Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Proposed reforms to the regulation of vapes

## Consultation paper

September 2023

# Overview

As part of the National Tobacco Strategy 2023-2030, the Government announced in May 2023 a comprehensive package of new measures to reduce vaping rates through stronger legislation, enforcement, education, and support. The Therapeutic Goods Administration (TGA) is supporting this work within the Department of Health and Aged Care in four main streams of activity to facilitate a national response:

- **Stream 1 – Development of new legislative and regulatory reforms** to regulate the importation, manufacture and supply of vapes.
- **Stream 2 – Implementation and enforcement of new legislative and regulatory reforms**. This will include both immediate and ongoing activities such as intelligence sharing across jurisdictions, increased compliance activities at the border, development of a national enforcement framework, and enforcement of regulatory controls across jurisdictions.
- **Stream 3 – Preventive public health campaigns** focused on vaping and smoking cessation.
- **Stream 4 – Increasing and improving vaping and smoking cessation support**. This includes redeveloping the My QuitBuddy app, developing a new online quitting hub, new clinical guidance for health professionals, and improved Quitline services. Where applicable, these initiatives will build on existing materials and resources that have been developed in other jurisdictions.

This consultation relates to activity Stream 1. It follows from TGA's public consultation on the regulation of nicotine vaping products (NVPs) in November 2022 (Proposed reforms to the regulation of nicotine vaping products - Therapeutic Goods Administration - Citizen Space (tga.gov.au) and the policy announcement of the Minister for Health and Aged Care on 2 May 2023 of the intention to take stronger action on smoking and vaping.

# Purpose and scope

The purpose of this consultation is to seek views on the proposed reforms to the regulation of vapes from an extensive range of targeted stakeholders. It will contribute to informing the development of the regulatory scheme and the preparation of an impact analysis. The consultation is structured as follows:

- **Part 1: Background**
- **Part 2: Reform proposals**

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

- the scheduling of nicotine in Schedule 4 to the Poisons Standard and the regulatory controls stemming from this scheduling in the states and territories.
- the regulation of products containing nicotine that are not vapes or a component of vapes (e.g. nicotine patches, gum or mouth sprays), except where such regulation might relate to vapes.
- clinical guidelines and recommended dosage regimes relating to therapeutic vapes for smoking cessation or the treatment of nicotine addiction.
- the Government's new tobacco control legislation, which has been the subject of separate consultation.

## What do we mean by 'vapes' in this consultation paper?

A vape is intended to have its ordinary meaning and comprises both e-liquid and device components, however manufactured, assembled or presented, which, when used together, are designed or intended to vaporise and administer the e-liquid component by inhalation in a manner that replicates, or produces an experience similar to, smoking.

The e-liquid component is the solution or material that is vaporised for administration by inhalation, and the device component supports the vaporisation and inhalation. On occasion, the device component may simply comprise a housing unit and battery. The e-liquid 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 materials (otherwise known as e-liquids, vape liquids or e-juices) will be referred to as **e-liquids** throughout this document. 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, cartridge or refillable liquid. However, some vapes, such as disposable single use 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 or release (or assist), by electronic means, an aerosol or vapour (i.e. mist or emission) for inhalation.

Vapes come in two main configurations:

- a **disposable single use** (closed system) vape[1] that is pre-filled with an e-liquid, cannot be refilled and is disposed of once the vaping substance runs out.
- a **refillable/reusable**[2] 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 a therapeutic use (e.g. smoking cessation or treatment of nicotine addiction), irrespective of nicotine content.

# Providing feedback

We invite you to provide your feedback by completing our online survey on the TGA Consultation Hub.

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

Submissions will be published in accordance with Australia's obligations under Article 5.3 of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). Consistent with those obligations and the National Tobacco Strategy 2023-2030, steps have been taken by the TGA as part of this consultation to protect Australia's public health policies

[1] Disposable single use (closed system) vapes when referenced in this document refer to sealed unit vapes.
[2] 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.

from all commercial and other vested interests of the tobacco industry, including those related to tobacco products and electronic nicotine delivery systems (vapes).

The Guidelines for implementation of Article 5.3 require that the Australian Government ensures that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent.

On request, we will remove individuals' names from submissions before publication. We will not publish personal email addresses, telephone numbers and home addresses. On request, we will consider redacting sensitive commercial information.

The views expressed in the submissions are those of the individuals or organisations who submit them, and their publication does not imply any acceptance of, or agreement with, these views by the TGA. The closing date for providing feedback is **21 September 2023**.

# Part 1: Background

## The 2021 reforms

The regulatory requirements for therapeutic vapes containing nicotine changed on 1 October 2021, 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 vaping products containing nicotine (also referred to as NVPs) were subject to regulatory controls under state and territory legislation relating to prescription medicines (the 2021 reforms).

The intention of the 2021 reforms was to prevent children and adolescents from accessing vaping products that contain nicotine, whilst allowing legitimate users to access the products for smoking cessation under medical supervision with a prescription. However, recent evidence suggests that the 2021 reforms are not meeting these objectives.

## Evidence of increasing vape use and public health risks

Vape marketing and use in Australia has increased in recent years, particularly among young people. These developments pose a major risk to population health and have the potential to disrupt the significant achievements that Australia has made in tobacco control to date.

### Prevalence of vaping in Australia

Despite regulatory settings, current evidence suggests that vape use in Australia is increasing, particularly among children and adolescents. Preliminary data analysed by Cancer Council Victoria[3] 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).
- 18-24 year olds reported the highest prevalence of current e-cigarette use (19.8%).

Research suggests that young people see vaping as socially acceptable and separate from smoking. The most important factors for young people vaping include flavours and taste, price, and the inconspicuous nature of vaping.[4]

### Impacts of vapes on tobacco smoking initiation

There is evidence that vaping is a gateway to smoking. Vaping mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely.[5]

Evidence from multiple countries suggests that young non-smokers who use e-cigarettes are consistently more prone than those avoiding e-cigarettes to initiate combustible cigarette smoking and become current smokers. Evidence also suggests that former smokers using

[3] 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

[4] Generation Vape is led by Cancer Council NSW in partnership with the Daffodil Centre and the University of Sydney, and funded by the Australian Government Department of Health, Minderoo Foundation, the NSW Ministry of Health and Cancer Institute NSW. Vaping product access and use among 14-17-year-olds in New South Wales: a cross-sectional study. September 2022. Watts, C., Egger, S., Dessaix, A., Brooks, A., Jenkinson, E., Grogan, P., Freeman, B.

[5] Baenziger ON, Ford L, Yazidjoglou A, Yazidjoglou A, Grace Joshy G ,Emily Banks E. E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis. BMJ Open 2021; 11(3): e045603.

e-cigarettes may be at a greater risk of relapse to tobacco smoking when compared to non-e-cigarettes users. Dual use of e-cigarettes and tobacco products is also common and harmful.[6]

Preliminary data analysed by Cancer Council Victoria (above) shows that:[7]

- rates of current[8] smoking among people aged 14 years and over remained relatively stable between 2020 (11.2%) and the first quarter of 2023 (11.8%)
  rates of current smoking among people aged between 14-17 years of age increased from ~5% in 2020 to ~13% in the first quarter of 2023.

**Impacts on human health**

Vapes are associated with a range of short-term health risks and their long-term health effects are not yet known. A review of global evidence published by the Australian National University in April 2022 found (among other things):

- substantial evidence that e-cigarette use by non-smokers results in dependence
- conclusive evidence that their use can cause respiratory disease, severe burns, nicotine poisoning and seizures.[9]

In June 2022, the National Health and Medical Research Council (NHMRC) published a CEO Statement providing public health advice on the safety and impacts of e-cigarettes. This statement was based on a review of the current evidence and broadly concluded that there are health and safety risks are associated with e-cigarette use.[10] The CEO Statement advises, among other things:

- e-cigarettes can be harmful. All e-cigarette users are exposed to chemicals and toxins that can harm your health.
- use of e-cigarettes can result in serious burns and injuries. In some cases, these burns and injuries have resulted in death. Poor-quality e-cigarette batteries or high-power devices increase the risk of explosions. Use of e-cigarettes can lead to seizures in some users.
- exposure to e-liquids that contain nicotine can result in poisoning for some users which, although it may not happen to everyone, can be severe and cause death.
- e-cigarette-related calls to Australian Poisons Information Centres have increased over the past 5 years. Most poisonings occur in toddlers and adults.
- use of e-cigarettes can result in a serious and sometimes fatal lung condition known as E-cigarette or Vaping Associated Lung Injury (EVALI) in some users. Most cases of EVALI reported in the United States of America were linked to cannabis oils and vitamin E acetate but other chemicals may also contribute to this condition.
- use of e-cigarettes that contain nicotine probably results in throat irritation, cough, dizziness, headaches and nausea.

[6] Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.
[7] 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: Current vaping and smoking in the Australian population aged 14 years or older – February 2018 to March 2023 | Australian Government Department of Health and Aged Care
[8] Use in the past 30 days of being surveyed.
[9] Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.
[10] 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

- there is not enough information from human research studies to know about the potential impacts of e-cigarette use on conditions such as cancer and cardiovascular disease, reproductive health, respiratory conditions (e.g. asthma) and mental illness.
- lack of information does not mean that e-cigarettes are safe. More information is needed to understand the long-term impacts of e-cigarette use.

### Vapes for smoking cessation and other cessation treatment options

It is acknowledged that vapes can also assist some people to give up smoking. Many submissions to the 2022 consultation provided personal accounts of how vapes had helped them to give up smoking.

While the scientific evidence about the effectiveness of vapes as a smoking cessation aid remains limited, a recently updated Cochrane Review (November 2022) compared the effects of NVPs with other ways of delivering nicotine, such as Nicotine Replacement Therapies (NRTs) like patches and chewing gum, e-cigarettes without nicotine, and behavioural support only/no support.[11] 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.[12] Of the included studies, 10 (all but 1 contributing to the authors' main comparisons) were rated at low risk of bias overall, 50 at high risk overall (including all non-randomized studies), and the remainder at unclear risk.[13]

In relation to quit rates:

- there was high certainty that quit rates were higher in people randomized to NVP than in those randomised to NRT (risk ratio RR 1.63, 95% CI 1.30 to 2.04; 6 studies, 2378 participants). In absolute terms, this might translate to an additional 4 quitters per 100 using NVPs.

- there was moderate-certainty evidence that quit rates were higher in people randomised to NVPs than to non-nicotine vaping products (RR 1.94, 95% CI 1.21 to 3.13; 5 studies, 1447 participants). In absolute terms, this might lead to an additional 7 quitters per 100 using NVPs.

- compared to behavioural support only/no support, quit rates were higher for participants randomised to NVPs (RR 2.66, 95% CI 1.52 to 4.65; 7 studies, 3126 participants). In absolute terms, this represents an additional 2 quitters per 100 using NVPs. However, this finding was of very low certainty, due to issues with imprecision and risk of bias.[14]

There are no therapeutic vapes that have been evaluated by the TGA as being safe and effective for smoking cessation. Further, there is a wide range of smoking cessation products already on the Australian market that have been rigorously assessed by the TGA with an established safety and efficacy profile. Many of these products are widely available in supermarkets and certain products are also subsidised on the Pharmaceutical Benefits Scheme.

[11,12,13,14] Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022, Issue 11. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full

**Summary**

Given the current evidence base, it is desirable for implement additional measures to denormalise and limit the marketing of all vapes, with a key focus on preventing uptake of vapes by young people and those who have never smoked. However, given the significant health impacts of smoking, it is considered appropriate for vapes to be accessed under medical supervision. A health practitioner can provide advice on the risks associated with using vapes and alternative treatment options.

## Accessing vapes in Australia

Vaping regulation 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. The proposed regulation of all vapes under therapeutic goods and customs legislation is a primary focus of this consultation.

Current legislation relating to nicotine vapes is designed to prevent their importation, manufacture and supply, while allowing smokers to obtain therapeutic vapes solely for smoking cessation under medical supervision with a prescription.

Nicotine vapes must only be lawfully dispensed by pharmacists in Australia. 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. 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 it is relatively limited and inconsistent. The device components of vapes are also currently subject to limited regulation.

## Commonwealth legislation

At the Commonwealth level, NVPs are regulated as medicines under the *Therapeutic Goods Act 1989* (the TG Act). This means that NVPs cannot be imported into, manufactured in, or supplied in Australia, unless registered in the Australian Register of Therapeutic Goods (the ARTG) or a lawful exception to registration applies, namely, exemption, approval or authority. Retail supply is not generally regulated under the TG Act.

There are currently no NVPs registered in the ARTG. However, NVPs may be accessed with a prescription via three main[15] established pathways for lawfully accessing 'unapproved' (meaning unregistered) medicines under the TG Act:

- Personal Importation Scheme: this scheme allows a person with a prescription from an Australian medical practitioner to directly import up to 3 months' supply of NVPs for their own personal use. A person may also import NVPs 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 NVPs to certain patients as an aid to stop smoking.

[15] There are also some other pathways to access unapproved goods that could be utilised to access NVPs, including through extemporaneous compounding or the clinical trial notification scheme. However, the TGA is not aware of significant supplies through these pathways and consideration is being given to excluding vapes from the extemporaneous compounding exemption.

- Special Access Scheme - Category B (SAS B): under this scheme, a health practitioner may apply to the TGA to supply NVPs to a single patient on a case-by-case basis.

Consumers may purchase NVPs from Australian pharmacies with a prescription from a practitioner authorised or approved under the AP or SAS B schemes.

While NVPs may be accessed through established pathways under the TG Act for "unapproved" (unregistered) goods, NVPs must currently meet minimum quality and safety requirements specified in a standard that came into force on 1 October 2021, *Therapeutic Goods (Standard for Nicotine Vaping Product) (TGO 110) Order 2021* (**TGO 110**).

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. It is proposed that the exclusion is revisited in the context of these reforms to ensure that proper controls and oversight are applied to device components of vapes moving forward.

## State and territory legislation

Responsibility for the regulation of all prescription medicines (including NVPs) is shared between the Commonwealth, states and territories.

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

Retail and wholesale supply of NVPs is currently controlled by state and territory legislation. NVPs contain scheduled (S4) substances and may therefore only be lawfully supplied by pharmacists to patients with a prescription. NVPs cannot be supplied by vape shops, convenience stores etc. Licensing requirements also apply to the wholesale supply of NVPs.

All states and territories restrict the supply of NVPs, and therapeutic 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 vaping devices as part of a medically supervised smoking cessation program.

## Federal cooperative scheme for therapeutic goods

The TG Act provides a substantially uniform national system of controls over therapeutic goods, facilitating trade between the states and territories and benefiting both patients and industry. All states (except for WA) and territories have enacted corresponding laws. These laws adopt the Commonwealth TG Act, as amended from time to time, as a law of its jurisdiction. This means that, under this cooperative scheme, any amendments to the Commonwealth TG Act are adopted automatically in participating jurisdictions.

In practice, the corresponding laws operate to extend the application of the Commonwealth TG Act to non-corporate entities and activities done during, or in preparation for, intrastate trade and commerce.

The TGA is considering utilising the federal cooperative scheme as the mechanism for implementing key aspects of the proposed reforms for the regulation of vapes, to ensure a simpler and more uniform approach in participating jurisdictions.

## Why is regulatory change needed?

Reforms are needed to address the disconcerting rate at which vape use is increasing in Australia outside lawful prescription pathways, and to make regulatory controls simpler to understand and easier to enforce.

Current regulation of vapes relies on demonstrating nicotine content. This is difficult both at the border and in retail settings because it is not possible to easily distinguish nicotine vapes from non-nicotine vapes without laboratory testing. There is a widespread practice of concealing nicotine content to avoid regulatory controls, as demonstrated in TGA published testing results (https://www.tga.gov.au/resources/lab-test-reports).

The concealment of nicotine in vapes is especially damaging for unwitting consumers, including children and adolescents, who are becoming addicted to nicotine. It has also significantly undermined the effectiveness of the 2021 reforms. Consequently, as part of this consultation, it is imperative to consider whether regulatory control is necessary to cover all vapes, irrespective of nicotine content or therapeutic claims.

The absence of any pre-market regulatory controls for “unapproved” therapeutic vapes by the TGA has meant that patients, practitioners and regulators are not clear about the therapeutic vapes that may be lawfully supplied in Australia. This has also impeded the 2021 reforms.

Failure to address these problems with substantial reforms will increase the likelihood of harms that may be experienced by a generation of users. The status quo has proven ineffective for controlling the importation, manufacture and supply of vapes, and the current patchwork of Commonwealth, state and territory laws does not send a comprehensive message of the need to restrict access for therapeutic purposes. Further, the complexity of regulation between the Commonwealth, states and territories has been difficult to enforce, and the gaps in coverage may be exploited by companies wishing to profit at the cost of population health.

## The 2022 public consultation

Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on a range of proposed measures relating to NVPs to better support the 2021 reforms. The consultation sought feedback on changes to border controls for NVPs, pre-market TGA assessment of NVPs, minimum quality and safety standards for NVPs, and clarification of 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/importers
- vaping retailers, including convenience stores and petrol stations
- pro-vaping associations
- individual healthcare professionals
- the general public, including individual vapers, smokers and ex-smokers.

## Changes to border controls

TGA's preferred option during the consultation was to strengthen border controls for NVPs by requiring licence and permits and to close off the personal importation scheme. This approach was largely supported by state and territory governments, health professional bodies, public health associations, individual health professionals, university researchers and companies marketing therapeutic vapes to Australian pharmacies.

Many (but not all) of these groups also submitted that border controls should be placed on zero nicotine vapes, which went further than the option proposed in the consultation paper.

Individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations did not generally support any border controls.

## Pre-market TGA assessment of NVPs

TGA's preferred option during the consultation (in the absence of a registered product) was to require pre-market TGA assessment of NVPs against a product standard specifying certain quality and safety requirements when supplied as unapproved goods (unregistered on the ARTG).

Companies supplying to the prescription pharmacy market supported this approach, as did about half of state and territory governments, half of health professional bodies and nearly half of individual health professionals.

Almost half of the public health associations and health professional bodies responding to the 2022 consultation proposed instead that all NVPs be registered in the ARTG and opposed pre-market assessment against a standard on account of concerns that it could be misinterpreted as TGA approval.

A large number of individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations supported at least some regulation to ensure quality and safety (but with NVPs regulated as consumer goods, rather than prescription medicines).

## Strengthening quality standards for NVPs

TGA's preferred option to strengthen Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 was strongly supported by state and territory governments, health professional bodies, individual health professionals, public health associations and university researchers. The proposed changes canvassed in the 2022 consultation included the introduction of warning statements (opposed by some), a requirement for pharmaceutical-like packaging, lower maximum allowable nicotine concentrations, a prohibition or restriction on flavours and certain other ingredients, and a limitation on vape volume and overall nicotine content.

Many respondents to the 2022 consultation also called for the imposition of similar controls on zero nicotine vapes, which was at the time outside the scope of the consultation.

Many individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations proposed abandoning the prescription model and TGO 110 (also outside the

scope of the consultation), but many in this category did support a degree of regulation to ensure vape quality and safety.

There was significant support for banning disposable single use vapes from all categories of submitters (including individual vapers), but this was opposed by some due to concerns a ban could affect accessibility for smoking cessation and the risks of using alternative products.

# Developments following the 2022 consultation

## Minister for Health and Aged Care's announcement

Following the results of the 2022 consultation and advice from health experts, the Minister for Health and Aged Care announced on 2 May 2023 the Government's intention to take strong action to address the importation, manufacture and supply of unlawful vapes by introducing a comprehensive range of reforms, including those to:

- stop the importation of non-prescription vapes
- increase the minimum quality standards for vapes including by restricting flavours, colours, and other ingredients
- require pharmaceutical-like packaging
- reduce nicotine concentrations and volumes
- ban all disposable single use vapes
- end vape sales in convenience stores and other retail settings.

During the 2022 consultation, most public health stakeholders and health professionals called for more extensive regulation of all vapes, noting the health risks of vapes and limited evidence of their effectiveness for smoking cessation. However, feedback also recognised that vapes may assist a cohort of people to give up smoking (as noted by many individuals who made submissions to the 2022 consultation). Given this, the proposed reforms would not prohibit the supply of all vapes in Australia. Certain vapes would continue to be available with a prescription, where clinically appropriate for therapeutic use, including smoking cessation or the treatment of nicotine addiction.

The approach aligns with most leading public health organisations in Australia, including the Australian Medical Association, the Royal Australian College of General Practitioners (RACGP), the Cancer Council, and the National Health and Medical Research Council. It also accords with the latest advice on smoking cessation from the RACGP, which provides that therapeutic vapes should not be a first-line treatment for smoking cessation.

## Further issues for consultation

The purpose of this consultation paper is to seek feedback on issues that were not canvassed in the 2022 consultation, as well as those arising from further consideration of the regulatory parameters following consultation feedback. In particular, the paper seeks feedback on proposed restrictions on the importation, manufacture and supply of all vapes (not only therapeutic vapes), changes to the regulation of device components, and further details of the proposed reforms as outlined in the 2022 consultation.

### Restrictions on importation, manufacture and supply of all vapes

The Government is proposing to prohibit the importation, manufacture and supply of any vapes that are not therapeutic vapes by relying on the federal cooperative scheme for therapeutic goods. Under this approach, therapeutic vapes will need to be included in the ARTG or subject to appropriate regulatory controls (including a notification of compliance

with the relevant quality standard, TGO 110) to be lawfully imported, manufactured or supplied in Australia.

Consistent with the Government's policy announcement, therapeutic vapes should only be accessed by patients under medical supervision and supplied in pharmacies with a prescription. Consideration is also being given to whether the restrictions should also apply to the exportation of vapes, except for those included in the ARTG and those subject to appropriate regulatory controls under the TG Act.

### Changes to the regulation of the device components of therapeutic vapes

Changes are also being considered to the current regulatory requirements for the device components of therapeutic vapes to address possible quality and safety risks, simplify the regulatory controls, and aid compliance and enforcement.

Following the 2021 reforms, most vaping devices were effectively excluded from regulation as therapeutic goods under the TG Act unless intended by the manufacturer to be exclusively used for the administration of a medicine. The current regulatory scheme for vaping devices that are subject to TGA regulatory control is complex. Some are categorised as medicines (disposable and non-refillable device components) and others as medical devices (open refillable device components).

A lack of consistency in the regulation of NVPs and vaping devices complicates compliance and enforcement efforts at the border and domestically. Failure to properly regulate the device components of therapeutic vapes under the TG Act presents a potential risk to patients. In the absence of regulatory controls under the TG Act, there is little quality or safety oversight of device components (other than through consumer legislation and tort laws). However, device components have been associated with numerous safety risks.

In June 2022, the National Health and Medical Research Council (NHMRC) published a Chief Executive Officer (CEO) Statement[16] summarising risks associated with vaping devices. There is reliable evidence that vapes have caused serious burns and injuries, which in some cases have resulted in death, life-threatening injury, permanent disfigurement or disability. As a result, broader regulatory oversight under the TG Act is being considered to guard against these risks.

[16] 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

# Part 2: Reform proposals

There are four broad proposals being considered to give effect to the national vaping reforms:

- **Proposal 1** - restrictions on importation, manufacture and supply of all vapes
- **Proposal 2** - changes to market accessibility requirements for therapeutic vapes
- **Proposal 3** - heightening quality and safety standards for therapeutic vapes
- **Proposal 4** - strengthening domestic compliance and enforcement mechanisms.

The proposed changes would need to be made through amendments to primary and subordinate legislation, including regulations under the *Customs Act 1901*. Amendments to subordinate legislation, including legislative instruments made under the TG Act, could be progressed separately and commence earlier than amendments to primary legislation, depending on the policy approach. However, all elements of the proposed reforms are likely to be needed to ensure that implementation is effective.

## Proposal 1 – Restrictions on importation, manufacture and supply of all vapes

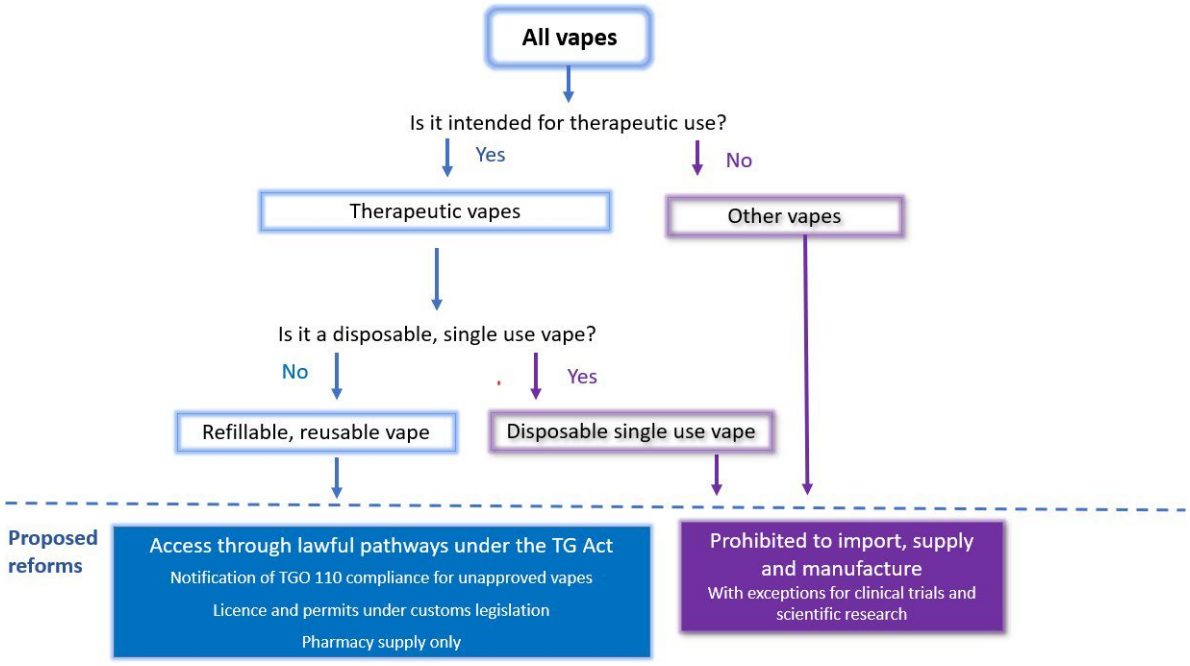
It is proposed to implement a nationally consistent response to vaping throughout Australia, in line with the policy announcement of the Minister for Health and Aged Care on 2 May 2023.

The proposed reforms would rely on the federal cooperative scheme for therapeutic goods, which (as mentioned above) is automatically applied in each state or territory, other than WA, through corresponding therapeutic goods laws. Specifically, the reforms are proposed to:

- expand the scope of the TG Act to prohibit the importation, manufacture and supply of disposable single use (closed system) vapes irrespective of nicotine content or therapeutic claims (with minor exceptions for clinical trials and scientific research)
- prohibit the importation, manufacture and supply of all other vapes unless included in the ARTG or subject to appropriate regulatory controls under the TG Act (including notification of compliance with the relevant quality standard)
- prohibit the advertising of vapes generally, consistent with the approach for prescription medicines, and otherwise to stop aggressive marketing of vapes to children and adolescents.

Any ban or restriction on the importation, manufacture or supply of vapes under the TG Act would be complemented by a prohibition on the importation of vapes under customs legislation. As mentioned above, consideration is also being given to a possible prohibition on exportation of vapes, depending on the international trade law risks.

**Figure 1.** Access to vapes under the proposed reforms




## 1.1 Prohibit the importation, manufacture and supply of all disposable single use vapes

It is proposed to ban all disposable single use (closed system) vapes, under the TG Act, irrespective of nicotine content or therapeutic claims, with minor exceptions, for example for clinical trials and scientific research. This approach was supported by most respondents to the 2022 consultation on the basis that disposable single use vapes are preferred by children and adolescents (due to their low cost and ease of concealment from parents and teachers).

It was also recognised that disposable single use vapes were damaging to the environment, as they are made predominantly of plastic and contain batteries that end up in landfill.

It is acknowledged that this proposal would have a significant impact on any businesses that may be currently importing, manufacturing or supplying zero nicotine disposable single use vapes.

It is proposed that the importation of disposable single use vapes would be prohibited under both the TG Act and *Customs (Prohibited Imports) Regulations 1956.* In addition, the TG Act would prohibit the domestic manufacture and supply of these products.

It is proposed that the prohibition on manufacturing of disposable single use vapes would extend to extemporaneous compounding. Consideration will also be given as to whether any amendments are necessary to the starting materials exemption in the *Therapeutic Goods Regulations 1990*.

## 1.2 Prohibit the importation, manufacture and supply of all other vapes

It is proposed that the importation, manufacture and supply of all other vapes is prohibited, except therapeutic vapes that comply with regulatory controls under the TG Act (with licensing and notification requirements). The proposal aims to significantly restrict the importation, manufacture and supply of vapes in Australia to legitimate therapeutic vapes, as illustrated in **Figure 1.**

Together with the ban on disposable single use vapes, this proposal would tighten the regulatory controls for vapes and thereby ease the compliance and enforcement effort at the border and domestically.

Under this proposal, the importation of all vapes (including both e-liquid and device components) would be prohibited under the *Customs (Prohibited Imports) Regulations 1956* unless a licence and permit are issued by the Office of Drug Control (ODC). The issue of the 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 Australian Border Force (ABF) and other compliance and enforcement officers in attempting to distinguish between lawful and unlawful vapes. Under the proposed reforms, the only vapes that may be imported, manufactured and supplied in Australia will be those for which the TGA has received a notification from an importer or manufacturer and published that notification on its website.

It is acknowledged that this will have a significant impact on businesses currently lawfully importing, manufacturing or supplying zero nicotine vapes (particularly e-liquids). However, stricter controls are considered necessary to address the serious public health risks posed by vaping.

Consideration is also being given to requiring import licences and permits under customs legislation for bulk nicotine imports to guard against the unlawful domestic manufacturing of vapes.

As above, the TGA is considering whether the prohibition on manufacturing should extend to extemporaneous compounding. Consideration will also be given as to whether any amendments are necessary to the starting materials exemption in the *Therapeutic Goods Regulations 1990.* It is not proposed to modify the ordinary requirement for domestic manufacture to comply with licensing requirements in Part 3-3 of the TG Act in the interests of quality and safety.

## 1.3 Prevent importation through the personal importation scheme

It is proposed to prevent the importations of all vapes to Australia through the Personal Importation Scheme, subject to the preservation of a traveller's exemption. The Personal Importation Scheme presently allows a person with a prescription from an Australian medical practitioner to directly import up to three months' supply of NVPs for their personal use. There can be any number of repeat transactions on the same prescription. This makes the scheme prone to abuse and 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 proposed reforms designed to simplify enforcement, which will depend on compliance and enforcement officers being able to clearly identify the vapes that may be lawfully supplied. Alongside the risks of accessing unregulated vapes, it is considered that the personal importation scheme poses an unacceptable risk to health of the users and is counterproductive to the overall regulation of lawful therapeutic vapes in Australia.

## 1.4 Preserve the traveller's exemption

Despite the proposed cessation of the personal importation scheme, it is proposed to preserve a limited travellers' 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:

- require a prescription or a letter from a medical practitioner (including a medical practitioner overseas) for passengers on a ship or plane; and
- apply appropriate quantity limits of vapes for such passengers, to avoid this exemption becoming a pathway for commercial quantities (such limits are proposed to be three months' treatment, or a numerical limit of 60 vapes and 2 vaping devices, subject to a consideration of the period of time the passenger is to be in Australia).

## 1.5 Prohibit the advertisement of vapes generally

Under the current TG framework, the advertising of prescription-only and certain pharmacist only medicines to the public is prohibited. Consistent with this prohibition, the TGA is proposing to prohibit the advertisement of vapes generally, with similar exceptions to those that apply under the TG Act presently, such as to allow appropriate marketing of therapeutic vapes to health practitioners, to allow health practitioners to provide advice to patients about use of therapeutic vapes in a clinical setting, and to allow limited advertising by pharmacies. The proposal is intended to stop aggressive marketing to children and adolescents and the promotion of vapes outside the prescription pathway.

This measure would interact with proposed changes to tobacco laws that are intended to be introduced to Parliament in coming months. The tobacco laws will include amendments to address the advertising of e-cigarettes. The interaction with those laws and the proposed prohibition on advertising of vapes under the TG Act is proposed to be considered as part of the development of legislative amendments to effect the vaping reforms. Any consequential amendments to tobacco legislation would be considered in that process.

### *Questions*

1. Do you support the proposed approach to ban disposable single use vapes absolutely and all other vapes, except those for legitimate therapeutic use in compliance with the TG Act?
2. How would you anticipate industry and consumers to respond to a ban on the importation, manufacture and supply of non-therapeutic vapes?
3. Do you support the proposal to remove the personal importation scheme exception for vapes? If not, what would be the impact on you?
4. Do you agree with the proposal to retain a traveller's exemption, including the proposed limits?
5. Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)?
6. [If applicable] Suppliers, what part of the supply chain do you occupy? For example, are you an importer, manufacturer, warehouser, wholesaler, retailer or a combination of these (please specify)?
    a. What proportion of your sales volumes is attributable to vape sales [i.e. quantity of vapes sold]?

b. What proportion of your sales revenue is attributable to vape sales [i.e. revenue earned from sales]?

c. What impact would the proposed measures have on your sales volumes?

d. What impact would the proposed measures have on your sales revenues?

e. What proportion of your vapes sales is attributable to disposable single use vapes versus refillable products?

f. How would restricting the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes in Australia impact you?

g. How much stock do you have in Australia currently and how long would it take to sell that stock?

h. What would be the cost to you if you were required to dispose or otherwise move on existing stock?

# Proposal 2 – Changes to market accessibility requirements, including better regulation of device components

The proposed reforms would prohibit the importation, manufacture or supply of vapes in Australia unless the vape is:

- registered on the ARTG, or
- subject to appropriate regulatory controls under the TG Act and accessed through lawful exceptions to registration.

Presently, there is no vape registered on the ARTG and any requirement for therapeutic vapes to be TGA-registered could result in no therapeutic vapes being available in Australia for many years. This situation would undermine legitimate access to therapeutic vapes for smoking cessation, treatment of nicotine addiction or other therapeutic purposes. Consequently, it is necessary to maintain lawful, alternative market access pathways under the TG Act for unregistered vapes to preserve therapeutic access, subject to appropriate regulatory controls, including those relating to device components.

The current regulation of vapes does not sufficiently address device components. The proposed reforms would address this situation by enhancing the existing requirements for the e-liquid component and specifying new quality and safety requirements for the device components in the relevant TGO 110.

The following proposed regulatory controls are discussed further below:

- pre-market notification of compliance with TGO 110
- streamlined access under the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme
- regulation of device components.

## 2.1 Pre-market notification of TGO 110 compliance

The 2022 consultation canvassed reforms to the regulatory requirements for therapeutic vapes, including requiring pre-market TGA assessment of “unapproved” (unregistered) NVPs

against a quality and safety standard, or requiring registration of therapeutic vapes in the ARTG following a successful evaluation of quality, safety and efficacy data.

There was mixed support for a pre-market assessment option. Nearly half of public health associations and health professional bodies opposed pre-market assessment due to concerns that it could be misinterpreted as TGA approval. Companies supplying to the prescription pharmacy market supported pre-market assessment, and a large number of individual vapers, vaping retailers, vaping manufacturers or importers and pro-vaping associations supported at least some regulation to ensure that minimum quality and safety requirements have been met.

Following this feedback, the TGA is no longer proposing to require pre-market assessment of unapproved vapes. The TGA is instead considering a revised position, where companies intending to supply such "unapproved" vapes in Australia would be required to notify the TGA regarding their products' compliance with the enhanced minimum quality and safety standards in TGO 110.

**Notification process**

Under the proposed reforms, TGO 110 would be expanded to deal with both e-liquid and device components. An importer or manufacturer of a vape would need to provide written notice declaring compliance with the heightened requirements in TGO 110 and the possession of necessary evidence verifying such compliance. Following receipt, TGA would consider whether the notification was effective and contains all relevant information, including compliant packaging and labelling. If the notification requirements are met, the name of the applicant and the list of therapeutic vapes would then be published by the TGA on its website to enable patients, practitioners and regulators to clearly identify those vapes that may be lawfully supplied in Australia without registration.

There will be no pre-market evaluation of therapeutic vapes for which notifications are received by the TGA, but notifications will be reviewed for completeness and products will be subject to post-notification scrutiny. It will be a strict requirement of the notification process for notifiers to hold documentation that demonstrates compliance with all aspects of TGO 110 and provide such documentation to the TGA on request. The documentation should include, but not be limited to, copies of batch-specific testing results from appropriately accredited facilities or laboratories, demonstration of ingredient quality to pharmacopoeial standards, and copies of compliant labelling and packaging.

Under the proposed arrangements, a new notification would need to be submitted in relation to each vape that is added to an importer or manufacturer's product range or any critical changes that renders the vape separate and distinct under the TG Act. The requirements for providing notification could be specified in either primary or subordinate legislation. At this stage, the TGA anticipates the notification process would be reflected in new exemptions under the *Therapeutic Goods Regulations 1990.* The current exemptions applying to NVPs and device components would be repealed. The notification process would be specified for 'unapproved' (unregistered) therapeutic vapes irrespective of nicotine content.

In practice, the notification process would provide a level of assurance to healthcare practitioners and patients on the quality and safety of vapes being lawfully prescribed, dispensed and used in Australia. The system would also ensure that patients, healthcare practitioners, regulators and law enforcement officers are readily able to distinguish between lawful and unlawful vapes (having regard to TGA's published list of notified vapes).

## *Questions*

7. Do you support the approach to require a pre-market notification of compliance with TGO 110?

8. [If applicable] For suppliers of therapeutic vapes, what impact would the proposed notification system have on your supply model and what transition period would you require to comply with the new notification requirement?

## 2.2 Streamlined access under SAS and AP schemes

It is proposed to 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 SAS B schemes.

As at 31 July 2023, the TGA had authorised 2,279 medical practitioners under the AP scheme, and had received 2,887 applications under SAS B, for the supply of therapeutic vapes. The fact that a limited number of health practitioners may prescribe therapeutic vapes is potentially a barrier to people accessing vapes for therapeutic purposes.

The TGA is considering whether to enable 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. This option would allow specified therapeutic vapes to be lawfully supplied by specified practitioners for therapeutic use. It would be achieved by an amendment to a legislative instrument made under the TG Act and would seek to minimise the administrative burden on the medical practitioners. 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 of a therapeutic vape being supplied to a patient.

The SAS C notification system has been in place under the TG Act for several years. In the last financial year alone, there were over 30,000 SAS C notifications for medicines. Further information about the SAS C notification system can be found on the TGA website.

The change would enable more timely access to unapproved vapes for individual patients and reduce the regulatory burden on practitioners, whilst maintaining a level of regulation commensurate with the risk posed by unapproved therapeutic vapes. It would also address the current problem that practitioners are experiencing in being required to supply SAS B and AP approvals to pharmacies to enable prescriptions to be dispensed.

As part of the nicotine reforms package, the TGA is exploring whether it is possible to further streamline reporting processes by integrating the SAS and AP forms into existing prescribing software to further minimise the impost on practitioners.

### *Questions*

9. Do you support the proposed access to vapes under the SAS C notification system? What impact would this pathway have on facilitating patient access to therapeutic vapes?
10. [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?
11. [If applicable] For prescribers, which access pathway (SAS B, SAS C or AP) would you envisage using to prescribe therapeutic vapes? Why?
12. [If applicable] For prescribers, would integration of SAS or AP applications or notifications into existing clinical software systems ease the administrative burden and/or encourage you to use the new pathway?

## 2.3 Regulation of device components

As discussed above, most device components of vapes are currently excluded from regulation under the TG Act. The TGA is reviewing this position due to safety concerns, the complexity of the current regulatory requirements for vapes, and the enforcement difficulties this creates.

The device components of vapes that are *not* excluded from the operation of the TG Act are regulated as medical devices under Chapter 4 of the Act. These devices must comply with a different regulatory framework to medicines or other therapeutic goods. In broad terms, medical devices must comply with safety and performance standards (known as essential principles) and must be manufactured in accordance with conformity assessment procedures, or comparable overseas requirements.

Under the proposed reforms, the device components of unapproved therapeutic vapes would be regulated under Chapter 3 of the TG Act. This would allow requirements for both e-liquid and device components to be specified in TGO 110 and would mean that TGO 110 could be a single source of truth for all safety, quality and performance requirements for vapes supplied lawfully in Australia. It would still be necessary to comply with ordinary regulatory requirements for the inclusion of device components on the ARTG.

This approach is designed to ensure that safety and performance requirements apply to unapproved devices, minimise complexity for sponsors, manufacturers, patients and health practitioners to the maximum extent possible, and ease the compliance and enforcement effort.

To support this outcome, it is proposed that:

- a legislative instrument would need to be made to displace the operation of Chapter 4 in the TG Act for unapproved vaping devices or device components of vapes
- changes would also need to be made to an item in the *Therapeutic Goods (Excluded Goods) Determination 2018* under the TG Act to ensure that vaping devices, or device components in vapes, are not excluded from the operation of the TG Act
- existing exemptions for vaping devices in the *Therapeutic Goods (Medical Device) Regulations 2022* would be repealed, and
- amendments to existing exemptions in the *Therapeutic Goods Regulations 1990* would also need to be made to specify the circumstances in which the lawful importation, manufacture and supply of unregistered therapeutic vapes (comprising both e-liquid components and device components) may occur in Australia.

In the short term, it would also be necessary to condition SAS approvals, AP authorities and/or exemptions with a requirement to supply device components of ‘unapproved’ (unregistered) vapes to patients in pharmacies. This is because the scheduling controls that require nicotine vapes to be supplied in pharmacies do not apply to the device components when supplied separately. When the TG Act is amended, it is proposed to include new provisions to require these products to be supplied to patients in pharmacies (subject to appropriate exceptions for clinical trials and scientific research).

### *Questions*

13. Do you agree with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity?

14. Will these changes have direct or indirect impact of you? Please provide details.

15. Do you require time to adjust to these requirements? If yes, how long?

# Proposal 3 – Improving quality standards for unapproved (unregistered) vapes

Potential options for strengthening TGO 110 to reduce youth appeal and improve quality standards for therapeutic vapes were raised in the 2022 consultation. After considering the responses, and noting the policy intent announced by the Government on 2 May 2023, the TGA is proposing to:

- enhance the requirements for e-liquid components and
- specify new requirements for device components.

## 3.1 Enhanced requirements for e-liquid components

### 3.1.1 Packaging and labelling changes

It is proposed that TGO 110 will 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 will also facilitate detection of non-compliant or illicit nicotine vapes (e.g., any brightly coloured products with pictorial representations).

Therapeutic vapes themselves would only be allowed to be manufactured and supplied in black, white or grey. The proposed packaging requirements would entail:

- predominantly white background for the retail pack (with only black and grey lettering permitted)
- prominent health warnings being:
    - "THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE"
    - "KEEP OUT OF REACH OF CHILDREN"
    - "Avoid contact with eyes"
    - "Avoid contact with skin"
- prohibition on use of certain product names, logos or brand names
- additional labelling requirements, in line with selective requirements applying to other prescription medicines under TGO91 (*Standard for labels of prescription and related medicines*), such as requirements for mentioning all specifying ingredients, including nicotine content, expiry date and batch number, as well as contact details for the sponsor.

Unlike approved prescription medicines, it is proposed that sponsors will not be required to produce Product Information (PI) or Consumer Medicine Information (CMI).

### 3.1.2 Limiting flavours to tobacco and mint

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. However, recognising concerns from people using vapes for smoking cessation about the unattractiveness of either unflavoured or tobacco

flavoured vapes, the TGA is proposing to allow the use of mint flavour (in addition to tobacco flavour).

The following flavours and definitions are proposed to be included in TGO 110:

- **Mint flavour:** the taste and aroma commonly associated with herbaceous plants in the *Mentha* genus of the family Lamiaceae, including for example peppermint, spearmint, horsemint and corn mint.
- **Tobacco flavour:** the taste and aroma derived from a combination of substances commonly associated with herbaceous plants in the *Nicotiana* genus of the family Solanaceae.

Menthol is a chemical found naturally in peppermint and other plants in the mint family, but it can also be produced synthetically. It has flavouring and local anaesthetic properties. Menthol can reduce the harshness and the irritation from nicotine[17].

When inhaled, menthol can allow users to tolerate greater quantities of nicotine. Menthol reduces nicotine breakdown within the body and potentially masks the early warning symptoms of respiratory problems.[18] As a result, the TGA would propose to restrict menthol to a maximum limit of 0.1% w/v in vapes. At this level, menthol is expected to result in added mint flavour and to reflect levels present in food and beverages.

### 3.1.3 Lowering maximum nicotine concentration in e-liquids

The TGA is proposing to limit the maximum allowable nicotine concentration to be reduced from 100 mg/ml to 20 mg/mL in base form (or base equivalent), to align with the limits in the EU, UK and Canada.

This was our preferred option in the 2022 consultation and was generally supported by many health experts and medical practitioners. We considered introducing a separate limit for nicotine salt, but it was noted that regulating the quality of products using single salt form concentration was not efficient. 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 can be standardised and efficiently enforced.

Zero-nicotine therapeutic vapes

Some manufacturers include a zero-nicotine vape in their product range used for smoking cessation. The absence of nicotine changes the scheduling applicable to the product and the safety profile of the vape, but the therapeutic claim still means it is regulated as a medicine. Consequently, it is proposed for regulatory simplicity and clarity that zero-nicotine therapeutic vapes will be subject to the same regulatory controls as other therapeutic vapes under the TG Act.

In the short term, it will be necessary to condition SAS approvals, AP authorities and/or exemptions with the requirement to supply zero nicotine vapes to patients in pharmacies. This is because the scheduling controls that require nicotine vapes to be supplied in pharmacies do not apply to zero nicotine vapes. When the TG Act is amended, it is

[17] American Lung Association. https://www.lung.org/quit-smoking/smoking-facts/health-effects/what-is_menthol#:~:text=Menthol%20is%20a%20chemical%20naturally,and%20the%20irritation%20from%20nicotine.

[18] American Lung Association. https://www.lung.org/quit-smoking/smoking-facts/health-effects/what-is_menthol#:~:text=Menthol%20is%20a%20chemical%20naturally,and%20the%20irritation%20from%20nicotine

proposed to include new provisions to require these products to be supplied to patients in pharmacies (subject to appropriate exceptions).

### 3.1.4 Restricting other ingredients in e-liquid components

There are three elements to this proposal:

- a list of permitted ingredients
- quality standards for ingredients (pharmacopoeial grade)
- a list of restricted substances

**List of permitted ingredients**

We propose to allow only six ingredients that can be mixed in the formulation of a vape and to limit the quantity of some ingredients. These permitted ingredients are **nicotine, propylene glycol, glycerine, tobacco flavour, mint flavour and water.**

Manufacturers have included various additives to the vapes, such as colouring agents, cooling agents, sweeteners, vitamins, minerals, and stimulants. These additives may enhance the appeal of vaping to children and adolescents and can increase the risk profile of the relevant vape.

Overseas jurisdictions have adopted a prohibitionary approach and prohibited several such ingredients from use in vapes by specifying individual chemical entities. For example, New Zealand's Smokefree Environment and Related Products Regulation 2021 includes an extended list of prohibited ingredients that are banned from e-liquid formulations. We have considered the option to include an extended list of prohibited ingredients in the TGO 110. However, this option would present a range of challenges, including:

- the sector is relatively new and evolving, so the list of such ingredients is changing rapidly and may become quickly outdated quickly.
- there is limited long term toxicological data available on most ingredients included in vapes, so it is difficult to have a comprehensive list of harmful ingredients.
- testing a huge number of prohibited ingredients would cost time and money, making it expensive for manufacturers and difficult to enforce.

We are therefore proposing to include a list of '*Permitted Ingredients',* rather than a prohibited ingredients list.

**Quality standards for ingredients (pharmacopeial grade)**

To further enhance the safety profile of therapeutic vapes, the TGA would propose that all ingredients in e-liquid, except for flavours, must comply with pharmacopoeia standard (*European Pharmacopoeia*, *British Pharmacopoeia* or *United States Pharmacopoeia*).

Permitted flavours would be exempted from this requirement as pharmacopoeial grade material is not available for '*Tobacco*' and '*Mint'* flavour.

**List of restricted substances**

It is recognised that there are chemicals, such as contaminants, degradation products, reaction products or residual compounds in the raw materials. These chemical entities may include known harmful substances such as formaldehyde, heavy metals, and

carbonyl compounds. For this reason, the TGA would propose to include a list of restricted chemicals that must remain below the stated limit in TGO 110.

**Limit the volume of e-liquid for retail units**

The TGA would propose to limit the maximum amount of e-liquid sold for open system vapes to 120 mL and for closed system vapes (pods) to 2 mL.

Currently, there is no restriction on the volume of e-liquid retail packs. As therapeutic vapes are classified as prescription only medicines, and nicotine is recognised as a substance with the potential for abuse, it is imperative to consider carefully the quantities allowed for supply to prevent misuse and unauthorised distribution. As the proposed limits are aligned with similar limits enforced in other jurisdictions such as the EU, UK and NZ, we do not expect any disruption of product availability in the market if these limits are enforced.

In effecting any changes to TGO 110, the TGA would also consider whether any consequential amendments are needed to other instruments made under the TG Act, including those relating to exempt monographs.

### *Questions*

16. Are the definitions of the nicotine and mint flavours appropriate? If not, please provide reasons.
17. Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons.
18. [If applicable] Importers, manufacturers and suppliers, would the restrictions on flavour proposed above impact you?
19. Do you agree with the proposal to require pharmaceutical-like packaging and presentation for vapes, e.g. vapes manufactured in black, white or grey coloured materials, predominantly white background on packaging, clear warning statements and other restrictions on labels in addition to other selective TGO 91 requirements for vapes?
20. [If applicable] What impact will the labelling and packaging changes have and how long would you need to transition your product to comply with the proposed requirements?
21. Do you agree with our approach to allow only permitted ingredients in vapes, instead of trying to prohibit individual chemical entities from use in e-liquids?
22. [If applicable] Importers, manufacturers and suppliers, will your therapeutic vapes need any re-formulation or other changes to comply with the permitted ingredients and ingredient quality requirements? How long will you need to make these changes? And what financial or business impacts would be associated with them?
23. Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?
24. What is the overall business cost on you to comply with a strengthened TGO 110?

## 3.2 Requirements for device components

Regulatory oversight is required to give consumers assurance of the quality and safety of device components.

The device components of a vape are parts that support the vaporisation and inhalation of the e-liquid component. On occasion, the device component may simply comprise a housing unit and battery, but it may also include a liquid cartridge or reservoir and sensors. Device components supplied as therapeutic goods in Australia generally must meet essential principles, which cover the design, quality, safety and use of the device.

However, as described in Proposal 2.3 above, it is proposed that the device components of 'unapproved' (unregistered) vapes would be regulated under Chapter 3 of the TG Act together with the e-liquid component. As such, the essential principles and the related conformity assessment procedures in Chapter 4 would not apply, and the applicable requirements would instead be specified in TGO 110.

At this stage, we would propose to specify the following matters in TGO 110 as requirements for the device component, to ensure minimum quality and safety standards are met:

- 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"

## *Questions*

25. Do you agree with the proposed requirements under TGO 110 that will apply to unapproved device components of vapes?

26. [If applicable] Suppliers, do you intend to include any vaping device on the register as an approved medical device? If not, why?

27. [If applicable] Importers, manufacturers and suppliers, are you familiar with, and do your vapes currently comply with, relevant US FDA or MRHA guidance, and/or EU standards covering vaping devices? If not, what requirements do you meet, and how long would it take to achieve compliance?

28. [If applicable] Importers, manufacturers and suppliers, are your vapes manufactured at facilities that hold relevant international standards for Quality Management Systems, such as ISO9001 or ISO 13485?

# Proposal 4 – Strengthening domestic compliance and enforcement mechanisms

It is proposed to strengthen the domestic compliance and enforcement mechanisms under the TG Act to support the broader policy intent of the vaping reforms, particularly those measures in Proposal 1.

Commonwealth, state and territory officials agree that effective compliance and enforcement mechanisms are essential to ensure the proposed reforms work 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 NVPs and vaping devices, most notably the general need to test for the presence of nicotine before compliance and enforcement action may be confidently undertaken.

## 4.1 Proposed compliance and enforcement measures

It is proposed that enhanced compliance and enforcement measures would be needed to support the new offences and civil penalties outlined in Proposal 1. As mentioned above, these offences and civil penalties would prohibit:

- the importation, manufacture and supply of disposable single use 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 (including pre-market notification of compliance with the relevant quality standard), and
- the advertisement of vapes generally.

Unlike present regulation, it is proposed that 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 need for laboratory testing.

The compliance and enforcement effort would also be simplified by enabling the publication of a consolidated list of registered vapes and other therapeutic vapes for which a notification has been received and published by the TGA (Proposal 2.1). Effectively, the importation, manufacture and supply of ‘unapproved’ (unregistered) vapes that do not appear on the published list would be unlawful.

Further, it is proposed that any reforms to the regulation of vapes in Australia would be supported by:

- new powers relating to the forfeiture and destruction of unlawful therapeutic goods (including therapeutic vapes) and vapes generally under the TG Act, similar to those in other relevant Commonwealth, state or territory legislation such as the *Customs Act 1901* and the *Agricultural and Veterinary Chemicals Code Act 1994*. The purpose of these powers would be to prevent unlawful therapeutic goods and vapes being returned to the market
- new criminal offence and civil penalties for the supply of vapes to consumers outside of a pharmacy (these provisions would be subject to some exceptions for clinical trials

and scientific research and aligned with state and territory legislation regulating Schedule 4 medicines)
- new criminal offences and civil penalties for the unlawful possession of therapeutic vapes or vapes generally in certain circumstances including retail or wholesale settings (it is not proposed that such offences or penalties would apply to possession for personal use, or to other therapeutic goods)
- new powers to make enforceable directions relating to the importation, manufacture, supply, advertisement and possession of therapeutic goods (including therapeutic vapes), goods reasonably suspected to be therapeutic goods, and vapes generally
- increased powers to share information with states and territories and other compliance and enforcement bodies for compliance and enforcement purposes for therapeutic goods (including therapeutic vapes), goods reasonably suspected to be therapeutic goods, and vapes generally
- revised powers to release and otherwise publish information relating to the importation, manufacture, supply and advertisement of goods reasonably suspected to be therapeutic goods, vapes generally, and related laboratory testing or compliance and enforcement action
- other compliance and enforcement measures to ensure the success of the vaping reforms and the protection of public health as necessary

## 4.2 Enabling state and territory officers to exercise powers and perform functions

The above measures are proposed to be integrated into an Australia-wide enforcement framework by enabling state and territory officers to exercise powers and perform functions of the Secretary under the TG Act, in particular compliance and enforcement powers 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 the reforms, it is proposed to enable state and territory officials to 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.

To facilitate appropriate authorisation and delegation within the various jurisdictions, consideration is also being given to enabling designated persons in states and territories to authorise officers under the TG Act and to sub-delegate certain powers and functions of the Secretary to officers in their jurisdictions. A range of schemes that include regulatory arrangements with state and territory officers already exists across the Commonwealth, including:

- compliance and enforcement activities under the Australian Consumer Law carried out by the Australian Competition and Consumer Commission, and state and territory consumer regulators, using a ‘one law, multiple regulators’ model.

- the authorisation of state and territory officers under the *Export Control Act 2020*, where agreed by trading partners.

## 4.3 Expand regulation making powers for laboratory testing

This proposal would extend the existing regulation making power for the sampling and testing of therapeutic goods (including therapeutic vapes) to cover vapes generally and goods reasonably suspected to be therapeutic goods to ensure that such powers are sufficiently comprehensive. In practice, an amendment of this nature would enable laboratory

testing to play a critical role in supporting effective compliance and enforcement action in the interests of public health, e.g. through the detection of prohibited toxic substances in vapes.

## *Questions*

29. Do you have any other comments in relation to this proposal?

## *Supplementary questions:*

30. [If applicable] Suppliers, please confirm if you intend to continue to supply therapeutic vapes under the proposed reforms described? If so, please outline the product range and the length of time it would take to meet the new requirements.

31. [If applicable] Suppliers, please confirm if you intend to register your therapeutic vapes in the next 2 years? If so, what guidance and/or clarity of supporting data requirements do you need from TGA?