultation or delaying their visit to the pharmacy. This, along with the TGA encouraging use of the AP pathway, was assessed in the last regulatory burden estimate to be likely deter the majority of doctors from going down the SAS B pathway. Therefore, it is estimated that only a small percentage of doctors may prefer to use the SAS B pathway, as evidenced by the latest reported figures for the respective prescription pathways.

As of 31 August 2023, there were 2,333 APs for the prescription of nicotine e-liquid and 69,987 unique patients had been provided prescriptions for nicotine e-liquid. Conversely, as at the same date, 641 unique medical practitioners and 17 Nurse Practitioners had received SAS B approvals to access nicotine e-liquid, and 2,987 unique patients had accessed nicotine e-liquid through this pathway. Based on these numbers, patients are currently over 20 times more likely to obtain nicotine e-liquid via the AP rather than the SAS B pathway.

Doctors complete AP application

Doctors who will choose to become APs for vapes, to service the expected shifting behaviour of 450,000 vapers from illegal to legal channels, will be required to acquaint themselves with the requirements associated with becoming an AP. Those who are not already familiar with the AP process will need to undertake initial reading on the AP scheme[110] to understand the application process and ongoing reporting requirements. The estimated reading time is 10 minutes for each doctor.[111]

Doctors who already have an account with a system hosted by the TGA will need to login to the AP portal with their username and password. The estimated time for login with an existing account is 30 seconds.

If a doctor does not already have a login, they will need to set up a new one including a username, password, email address and personal information such as full name, health practitioner type, AHPRA registration number and contact details. The estimated time to establish an account is 5 minutes.

The next step is completing and applying to become an AP. For nicotine vapes, the application process has been streamlined as there is no requirement for endorsement or approval via a human research ethics committee or specialist college to become an AP for products without an established history. Doctors need to complete four simple steps before reviewing and submitting the application.

[109] Note this requirement will no longer be applicable once a vape is entered on the ARTG.

[110] Such as the Authorised Prescriber user guidance document from the TGA – https://www.tga.gov.au/publication/authorised-prescriber-user-guidance.

[111] This estimated time came from doctors reading material on the TGA website such as Access to nicotine-containing e-cigarettes – https://www.tga.gov.au/news/media-releases/access-nicotine-containing-e-cigarettes), material on the Special Access Scheme page – https://www.tga.gov.au/form/special-access-scheme, and on the Authorised Prescribers page – https://www.tga.gov.au/form/authorised-prescribers.

The estimated time for making a new AP application is 5 minutes. Each application is valid for 5 years.[112]

As of 31 August 2023, there were 2,333 APs for the prescription of nicotine e-liquid.

Doctors complete AP 6 monthly reports

A requirement under the AP scheme is that doctors must report on the number of new and existing patients who have been prescribed nicotine vapes within each 6-month reporting period. This enables the TGA to monitor the quantities of new and repeat patients prescribed nicotine vapes under the proposed regulatory change.

APs can submit this information by using the online portal. To complete a report, they will need to login and complete the report template provided, which is a simple one-pager requiring a doctor to provide some initial details, including name, product, approval number and time of reporting. They are then required to enter the number of new and repeat patients in the previous 6-month period. APs should be able to easily access and transfer this information from their prescription software. There should not be any requirement for an AP or their support to change their record keeping processes or update patient databases to obtain this information. The estimated time for submitting an AP 6 monthly report is 10 minutes per AP.

Doctors complete SAS B applications

Doctors and nurse practitioners who are not already familiar with the SAS B process will need to undertake initial reading[113] to understand the submission process and ongoing requirements. The estimated reading time is 10 minutes for each doctor.

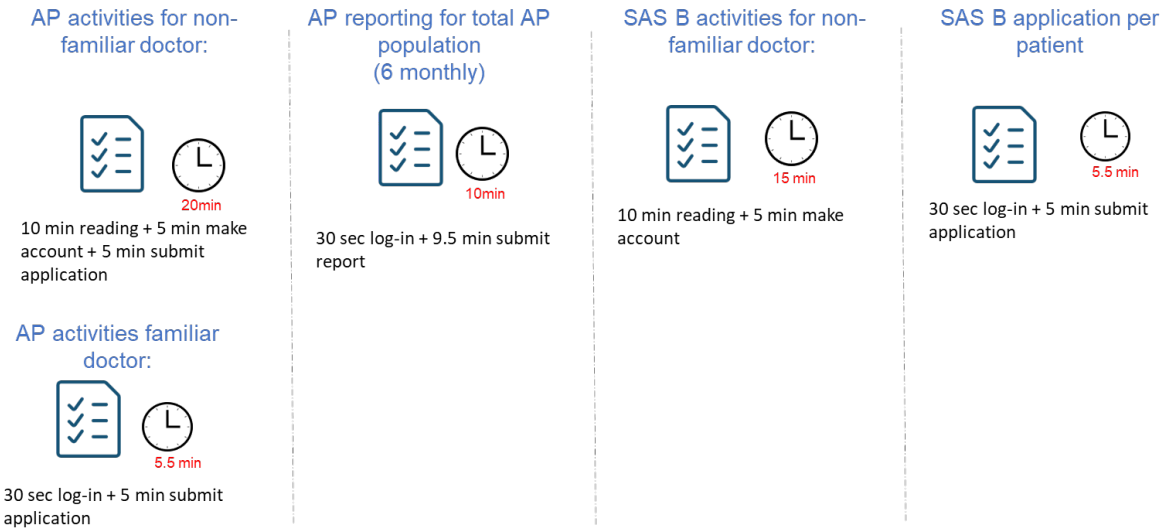
If a practitioner does not already have a login, they will need to set up a new one including a username, password, email address and personal information such as full name, health practitioner type, AHPRA registration number and contact details. The estimated time to establish an account is 5 minutes.

All prescribers who are using the SAS B route must then make a new SAS B submission for each patient for whom they are prescribing nicotine vapes. They must first login, select ‘New SAS submission’, fill in the active ingredient, dosage form and indication, and provide patient details and a diagnosis and clinical justification for the prescription. The prescriber must then read a disclaimer and submit the application to the TGA. The estimated time for each new SAS B submission is 5 minutes.

[112] An AP application expires after 5 years. After this time doctors will be required to make a new AP submission for nicotine if they wish to continue prescribing under the scheme.

[113] Such as the SAS Online System Guidance document from the TGA – https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-online-system-guidance

Figure B1. AP/SAS B requirements and associated timings



Changes to the regulatory burden (SAS C)

The regulatory burden of the SAS C pathway is considerably lower than that of the SAS B pathway, while both have a higher regulatory burden than the AP route, principally due to the need to submit applications per patient. Under the SAS C pathway, prescribers would need to acquaint themselves with the relevant guidance as well as establish a login with the TGA hosted system. However, noting that as of 31 August 2023, 641 unique medical practitioners and 17 Nurse Practitioners had already received SAS approvals to access nicotine e-liquid, it is assumed that many, if not the majority, of these practitioners will simply switch from the SAS B to SAS C. Unlike under SAS B, pre-approval for prescribing is not required for SAS C. Rather, a form must be submitted to the TGA per individual within 28 days after each prescription. A copy of the form must be kept with the patient's medical record, as is the case of the approval provided by the TGA for SAS B. As the information required on the SAS C notification form is less than that required for an SAS B application form, the use of the SAS C rather than SAS B pathway represents a reduction in the existing regulatory burden with completion time being 5 minutes per patient rather than 3 minutes under SAS B. However, the regulatory burden of the AP pathway on a unit level is much less than via either SAS B or C, and AP will likely remain the preferred prescription route going forward.

Future Growth in AP population

As noted above, as of 31 August 2023 there were 2,333 APs. Based on the average daily historical growth rate for APs since the October 2021 reforms, the base number of APs as of 1 July 2024 is estimated to be 3,220. It is also estimated that once the proposed regulatory changes are in place, the number of APs will grow by 10% in the first year, premised on more confidence by practitioners in the new regulatory regime and pressure from patients, and then 2% per year afterwards.

Table B2. Projected growth in APs

	Year	Growth Rate (%)	Total APs	Additional APs	Additional AP reports per year
Base (3220 as of 1 July 24)					
Year 1	24/25	10	3,542	322	644

	Year	Growth Rate (%)	Total APs	Additional APs	Additional AP reports per year
Year 2	25/26	2	3,613	71	786
Year 3	26/27	2	3,685	72	930
Year 4	27/28	2	3,759	74	1,078
Year 5	28/29	2	3,834	75	1,228
Year 6	30/31	2	3,911	77	1,382
Year 7	31/32	2	3,989	78	1,538
Year 8	32/33	2	4,069	80	1,698
Year 9	33/34	2	4,150	81	1,860
Year 10	34/35	2	4,233	83	2,026
			Total	**1,013**	**13,170**

Future growth in SAS population

Any existing practitioners who have previously utilised the SAS B pathway and who now choose to use the SAS C pathway will generate a reduction in the existing regulatory burden. However, the number of prescribers who have utilised the SAS B pathway in the past (641) is minor compared to the number of estimated primacy care practitioners. It is expected that the SAS C pathway will be more likely used by Nurse Practitioners (NP), and as of 30 June 2023, there were 2656 endorsed NPs in Australia.[114] Over the course of the ten-year default period for the regulatory costing the total number of NPs using the SAS C pathway is expected to rise to 5% (n=133). The current number of NP utilising the SAS B pathway is 17, so this represents an increase of 116 (or 12 per year). This increase in population is not material to the overall regulatory costing and any increase in regulatory costing is likely counterbalanced by a reduction in regulatory burden arising from the shifting from the SAS B to SAS C pathways.

Key assumptions

- It is estimated that once the regulatory changes are in place the number of APs will grow by 10% in the first year (based on more confidence by prescribers in the new regulatory regime and pressure from patients) and then 2% per year thereafter. This equates to an additional 691 APs over the 10-year default period for the regulatory costing.
- It is assumed that additional APs are neither familiar with the AP process nor have an existing AP account with the TGA, as previously users of the AP pathway were likely early adopted for using this pathway to prescribe nicotine vapes.
- Current SAS B pathway users will likely switch over to the SAS C pathway and while some growth is expected in the number of NPs who will be using the SAS C pathway, given the time savings arising from using the SAS C rather than the SAS B pathway, the additional regulatory burden is expected to minimal and is not material to this regulatory costing.
- The growth in nicotine vape prescriptions will almost entirely be met using the AP pathway, until and unless a vape is registered on the ARTG.

Inputs

- Number of additional GPs using the AP pathway (over the 10-year period) = 1,013.

[114] Australian Health Practitioner Regulation Agency, 'Nursing and Midwifery Board of Australia – Registrant Data: Reporting period: 1 April 203 to 30 June 2023,' Available at: https://www.nursingmidwiferyboard.gov.au/About/Statistics.aspx

- Time to become familiar with AP pathway, create account and submit application (one-off) = 20 minutes.
- Number of additional AP reports submitted (over the 10-year period) = 13,170.
- Compile and submit an AP report = 10 minutes.
- Hourly work-related labour cost for GPs = $146.09.

Regulatory costing

Note while figures are shown as rounded, the actual rounding occurs only in the final step.

Step 1. Calculate total time in minutes to fulfil regulatory requirement:

One-off activities:

- Familiarisation, account creation and AP application: Additional AP population (1013) x familiarisation training et al (20 minutes) = 20,260 minutes.
- Aggregated activities (over 10-year period):
- Compile AP reports = Additional AP reports (13,170) x report compilation and submission (10 mins) = 131,700 minutes.

Step 2. Calculate total time in hours to fulfil regulatory requirement:

- One-off: 20,260/60 = 337.67 hours.
- Aggregated activities: = 131,700/60 = 2,195 hours.

Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

- One off: 337.67 hours x hourly rate ($146.09) = $49,329.72.
- Aggregated activities: 2,195 hours x hourly rate ($146.09) = $320,618.85.

Step 4. Determine the average annual cost over the ten-year default period for regulatory changes:

- 4,932.97 ($49,329.72 /10) (one-off costs) + $32,061.89 ($320,618.85/10) (aggregated costs) = $36,994.86.

Average annual cost: $36,994.86

Average cost per year for medical practitioners (businesses) over the default ten-year period under the regulatory burden framework measurement = **$36,994.86.**

Impact on pharmacists

Overview

As per the impact on medical practitioners, most of the proposed regulatory measures that comprise Option 3 would not have a direct regulatory impact on pharmacists, but indirectly the changes will lead to a significant shifting of consumer behaviour from illegal to legal channels and therefore increase demand for obtaining nicotine vapes under prescription through a pharmacy. In particular,

> **Measure 1.** The restrictions on importation, manufacture, and supply of all vapes will indirectly but significantly increase the demand for pharmacists to understand dispensing of this new product range. As vapes are currently unapproved goods, the mechanism to access vapes is more onerous than for approved prescription medicines.
>
> **Measure 2.** The measures will not significantly impact pharmacy supply, as they relate to the consultation and prescribing pathways for vapes.

Measure 3. The heightened requirements around the quality and safety of vapes will have no direct regulatory impact on pharmacists.

A pharmacist cannot dispense stock of any unapproved Schedule 4 (prescription only) medicine unless it has been approved for supply via a TGA approved pathway, subject also to state and territory legislation, noting some jurisdictions have technical restrictions on the ability to 'wholesale' unapproved medicines. For this to occur, the pharmacist must confirm that the prescriber is authorised by the TGA to prescribe the specific medicine. This is accomplished by the pharmacist viewing documentary evidence from the prescriber of their authority to prescribe.

Pharmacies may obtain nicotine vapes and hold them in their dispensary prior to receiving prescriptions issued under AP or SAS provisions. The current TGA advice to pharmacists is that if sourcing nicotine e-liquid from an Australian sponsor or pharmaceutical wholesaler, they should make inquiries 'about conformance to TGO 110 prior to ordering the products.[115] You should only dispense products that conform to the requirements of TGO 110,[116] and if sourcing directly from overseas suppliers, then the pharmacist would be considered the Australian sponsor and be primarily responsible for ensuring the products conform to the requirements of TGO 110.[117] Under the proposed regulatory changes, this checking by pharmacist will no longer be needed, as import will be dependent on compliance with TGO 110.

The baseline regulatory burden for pharmacists is relatively low, relating only to increased engagement to fill prescriptions. Pharmacists are already familiar with vapes under the current regime, as well as any associated training already required.

Changes to the regulatory burden

Unverified data indicates that at least a third and potentially as high as half of all community pharmacies in Australia stock nicotine e-liquid.[118] The expected increase in prescriptions for nicotine vapes (450,000 additional prescriptions per year) will translate into increased volume of supply of nicotine vapes by pharmacies as, under the implementation of the proposed regulatory changes, they will be the only legal avenue of domestic supply. Evidence provided by wholesalers in response to the September 2023 consultation paper indicates that while nicotine vapes may be widely stocked across community pharmacies, actual sales are low and much smaller than the number of unique prescriptions made for nicotine vaping. This suggests that many patients with a prescription are currently purchasing from an overseas online supplier, relying on the provisions of the Personal Importation Scheme.

An output from the implementation of Measure 3 will be publication by the TGA of a list vapes that have been certified as compliant with quality requirements. The publication of this list would simplify the TGO 110 conformance activity undertaken by community pharmacies.

[115] Noting that the current TGO 110 does not have provide any guidance as to the safety and quality aspect requirements for vaping devices (as opposed to the e-liquid).

[116] Department of Health and Aged Care, 'Nicotine vaping products: Information for pharmacists', (16 March 2022). Available at: https://www.tga.gov.au/resources/resource/guidance/nicotine-vaping-products-information-pharmacists

[117] Advice from the Pharmaceutical Society of Australia is that pharmacists should consider importing nicotine e-liquid from countries with regulatory requirements that are similar to TGO 110 (e.g., UK, EU, Canada, US and NZ) and where there is evidence that the imported product complies with the regulatory requirements of that country. See Pharmaceutical Society of Australia, 'Guidelines for pharmacists providing smoking cessation support', September 2021.

[118] Table 13 (p.18) of the PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022 produced by the Department of Health and Aged Care details that as of 30 June 2022 there were 5,901 community pharmacies as approved suppliers under the PBS. The smokefree webpage (https://smokefreeclinic.com.au/) operated by Telehealth Clinics Australian Pty Ltd details that over 2,200 community pharmacies stock nicotine e-liquid, (https://smokefreeclinic.com.au/nicotine-vapes-australia/)

Under the Pharmaceutical Society of Australia's Code of Ethics for Pharmacists,[119] Care Principle 1 states that 'a pharmacist makes the health and wellbeing of the patient their first priority'. Under this principle a pharmacist, 'before recommending a therapeutic product, considers available evidence and supports the patient to make an informed choice and only supplies a product when satisfied that it is appropriate, and the person understands how to use it correctly'. To this end, pharmacists should have already completed training to become familiar with the risks of vapes and the safe operation of various vaping devices.

Key assumptions

- All practising Australian pharmacists should already be familiar with dispensing nicotine vapes, and a standard training program is in place to maintain knowledge of therapeutic vapes as they become available.
- For each nicotine vape dispensed a pharmacist will spend on average 1 minute engaging with the consumer about the risks and safe operation of a vape. This is an average figure because some consumers will be familiar with vapes while others will not and will therefore require more detailed advice from the pharmacist.

Inputs

- Engagement with consumer (per dispensing) = 1 minute.
- Annual number of nicotine vaping prescription filled by physical pharmacies = 2,700,000 (from earlier prescription modelling).
- Hourly work-related labour cost for pharmacists = $146.09.

Regulatory costing

Note while figures are shown as rounded, the actual rounding occurs only in the final step.

Step 1. Calculate total time in minutes to fulfil regulatory requirements:

- Annual activities (over 10-year period):
- Engagement with consumer: Number of interactions annually = 2,700,000 x 1 min per interaction = 2,700,000 minutes.

Step 2. Calculate total time in hours to fulfil regulatory requirement:

- Annual: 2,700,000 minutes/60 = 45,000 hours

Step 3. Apply the hourly rate to determine annual regulatory compliance cost:

- Annual: 45,000 hours x hourly rate ($146.09) = $6,574,050.

Average annual cost: $6,574,050

Average cost per year for pharmacists (businesses) over the default ten-year period under the regulatory burden framework measurement is $6,574,050 (engagement with consumers) or **$6.57m.**

[119] Pharmaceutical Society of Australia, 'Code of Ethics for Pharmacists,' (January 2017). Available at: https://www.psa.org.au/wp-content/uploads/2018/07/PSA-Code-of-Ethics-2017.pdf#:~:text=These%20values%20reflect%20the%20commitment%20of%20pharmacists%20to,ensure%20fair%20and%20equitable%20allocation%20of%20resources%20%28justice%29

Impact on manufacturers and suppliers

Overview

Of the main stakeholder segments examined in the regulatory burden estimate, the impact of the proposed regulatory changes will be significantly felt by manufacturers and suppliers (sponsors). In particular:

> **Measure 1.** The restrictions on importation, manufacture, and supply of vapes other than for therapeutic use will prevent supply from most currently existing manufacturers and suppliers. The range of products in the market will diminish substantially, with all non-therapeutic vapes or disposable single use vapes being banned from domestic sale and export. For manufacturers and suppliers looking to work within the legal provisions, these changes will support the viability of their supply model. Note that currently nicotine vapes already can only be legally supplied through pharmacies, so any other supply is considered illegal, and the arising impact of the proposed regulatory changes is not measured in the costing. However, for zero-nicotine vapes most supply is currently legal, and both domestic and overseas manufacturers would be significantly impacted by these measures, noting that the impact on overseas manufacturers is excluded from the regulatory costing.
>
> **Measure 2.** The measures to change market accessibility requirements for therapeutic vapes will not significantly impact manufacturers and suppliers, with the exception of a minor impact arising from licencing and permit requirements for those supplying therapeutic vapes to pharmacies.
>
> **Measure 3**. The heightened requirements around the quality and safety of both the e-liquid and the device components will have a significant regulatory impact on manufacturers and suppliers, forcing them to reformulate and re-package their product range if they wish to supply therapeutic vapes to pharmacies (else they will need to exit the vaping market).

Nicotine vapes (including disposable single use vapes)

While currently no therapeutic vapes are registered on the ARTG, some companies are legally supplying nicotine vapes and a proportion of these suppliers are looking to continue to supply under the proposed reforms. All manufacturers are likely to have to make changes to the range of vapes supplied, labelling and potentially re-formulation. Other current suppliers do not have vapes that meet the new requirements and without substantial product change will be withdrawn from the market in Australia. There are also a large number of illegal suppliers, but the impact of the measures on these entities is not captured in this regulatory costing.

Some suppliers are looking to position themselves to submit an application to register vapes, but the pre- and post-market regulatory burden arising from this process was captured in the 2021 regulatory burden estimate and is not impacted by the proposed regulatory changes.

The TGA is not aware of any current domestic manufacturers of nicotine vapes, although some domestic manufacturers of zero-nicotine vapes may be able to pivot to supply compliant therapeutic vapes.

Zero-nicotine vapes

Most supply of zero-nicotine vapes is currently legal in Australia, so the impact of the ban on the manufacture and supply of these vapes will be substantial. All domestic manufacturers of zero-nicotine e-liquids will be severely impacted by the proposed regulatory changes, and without finding other revenue streams such as producing pharmaceutical-grade therapeutic vapes, will not be economically viable.

Desktop research identified 7 Australian manufacturers of zero-nicotine e-liquids, but the majority of zero-nicotine e-liquids appear to be imported, with one of the leading Australian online vape stores listing over 130 different brands, with international ‘juices’ from the USA, UK and Malaysia. Another

advertised e-liquids made in-house as well e-liquid supplied from New Zealand, Malaysia, USA, UK and Canada.

Changes to the regulatory burden

Tightening of import restrictions

There will remain a legal Australian market for vapes to be supplied for therapeutic purposes, with a valid prescription, via community pharmacies and pharmaceutical wholesalers. However, under these reforms, a licensing and permit scheme for vapes will be introduced and administered by the Office of Drug Control (ODC).

The regime will require an annual renewal of the permit, to provide appropriate control measures such as licences and permits to regulate the supply of imported vapes to the Australian market, and to reduce the risk of diversion of vapes into the black market. The proposed regulatory scheme is as follows:

1. **Licence application form**

An online licence application form is completed and submitted. The form requires information on a range of topics including:

- the nature of the organisation applying for the licence including ABN, and the uploading of a company extract as well as the provision of primary and alternate contact details
- a fit and proper person check including the uploading of an informed consent form, details of any convictions, civil penalties and revocation, and financial background
- state/territory licences to trade nicotine
- details of standard operating procedures relating to security and control measures
- site details including physical security details.

It is estimated that the time taken to review the guidance material, source and potentially compile the likely required background information, and complete the online application form for a vape importer licence is 8 hours, plus another 8 hours if standard operating procedures relating to security and control measures, the retention of records and the engagement and retention of suitable staff need to be compiled. This time includes an allowance for responding to any follow-up questions from the ODC. The licence will be perpetual but may be subject to surrender, suspension or revocation.

2. **Permit application form**

A separate permit application form will be completed to import vapes. Permits will be valid for 12 months, and a permit is required per product (e.g., nicotine concentration/flavour). A new permit application form will be required each time an importer adds a new product to the product range. This is a downloadable form that is submitted via email. The form requires details such as:

- licence details
- overview of activities which the licence holder intends to undertake under the permit
- proposed permit start date (permits are granted for a standard 12 months from date of grant)
- supply details, including the details of the overseas manufacturer (likely supported by commercial documentation detailing the intention to purchase and supply)
- reference to standing operating procedures relating to security and control measures
- declaration section.

It is estimated that the time taken to review the guidance material, complete the form, source the required supporting documentation (noting that much of it will already be generated as part of

standard commercial transactions between an importer and an overseas supplier) and submit is 30 minutes per permit. As applicants become more familiar with the process, less time will be needed to review the guidance material, but this time saving is not considered material to the overall time taken, noting that the responsibility for completing the permit may not always rest with the same individual.

It has been assumed that a permit will be submitted per year per product from the start of the regulatory changes coming into effect, that each sponsor will have four different formulations of vapes, and that each importer will update their product range with new products 3 times over a ten-year period. Updates may include variation in vaping devices, packaging, pack-size or flavouring ingredients such as concentration of mint flavour, tobacco flavour or menthol. With a sponsor population of 5, this gives a total count of permit applications of 200 over the ten-year period (5 sponsors x 4 permits per year x 10 years). It is assumed any new product will take the place of an existing product, and so this will not alter the overall number of permits applied for.

3. Activity report

As a signatory to the Single Convention on Narcotic Drugs 1961, Australia has reporting requirements to the International Narcotic Control Board. It is unlikely that similar reporting requirements will arise for vapes but the ODC may use a quarterly reporting cycle (similar reporting frequency for other controlled activities) for monitoring purposes. This report could be used to acquit permits issued against permits used, as this information may not be provided back to the ODC by the ABF. Importers will be required to provide quarterly and on-demand reports for any adverse events. This report is estimated to take 30 minutes to complete, so with 4 reports per year total completion time is estimated to be 2 hours per sponsor. No estimate has been made for the number of adverse events reports submitted but this is expected to be minimal, given the quality and safety specifications in the revised TGO 110.

4. Inspection and audits

It is not currently envisaged that an audit and inspection regime will apply to vapes importation licence holders.

5. Fees and charges

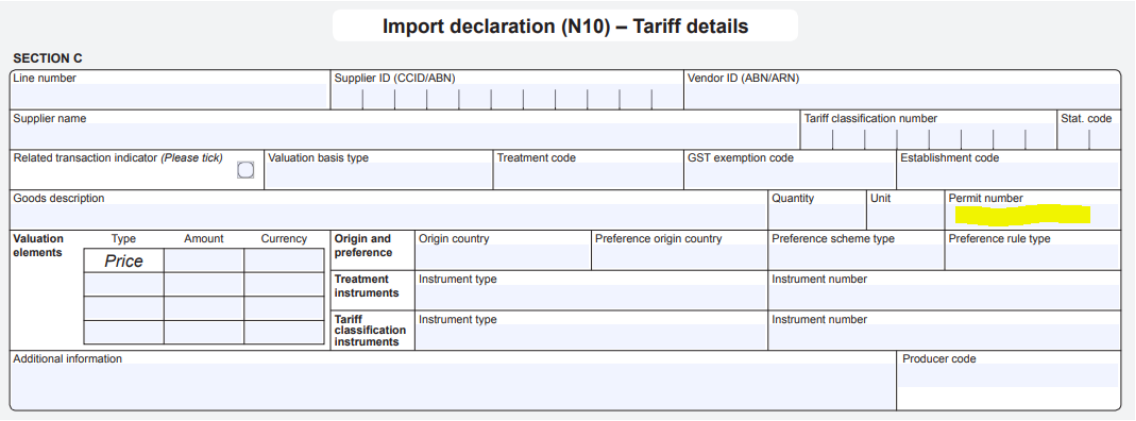
The policy position that ODC licensing and permit activities will not be cost recovered excludes this form of activity from the regulatory burden estimate.

6. Border documentation

For vapes to legally enter Australia, the importer, or the customs broker working on their behalf, must complete an import declaration form (Form N10), which is submitted to the ABF. It is assumed that future importers will likely already have in place business-to-business data interchange software to largely automate the production of the required importation documentation. Their stock management system will provide the necessary details to their customs broker/or via an application programming interface (API) with Integrated Cargo System (ICS) to complete the importation documentation.

The proposed regulatory changes do not impact upon the border regulatory processes except in one aspect, which is the inclusion of the permit number on the import declaration, as depicted below. To facilitate border clearance is it likely that a copy of the permit will also be provided for review by the ABF. It is estimated that the time taken to enter the permit number and provide a copy of the permit to the ABF is 5 minutes per consignment.

Figure B2. Section C of the Import Declaration (N10)



Import declaration (N10) – Tariff details

SECTION C

Line number	Supplier ID (CCID/ABN)			Vendor ID (ABN/ARN)				
Supplier name					Tariff classification number			Stat. code
Related transaction indicator *(Please tick)* ☐	Valuation basis type	Treatment code		GST exemption code		Establishment code		
Goods description					Quantity	Unit	Permit number	
Valuation elements Type: *Price*	Amount	Currency	**Origin and preference**	Origin country	Preference origin country	Preference scheme type	Preference rule type	
			Treatment instruments	Instrument type		Instrument number		
			Tariff classification instruments	Instrument type		Instrument number		
Additional information							Producer code	

If a package containing vapes is detected at the border by the ABF without an appropriate permit, then the standard process, in general terms, is as follows:

- the ABF detects a good that could breach the *Customs Act 1901*
- the ABF refers the good to the ODC, as the permit authority
- the ODC writes to the importer requesting that they provide evidence, within a two-week timeframe, that the importation is lawful. The importer will need to provide the necessary documentary evidence to demonstrate a legal right to the good- in this case, a valid permit
- if the importer provides sufficient evidence to the ODC that the importation is lawful the ODC advises the ABF to release the good and advises the importer- usually by email- of this decision. If sufficient evidence is not provided, the ODC provides a letter to the ABF requesting them to seize the good.

If the ABF is requested to seize the good by the ODC, then the ABF seizure process is followed with the importer able to submit a Claim for Return of Seized Goods (Form B144) or contest the matter in court. Neither avenue is likely to be successful for the importer, as without a valid permit they have no legal right to import nicotine vapes into Australia. This aspect has therefore been excluded from the regulatory burden estimate.

Overall regulatory burden of the proposed regulatory changes

Key assumptions

- The ODC will institute a licensing and permit scheme to control the importation of vapes into Australia. Granting of licences will be perpetual and permits will need to be renewed annually or if new products are added to the product range.
- Any regulatory activities undertaken by the ODC in relation to vapes will not be subject to cost recovery.
- All nicotine vapes (e-liquid and devices) will continue to be manufactured offshore.
- Companies involved with the importation of nicotine vapes into Australia are experienced importers.
- Each importer will import one consignment per quarter.
- Each sponsor will have four different formulations of vapes (hence 4 permits per year).
- The time spent by sponsors to complete licence application is considered an upper estimate.
- Over the 10-year period of the regulatory costing, sponsors will update their product range with 3 new products, but these new products will displace existing products and so will not increase the overall number of permits submitted.

- Most current importers of zero-nicotine e-liquids or vaping devices for non-therapeutic use will pursue other markets rather than pursue the therapeutic pathway to supply vapes.

Inputs

- Number of separate sponsors importing nicotine vapes into Australia = 5.
- Time spent by sponsors to complete licence application = 16 hours (960 minutes).
- Number of permit applications per sponsor per year = 4 (4 x products).
- Time spent by licence holders to complete a permit application = 30 minutes
- Number of consignments per importer per year = 4.
- Time spent by licence holders to compile each activity report = 30 minutes.
- Activity reports per year = 4.
- Time spent by importers to enter permit information into import declaration and provide a copy of the permit to the ABF (per consignment) = 5 minutes.
- Hourly work-related labour cost = $79.63.

Future population (importers/sponsors)

Note while figures are shown as rounded, the actual rounding occurs only in the final step.

Step 1. Calculate total time in minutes to fulfil regulatory requirement:

One-off activities:

- Licence application: Apply for licence (960 minutes) x importer population (5) = 4,800 minutes.
- Annual activities:
    - Permit application (annual): apply for permit (30 minutes) x number of permits per importer per year (4) x importer population (5) = 600 minutes.
    - Border documentation: provide permit details to ABF (5 minutes)) x number of consignments per importer per year (4) x importer population (5) = 100 minutes.
    - Activity reporting: Complete activity report (30 minutes) x number of reports per year (4) x importer population (5) = 600 minutes.

Summary of annual activities: annual permit application (6,000 minutes) + border documentation (100 minutes) + activity reporting (600 minutes) = **1,300 minutes.**

Step 2. Calculate total time in hours to fulfil regulatory requirement:

- One-off: 4,800/60 = 80 hours.
- Annual activities: = 1,300/60 = 21.67 hours.

Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

- One-off: 80 hours x hourly rate ($79.63) = $6,270.40.
- Annual activities: 21.67 hours x hourly rate ($79.63) = $1,725.32.

Step 4. Determine the average annual cost over the ten-year default period for regulatory changes:

- $637.04 ($6,270.40/10) (one-off costs) + $1,725.32 (annual costs) = $2,362.36.
- Average annual cost = $2,362.36 or $0.002m.

Requirement for a pre-market notification of vapes to the TGA supported by evidentiary documentation

It is envisaged that pre-market notification will be provided on a paper-based form. It is intended that the sponsor of the vapes will complete a declaration stating that each of their products complies with all specified matters in the revised TGO 110, including e-liquid composition and device safety and quality requirements. This declaration is therefore likely to be limited to one per sponsor, per formulation. While notifications are perpetual, new notifications will need to be provided if new formulations are added to the supplier's product range. Although the notification form has yet to be designed, it is estimated that this form will take 20 minutes to complete and submit.

It is a legal requirement that the sponsor produce upon demand by the TGA evidence to demonstrate how they have met the matters specified in TGO 110. It is expected that this evidence is held for each batch of vapes supplied. The testing required on the e-liquid is expected to be equivalent to the current level of testing, but for demonstration of the device components some additional cost is expected, and this has been rolled into the overall costs to meet revised TGO 110 specifications.

Although the notification form has yet to be designed, it is estimated that this form will take 20 minutes to complete and submit.

Overall regulatory burden of the proposed regulatory changes

Key assumptions

- Pre-market notifications will be provided on a paper-based form which will be printed, scanned and emailed, rather than online via TGA Business Services (TBS).
- Any regulatory activities undertaken by the TGA in relation to vapes will not be subject to cost recovery.
- Each sponsor will have 4 vape products when they complete the initial round of pre-market notifications.
- Three new products will be added to the vape range per sponsor over a 10-year period.

Inputs

- Number of sponsors of vapes in Australia = 5.
- Time spent by importation licence holders to compile pre-market notification = 20 minutes.
- Hourly work-related labour cost = $79.63.

Future population (importers/sponsors)

Note while figures are shown as rounded, the actual rounding occurs only in the final step.

Step 1. Calculate total time in minutes to fulfil regulatory requirement:

- Aggregated activities (over a 10-year period): complete pre-market notification (20 minutes) x number of notifications over 10 years ((4 (initial products) +3 (new products)) x importer population (5)) = 700 minutes.

Step 2. Calculate total time in hours to fulfil regulatory requirement:

- One-off: 700/60 = 11.67 hours.

Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

- Aggregated: 11.67 hours x hourly rate ($79.63) = $929.02.

Step 4. Determine the average annual cost over the ten-year default period for regulatory changes:

- $929.02/10 = $92.90.
- Average annual cost = $92.90 ($93).

Meeting revised requirements for TGO 110

The supply of vapes will need to accord with the revised TGO 110 (Measure 3) and as such it is anticipated that over the ten-year period of the regulatory costing there will likely be no more than 5 legal importers.[120] It is assumed that the current importers of vaping devices (without associated nicotine e-liquid) and zero-nicotine e-liquids, as well as the domestic manufacturers of zero-nicotine e-liquid, will exit the market. The underlying rationale for the small number of sponsors is that the impact of the proposed changes to TGO 110, particularly in relation to formulation of the nicotine e-liquid and the safety and quality requirements for vaping devices, will reduce the scope for product and therefore brand differentiation.

Collectively, the requirements outlined in TGO 110 are internationally unique, and are likely to require some level of re-formulation and/or packaging specific for the Australian market. Below we have outlined the likely impact for each set of requirements, and these have been costed collectively. This is largely due to the limited availability of data from the sector and large variation of individual costs for each supplier.

Pharmaceutical-like packaging

The vast majority of nicotine e-liquids worldwide are not supplied in plain packaging, but pharmaceutical or 'plain' packaging is required in Israel and has been proposed but not yet enacted in the Netherlands.[121] It is noted, however, that some existing nicotine e-liquid suppliers in Australia are going down the pharmaceutical pathway have also moved substantially towards plain packaging, with others being supportive of its introduction.

While plain packaging is widespread in the pharmaceutical industry and is becoming more prevalent in the manufacture of traditional tobacco products such as cigarettes, the cross-over of the manufacturing base of these industries and that for vapes is not known at this time. If plain packaging requirements are restricted to cardboard outer packaging, then the switch-over is relatively straightforward, particularly if the implementation period crosses over standard industry rebranding cycles. In this instance, the revised packaging would need to be passed to a graphic designer with the inhouse management/legal team signing-off on the packaging mock-up. The revised design is then forwarded to a commercial printer to produce the outer packaging, which is delivered to the production facility for incorporation into the production run. The incorporation of plain packaging requirements becomes more complicated when applied to the immediate packaging of the therapeutic product.

The switch to plain packaging for vapes is likely to entail substantial compliance costs as, at least in the short term, separate production runs would likely need to be set up by overseas manufacturers to specifically provide product for the Australian market, noting that other markets exist for products that accord with the flavour and nicotine concentrations being considered. These costs have not been separately estimated.

Restricting other ingredients in the e-liquid

The current requirements set out in TGO 110 for the quality of the e-liquid are not changing substantially under these reforms. In fact, the testing requirements to demonstrate compliance are expected to be lower than required by other countries, where the absence of specified prohibited

[120] A proxy indicator for the number of sponsors is what would be considered a mature product line for existing NRT products listed on the ARTG (n=103) of which there are only five sponsors (Alphapharm Pty Ltd, Haleon Australian Pty Ltd, Johnson & Johnson Pacific Pty Ltd, Medis Pharma Pty Ltd and Orion Laboratories Pty Ltd trading as Perrigo Australia). The estimation of 5 sponsors also accords with responses to the September 2023 consultation paper, with 4 organisations indicating that they were well advanced in going down this pathway and one other organisation indicting it was under consideration.

[121] Plain packaging of vaping products came into force in the Canadian province of British Columbia on 11 August 2020 but were repealed on 4 April 2022.

ingredients must be demonstrated. It is not expected that formulation changes will need to be made to meet the new requirements.

Flavours

As noted in the November 2022 TGA consultation paper, several comparable international regulators have restricted or indicated an intention to restrict flavours. A cursory review of online international vaping retailers reveals that the flavours being considered for nicotine e-liquids are readily available. Additionally, existing nicotine e-liquid suppliers in Australia going down the therapeutic pathway already utilise the likely flavours being considered. However, if the formulation of the flavours is different to the current vapes, such as restricting the amount of menthol present, then there would be a substantial additional regulatory cost to manufacturers.

Nicotine concentration

As noted in the November 2022 TGA consultation paper, at least 34 other international regulators, including the UK, Canada, Saudi Arabia and the EU countries, have set maximum freebase nicotine concentrations for nicotine e-liquid. The likely Australian sponsors for vapes should be able to readily obtain e-liquid of the specified maximum concentration from overseas suppliers. Some vapes containing higher concentrations of nicotine may be prohibited, but re-formulation is not expected, hence there would be no direct regulatory cost.

Medical devices considerations

The revised TGO 110 will also establish our requirements to address the safety and quality for device components of vapes. Based on feedback from the consultation, most manufacturers of vapes manufacturers stated that they are familiar with international standards (FDA, MHRA and EU) for devices, and all but one meet QMS requirements. Based on this feedback the cost to individual manufacturers of meeting these requirements will vary greatly, but it will be substantial for some.

Overall regulatory burden of the proposed regulatory changes

Key assumptions

- Any regulatory activities undertaken by the TGA in relation to vapes will not be subject to cost recovery.
- Assumed cost per sponsor for entire product range for all activities to comply with revised TGO 110 requirements (including product reformulation, changes to packaging, device product measures (including product testing to confirm adherence to device safety and quality requirements) = $1,500,000.

Inputs

- Number of sponsors for vapes that meet TGO 110 requirements = 5.
- Cost to meet revised TGO 110 requirements = $1,500,000.

Future population (importers)

Step 1. Calculate aggregate cost to fulfil regulatory requirements:

- One-off cost: number of sponsors (5) = x cost to meet revised TGO 110 requirements ($1,500,000) = $7,500,000.

Step 2. Calculate the average annual cost over the 10-year default period for a regulatory costing:

- $7,500,000/10 = $750,000.
- Average annual cost = $750,000.

Average cost per year for manufacturers and suppliers (businesses) over the default ten-year period under the regulatory burden framework measurement is $2,362 (licences and permits) + $93 (notifications) + $750,000 (compliance with revised TGO 110 requirements) = $752,515 or **$0.75m**

Impact on retailers

Of all the stakeholder group considered in this regulatory burden measurement the greatest impact of the proposed regulatory changes will be borne by specialist vaping retailers. There will no longer be any legal retail market for vapes outside pharmacies. In particular,

> **Measure 1.** The restrictions on importation, manufacture, and supply of vapes other than for therapeutic use will prevent any import and supply of vapes by retailers.
>
> **Measure 2**. The measures to change market accessibility requirements for therapeutic vapes will not significantly impact vaping retailers, as these measures relate to the consultation, prescribing and supply pathways for vapes.
>
> **Measure 3.** The heightened requirements around the quality and safety of both the e-liquid and the device components will not have a significant regulatory impact on vaping retailers.

The extent of the impact on individual retailers will be dependent on the centrality of vapes to their business model and the duration of the transition period.

Some retailers, such as convenience stores, will be able to pivot to focus on other product lines:

- Specialist tobacconists (many of whom stock vapes) will incur significant reductions to their revenue and profitability speciality vape stores will most likely close.
- A small number of domestic manufacturers of zero-nicotine e-liquids (n=7) will also likely be severely impacted by the proposed regulatory changes and without finding other revenue streams (such producing pharmaceutical-grade nicotine vapes) will struggle to be economically viable.

Noting that the supply of zero-nicotine vapes to those aged 18 years old and over is currently legal in all states with the exception of WA, a transition period of at least a year for the withdrawal from sale of all non-TGO 110 compliant vapes would allow vape retailers to use up existing purchased raw materials and run down stockholdings. Conversely, the impending ban on importation, manufacture and sale of zero-nicotine vapes in Australia is likely to create increased demand among vapers, as they will seek to stock up on vapes prior to them being withdrawn from retail sale.

Currently, it is estimated that there are 7,171 Australian retailers with 8,775 physical stores selling vapes in Australia. Most (97%) of these retailers are convenience stores where vapes make up a small percentage of their product mix. However, these Australian retailers also include 205 vape specialist stores with a product mix that focuses on vapes and 1,592 tobacconist stores where a significant part of their product mix comprises of vapes. These retailers will be most impacted by the proposed regulatory changes.

There is no doubt that the proposed regulatory changes will generate significant economic loss and economic hardship for speciality vape stores, many of which business have been built-up over a number of years, have made significant investment in retail fixtures and/or the development of an online marketplace, and have likely entered into long-term financial arrangements, such as property leases. Some owners will likely be bankrupted, and employees will most likely lose their jobs. While these indirect costs, defined as costs that may arise due to changes in market structure and competition impacts, are excluded under the RBM framework, the associated impacts are acknowledged. As there is significant variety among vape retailers in relation to investments made, staff numbers and long-term financial arrangements, the overall impact of the closing down of the vape retailer sector cannot be accurately estimated. However, it is reasonable to assume that this will result in several hundred lost jobs (just for vape speciality stores) and probably over $100m in lost investment and additional costs arising from the breaking of long-term financial arrangements, if we assume a financial loss of approximately $500,000 per vape specialist store. To these broad impact

estimates would need to be added the impact on the other Australian vape retailers identified above outside vape specialist stores.

The proposed reforms are not directly seeking to effect a change in the operation of the market, in the way that actions undertaken by the Australian Government, for example by the Australian Competition and Consumer Commission (ACCC), may seek to address a market failure. Rather the objectives of the proposed regulatory changes are seeking to achieve a public health benefit by removing the supply of vapes outside a therapeutic pathway requiring a prescription and supply by a pharmacy. Vape retailers can choose to stock consumer goods rather than vapes and still operate in the retail market, noting this would require a substantial adjustment to their existing business model for some retailers, and recognising not all would be willing or able to do so.

While some vape retailers may have reduced their stockholdings due to the publicity given to the Government's stated intention to ban the domestic sale of vapes, others might have increased stockholdings in expectation of increased consumer demand driven by the impending ban or in the expectation either that they will be compensated by the Government for economic losses arising from the regulatory changes or that the regulatory changes will not come to pass. As noted earlier, the incurred cost of changing business model would be reduced by a longer transition period for the withdrawal from sale of all non-TGO 110 compliant vapes, to allow vaping retailers to use up existing purchased raw materials and run down stockholdings. In the absence of a transition period, such as should there be immediate prohibition of any vape sales outside a pharmacy, the costs incurred by vape retailers are difficult to quantify in the absence of the relevant market data, but would be much greater, and perhaps over $200 million.[122] This estimation is based on the historical size of the Australian market, noting a portion of these vaping retail sales, perhaps even the majority, would relate to nicotine vapes that since October 2021 can only legally be supplied via a pharmacy. The extent to which this factor would impact on the potential economic cost of shutting down the vaping retail sector cannot be determined at this time.

Average cost per year for stakeholders for all measures captured by Option 3, over the default ten-year period = **$59.46m (plus costs on vaping store closures)**

Option 4

Option 4, in which vapes would only be available if they are an approved good on the ARTG, would largely replicate the arising regulatory burden as for Option 3, except:

- Consumers would have no legal pathway to access vapes unless and until a product is entered on the ARTG, so the costing impacts would be delayed, but other impacts will largely be the same over the 10 years.
- Medical practitioners would initially have less regulatory burden, as there will be a delay in consumers needing prescriptions and then will no longer be a requirement for AP or SAS pathway activities.
- Pharmacists are likely to be less impacted initially, as consumers are not able to get a prescription until there is an approved product, but the impact will be the same over the 10 years.
- For manufacturers and suppliers the impact would be significant, as they would need to upgrade facilities to meet the GMP requirements and collate data to meet the full prescription medicine requirements. There would be no need to obtain a licence or permits (Measure 1 of Option 3), nor notify the TGA of compliance with the specifications of TGO 110 (Measure 2 of

[122] The value of the vaping market in Australia was estimated in 2019 to be $125m (USD) = $188m (AUD). The market has had consistent year-on-year growth (since 2014 – the start year for the report) and so would be expected to be significant larger than the 2019 figure, noting the impact of the October 2021 reforms on legal sales of vapes in retail settings would need to be determined. See < Australia: e-cigarette and vaping sales value 2019 | Statista>.

Option 3), so the associated regulatory costs for these regulatory changes have not been take forward into Option 4.

While, at least in the short term, this policy is likely to further incentivise growth in the black market for sale of nicotine vapes, this is excluded from the regulatory costing.

The impact on vape retailers would be the same as under Option 3, in that the sector will cease to exist.

The costs on manufacturers and sponsors cannot, at this stage, be accurately quantified, but are likely to be at least double those of achieving compliance with the revised TGO 110 specifications (under Measure 3 of Option 3) - so $1.5 x 2 = $3m.

Overall regulatory burden of the proposed regulatory changes

Key assumptions

- Any regulatory activities undertaken by the TGA in relation to vapes will not be subject to cost recovery.
- The impact on consumers and pharmacists is the same as those costed for Option 3 ($16.14m and $2.57m, respectively).
- Assumed cost per sponsor for entire product range for all activities to comply ARTG registration requirements = $3,000,000.

  These requirements may be too onerous for some manufacturers, who may choose not to seek registration (so the number of potential sponsors has been reduced from 5 to 4).

Inputs

- Number of sponsors likely to seek registration = 4.
- Cost to meet ARTG registration requirements = $3,000,000.

Future population (importers)

Step 1. Calculate aggregate cost to fulfil regulatory requirements:

- Aggregate cost: number of sponsors (4) = x cost to meet registration requirements ($3,000,000) = $12,000,000.

Step 2. Calculate the average annual cost over the 10-year default period for a regulatory costing:

- $12,000,000/10 = $1,200,000.
- Average cost per year = $1,200,000.

Average cost per year for manufacturers and suppliers (businesses) over the default ten-year period under the regulatory burden framework measurement is meet ARTG registration requirements is $1.20m + $52.1m (consumers) + $6.57m (pharmacists) = **$59.87m (plus costs on vaping store closures)**

Conclusion

As per the Australian Government's requirements and OIA guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost. The following table provides the average estimated regulatory compliance costs arising from the proposed regulatory changes.

Table B3: Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) ($million)

Change in costs	Business	Community Organisation	Individual	Total change in costs
Option 1				
Maintain the status quo: Personal Importation Scheme remains as does current complexity of border enforcement activities				
Option 2				
Regulating vapes under a consumer model				
Option 3				
Measure 1: Restrictions on importation, manufacture and supply of all vapes	6.57 (Pharmacists) 0.002 (Manufacturers and Suppliers) Total = 2.57		52.1	58.67
Measure 2: Changes to market accessibility requirements, including better regulation of device components	0.035 (Medical Practitioners) 0.0009 (Manufacturers and Suppliers) Total = 0.04			0.04
Measure 3: Improving quality standards for unapproved (unregistered) vapes	0.75 (Manufacturers and Suppliers)			0.75
Measure 4. Strengthening domestic compliance and enforcement mechanisms				
Total for Option 3	7.36		52.1	59.46
Option 4				
Same as for Option 3, except requiring vapes to be registered on the ARTG (and not available as 'unapproved' therapeutic goods)	6.57 (Pharmacists) 1.2 (Manufacturers and Suppliers)		52.1	59.87

Therapeutic Goods Administration

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