EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024

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 Therapeutic Vaping Goods) (TGO 110) Order 2021* ("TGO 110") is an order made under section 10 of the Act for the purposes of establishing a ministerial standard for certain therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are indicated for smoking cessation or the management of nicotine dependence. These goods are principally not registered goods or otherwise included in the Australian Register of Therapeutic Goods.

The *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024* ("the Amendment Instrument") amends TGO 110 to strengthen the minimum quality and safety standards for the goods to which it applies. These amendments include reducing maximum nicotine concentration, imposing limits on container volumes, restricting the ingredients that are permitted to be added to therapeutic vaping substances, and introducing pharmaceutical-like labelling and packaging requirements.

The Amendment Instrument also makes consequential amendments to the *Therapeutic Goods (Exempt Monographs) Determination 2021* to remove an item relating to therapeutic vaping substances and therapeutic vaping substance accessories to which TGO 110 applies.

Background

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.

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 vaping, while allowing current smokers to access therapeutic vaping goods 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 were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

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 that the long-term health risks of vaping are not yet known.

The Government's vaping reforms are being implemented in stages over 2024. The *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* ("the Amendment Act") is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms comprised amendments to *the Customs (Prohibited Imports) Regulations 1956*, *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002*. These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.

- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.

- since 1 March 2024, stronger regulatory controls have applied to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

The Amendment Act commenced on 1 July 2024, and implements the second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, manufacture, supply, commercial possession and advertisement of vaping goods in Australia unless certain requirements under the Act are met. Therapeutic vaping goods that meet regulatory requirements under the Act will continue to be available where clinically appropriate. The reforms align with 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 certain therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack indicated for smoking cessation or the management of nicotine dependence where those vaping goods are not registered goods or otherwise included in the Australian Register of Therapeutic Goods.

The Amendment Instrument is made in accordance with subsection 10(3A) of the Act, principally to:

- reduce the maximum allowable nicotine concentration from 100 mg/mL to 50 mg/mL (base equivalent);
- introduce maximum container volumes of 60 mL for therapeutic vaping substances and 5 mL for therapeutic vaping substance accessories;
- remove the 'prohibited ingredients' list and replacing it with a list of 'permitted ingredients', with the effect of limiting the ingredients that may be added to a therapeutic vaping substance;
- introduce a requirement that all ingredients, other than flavouring agents that are not menthol, in a therapeutic vaping substance must comply with all applicable monographs in at least one of the British Pharmacopoeia, European Pharmacopoeia or the United States Pharmacopeia-National Formulary;
- impose restrictions in relation to the name of the good, in particular the name of the good must not suggest that the good is a food, beverage or cosmetic product, and must not be attractive to children or adolescents;
- require therapeutic vaping goods to have pharmaceutical-like packaging;
- introduce new, comprehensive labelling and packing requirements for therapeutic vaping goods, similar to requirements currently applying to other prescription medicines, to better support the safe use of such goods and to assist consumers and health practitioners to identify and understand their components; and
- remove alternative conformity provisions for vaping goods that are the subject of, and compliant with, a premarket tobacco product marketing order issued by the United States Food and Drug Administration.

The Amendment Instrument gives effect to the third stage of legislative amendments that are intended to increase the minimum quality, safety and performance 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 quality, safety and performance of these goods is important as most of these goods are entering the Australian market as 'unapproved' goods. That is, these products have not been assessed by the TGA for quality, safety and efficacy or performance. Evidence about the impacts of vaping on health outcomes is still emerging and requires more long-term research. The intent of these changes to product standards is to reduce the relative risk of these products (thereby improving their relative safety), however these products are not evaluated by the TGA prior to market entry, nor are they subject to the same regulatory oversight as approved therapeutic goods that are included on the Australian Register of Therapeutic Goods.

Incorporation by reference

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003*, an order (or variation of an order) made under subsection 10(1) of the Act 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 following identifies and explains the documents that are incorporated by reference in the Amendment Instrument, and the intended manner of incorporation.

Medical device standard

The Amendment Instrument 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.

Pharmacopoeia

The Amendment Instrument incorporates by reference the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopeia-National Formulary, which are default standards for the purposes of the Act. The note in section 4 of the Amendment Instrument makes it clear that each is defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to each publication as being in force from time to time. The intention in the Amendment Instrument is therefore to adopt the defined meaning of the pharmacopoeia as set out in subsection 3(1) of the Act. The pharmacopoeia are therefore incorporated as in force of existing from time to time, in accordance with these provisions, an approach permitted by subsection 10(4) of the Act and may be accessed from www.pharmacopoeia.com/, https://pheur.edqm.eu/home and www.uspnf.com/ respectively.

While unfortunately the pharmacopoeia are not available for free, it is anticipated that persons most affected by their adoption in the Amendment Instrument (importers and manufacturers of therapeutic vaping goods) would be in possession of these documents in order to import, manufacture or supply such goods. As important international benchmarks for the quality and safety of therapeutic goods, it is not feasible from a regulatory perspective to refuse to adopt such benchmarks on the basis that pharmacopoeia are not freely available. This is particularly in relation to therapeutic vaping goods that are not entered in the Australian Register of Therapeutic Goods (the Register) and as such not evaluated by the Secretary for quality, safety, performance and efficacy before being made available for patients in Australia.

Members of the public may request to view the pharmacopoeia without charge at the office of the TGA in Fairbairn, ACT, by prior written arrangement.

It should also be noted that that the National Library's Trove online system (www.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where editions, in most cases, earlier editions, of the pharmacopoeia may be viewed. For example, the University of Tasmania or the University of Western Australia in relation to the British Pharmacopoeia.

Members of the public may also approach any library that participates in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy or a particular part or monograph for personal study or research, but not for commercial purposes. Fees may apply in relation to the making of such a request. Enquiries should be made with local libraries, state libraries or the National Library.

Child resistant packaging

The Amendment Instrument incorporates by reference, section 8, section 9 (other than subsection 9(6)) and section 10 of the *Therapeutic Goods Order No. 95 – Child resistant packaging requirements for medicines 2017* (TGO 95). TGO 95 is a legislative instrument, which similarly constitutes a standard for the purposes of section 10 of the Act, that sets out requirements for child-resistant packaging.

The Amendment Instrument also incorporates by reference the child-resistant packaging requirements specified in:

- sections 50 to 54 of the Vaping Products Labelling and Packaging Regulations of Canada;
- article 20(3)(g) of the *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014*;
- any regulations made under the *Smokefree Environments and Regulated Products Act 1990* (NZ);
- paragraph 36(7) of the *Tobacco and Related Products Regulations 2016* of the United Kingdon; and
- 6 CFR § 1700.15 of the Poison prevention packaging standards of the United States.

TGO 95 and the internation regulations identified above are incorporated as in force from time to time, in accordance with subsection 10(4) of the Act. TGO 95 is freely available from the Federal Register of Legislation website at www.legsilation.gov.au. Similarly, the international regulations are also available without charge from the following websites:

- Canada – laws-lois.justice.gc.ca/eng/;
- Europe – eur-lex.europa.eu;
- New Zealand – www.legislation.govt.nz/;
- the United Kingdom – www.legislation.gov.uk/; and
- the United States – ecfr.federalregister.gov/.

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 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 2023 and 21 September 2023 on the regulatory proposals developed in consultation with states and territories, in addition to holding numerous webinars and stakeholder meeting. Submissions and survey responses to this 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.

On 28 November 2023, the Minister announced the *Next steps on vaping reforms*, including the commencement of the first stage of vaping reforms on 1 January 2024. The TGA engaged in further updates with supply chain stakeholders, including importers, manufacturers, suppliers, pharmacies, pharmaceutical wholesalers, healthcare professionals and public health organisations, following the Minister's announcement.

On 17 January 2024, the TGA hosted a public webinar to outline the reforms. On 22 and 27 February 2024, the TGA held additional webinars with medical practitioners and pharmacists respectively. On 29 April 2024, the TGA consulted on the proposed requirements in the Amendment Instrument

through a public webinar titled: "*Progress on the next update to TGA Standards for nicotine vapes and vaping devices*". Feedback was sought on the proposed product standards, which led to further refinement of the requirements for therapeutic vaping substances and therapeutic vaping substance accessories contained in the Amendment Instrument.

Between 29 August and 10 September 2024, the TGA consulted with IP Australia in relation to the proposed Amendment Instrument, including the text of the proposed amendments. IP Australia's comments were considered carefully, particularly in relation to the definition of 'name' and informed the drafting of related provisions in the Amendment Instrument.

Other details

Details of Amendment Instrument are set out in **Attachment A**.

The Amendment Instrument 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 on the proposed reforms relating to the regulation of vapes, 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 on the OIA website at: oia.pmc.gov.au/.

The Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 1 October 2024.

ATTACHMENT A

Details of the *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024* (the Amendment Instrument).

Section 2 – Commencement

This section provides that the Amendment Instrument commences on 1 October 2024.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument 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 made to the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* are made in accordance with this subsection.

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where and 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 Instrument is amended as set out in the applicable items in that Schedule. The Amendment Instrument makes amendments to the:

- *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110); and
- *Therapeutic Goods (Exempt Monographs) Determination 2021* (the Determination).

Schedule 1 – Amendments

Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021

Item 1 – Section 4 (note)

This item repeals and replaces the original note in section 4, principally to update the list of terms used in TGO 110 that are defined in the Act. It also introduces two new notes.

The replacement note provides that a number of expressions used in TGO 110 are defined in subsection 3(1) of the Act, and therefore have the same meaning as in the Act, namely ‘batch’, ‘British Pharmacopoeia’, ‘container’, ‘essential principles’, ‘European Pharmacopoeia’, ‘manufacture’, ‘medicine’, ‘primary pack’, ‘registered goods’, ‘sponsor’, ‘standard’, ‘supply’, ‘therapeutic goods’, and ‘United States Pharmacopeia-National Formulary’.

The second note reproduces the definition of 'container' in the Act. Relevantly, ***container***, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.

The third note clarifies, for the avoidance of doubt, the container of a therapeutic vaping substance or therapeutic vaping substance accessory is the bottle, cartridge, capsule, pod or other vessel that contains the therapeutic vaping substance, and not the blister pack, strip pack or other wrapper in which the container is supplied.

Items 2 and 4 – Section 4

These items introduce new definitions to section 4 of TGO 110, including definitions of 'batch number', 'batch number prefix', 'capacity', 'contact details', 'expiry date', 'expiry date prefix', 'fill volume', 'flavouring agent', 'intermediate packaging', 'label', 'main label', 'menthol flavour', 'mint flavour', 'name', 'Poisons Information Centre contact information', 'relevant goods', 'relevant indications', 'small container', 'text size', 'tobacco flavour', and 'very small container'.

Item 3 – Section 4 (definition of *stated content*)

This item amends the definition of 'stated content' in section 4 of TGO 110 to make clear that the term means the concentration of nicotine that is stated on the label to be present in a therapeutic vaping substance or therapeutic vaping substance accessory.

Item 5 – Section 5

This item repeals section 5 on the basis that the authority and application provisions in TGO 110 may be read together to determine that the matters specified in TGO 110 constitute a standard for the goods identified therein.

Item 6 – Before section 6

This item makes a minor amendment to introduce a new heading, Part 1A—Application, before section 6 in TGO 110.

Item 6 – Subsection 6(1)

This item makes editorial amendments to subsection 6(1) of TGO 110 to combine subsections (1) and (2) in providing for the goods that TGO 110 applies to and those to which it does not apply.

This item also introduces new subsection 6(2) which clarifies, for the avoidance of doubt, that TGO 110 applies to therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping devices and therapeutic vaping device accessories that are contained in a therapeutic vaping kit or therapeutic vaping pack, as relevant.

Item 8 – Parts 2, 3, 4 and 5

This item repeals Parts 2, 3, 4 and 5 of TGO 110 and introduces new Parts 2, 3, 4, 5, 6 and 7.

New Part 2 contains general provisions, Part 3 specifies requirements relating to ingredients, Part 4 specifies requirements relating to containers, Part 5 specifies requirements relating to labelling and packaging, Part 6 specifies requirements relating to information leaflets, and Part 7 provides application, saving and transitional arrangements.

Part 2—General provisions

Name of the good (new section 7)

New section 7 specifies requirements relating to the name of a relevant good.

New subsection 7(1) provides that the name of a relevant good must not be in any way attractive to children or adolescents and must not suggest, either expressly or by implication, that the good, is a food, beverage or cosmetic product, has health benefits or is safe or without harm or side effects. Further, new subsection 7(1) provides that the name of a relevant good must not, whether expressly or by implication, promote the use or supply of the goods, exaggerate, or be likely to exaggerate the efficacy or performance of the goods, or encourage, or be likely to encourage in appropriate or excessive use of the goods.

New subsection 7(2) provides that goods in a therapeutic vaping pack must only be supplied in a therapeutic vaping pack where the name of the pack complies with the requirements specified in subsection (1) as if the pack were a relevant good.

Goods in a therapeutic vaping kit or therapeutic vaping pack (new section 8)

New subsection 8(1) provides that each therapeutic vaping substance and therapeutic vaping substance accessory in a therapeutic vaping kit or a therapeutic vaping pack must:

- be a finished product; and
- be indicated only for use for smoking cessation or the management of nicotine dependence; and
- conform with the requirements for therapeutic vaping substances and therapeutic vaping substance accessories specified in TGO 110.

The effect of this provision is that the requirements relating to therapeutic vaping substances and therapeutic vaping substance accessories in TGO 110 will apply to those goods whether the goods are supplied as individual goods, or as part of a kit or pack.

New subsection 8(2) provides that each therapeutic vaping device and therapeutic vaping device accessory in a therapeutic vaping pack must:

- be a finished product; and
- be intended only to administer, or contain, a therapeutic vaping substance for which the only indication is use for smoking cessation or the management of nicotine dependence; and
- for a therapeutic vaping device or therapeutic vaping device accessory to which the MDSO applies—conform with either the MDSO or the essential principles;
- for a therapeutic vaping device or therapeutic vaping device accessory to which the MDSO does not apply—conform with the essential principles.

New subsection 8(3) provides that the goods in a therapeutic vaping pack must all be therapeutic goods, or goods intended by the manufacturer of the goods to assist with the use of a therapeutic vaping device or therapeutic vaping device accessory (such as a funnel or extender). The effect of this provision is that a therapeutic vaping pack must not contain anything other goods – for example, a therapeutic vaping pack must not contain stationary, toys or clothing items.

Part 3—Ingredients

General requirements (new section 9)

New section 9 provides that all ingredients, other than a flavouring agent that is not menthol, in a therapeutic vaping substance or a therapeutic vaping substance accessory must comply with one or

more of the pharmacopoeia, being the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary.

Flavouring agents that produce the taste or smell of mint flavour and tobacco flavour are excluded from this requirement, as pharmacopoeia grade material is currently not available for such ingredients.

Active ingredients (new section 10)

New subsection 10(1) provides that a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine must contain nicotine as the only active ingredient.

New subsection 10(2) provides that the equivalent base form concentration of nicotine in a therapeutic vaping substance or a therapeutic vaping substance accessory must not be more than 50 mg/mL in solution (equivalent base form). The current limit presents risks associated with 'home dilutions' if not done correctly or accurately, as the therapeutic vaping substance needs to be diluted before use when at a higher concentration.

New subsection 10(3) provides that the concentration of nicotine in a therapeutic vaping substance or a therapeutic vaping substance accessory must be within 10% more or less of the stated content.

New subsection 10(4) provides that a therapeutic vaping substance or a therapeutic vaping substance accessory that does not contain nicotine must not contain any other active ingredient.

Relevantly, the requirements relating to active ingredients specified in subsections 10(1) and (4) are the same as the requirements specified in TGO 110 immediately before the commencement of the Amendment Instrument.

Permitted ingredients (new section 11)

Section 11 provides requirements relating to ingredients that are permitted to be included in a therapeutic vaping substance or a therapeutic vaping substance accessory.

New subsection 11(1) provides that only ingredients that are specified in column 2 of the table in Schedule 1 (as introduced below) may be used in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory.

The first note to subsection 11(1) clarifies that the requirements relating to the manufacture of the container of the therapeutic vaping substance accessory (i.e. the metal or plastic component that houses the therapeutic vaping substance) are specified in section 15. Further, the second note to subsection 11(1) clarifies, for the avoidance of doubt, that this subsection applies to the manufacture of therapeutic vaping substances including those contained in a therapeutic vaping substance accessory.

New subsection 11(2) provides that for each item of the table in Schedule 1, the ingredients specified in column 2 must comply with the requirements specified in column 3 (if any).

The effect of section 11 is to limit the ingredients that can be added to formulations of therapeutic vaping substances and therapeutic vaping substance accessories. Previously manufacturers have included various ingredients such as colouring agents, cooling agents, sweeteners, vitamins, minerals and stimulants. These ingredients may enhance the appeal of vaping substances to children and adolescents and may increase the risk profile of the vaping goods.

Restricted substances (new section 12)

Section 12 deals with substances that are present in a therapeutic vaping substance or a therapeutic vaping substance accessory as contaminants or residual impurities. The substances specified in column 2 of an item in the tables in Parts 1, 2 or 3 to Schedule 2 (as introduced below) must not be added to a therapeutic vaping substance or a therapeutic vaping substance accessory, and if present, must be below the limit specified in column 3 of that item.

The inclusion of a 'restricted substances' list reflects the need to mitigate the risk of harmful substances, such as formaldehyde, heavy metals and carbonyl compounds, being present as contaminants, degradation products, reaction products or residual compounds in therapeutic vaping substances or therapeutic vaping substance accessories, as a result of manufacturing processes. The presence of such substances must be below stated limits to minimise the risk of harm associated with inhaling such substances. These substances must not be added to therapeutic vaping substances either.

Flavour (new section 13)

Section 13 specifies requirements relating to flavours contained in therapeutic vaping substances or therapeutic vaping substance accessories.

New subsection 13(1) provides that a therapeutic vaping substance or a therapeutic vaping substance accessory may only contain flavouring agents that produce one of the following:

- menthol flavour;
- mint flavour; or
- tobacco flavour.

New subsection 13(2) provides that for the avoidance of doubt, a therapeutic vaping substance or a therapeutic vaping substance accessory must not contain flavouring agents that produce a combination of flavours. The note to subsection 14(2) provides examples of prohibited flavour combinations, including sweet mint, chocolate mint and tobacco mint.

Part 4—Containers

Containers of therapeutic vaping substances (new section 14)

Section 14 specifies requirements relating to containers of therapeutic vaping substances.

New subsection 14(1) provides that the container of a therapeutic vaping substance must have a fill volume of not more than 60 mL. That is, the maximum container volume permitted is 60 mL. This limit was introduced to address the known risks associated with high volumes of therapeutic vaping substances and encourage the use of safer closed systems.

New subsection 14(2) provides that the container of a therapeutic vaping substance must be predominantly either black, white, grey or clear, and feature no more than 4 other colours or shades, included the colour or shade of any text.

The effect of subsection 14(2) is to introduce a requirement for a pharmaceutical-like appearance for the container of a therapeutic vaping substance, while allowing the container to also feature a limited number of colours or shades to identify a particular flavour or strength.

Containers of therapeutic vaping substance accessories (new section 15)

Section 15 specifies requirements relating to containers of therapeutic vaping substance accessories. The container of a therapeutic vaping substance accessory is the pod, capsule, vessel or other article that contains the therapeutic vaping substance.

New subsection 15(1) provides that the container of a therapeutic vaping substance accessory must have a fill volume of not more than 5 mL. This means that the maximum container volume permitted for therapeutic vaping substance accessories is 5 mL. This represents an increase from 2 mL and was introduced to balance safety concerns associated with the need to replace coils and wicks with a concession to assist with affordability of closed systems.

New subsection 15(3) provides that the container of 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 the essential principles, except the requirements relating to labelling and packaging;
- 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 except the requirements relating to labelling and packaging.

The effect of subsection 15(2) is that the parts of a therapeutic vaping substance accessory that are not the therapeutic vaping substance, such as the metal or plastic components that house the therapeutic vaping substance, must comply with the requirements, other than requirements relating to labelling and packaging, specified in the MDSO or the essential principles (as applicable). These requirements would include, for example, requirements relating to the construction, design and appearance of the cartridge, capsule, pod or other vessel and any integrated component, such as a coil.

The note to subsection 15(2) states that requirements relating to the labelling and packaging of a container of a therapeutic vaping substance accessory are specified in Part 5 of this instrument.

New subsection 15(3) provides additional requirement that apply to the container of a therapeutic vaping substance accessory. The container of a therapeutic vaping substance accessory must be predominantly either matte white, matte grey or matte black, and feature no more than 3 other matte colours or shades, including the colour or shade of any text. Where the container of a therapeutic vaping substance accessory features a colour or shade other than matte white or matte grey, that colour must not be visible when the therapeutic vaping device is fully assembled for use. Further, the container of a therapeutic vaping device accessory may have a clear panel, which must be the smallest size that enables visibility of the amount of therapeutic vaping substance in the container. The clear panel is not intended to be large or a feature of the container, and is intended to be as small as possible, while still allowing users to see the level of the therapeutic vaping substance that is in the container. These requirements are the same as the requirements in the MDSO for a therapeutic vaping device accessory.

Part 5—Labelling and packaging

Division 1—General

General requirements (new section 16)

Section 16 provides that the label, primary pack, intermediate packaging (if any) and container of a relevant good must comply with the requirements specified in Division 1.

The information required to be included on the label of a relevant good must be in English, clearly legible, printed in a manner that is durable, and in a colour that contrasts strongly with the background, except for the expiry date, expiry date prefix, batch number or batch number prefix, when that information is embossed or debossed and not printed.

For information to be clearly legible, it must also be clearly visible, easy to read, and not obscured. The information must be printed in a manner that is durable, which means the information must be printed in a manner such that the information remains on the label for the life of the good and does not, for example, rub off or fade off.

Appearance (new section 17)

This section provides that the label and primary pack, other than a primary pack that is a container, of a relevant good must be predominantly white, and feature no more than 4 other colours or shades, including the colour or shade of any text.

The first note to this section makes it clear that the 4 colours or shades includes the black text required for warning statements. The second note refers to Part 4, which specifies requirements relating to a primary pack that is a container.

The effect of section 17 is to introduce pharmaceutical-like labelling and packaging for the goods, while allowing the label or package to also feature a limited number of colours or shades to identify a particular flavour or strength.

Prohibited features (new section 18)

New subsection 18(1) provides that the label, primary pack, intermediate packaging (if any) and container of a relevant good must not contain the following:

- any feature that suggests, whether expressly or by implication, that the good is a food, beverage or cosmetic product, has health benefits other than its indications, including healing, vitalising, natural, organic or rejuvenating properties;
- any words, symbols, trade marks, images, figures, logos or emblems that are in contravention of another provision of this instrument;
- any promotional statement, pictorial representation or design.

New subsection 18(2) provides that the label, primary pack, immediate packaging (if any) and container of a relevant good must not include any features designed to change the appearance of the label, container or package, including any of the following:

- heat activated inks;
- inks or embellishments designed to appear gradually over time;
- inks that appear fluorescent in certain light;
- panels designed to be scratched or rubbed to reveal an image or text.

Dispensing labels (new section 19)

New section 19 provides that, unless precluded by the dimensions of the primary pack, the primary pack of a relevant good must include a minimum space of 70 mm x 30 mm for the dispensing label.

The inclusion of a requirement to include a defined space for a dispensing label ensures that important information about the goods is not covered up when a dispensing label is applied by a pharmacist.

Warning statement panel (new section 20)

New section 20 sets out requirements in relation to warning statement panels.

New subsection 20(1) provides that a warning statement panel must be at least 30% of the total main label size and display the warning statement "THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE".

New subsection 20(2) provides that the text of the warning statements required by subsection (1) must be:

- in bold-face, sans serif, capital letters of uniform thickness and size; and
- in black text on a white background; and
- orientated in the same direction as the name of the good; and
- of such a size that the text fills, as much as possible, the background of the warning statement panel.

Child-resistant packaging (new section 21)

New section 21 provides that a therapeutic vaping substance or a therapeutic vaping substance accessory must comply with the child-resistant packaging requirements specified in section 8, section 9 (except subsection 9(6)) and section 10 of the *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95), unless the product is packaged for supply in Canada, the European Union, New Zealand, the United Kingdom or the United States, and has child-resistant packing compliant with the requirements in those jurisdictions.

The requirements relating to child-resistant packaging specified in section 21 are the same as the requirements that were specified in TGO 110 immediately before the commencement of the Amendment Instrument.

Division 2—Therapeutic vaping substances and therapeutic vaping substance accessories

Division 2 specifies requirements relating to the labelling of therapeutic vaping substances and therapeutic vaping substance accessories.

Subdivision 2.1—Primary pack

Information to be included on the main label of a primary pack (new section 22)

New section 22 specifies the kind and form of information that must be included on the *main label* of the primary pack of a therapeutic vaping substance or a therapeutic vaping substance accessory.

New subsection 22(1) specifies the information that must be included on the main label of the primary pack of a therapeutic vaping substance or a therapeutic vaping substance accessory including, the name of the good, the concentration of nicotine, the flavour of the good, and the fill volume in mL.

New subsection 22(2) sets out the requirements relating to the text size of information displayed on the main label and makes it clear that the information must be orientated in the same direction.

New subsection 22(3) provides that the name of the good on the main label must be presented in a continuous uninterrupted manner and not be broken up by additional words or images.

New subsection 22(4) provides that where a therapeutic vaping substance or a therapeutic vaping substance accessory contains nicotine, the name of the good, the word "nicotine" and the concentration of nicotine must:

- appear as a cohesive unit by placing the word “nicotine” and the concentration of nicotine together in a single line of text immediately below the name of the good; and
- not be separated by additional words or images.

New subsection 22(5) provides that where a therapeutic vaping substance or a therapeutic vaping substance accessory does not contain nicotine, the name of the good and the concentration of nicotine must:

- appear as a cohesive unit by placing the words “nicotine 0 mg/mL” immediately below the name of the good; and
- not be separated by additional words or images.

New subsection 22(6) specifies that where a therapeutic vaping substance or a therapeutic vaping substance accessory contains nicotine, the main label on the primary pack must contain a warning statement panel as specified in section 20.

The effect of new section 23 is to ensure that critical information about the good, including information about the active ingredient, is clearly and prominently displayed in a consistent location to assist in product identification and reduce opportunity for selecting incorrect goods.

Information to be included on the label of a primary pack (new section 23)

New section 23 specifies the information that must be included on the *label* of a primary pack of a therapeutic vaping substance or a therapeutic vaping substance accessory. This information may be included on the main label or on another part of the label or a separate label.

The information required includes the name of each ingredient, the batch number and batch number prefix, the expiry date and expiry date prefix, and the name and contact details of the sponsor, storage conditions for the goods, Poisons Information Centre contact details, and certain warning statements.

The information included on the label of a primary pack must be in a text size of at least 1.5 mm.

Subdivision 2.2—Intermediate packaging

Information to be included on the main label of intermediate packaging (new section 24)

New section 24 specifies the kind and form of information that must be included on the *main label* of intermediate packaging (if any) of a therapeutic vaping substance or a therapeutic vaping substance accessory.

New subsection 24(1) specifies the information that must be included on the main label of the intermediate packaging of a therapeutic vaping substance or a therapeutic vaping substance accessory (if any) including, the name of the good, the concentration of nicotine, the batch number and batch number prefix, expiry date and expiry date prefix and certain warning statements.

New subsections 24(2) and (3) specify requirements relating to text size and formatting of information to be included on the main label of the intermediate packaging.

Subdivision 2.3—Containers

Information to be included on the main label of a container (new section 25)

New section 25 specifies the kind and form of information that must be included on the *main label* of a container of a therapeutic vaping substance.

New subsection 25(1) makes it clear that new section 25 does not apply to containers that are small containers or very small containers. Relevantly, 'Small container' is defined in section 4 of TGO 110 as meaning a container that has a capacity of 25 mL or less and is not a very small container. 'Very small container' is defined in section 4 of TGO 110 as meaning a container that has a capacity of 5 mL or less. A therapeutic vaping substance accessory is characterised as a very small container, as the maximum fill volume is 5 mL. The information required by this provision would not fit on a container that is either a small container or very small container. Separate requirements are imposed on small containers and very small containers below.

New subsection 25(2) specifies the information that must be included on the main label of a container of a therapeutic vaping substance that is enclosed in a primary pack, including the name of the good, the concentration of nicotine, the flavour of the good and the fill volume in mL.

New subsection 25(3) sets out the requirements relating to the text size of information displayed on the main label and makes clear that the information must be orientated in the same direction.

New subsection 25(4) specifies that the name of the good must be presented in a continuous uninterrupted manner and not be broken up by additional words or images.

New subsection 25(5) provides that where a therapeutic vaping substance contains nicotine, the name of the good, the word "nicotine" and the concentration of nicotine must:

- appear as a cohesive unit by placing the word "nicotine" and the concentration of nicotine together in a single line of text immediately below the name of the good; and
- not be separated by additional words or images.

New subsection 25(6) provides that where a therapeutic vaping substance does not contain nicotine, the name of the good and the concentration of nicotine must:

- appear as a cohesive unit by placing the words "nicotine 0 mg/mL" immediately below the name of the good; and
- not be separated by additional words or images.

New subsection 25(7) specifies that where a therapeutic vaping substance contains nicotine, the main label on the container must contain a warning statement panel as specified in section 20.

Information to be included on the label of a container (new section 26)

New section 26 specifies the information that must be included on the *label* of a container of a therapeutic vaping substance.

New subsection 26(1) provides that new section 26 does not apply to containers that are small containers or very small containers. The information required by this provision would not fit on a container that small. Separate requirements are imposed on small and very small containers below. This provision does not apply to a therapeutic vaping substance accessory as the maximum volume is 5 mL which would be a very small container.

New subsection 26(2) specifies the information that must be included on the label of a container including for example, the name of each ingredient, the batch number and batch number prefix, the expiry date and expiry date prefix, and the name and contact details of the sponsor, storage conditions applicable to the goods, Poisons Information Centre contact information and certain warning statements.

New subsection 26(3) specifies requirements relating to text size of information to be included on the label of a container.

Information to be included on the main label of a small container (new section 27)

New section 27 specifies the kind and form of information that must be included on the *main label* of a small container of a therapeutic vaping substance. This provision does not apply to very small containers. The information required by this provision would not fit on a container that is a small container. Separate requirements are imposed on very small containers below. This provision does not apply to a therapeutic vaping substance accessory, which is characterised as a very small container, as the maximum fill volume is 5 mL.

New subsection 27(1) specifies the information that must be included on the main label of a small container of a therapeutic vaping substance that is enclosed in a primary pack, including the name of the good, the concentration of nicotine, the flavour of the good, the fill volume in mL and a warning statement for goods containing nicotine. If a small container is not in a primary pack, the labelling requirements of a primary pack apply to the small container as it would then be the primary pack.

New subsection 27(2) sets out the requirements relating to the text size of information displayed on the main label and makes it clear that the information must be orientated in the same direction.

New subsection 27(3) specifies that the name of the good must be presented in a continuous uninterrupted manner and not be broken up by additional words or images.

New subsection 27(4) specifies that the warning statement in item 8 of the table in subsection (1) must be displayed in capital letters.

Information to be included on the label of a small container (new section 28)

New section 28 specifies the information that must be included on the *label* of a small container of a therapeutic vaping substance. This provision does not apply to very small containers. The information required by this provision would not fit on a container that small. Separate requirements are imposed on very small containers below. This provision does not apply to a therapeutic vaping substance accessory as the maximum volume is 5 mL which would be a very small container.

New subsection 28(1) specifies the information that must be included on the label of a small container of a therapeutic vaping substance that is enclosed in a primary pack, including the batch number and batch number prefix, the expiry date and expiry date prefix, and the name of the sponsor, storage conditions applicable to the goods and certain warning statements. If a small container is not in a primary pack, the labelling requirements of a primary pack apply to the small container as it would then be the primary pack.

New subsection 28(2) specifies requirements relating to text size of information to be included on the label of a small container.

Information to be included on the main label of a very small container (new section 29)

New section 29 specifies the kind and form of information that must be included on the *main label* of a very small container of a therapeutic vaping substance or a therapeutic vaping substance accessory.

New subsection 29(1) specifies the information that must be included on the main label of a very small container of a therapeutic vaping substance or a therapeutic vaping substance accessory that is enclosed in a primary pack, including the equivalent base form concentration of nicotine, the flavour of the good and the fill volume in mL. If a very small container is not in a primary pack, the labelling requirements of a primary pack apply to the very small container as it would then be the primary pack.

New subsection 29(2) sets out the requirements relating to the text size of information displayed on the main label and makes it clear that the information must be orientated in the same direction.

Information to be included on the label of a very small container (new section 30)

New section 30 specifies the information that must be included on the *label* of a very small container of a therapeutic vaping substance or a therapeutic vaping substance accessory.

New subsection 30(1) specifies the information that must be included on the label of a very small container of a therapeutic vaping substance or a therapeutic vaping substance accessory that is enclosed in a primary pack, including the batch number and batch number prefix and the expiry date and expiry date prefix. If a very small container is not in a primary pack, the labelling requirements of a primary pack apply to the very small container as it would then be the primary pack.

New subsection 30(2) specifies requirements relating to text size of information to be included on the label of a very small container.

Division 3—Therapeutic vaping kits

Division 3 specifies requirements relating to the labelling of therapeutic vaping kits.

General (new section 31)

New section 31 provides that each therapeutic vaping substance and therapeutic vaping substance accessory in a therapeutic vaping kit must be enclosed in a primary pack that complies with the labelling and packing requirements specified in Division 2, other than section 19.

The effect of this provision is that each of the goods that are included in a therapeutic vaping kit must be enclosed in their own primary pack that complies with the requirements in Division 2, except the requirement to include a space for a dispensing label, as if those goods were supplied as individual goods.

Information to be included on the main label of a therapeutic vaping kit (new section 32)

New section 32 specifies the kind and form of information that must be included on the *main label* of a therapeutic vaping kit.

New subsection 32(1) specifies the information that must be included on the main label of a therapeutic vaping kit, including the name of the kit, the presence and concentration of nicotine in each therapeutic vaping substance and therapeutic vaping substance accessory in the kit, and the flavour (if any) of each good in the kit. The information that is required to be as stated on the main label of the primary pack must be in accordance with the requirements for the main label of the primary pack specified above (i.e. size and orientation requirements apply).

New subsection 32(2) sets out the requirements relating to the text size of information displayed on the main label and makes it clear that the information must be orientated in the same direction.

New subsection 32(3) provides that the name of the kit must be presented in a continuous uninterrupted manner and not be broken up by additional words or images.

New subsection 32(4) specifies that where a therapeutic vaping kit contains a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine, the main label on the kit must contain a warning statement panel as specified in section 20.

Information to be included on the label of a therapeutic vaping kit (new section 33)

New subsection 33(1) specifies the information that must be included on the *label* of a therapeutic vaping kit, including the batch number and batch number prefix, the name and contact details of the sponsor and the expiry date, expiry date prefix, the storage conditions applying to each good in the kit, Poisons Information Centre contact information and certain warning statements.

Importantly, the expiry date of a therapeutic vaping kit will be the expiry date of the good in the kit that has the earliest expiry date.

New subsection 33(2) specifies requirements relating to text size of information to be included on the label of a therapeutic vaping kit.

Division 4—Goods in a therapeutic vaping pack

Division 4 specifies requirements relating to the labelling of goods in a therapeutic vaping pack.

General (new section 34)

New section 34 provides that goods in a therapeutic vaping pack must be supplied in a therapeutic vaping pack that complies with the labelling and packaging requirements for a primary pack specified in Division 1, as if the pack was a relevant good.

Information to be included on the main label of a therapeutic vaping pack (new section 35)

New section 35 specifies the kind and form of information that must be included on the *main label* of a therapeutic vaping pack.

New subsection 35(1) provides that goods in a therapeutic vaping pack must be supplied in a therapeutic vaping pack that that contains all the following information on the main label of the pack:

- the name of the therapeutic vaping pack;
- for each therapeutic vaping substance and therapeutic vaping substance accessory—the name of the good, presence and concentration of nicotine and the flavour of the good (if any);
- for each therapeutic vaping device or therapeutic vaping device accessory—the name and model of the therapeutic vaping device or therapeutic vaping device accessory.

The information that is required to be as stated on the main label of the primary pack must be in accordance with the requirements for the main label of the primary pack specified above (i.e. size and orientation requirements apply).

New subsection 35(2) sets out requirements relating to text size of information displayed on the main label and makes it clear that the information must be orientated in the same direction.

New subsection 35(3) provides that the name of the therapeutic vaping pack must be presented in a continuous uninterrupted manner and not be broken up by additional words or images.

New subsection 35(4) specifies that goods in a therapeutic vaping pack contain nicotine, must be supplied in a therapeutic vaping pack that contains a warning statement panel as specified in section 20 on the main label.

Information to be included on the label of a therapeutic vaping pack (new section 36)

New subsection 36(1) specifies the information that must be included on the *label* of a therapeutic vaping pack, including the batch number and batch number prefix, expiry date and expiry date prefix,

the name and contact details of the sponsor and manufacturer, storage conditions applicable to each good in the pack, Poisons Information Centre contact information and certain warning statements.

New subsections 36(2) and (3) specifies requirements relating to the text size and form in which the information required to be included on the label of a therapeutic vaping pack must appear.

Part 6—Information leaflet

To reflect the availability of some vapes under a Schedule 3 pathway, an information leaflet will be included in all vapes. The leaflet has been designed to facilitate the dispensing obligations of the pharmacist, such as a statement that the vape is an unapproved good. The design of the information leaflet marries that imposed on similar medicines available as pharmacist only medicines.

General requirements (new section 37)

New section 37 specifies requirements for information leaflets. This has been introduced to reflect the availability of some vapes as pharmacist only medicines, which do not require a prescription, and to facilitate compliance the dispensing obligations of the pharmacist for such medicines. The design of the information leaflet is equivalent to that imposed on similar pharmacist only medicines.

New subsection 37(1) provides that relevant goods must be accompanied by an information leaflet is either:

- enclosed within the packaging;
- on a surface of the packaging;
- affixed to a surface of the packaging; or

is accompanied by instructions for accessing an information leaflet in electronic form, supplied as a PDF file or a HTML file.

New subsection 37(2) provides that an information leaflet must contain the headings specified in column 2 of an item in Schedule 3, followed immediately by the information specified in column 3 of that item.

New subsection 37(3) specifies that the information in an information leaflet must be in English, clearly legible and written in language that will easily be understood by patients.

Part 7—Application, saving and transitional provisions

Application, saving and transitional provisions (new section 38)

New section 38 sets out application, saving and transitional provisions relating to therapeutic vaping goods.

New subsection 38(1) introduces the definition of 'former TGO 110' for the purposes of section 38. Former TGO 110 means the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, as in force immediately before the commencement of the Amendment Instrument.

New subsection 38(2) provides that despite the amendments made by the Amendment Instrument, 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 2025, and supplied before 1 July 2025. Subsection (3) provides that this section ceases to apply on 1 July 2025.

The effect of subsections 38(2) and (3) 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 2025, may continue to comply with the requirements in the former Order until 1 July 2025. From 1 July 2025, all such goods must comply with the Principal Order as amended.

Item 9 – Schedule 1

This item replaces Schedule 1 to TGO 110 to introduce a list of ingredients permitted to be added to a therapeutic vaping substance or a therapeutic vaping substance accessory, pursuant to section 11.

An ingredient specified in column 2 of an item in the table in Schedule 1 is permitted to be added to a therapeutic vaping substance or a therapeutic vaping substance accessory, subject to compliance with the requirements specified in column 3, if any. The ingredients permitted to be added to a therapeutic vaping substance or a therapeutic vaping substance accessory include water, glycerol, nicotine, propylene glycol and flavouring agents that produce menthol flavour, mint flavour or tobacco flavour.

Column 3 of item 1 specifies the requirements relating to the inclusion of flavouring agents in a therapeutic vaping substance or a therapeutic vaping substance accessory. These requirements include:

- only the minimum number of the flavouring agents that are necessary to produce the relevant flavour, or to maintain the stability of the flavouring agent are permitted; and
- flavouring agents must not contain any of the following:
    - 2,3-pentanedione;
    - acetoin;
    - benzaldehyde;
    - cinnamaldehyde;
    - diacetyl;
    - any substance that, whether heated or unheated, would pose a risk to human health; and
- any menthol in a flavouring agent must be at a concentration of not more than 20 mg/mL.

Item 10 – Schedule 2

This item replaces Schedule 2 to TGO 110 to introduce a list of substances that may be present in a therapeutic vaping substance or a therapeutic vaping substance accessory, pursuant to section 12.

A substance specified in column 2 of an item in a table in Parts 1, 2 or 3 of Schedule 2 is permitted to be present in a therapeutic vaping substance or a therapeutic vaping substance accessory provided that the substance is:

- not intentionally added to a therapeutic vaping substance or a therapeutic vaping substance accessory; and
- at a concentration below the limit specified in column 3.

Part 1 of Schedule 2 specifies the list of compounds that may be present in a therapeutic vaping substance or a therapeutic vaping substance accessory, including, for example, acetaldehyde at a concentration of not more than 0.2 mg/mL.

Part 2 of Schedule 2 specifies the list of metals that may be present in a therapeutic vaping substance or a therapeutic vaping substance accessory, including, for example, aluminium at a concentration of not more than 0.012 mg/mL.

Part 3 of Schedule 2 specifies the list of tobacco-specific nitrosamines that may be present in a therapeutic vaping substance or a therapeutic vaping substance accessory, including, for example, N-nitrosonornicotine at a concentration of not more than 0.050 µg/mL.

Item 11 – At the end of the instrument

This item adds new Schedule 3 to TGO 110 to specify the headings and supporting information that must be included in an information leaflet, pursuant to section 37.

An information leaflet must include:

- the name of the good;
- information about why a person is using the good, including the indication of the good, being for smoking cessation or the management of nicotine dependence;
- information relating to what a patient should know before using the good, including relevant warning statements and contraindications for the good;
- information about what a patient should do if they are taking other medication;
- information relating to the use of the good, including how frequently the good should be used, maximum daily usage and relevant warning statements;
- information the patient should know why using the good, including instructions for dealing with overuse;
- information about side effects, including listing common side effects, serious side effects and how to report side effects; and
- product details, including details about the active ingredients, other ingredients and potential allergens.

Schedule 2 – Amendments

Therapeutic Goods (Exempt Monographs) Determination 2021

Section 3 of the Act defines '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 Pharmacopeia-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, do not constitute a standard for the therapeutic goods specified in the order or therapeutic goods generally.

Items 1 and 2 – Section 4

These items make amendments to section 4 of the *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the Determination") consequential to the amendment made by item 3 below.

Item 1 repeals paragraphs (a) and (b) in the note to section 4.

Item 2 repeals the definitions of 'regulations', 'TGO 110', 'therapeutic vaping substance', and 'therapeutic vaping substance accessory'.

Item 3 – Schedule 1 (table item 1)

This item repeals item 1 of the table in Schedule 1 to the Determination with the effect that monographs in the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopeia-National Formulary are no longer exempt for the purposes of 'standard' in subsection 3(1) of the Act for therapeutic vaping substances or therapeutic vaping substance accessories.

The effect of this amendment is that therapeutic vaping substances and therapeutic vaping substance accessories must comply with all monographs in the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopeia-National Formulary to which those goods are subject, noting that section 13 of the Act would apply to resolve any inconsistency.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024

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 Therapeutic Vaping Goods) (TGO 110) Order 2021* ("TGO 110") is an order made under section 10 of the Act for the purposes of establishing a ministerial standard for certain therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are indicated for smoking cessation or the management of nicotine dependence. These goods are principally not registered goods or otherwise included in the Australian Register of Therapeutic Goods.

The *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024* ("the Amendment Instrument") amends TGO 110 to strengthen the minimum quality and safety standards for the goods to which it applies. These amendments include reducing maximum nicotine concentration, imposing limits on container volumes, restricting the ingredients that are permitted to be added to therapeutic vaping substances, and introducing pharmaceutical-like labelling and packaging requirements.

The Amendment Instrument also makes consequential amendments to the *Therapeutic Goods (Exempt Monographs) Determination 2021* to remove an item relating to therapeutic vaping substances and therapeutic vaping substance accessories to which TGO 110 applies.

Background

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.

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 vaping, while allowing current smokers to access therapeutic vaping goods 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 were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

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 that the long-term health risks of vaping are not yet known.

The Government's vaping reforms are being implemented in stages over 2024. The *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* ("the Amendment Act") is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms comprised amendments to *the Customs (Prohibited Imports) Regulations 1956*, *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002*. These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.

- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.

- since 1 March 2024, stronger regulatory controls have applied to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

The Amendment Act commenced on 1 July 2024, and implements the second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, manufacture, supply, commercial possession and advertisement of vaping goods in Australia unless certain requirements under the Act are met. Therapeutic vaping goods that meet regulatory requirements under the Act will continue to be available where clinically appropriate. The reforms align with 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 certain therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack indicated for smoking cessation or the management of nicotine dependence where those vaping goods are not registered goods or otherwise included in the Australian Register of Therapeutic Goods.

The Amendment Instrument is made in accordance with subsection 10(3A) of the Act, principally to:

- reduce the maximum allowable nicotine concentration from 100 mg/mL to 50 mg/mL (base equivalent);
- introduce maximum container volumes of 60 mL for therapeutic vaping substances and 5 mL for therapeutic vaping substance accessories;
- remove the 'prohibited ingredients' list and replacing it with a list of 'permitted ingredients', with the effect of limiting the ingredients that may be added to a therapeutic vaping substance;
- introduce a requirement that all ingredients, other than flavouring agents that are not menthol, in a therapeutic vaping substance must comply with all applicable monographs in at least one of the British Pharmacopoeia, European Pharmacopoeia or the United States Pharmacopeia-National Formulary;
- impose restrictions in relation to the name of the good, in particular the name of the good must not suggest that the good is a food, beverage or cosmetic product, and must not be attractive to children or adolescents;
- require therapeutic vaping goods to have pharmaceutical-like packaging;
- introduce new, comprehensive labelling and packing requirements for therapeutic vaping goods, similar to requirements currently applying to other prescription medicines, to better support the safe use of such goods and to assist consumers and health practitioners to identify and understand their components; and
- remove alternative conformity provisions for vaping goods that are the subject of, and compliant with, a premarket tobacco product marketing order issued by the United States Food and Drug Administration.

The Amendment Instrument gives effect to the third stage of legislative amendments that are intended to increase the minimum quality, safety and performance 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 quality, safety and performance of these goods is important as most of these goods are entering the Australian market as 'unapproved' goods. That is, these products have not been assessed by the TGA for quality, safety and efficacy or performance. Evidence about the impacts of vaping on health outcomes is still emerging and requires more long-term research. The intent of these changes to product standards is to reduce the relative risk of these products (thereby improving their relative safety), however these products are not evaluated by the TGA prior to market entry, nor are they subject to the same regulatory oversight as approved therapeutic goods that are included on the Australian Register of Therapeutic Goods.

Human rights implications

The Amendment Instrument 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 youth and young adults and poses a major risk to population health and Australia's success in tobacco control.

The reforms to the regulation of vapes support the availability of therapeutic vaping goods to persons who require such goods for smoking cessation or the management of nicotine dependence under the supervision of a health practitioner and ensure the application of minimum quality and safety standards to vaping goods.

Collectively, the reforms are intended to arrest the increasing uptake of recreational vaping, especially by youth and young adults, and to strike 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 Amendment Instrument takes positive steps to promote the right to health by enhancing the safety and quality of therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are supplied in Australia. The Amendment Instrument does this through strengthening the minimum quality standards and making safety-related amendments for such goods that are for use in smoking cessation or the management of nicotine dependence, including by:

- reducing maximum nicotine concentration and imposing maximum container volumes;
- introducing requirements for ingredients to comply with pharmacopeial standards;
- introducing comprehensive labelling and packaging requirements to better support the safe use of such products and to assist consumers and health practitioners to identify and understand their key components; and
- requiring pharmaceutical-like packaging, to reduce to appeal of such goods to young people.

Strengthening the minimum safety standards that apply to therapeutic vaping goods is particularly important as these goods are not included in the Australian Register of Therapeutic Goods, and therefore have not been evaluated by the TGA for safety, quality, and efficacy or performance. The imposition of robust minimum quality and safety standards for therapeutic vaping goods is critical in protecting Australian patients from potential safety risks associated with the use of such goods.

Conclusion

The Amendment Instrument 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.