

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*

The Therapeutic Goods Act 1989 (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health and Aged Care (“the Department”).

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, the quantity of the goods when contained in specified containers, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that therapeutic goods or a class of therapeutic goods specified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary, may however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* (“TGO 110”) is made under section 10 of the Act. TGO 110 establishes a ministerial standard for nicotine vaping products, principally by reference to the labelling, packaging, ingredients and nicotine content of those products.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023* (“the Amendment Order”) amends TGO 110 to introduce minimum safety and quality requirements for therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack. The Amendment Order also introduces restrictions on the flavours of therapeutic vaping substances and substance accessories.

### **Background**

#### *The public health problem*

Vaping 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 used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes in Australia.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and

young adults from taking up vapes, while allowing current smokers access for smoking cessation under appropriate medical supervision. 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. Further measures are therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by youth and young adults.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known.

### *Reforms to the regulation of vapes*

The Australian Government is implementing reforms to the regulation of vapes to address the growing public health problem associated with vaping. The reforms are proposed to ban the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes while strengthening the regulatory controls of all therapeutic vapes. This will be achieved through amendments to the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, the *Customs Act 1901* and the *Customs (Prohibited Imports) Regulations 1956*, as well new and amended delegated instruments under the Act. A transitional approach will apply to the commencement of the reforms to allow a reasonable time for importers, manufacturers and suppliers to comply with the enhanced regulation, while maintaining legitimate patient access to therapeutic vaping goods for smoking cessation or the management of nicotine dependence.

The reforms are intended to address the risks posed by vaping to youth and young adults in Australia, the possible long term adverse health effects of vaping to Australians who use vapes, and the adverse health effects of toxic chemicals and other ingredients found in vapes. At the same time, the proposed amendment would preserve patient access to therapeutic vapes under the supervision of relevant health practitioners.

In broad terms, the reforms will:

- prohibit the importation of disposable single use vapes, irrespective of therapeutic claims, subject to limited exceptions, from 1 January 2024;
- prohibit the importation of non-therapeutic vapes, irrespective of nicotine content, subject to limited exceptions, from 1 March 2024;
- introduce the requirement for importers to obtain a customs licence and permit to import therapeutic vapes, subject to limited exceptions, from 1 March 2024, with applications to be enabled from 1 January 2024;
- end the personal importation scheme for therapeutic vapes – the scheme will cease to operate on 1 March 2024, but the importation of disposable vapes will be prohibited from 1 January 2024;
- retain a limited traveller’s exception that allows persons arriving in Australia by ship or plane to carry a limited quantity of vapes for their treatment or the treatment of someone travelling with them under their care – revisions to the traveller’s exemption will commence on 1 March 2024 with restrictions on disposable vapes commencing 1 January 2024;
- introduce the requirement for importers and manufacturers to notify the Secretary that therapeutic vapes intended to be imported, or released for supply in Australia, comply with relevant product standards or essential principles, as the case may be – this requirement will commence on 1 March 2024, with notifications to be enabled from 1 January 2024;

- modify the exemptions relating to unregistered therapeutic vapes to require such goods to be supplied through prescription medicine supply chains to patients for smoking cessation or the management of nicotine dependence – this requirement will commence on 1 March 2024;
- make minor changes to relevant product standards to facilitate the introduction of the notification and permit schemes, introduce restrictions on flavours and ensure minimum standards for device components; and
- enable therapeutic vapes to be accessed by patients under the Special Access Scheme – Category C, to facilitate more timely access to unregistered therapeutic vapes and reduce regulatory burden on practitioners, while maintaining regulation commensurate with the risk.

These reforms will be supplemented by strengthened domestic compliance and enforcement mechanisms to support the broader policy intent. Changes will be made to the Act to provide additional powers and offences for the regulation of disposable single use and non-therapeutic vapes. Australia-wide compliance and enforcement within and between jurisdictions is essential to effectively address the risk of vaping to population health.

The framework will support the following 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 dependence and reduce the risk of future tobacco use;
- safeguard public health by requiring unregistered therapeutic vapes to meet minimum quality and safety standards.

The reforms will support the Government’s broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

## **Purpose**

TGO 110 is made under section 10 of the Act. TGO 110 specifies the minimum requirements for the quality and safety of unregistered nicotine vaping products and is intended to provide an assurance to medical practitioners and patients that nicotine vaping products meet minimum safety and quality requirements.

The Amendment Order is made under section 10 of the Act, in accordance with subsection 10(3A) of the Act. Most notably the amendments to TGO 110 introduced by the Amendment Order, extend TGO 110’s application. Principally, TGO 110 now also applies to therapeutic vaping substances and substance accessories that do not contain nicotine. TGO 110 also now applies to goods included in therapeutic vaping packs that would otherwise be regulated as medical devices if they were not included in such a pack.

The Amendment Order:

- limits the application of the order to therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are finished products and the only indications for the goods are use for smoking cessation or the management of nicotine dependence;
- introduces limitations on the flavour of therapeutic vaping substances to only permit menthol, mint and tobacco flavour;
- establishes minimum standards relating to the ingredients, labelling and packaging of therapeutic vaping substances and therapeutic vaping substance accessories that do not contain nicotine;

- establishes minimum standards related to device components of therapeutic vaping substance accessories;
- establishes minimum standards related to therapeutic vaping kits, and goods in a therapeutic vaping pack (including therapeutic device and device accessories).

The Amendment Order makes a number of minor editorial amendments to update nomenclature used throughout the instrument to reflect the new definitions introduced by *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (“the Amendment Regulations”). As TGO 110 now applies to the goods described in the exemptions provided by the Amendment Regulations, and indeed, sponsors of such goods must notify the Secretary of compliance with TGO 110 (among other applicable standards), it was necessary to include these definitions. These definitions are also crucial in allowing TGO 110 to apply more broadly than the former TGO 110 to therapeutic vaping substance and substance accessories that do not contain nicotine, and devices and device accessories that would otherwise be treated as medical devices if not for their inclusion in a therapeutic vaping pack. Importantly, other than the amendments relating to flavours, the Amendment Order does not make any substantive changes to the requirements that currently apply to therapeutic vaping substances and substance accessories that contain nicotine (presently described as nicotine vaping products).

The Amendment Order gives effect to the first stage of legislative amendments that are intended to increase the minimum safety and quality requirements for therapeutic vaping goods that are for use in smoking cessation or the management of nicotine dependence. The proposal to elevate the minimum standards of safety and quality of these goods is intended to curb the importation and supply of therapeutic vapes that present a risk to public health and safety.

### **Incorporation by reference**

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* (“the Legislation Act”), an order (or variation of an order) under this provision may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The Amendment Order incorporates by reference the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (“the MDSO”). The MDSO is a legislative instrument made under section 41CB of the Act and sets out minimum safety and performance requirements for certain vaping devices. The MDSO is incorporated as in force from time to time, in accordance with subsection 10(4) of the Act. The MDSO is available for free from the Federal Register of Legislation website at [www.legislation.gov.au](http://www.legislation.gov.au).

### **Consultation**

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook public consultation (“the 2022 consultation”) on reforms to the regulation of nicotine vaping products in Australia. 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, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through the Health Ministers’ Meeting and its subordinate National 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 in Australia.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 (“the 2023 Consultation”) on the regulatory proposals developed in consultation with states and territories. Submissions and survey responses to the 2023 Consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for the Department of Health and Aged Care on regulatory measures to be implemented.

### **Other details**

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

An impact analysis (“IA”) was prepared in relation to the proposed reforms relating to vaping, taking into account the feedback received from stakeholders throughout the consultations. The Office of Impact Analysis (“OIA”) determined that the IA was consistent with good practice and met Australian Government best practice regulation requirements (OBPR23-03933). The IA has been published, or will be published prior to commencement of the Amendment Order, on the OIA website at: [oia.pmc.gov.au/](http://oia.pmc.gov.au/).

The Amendment Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences at the same time as the commencement of the Amendment Regulations. However, the Amendment Order does not commence at all if the Amendment Regulations do not commence.

## **Details of the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023* (“the Amendment Order”).

### **Section 2 – Commencement**

This section provides that the Amendment Order commences at the same time as the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (“the Amendment Regulations”). However, the Amendment Order does not commence at all if the Amendment Regulations do not commence.

### **Section 3 – Authority**

This section provides that the legislative authority for making the Amendment Order is sections 3C and 10 of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 10(3A) of the Act relevantly provides that, the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act. The amendments to the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* are made in accordance with this subsection.

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The amendments to the *Therapeutic Goods (Exempt Monographs) Determination 2021* are made in accordance with that provision.

### **Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to the Amendment Order is amended as set out in the applicable items in that Schedule. The Amendment Order makes amendments to the:

- *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* (“TGO 110”); and
- *Therapeutic Goods (Exempt Monograph) Determination 2021* (“the Determination”).

### **Schedule 1 – Amendments**

*Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*

#### **Item 1 – Subsection 1(1)**

This item makes a minor amendment to update the name of TGO 110 to reflect that the instrument constitutes a standard for a broader range of therapeutic vaping goods, and is no longer limited to just those products containing nicotine.

### **Items 2 and 3– Section 4 (in the note) and section 4 (at the end of the note)**

These item amends the note to section 4 of TGO 110 to include additional terms ‘essential principles’, ‘standard’, ‘supply’, and ‘therapeutic goods’ that are defined in the Act.

### **Items 4, 5, 7 and 8– Section 4 (definitions of *finished product*, *flavour*, *nicotine vaping product* and *other ingredient*)**

These items amend section 4 of TGO 110 by repealing the definitions for ‘finished product’, ‘flavour’, ‘nicotine vaping product’ and ‘other ingredient’. The definition of ‘nicotine vaping product’ is now redundant as now TGO 110’s application is no longer limited to those goods that contain nicotine. The other repealed terms are left to take on their ordinary meaning.

### **Items 6 and 10 – Section 4**

These items introduce new definitions to section 4 of TGO 110, including definitions of ‘MD Regulations’ and ‘MDSO’. These items also introduce new definitions that have the same meaning as in the *Therapeutic Goods Regulations 1990* (“the Regulations”) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”), including ‘therapeutic vaping device’, ‘therapeutic vaping device accessory’, ‘therapeutic vaping substance’, ‘therapeutic vaping substance accessory’, ‘therapeutic vaping kit’ and ‘therapeutic vaping pack’. Importantly, these new definitions are not limited to goods that contain nicotine.

### **Item 9 – Section 4 (definition of *stated content*)**

This item amends section 4 of TGO 110 to omit and substitute certain words in the definition of ‘stated content’. This item omits “in a nicotine vaping product on the label of that product” and substitutes “on a label”.

### **Item 11 – Section 5**

This item section 5 of TGO 110 to provide that TGO 110 constitutes a standard for therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, and goods in a therapeutic vaping pack. This amendment was necessary to reflect the effect of the Amendment Order in providing a standard for a broader range of goods than the former TGO 110.

### **Item 12 – Section 6**

This item replaces section 6 of TGO 110 to set out the goods to which TGO 110 does and does not apply.

Subsection 6(1) provides that, subject to subsection (2), TGO 110 applies to:

- therapeutic vaping substances;
- therapeutic vaping substance accessories;
- therapeutic vaping kits;
- goods in a therapeutic vaping pack;

that are finished products and the only indications for the goods are use for smoking cessation or the management of nicotine dependence.

Subsection 6(2) provides that TGO 110 does not apply to:

- registered goods;
- good manufactured in, or imported into, Australia for export only;
- therapeutic goods carried by a passenger on a ship or aircraft in accordance with item 1A of Schedule 5A to the Regulations;

- therapeutic goods mentioned in item 16 of Schedule 5A to the Regulations;
- components or articles mentioned imported into Australia for use in the manufacture of a therapeutic vaping device or therapeutic vaping device accessory; or
- therapeutic goods that are imported by particular persons or are part of medical supplies of a visiting ship or aircraft as mentioned in items 4, 8, 10, 11 and 12 of Schedule 5A to the Regulations.

### **Item 13 – Part 2 (heading)**

This item replaces the heading of Part 2 of TGO 110 to reflect ‘Therapeutic vaping substances and therapeutic vaping substance accessories’. This reflects the new operation of Part 2 of TGO 110, as the requirements in this part used to only apply to goods that contain nicotine.

### **Items 14 – Subsection 7(1)**

This item makes a minor amendment to subsection 7(1) of TGO 110 to refer to a therapeutic vaping substance or therapeutic vaping substance that contains nicotine instead of a nicotine vaping product.

### **Items 15 and 16 – Subsection 7(2)**

These items make minor amendments to subsection 7(2) of TGO 110.

Item 15 makes a minor amendment to refer to a therapeutic vaping substance or therapeutic vaping substance instead of a nicotine vaping product.

Item 16 introduces new subsection 7(2A), which provides that a therapeutic vaping substance or therapeutic vaping substance accessory that does not contain nicotine must not contain any active ingredient.

### **Item 17 – Subsection 7(3)**

This item makes a minor amendment to subsection 7(3) to refer to a therapeutic vaping substance or therapeutic vaping substance accessory instead of a nicotine vaping product. This amendment has the effect of broadening the application of the prohibited ingredients list specified in Schedule 1 to TGO 110 to those goods that may not contain nicotine.

### **Item 18 – After subsection 7(3)**

This item introduces new subsections 7(4) and 7(5) to specify requirements relating to flavour contained in therapeutic vaping substances and therapeutic vaping substance accessories.

New subsection 7(4) provides that a therapeutic vaping substance or therapeutic vaping substance may only contain ingredients or components that produce the taste or smell that a reasonable person would associate with mint or menthol flavour, or tobacco flavour. The requirement for a vaping substance to only contain a mint, menthol or tobacco flavour incorporates a reasonable person test because of the varieties of ingredients or components that may be used to create mint, menthol or tobacco flavour.

This provision will enable the continued supply of therapeutic vaping goods containing flavours, in a manner that would not require a formulation change at this stage. Accordingly, a therapeutic vaping substance or therapeutic vaping substance accessory that a reasonable person would associate with the taste or smell of mint, menthol or tobacco would comply with this standard.



New subsection 7(5) provides that a therapeutic vaping substance or therapeutic vaping substance accessory must not contain ingredients or components that produce a combination of flavours. The note to new subsection 7(5) provides examples of prohibited flavour combinations, including cherry mint, chocolate mint and tobacco mint.

#### **Item 19 – Section 8**

This item replaces section 8 of TGO 110 to specify the requirements that apply to the label of a therapeutic vaping substance or therapeutic vaping substance accessory.

Subsection 8(2) provides that a therapeutic vaping substance or therapeutic vaping substance that contains nicotine must be labelled with the information set out in Part 1 of Schedule 2 to TGO 110. These requirements have not changed as a result of this amendment, and reflect those requirements that were previously imposed on nicotine vaping products. The notes to subsection 8(2) clarify that the information must either be on or attached to the container or primary pack of the product, including by way of over-stickering, or supplied with the container or primary pack of the product, such as an information sheet. It is not necessary for each piece of information to be provided in the same manner; a therapeutic vaping substance or therapeutic vaping substance accessory may include some of the information on the container or primary pack and provide other aspects of the information in an information sheet.

Subsection 8(3) provides that that a therapeutic vaping substance or therapeutic vaping substance that does not contain nicotine must be labelled with the information set out in Part 2 of Schedule 2 to TGO 110. This is a new provision that prescribes the labelling requirements for goods that do not contain nicotine. The labelling requirements are very similar to the existing requirements for nicotine vaping products, with some modifications appropriate to therapeutic vaping substances and therapeutic vaping substance accessories that do not contain nicotine. The notes to subsection 8(3) clarify that the information must either be on or attached to the container or primary pack of the product, including by way of over-stickering, or supplied with the container or primary pack of the product, such as an information sheet. It is not necessary for each piece of information to be provided in the same manner; a therapeutic vaping substance or therapeutic vaping substance accessory may include some of the information on the container or primary pack and provide other aspects of the information in an information sheet.

Subsection 8(4) provides that all information that is displayed on the label of a therapeutic vaping substance or therapeutic vaping substance accessory, must be in English, legible, visible and not obscured, and durable.

#### **Items 20, 21, 22 and 23– Section 9, section 10, subsection 10(3) and subsection 11(1)**

These items make minor amendments to replace any now incorrect or redundant references within section 9, section 10 and subsection 11(1) of TGO 110.

Items 20 and 21 replace all references to nicotine vaping product in sections 9 and 10 of TGO 110, to refer to therapeutic vaping substance or therapeutic vaping substance accessory. The effect of the amendments made by items 20 and 21 is that the requirements relating to child resistant packaging and the keeping of records will apply to therapeutic vaping substances and therapeutic vaping accessories irrespective of whether they contain nicotine.

Item 22 replaces the reference to item 1 of Schedule 5A to the Regulations in subsection 10(3) of TGO 110 to refer to item 1A of Schedule 5A to the Regulations. Item 1A of Schedule 5A to the Regulations is the new traveller's exemption that applies to therapeutic vaping substances and therapeutic vaping substance accessories as inserted by the Amendment Regulations. Subsection 10(3) makes it clear that the record keeping obligations do not apply to therapeutic vaping substances

or therapeutic vaping substance accessories that are imported into Australia under the traveller's exemption in accordance with item 1A of Schedule 5 to the Regulations.

Item 23 replaces the reference to nicotine vaping product in subsection 11(1) of TGO 110 with a reference to a therapeutic vaping substance or therapeutic vaping substance accessory that contains nicotine. This makes it clear that a therapeutic vaping substance or therapeutic vaping substance accessory that contains nicotine is taken to comply with the requirements specified in section 7, 9 and 10 of TGO 110, if the good satisfies the criteria mentioned in paragraphs 11(1)(a)-(c).

#### **Item 24 – After section 11**

This item introduces new section 12 and new Parts 3, 4 and 5 to TGO 110.

New section 12 specifies requirements for therapeutic vaping substance accessories, new Parts 3 and 4 specify requirements relating to therapeutic vaping kits and therapeutic vaping packs and new Part 5 provides transitional provisions.

New section 12 provides that a therapeutic vaping substance accessory must comply with the following:

- for a therapeutic vaping substance accessory that, if it did not contain a therapeutic vaping substance, would be a therapeutic vaping device accessory to which the MDSO ordinarily applies—either the MDSO or essential principles;
- for a therapeutic vaping substance accessory that, if it did not contain a therapeutic vaping substance, would be a therapeutic vaping device accessory to which the MDSO does not ordinarily apply—the essential principles.

The effect of this section is that those parts of a therapeutic vaping substance accessory that are not the therapeutic vaping substance, for example, the metal or plastic components that house the therapeutic vaping substance or coils used in the vaporisation of the therapeutic vaping substance, must comply with the MDSO or the essential principles (as applicable).

New Part 3 specifies requirements relating to goods in a therapeutic vaping kit. New section 13 of Part 3 provides that each therapeutic vaping substance or therapeutic vaping substance accessory in a therapeutic vaping kit must comply with the requirements in Part 2, including requirements relating to ingredients, labelling, child resistant packaging and record keeping as well as those requirements applying to therapeutic vaping substance accessories as provided by the new section 12 of Part 2 to TGO 110.

New Part 4 specifies requirements relating to goods in a therapeutic vaping pack. New subsection 14(1) provides that each therapeutic vaping substance or therapeutic vaping substance accessory in a therapeutic vaping pack must comply with the requirements in Part 2, including requirements relating to ingredients, labelling, child resistant packaging and record keeping as well as those requirements applying to therapeutic vaping substance accessories as provided by the new section 12 of Part 2 to TGO 110.

New subsection 14(2) specifies requirements relating to therapeutic vaping devices and therapeutic vaping device accessories that are in a therapeutic vaping pack.

New paragraph 14(2)(a) provides that a therapeutic vaping device or therapeutic vaping device accessory in a therapeutic vaping pack to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (“the MDSO”) ordinarily applies, must comply with either:

- the MDSO; or
- the essential principles.

New paragraph 14(2)(b) specifies that a therapeutic vaping device or therapeutic vaping device accessory in a therapeutic vaping pack to which the MDSO does not ordinarily apply, must comply with the essential principles.

New Part 5 sets out transitional provisions relating to therapeutic vaping goods.

New subsection 15(1) introduces the definition of the ‘former TGO 110’ for the purposes of section 15. The former TGO 110 means the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*, as in force immediately before the commencement of the Amendment Order.

New subsection 15(2) provides that, despite the amendments made by the Amendment Order, the former TGO 110 continues to apply in relation to therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack, that are imported or manufactured before 1 March 2024.

New subsection 15(3) provides that new subsection 15(2) ceases to apply on 1 July 2024.

The effect of section 15 is that therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack, that are imported or manufactured before 1 March 2024, may continue to comply with the requirements in the former TGO 110 for the duration of the transitional provision.

## **Item 25 – Schedule 2**

This item replaces Schedule 2 to TGO 110, principally to introduce labelling requirements for therapeutic vaping substances and therapeutic vaping substance accessories that do not contain nicotine.

Part 1 of Schedule 2 sets out, for the purposes of subsection 8(2), the information that must be included on the label of a therapeutic vaping substance or therapeutic vaping substance accessory that contains nicotine, including:

- an ingredients list setting out the name of each active ingredient, the name of each other ingredient, and either a description of the flavour with the word “flavour” (e.g. “mint flavour”) or the name of each ingredient or component producing that flavour;
- the base form, or equivalent base form, nicotine concentration of the good in mg/mL; and
- the warning statements “KEEP OUT OF REACH OF CHILDREN”, “Avoid contact with eyes” and “Avoid contact with skin”.

These amendments have not changed the requirements and the only changes to this Part are to clarify that it only applies to therapeutic vaping substances or therapeutic vaping substance accessories that contain nicotine, not those substances and substance accessories that do not contain nicotine.

Part 2 of Schedule 2 sets out, for the purposes of subsection 8(3), the information that must be included on the label of a therapeutic vaping substance or therapeutic vaping substance accessory that do not contain nicotine, including:

- an ingredients list setting out the name of each ingredient (other than those ingredients or components of a flavour); and
- either a description of the flavour with the word “flavour” (e.g. “mint flavour”) or the name of each ingredient or component producing that flavour;
- the warning statement “KEEP OUT OF REACH OF CHILDREN”.

## **Schedule 2 – Amendments**

### *Therapeutic Goods (Exempt Monographs) Determination 2021*

Section 3 of the Act defines a ‘standard’ in relation to therapeutic goods as a standard that is constituted by the matters specified in an order under section 10 of the Act that is applicable to the goods, any monographs to which the goods are subject in the British Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia-National Formulary (each defined as a ‘default standard’) and homeopathic and anthroposophic standards.

Section 3C of the Act provides that the Minister may, by legislative instrument, determine that specified default standards, or specified statements in default standards, are exempt for the purposes of the definition of ‘standard’ in section 3 of the Act. That is, the default standards or statements in default standards do not constitute a standard for the therapeutic goods specified in the order or therapeutic goods generally.

### **Items 1, 2 and 3– Section 4 (definitions)**

These items make amendments to section 4 of the *Therapeutic Goods (Exempt Monographs) Determination 2021* (“the Determination”) consequential to the amendment made by item 5 below.

Item 1 repeals the definition of ‘nicotine vaping product’.

Items 2 and 3 introduce new definitions of ‘regulations’, ‘therapeutic vaping substance’ and ‘therapeutic vaping substance accessory’.

### **Item 4 – Section 4 (definition of TGO 110)**

This item makes a minor amendment to the definition of TGO 110 to clarify that TGO 110 means the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO110) Order 2021*.

### **Item 5 – Schedule 1 (table item 1, column 4)**

This item replaces the reference to nicotine vaping product in column 4 of item 1 in the table in Schedule 1 to the Determination, with therapeutic vaping substance or therapeutic vaping substance accessory. The effect of this amendment is that all monographs in the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopoeia-National Formulary that would otherwise apply to a therapeutic vaping substance or a therapeutic vaping substance accessory to which TGO 110 applies does not apply.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

### *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### Overview of the Legislative instrument

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, the quantity of the goods when contained in specified containers, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that therapeutic goods or a class of therapeutic goods specified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary, may however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* (“TGO 110”) is made under section 10 of the Act. TGO 110 establishes a ministerial standard for nicotine vaping products, principally by reference to the labelling, packaging, ingredients and nicotine content of those products.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023* (“the Amendment Order”) amends TGO 110 to introduce minimum safety and quality requirements for therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack. The Amendment Order also introduces restrictions on the flavours of therapeutic vaping substances and substance accessories.

#### Background

##### *The public health problem*

Vaping 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 used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes in Australia.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine

for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers access for smoking cessation under appropriate medical supervision. 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. Further measures are therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by youth and young adults.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long term health risks of vaping are not yet known.

### *Reforms to the regulation of vapes*

The Australian Government is implementing reforms to the regulation of vapes to address the growing public health problem associated with vaping. The reforms are proposed to ban the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes while strengthening the regulatory controls of all therapeutic vapes. This will be achieved through amendments to the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, the *Customs Act 1901* and the *Customs (Prohibited Imports) Regulations 1956*, as well new and amended delegated instruments under the Act. A transitional approach will apply to the commencement of the reforms to allow a reasonable time for importers, manufacturers and suppliers to comply with the enhanced regulation, while maintaining legitimate patient access to therapeutic vaping goods for smoking cessation or the management of nicotine dependence.

The reforms are intended to address the risks posed by vaping to youth and young adults in Australia, the possible long term adverse health effects of vaping to Australians who use vapes, and the adverse health effects of toxic chemicals and other ingredients found in vapes. At the same time, the proposed amendment would preserve patient access to therapeutic vapes under the supervision of relevant health practitioners.

In broad terms, the reforms will:

- prohibit the importation of disposable single use vapes, irrespective of therapeutic claims, subject to limited exceptions, from 1 January 2024;
- prohibit the importation of non-therapeutic vapes, irrespective of nicotine content, subject to limited exceptions, from 1 March 2024;
- introduce the requirement for importers to obtain a customs licence and permit to import therapeutic vapes, subject to limited exceptions, from 1 March 2024, with applications to be enabled from 1 January 2024;
- end the personal importation scheme for therapeutic vapes – the scheme will cease to operate on 1 March 2024, but the importation of disposable vapes will be prohibited from 1 January 2024;
- retain a limited traveller's exception that allows persons arriving in Australia by ship or plane to carry a limited quantity of vapes for their treatment or the treatment of someone travelling with them under their care – revisions to the traveller's exemption will commence on 1 March 2024 with restrictions on disposable vapes commencing 1 January 2024;
- introduce the requirement for importers and manufacturers to notify the Secretary that therapeutic vapes intended to be imported, or released for supply in Australia, comply with

relevant product standards or essential principles, as the case may be – this requirement will commence on 1 March 2024, with notifications to be enabled from 1 January 2024;

- modify the exemptions relating to unregistered therapeutic vapes to require such goods to be supplied through prescription medicine supply chains to patients for smoking cessation or the management of nicotine dependence – this requirement will commence on 1 March 2024;
- make minor changes to relevant product standards to facilitate the introduction of the notification and permit schemes, introduce restrictions on flavours and ensure minimum standards for device components; and
- enable therapeutic vapes to be accessed by patients under the Special Access Scheme – Category C, to facilitate more timely access to unregistered therapeutic vapes and reduce regulatory burden on practitioners, while maintaining regulation commensurate with the risk.

These reforms will be supplemented by strengthened domestic compliance and enforcement mechanisms to support the broader policy intent. Changes will be made to the Act to provide additional powers and offences for the regulation of disposable single use and non-therapeutic vapes. Australia-wide compliance and enforcement within and between jurisdictions is essential to effectively address the risk of vaping to population health.

### **Purpose**

TGO 110 is made under section 10 of the Act. TGO 110 specifies the minimum requirements for the quality and safety of unregistered nicotine vaping products and is intended to provide an assurance to medical practitioners and patients that nicotine vaping products meet minimum safety and quality requirements.

The Amendment Order is made under section 10 of the Act, in accordance with subsection 10(3A) of the Act. Most notably the amendments to TGO 110 introduced by the Amendment Order, extend TGO 110's application. Principally, TGO 110 now also applies to therapeutic vaping substances and substance accessories that do not contain nicotine. TGO 110 also now applies to goods included in therapeutic vaping packs that would otherwise be regulated as medical devices if they were not included in such a pack.

The Amendment Order:

- limits the application of the order to therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are finished products and the only indications for the goods are use for smoking cessation or the management of nicotine dependence;
- introduces limitations on the flavour of therapeutic vaping substances to only permit menthol, mint and tobacco flavour;
- establishes minimum standards relating to the ingredients, labelling and packaging of therapeutic vaping substances and therapeutic vaping substance accessories that do not contain nicotine;
- establishes minimum standards related to device components of therapeutic vaping substance accessories;
- establishes minimum standards related to therapeutic vaping kits, and goods in a therapeutic vaping pack (including therapeutic device and device accessories).

The Amendment Order makes a number of minor editorial amendments to update nomenclature used throughout the instrument to reflect the new definitions introduced by *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (“the Amendment Regulations”). As TGO 110 now applies to the goods described in the exemptions provided by the Amendment Regulations, and indeed, sponsors of such goods must notify the Secretary of compliance with TGO 110, among other applicable standards, it was necessary to include these definitions. These definitions are also crucial in allowing TGO 110 to apply more broadly than the former TGO 110 to therapeutic vaping substance and

substance accessories that do not contain nicotine, and devices and device accessories that would otherwise be treated as medical devices if not for their inclusion in a therapeutic vaping pack. Importantly, other than the amendments relating to flavours, the Amendment Order does not make any substantive changes to the requirements that currently apply to therapeutic vaping substances and substance accessories that contain nicotine (presently described as nicotine vaping products).

The Amendment Order gives effect to the first stage of legislative amendments that are intended to increase the minimum safety and quality requirements for therapeutic vaping goods that are for use in smoking cessation or the management of nicotine dependence. The proposal to elevate the minimum standards of safety and quality of these goods is intended to curb the importation and supply of therapeutic vapes that present a risk to public health and safety.

### **Human rights implications**

The Amendment Order engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health* (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

Vaping has been associated with a range of short-term health risks and its long-term health effects are still unknown. Vape marketing and use in the community has increased rapidly in recent years, particularly among young people and poses a major risk to population health and Australia’s success in tobacco control.

Collectively, the reforms are intended to arrest the increasing uptake of recreational vaping, especially by youth and young adults. Restricting the domestic supply of non-therapeutic vapes, while still allowing for therapeutic use, strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to Australians combating smoking addiction or nicotine dependence. Ensuring vapes are only accessed under health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The new framework will support the following public health objectives:

- to arrest the uptake of vapes, other than for therapeutic purposes, especially in youth and young adults aged below 25 years;
- to counteract the marketing of vapes to youth and young adults, especially through product features such as flavours and packaging;
- to reduce rates of nicotine dependence and the risk of future tobacco use; and
- to safeguard public health by requiring unregistered therapeutic vapes to meet minimum quality and safety standards.

Importantly, the reforms will promote the Government’s broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.



The Amendment Order takes positive steps to promote the right to health by helping to ensure the safety and quality of therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack supplied in Australia. The Amendment Order does this through requiring these goods comply with specified requirements relating to ingredients, labelling and packaging, to align with requirements currently specified for nicotine vaping products. It also sets minimum standards for flavours (restricting flavours to menthol, mint and tobacco flavours) to prohibit flavours that are particularly attractive to young people (such as fruit and bubble gum flavours).

The introduction of minimum standards for such goods is particularly important as these goods that are available for supply in Australia are not included in the Australian Register of Therapeutic Goods and, as such, are not subjected to a process of pre-market scrutiny before being available. The imposition of minimum standards for the safety and quality of therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack, is critical in protecting patients from the potential public health and safety risks of using these goods where they do not meet minimum requirements.

### **Conclusion**

The Amendment Order is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.