

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 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”).

Under section 41C of the Act, the regulations may set out requirements for medical devices, to be known as the essential principles. The essential principles are important mandatory requirements or standards that apply to medical devices, and provide minimum benchmarks for the safety, design, quality and performance of medical devices. The essential principles are set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”).

The essential principles include, for example, requirements relating to the design and construction of medical devices, requirements that medical devices must perform in the way intended by the manufacturer, and requirements relating to their long-term safety and the chemical, physical and biological properties of materials used in a medical device.

Persons who apply to include a kind of medical device in the Australian Register of Therapeutic Goods (“the Register”) must certify, among other things, that the kind of medical device complies with the essential principles (paragraph 41FD(d) of the Act refers). Further, a kind of medical device may be cancelled from the Register if the Secretary is satisfied that such a certification is incorrect or is no longer correct (paragraph 41GN(1)(f) of the Act refers).

The Act also contains offences for importing, supplying or exporting a kind of medical device that does not comply with the essential principles (Division 1 of Part 4-11 of the Act refers).

Subsection 41CB(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a medical device standard for the kinds of medical devices identified in the order, and provides that medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in the standard. Subsection 41CB(2) provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

Section 41CC of the Act provides that, without limiting the scope of section 41CB, an order establishing a medical device standard for kinds of medical devices may be specified by reference to matters mentioned in paragraphs 41CC(1)(a) to (f) which include, for example, the safety or performance characteristics of the devices, a standard published by a standards organisation (subsection 41CC(2) of the Act provides further details on such organisations), or such other matters as the Minister thinks fit.

The *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (“the Principal Order”) is made under subsection 41CB(1) of the Act. The Principal Order constitutes a medical device standard for certain therapeutic vaping devices and therapeutic vaping device accessories. The effect of the Principal Order is to provide an alternative means for sponsors and manufacturers of such devices to demonstrate compliance with the essential principles.

The *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024* (“the Amendment Order”) is made under section 41CB of the Act. The Amendment Order amends the Principal Order to update the requirements that sponsors and manufacturers of

therapeutic vaping devices and therapeutic vaping device accessories may comply with as an alternative means to demonstrate compliance with the essential principles. This includes strengthening the product specific standards for these devices, and updating the manufacturing requirements. The changes seek to further protect Australians, particularly young people, from the harmful effects of vaping and nicotine dependence, while enabling those with a legitimate need to access therapeutic vapes to continue to do so, where clinically appropriate.

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 use 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, has been 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, has been 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

The purpose of the Amendment Order is to strengthen the medical device standard for therapeutic vaping devices and therapeutic vaping device accessories by introducing further product-specific standards and updated manufacturing requirements for these devices.

The Principal Order provides sponsors and manufacturers of therapeutic vaping devices and therapeutic vaping device accessories that were previously excluded from the therapeutic goods framework with an alternative option for demonstrating compliance with the essential principles. The Principal Order specifies that therapeutic vaping devices or therapeutic vaping device accessories that comply with the matters in Schedule 1 to the Principal Order are to be treated as complying with all of the essential principles in Schedule 1 to the MD Regulations.

It is important to note that compliance with an order made under subsection 41CB(1) of the Act is not mandatory for sponsors of medical devices to which the order applies. Rather, such orders are designed to assist sponsors by providing an alternative mechanism that sponsors may elect to use for the purposes of demonstrating compliance with the essential principles.

The Amendment Order amends the Principal Order to strengthen the minimum requirements for the quality, safety and performance of therapeutic vaping devices and therapeutic vaping device accessories that were previously excluded goods and that are intended by the person under whose name the device is or is to be supplied only to administer or contain a therapeutic vaping substance for which the only indications are used for smoking cessation or the management of nicotine dependence.

The amendments made by the Amendment Order include:

- requiring compliance with international standards for the manufacture of the devices and application or risk management to the devices;
- requiring compliance with international standards and Australian regulatory requirements for batteries;
- requiring compliance with Australian Standards in relation to electrical charges for devices that are rechargeable;
- introducing minimum standards for the design and construction of the device to minimise risks to users, including risks of overheating, inadvertent actuation, variable dose delivery and leaking;
- imposing restrictions in relation to the name of the device, in particular the name of the device must not suggest that the good is a food, beverage or cosmetic product, and must not be attractive to children or adolescents;
- requiring instructions for use be supplied with the device;

- requiring a plain appearance and packaging;
- introducing new, comprehensive labelling and packing requirements, to better support the safe use of such device and to assist consumers and health practitioners to identify and understand their components; and
- introducing requirements for performance of a toxicological risk assessment of the emissions from the device.

The Amendment Order 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 41CB(3) 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 41CB(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 Order, and the intended manner of incorporation.

Australian consumer law standards

The Amendment Order incorporates by reference the following Australian consumer law standards:

- *Consumer Goods (Button/Coin Batteries) Information Standard 2020*;
- *Consumer Goods (Button/Coin Batteries) Safety Standard 2020*;
- *Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020*;
- *Consumer Goods (Products Containing Button/Coin Batteries) Information Standard 2020*.

These standards are incorporated as in force or existing from time to time, and are freely available from the Federal Register of Legislation website at www.legislation.gov.au.

Australian/New Zealand and international standards

The Amendment Order incorporates by reference, the following standards, as in force or exiting from time to time:

- Australian/New Zealand Standard AS/NZS 3820, *Essential safety requirements for electronic equipment*;
- Australian/New Zealand Standard AS/NZS 4417.1, *Marking of electronic products to indicate compliance with regulations*;
- IEC 60086-1, *Primary Batteries – Part 1: General*;
- IEC 62133-1, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems*;

- IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*;
- ISO 14971, *Medical devices – Application of risk management principles to medical devices*;
- ISO 17025, *Testing and calibration laboratories*.

AS/NZS 3820 and AS/NZS 4417.1 are published at www.standards.org.au. IEC60086-1, IEC62133-1 and IEC62133-2 are published at www.webstore.iec.ch and ISO 14971 and ISO 17025 are published at www.iso.org.

While these standards are not available for free, it is anticipated that persons most affected by their adoption in the Amendment Order (importers and manufacturers of therapeutic vaping devices and therapeutic vaping device accessories) would likely be in possession of these standards in order to import, manufacture or supply such goods.

As important benchmarks for the quality, safety and performance of therapeutic goods and other consumer goods, it is not feasible from a regulatory perspective, to refuse to adopt such benchmarks on the basis that they are not freely available. This is particularly the case in relation to therapeutic vaping devices and therapeutic vaping device accessories that are not included in the Register and therefore not evaluated by the Secretary for quality, safety, performance and efficacy before being available for patients in Australia,

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

United Nations document

The Amendment Order incorporates by reference section 38.3 of the United Nations document *Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria* (UN/DOT 38.3).

UNDOT 38.2 is incorporated as in force or existing from time to time and is freely available from the United Nations Economic Commission for Europe (UNECE) website at www.unce.org.

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 the 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 meetings. 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.

A third, targeted consultation was undertaken with stakeholders between 20 February 2024 and 10 March 2024. This consultation took the form of a stakeholder survey on the proposed changes to the product standards for therapeutic vaping devices and therapeutic vaping device accessories. Stakeholder feedback from this consultation informed the new requirements that would apply to therapeutic vaping devices and therapeutic vaping device accessories introduced by the Amendment Order.

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 Order 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 Order.

Between 29 August and 10 September 2024, the TGA consulted with IP Australia in relation to the proposed Amendment Order, including providing the text of the proposed amendments. IP Australia’s comments were considered carefully and informed the drafting of the provisions in the Amendment Order.

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 on the proposed reforms 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 (OBPR reference: 23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

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

Details of the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024* (“the Amendment Order”).

Section 2 – Commencement

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

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Order is section 41CB of the *Therapeutic Goods Act 1989* (“the Act”).

Relevantly, subsection 41CB(2) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 41CB(1) of the Act. The amendments made to the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* are made in accordance with that subsection.

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.

Schedule 1 – Amendments

Schedule 1 amends the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (“the Principal Order”).

Items 1, 4, 7 and 10 – Section 4

These items introduce new definitions in section 4 of the Principal Order, including ‘accredited certification body’, ‘AS/NZS 3820’, ‘AS/NZS 4417.1’, ‘IEC 60086-1’, ‘IEC 62133-1’, ‘IEC 62133-2’, ‘instructions for use’, ‘ISO 14971’, ‘ISO 17025’, ‘ISO 17025 accredited laboratory’, ‘TG Regulations’, ‘text size’, ‘therapeutic vaping substance’, ‘UN/DOT 38.3’ and ‘venting’.

Items 2 and 5 – Section 4 (definitions of *EU Directive 2014/40/EU* and *ISO 9001*)

These items repeal the definitions for ‘EU Directive 2014/40/EU’ and ‘ISO 9001’ from section 4 of the Principal Order. These amendments are consequential to the amendments made to Schedule 1 to the Principal Order outlined below.

Item 3 – Section 4 (definition of *IAF accredited organisation*)

This item amends the definition for ‘IAF accredited organisation’ in section 4 of the Principal Order to remove the reference to ‘ISO 9001’. This amendment is also consequential to the amendments made to Schedule 1 to the Principal Order as outlined below.

Item 6 – Section 4 (definition of Regulations)

This item makes a minor amendment to change the reference to ‘Regulations’ to ‘MD Regulations’ to avoid confusion with the TG Regulations.

Items 8 and 9 – Section 4 (definitions of *therapeutic vaping device* and *therapeutic vaping device accessory*)

These items make a minor amendment to these definitions to replace the reference to ‘Regulations’ with ‘MD Regulations’.

Item 11 – Section 5

This item repeals section 5 as it is in effect duplicated in section 6.

Item 12 – Section 6

This item replaces section 6 of the Principal Order to correct some editorial errors and make a minor amendment to correct the name of the instrument referred to in paragraph 6(a) of the Principal Order. This amendment also effectively repeals paragraph 6(c) to align with the repeal of section 7 of the *Therapeutic Goods (Excluded Goods) Determination 2018* (“the Excluded Goods Determination”) by the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024* (“the Amendment Determination”) on 1 July 2024.

The Amendment Determination had the effect of bringing certain medical devices imported or manufactured before 1 March 2024, that were previously excluded from the operation of the *Therapeutic Goods Act 1989*, within the regulatory scheme. Both section 7 of the Excluded Goods Determination and paragraph 6(c) of the Principal Order did not effect any permanent exclusion of the goods from the regulatory scheme. Rather, those instruments specified the law to apply to the relevant goods for the time-being as part of the vaping reforms. The intent was to allow a transition period for sponsors to use or sell down stock.

The effect of section 6, coupled with new section 8 outlined below, is that goods imported before 1 March 2024 but supplied after 1 July 2025, will need to comply with the essential principles or the Principal Order as amended by the Amendment Order. Therefore, this amendment will only have practical effect from 1 July 2025.

Item 13 – Subsection 7(2)

This item makes a minor amendment to subsection 7(2) of the Principal Order to replace the reference to ‘Regulations’ with ‘MD Regulations’.

Item 14 – After section 7

This item introduces new section 8 in the Principal Order, which sets out application, saving and transitional arrangements for therapeutic vaping devices and therapeutic vaping device accessories in certain circumstances.

New subsection 8(1) provides that, in section 8, “former order” means the Principal Order, as in force immediately before the commencement of the Amendment Order.

New subsection 8(2) provides that, despite the Amendment Order, the former Order continues to apply in relation to therapeutic vaping devices and therapeutic vaping device accessories that are imported or manufactured before 1 March 2025, and supplied before 1 July 2025. Subsection (3) provides that subsection (2) ceases to apply on 1 July 2025.

The effect of subsections 8(2) and (3) is that therapeutic vaping devices and therapeutic vaping substance accessories 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 15 – Schedule 1

This item replaces Schedule 1 to the Principal Order to specify new matters that constitute a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories.

Therapeutic vaping devices and therapeutic vaping device accessories that comply with the matters specified in Schedule 1 are treated as complying with all of the essential principles.

Item 1 – ISO 13485 certification and compliance (Quality Management System)

Item 1 of the table of Schedule 1 specifies matters relating to quality management system compliance.

Therapeutic vaping devices and therapeutic vaping device accessories are required to have:

- ISO 13485 certification for the manufacture of the devices or accessories, issued by one of the following:
 - an IAF accredited body;
 - a notified body;
 - an auditing organisation recognised by Health Canada;
 - an Australian conformity assessment body determined under the MD Regulations;and
- compliance with ISO 13485 for the manufacture of the device or accessories.

ISO 13485 is an international standard that sets out requirements for a quality management system for the manufacture of medical devices. Manufacturers of therapeutic vaping devices and therapeutic vaping device accessories need to demonstrate their ability to manufacture goods that are safe and effective for their intended use.

This requirement establishes the need for both ongoing compliance to ISO 13485, and separately, certification to ISO 13485 by a relevant body. Certification provides a significant level of assurance of compliance to ISO 13485. Requiring ISO 13485 compliance separately, in addition to certification, enables the TGA to directly assess compliance of the manufacturing of the device against the relevant requirements in ISO 13485.

Item 2 – ISO 14971 (Risk management)

Item 2 of the table in Schedule 1 specifies matters relating to managing risks and hazards.

Therapeutic vaping devices and therapeutic vaping device accessories must comply with ISO 14971 (an international standard for the risk management of medical devices).

To comply with ISO 14971, manufacturers must manage all of the following hazards or risks:

- hazards or risks relating to the toxicity of emissions from the therapeutic vaping device or the therapeutic vaping device accessory, for the expected lifetime of the product, as identified in a toxicological risk assessment;
- hazards or risks relating to the toxicity of the materials within the therapeutic vaping device or therapeutic vaping device accessory, and any residues or contaminants, for the expected lifetime of the good;
- hazards or risks relating to batteries (if applicable), including risk of fire or explosion;

- electrical hazards or risks;
- hazards or risks relating to the usability of the therapeutic vaping device or the therapeutic vaping device accessory;
- hazards or risks relating to the reasonably foreseeable misuse of the therapeutic vaping device or the therapeutic vaping device accessory;
- hazards or risks relating to the containment of a therapeutic vaping substance in, and the administration of a therapeutic vaping substance by, the therapeutic vaping device or the therapeutic vaping device accessory;
- hazards or risks relating to heating of the therapeutic vaping device or therapeutic vaping device accessory.

These hazards and risks are inherent in the design, manufacture or function of portable thermal vaporising devices for the administration of a medicine, and therefore must be assessed and managed through the ISO 14971 risk management process. In addition to the hazards and risks specified in item 2, compliance with ISO 14971 requires manufacturers to undertake a complete risk assessment as specified in ISO 14971.

As part of the compliance with ISO 14971, manufacturers are required to establish and maintain a risk management file, which contains evidence necessary to demonstrate that a manufacturer has identified hazards or risks associated with a therapeutic vaping device or therapeutic vaping device accessory, mitigated those hazards or risks, and evaluated them once the appropriate mitigations are in place.

Item 3 – Battery standards

Item 3 of the table in Schedule 1 specifies matters relating to battery standards.

Therapeutic vaping devices and therapeutic vaping device accessories that contain batteries must comply with the following standards, as applicable to the good:

- for a primary battery (other than a button battery)—IEC 60086-1 certification (as applicable) issued by an accredited certification body;
- for a secondary battery (other than a button battery) that is a lithium battery—all of the following:
 - UN/DOT 38.3 certification, or declaration of conformity with UN/DOT 38.3, supported by independent test reports from an ISO 17025 accredited laboratory;
 - IEC 62133-2 certification issued by an accredited certification body.
- for a secondary battery (other than a button battery) that is a nickel system battery—IEC 62133-1 certification issued by an accredited certification body;
- for a button battery—compliance with all of the following legislative instruments:
 - the *Consumer Goods (Button/Coin Batteries) Information Standard 2020*;
 - the *Consumer Goods (Button/Coin Batteries) Safety Standard 2020*;
 - the *Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020*;
 - the *Consumer Goods (Products Containing Button/Coin Batteries) Information Standard 2020*.

The note in item 3 provides that these legislative instruments are publicly (and therefore freely) available on the Federal Register of Legislation.

Portable therapeutic vaping devices generally contain batteries, which present specific risks, such as overheating, fires and explosions. Compliance with the battery standards (as relevant to the therapeutic vaping device or therapeutic vaping device accessory) is intended to reduce the risks associated with devices containing batteries.

Item 4 – Electrical safety standards

Item 4 specifies matters relating to electrical safety standards.

Therapeutic vaping devices and therapeutic vaping device accessories must comply with the following standards as applicable to the goods:

- AS/NZS 3820 compliance with essential safety requirements for low voltage electrical equipment;
- AS/NZS 4417.1 compliance with marking of electrical products to indicate compliance with regulations.

Compliance with the joint Australian and New Zealand electrical safety standards (where applicable) will ensure therapeutic vaping devices and therapeutic vaping device accessories meet appropriate standards, consistent with other electrical equipment.

Item 5 – Design and construction

Item 5 of the table in Schedule 1 specifies matters relating to the design and construction of therapeutic vaping devices and therapeutic vaping device accessories.

A therapeutic vaping device, or a therapeutic vaping device accessory as applicable, must be designed and constructed in a way that:

- when operated in accordance with the instructions for use, the device provides the emitted mass or dose as specified and verified by the manufacturer; and
- incorporates a reliable venting mechanism that channels the pressure wave in the direction where the harm is minimised; and
- minimises the risk of inadvertent actuation; and
- ensures any external parts or accessible surfaces, other than the mouthpiece, of the therapeutic vaping device or therapeutic vaping device accessory, that may be held or grasped during use does not exceed 48°C during use; and
- ensures the external surface of the mouthpiece does not exceed 55°C during use; and
- ensures the therapeutic vaping device or therapeutic vaping device accessory will withstand regular use, and foreseeable misuse or abuse without breaking, leaking or failing in an unsafe manner;
- incorporates child-resistant features to prevent operation of the therapeutic vaping device or therapeutic vaping device accessory by children or the accidental ingestion of components of, or substances contained in, the therapeutic vaping device or therapeutic vaping device accessory; and
- accords with relevant electrical safety standards to protect against overheating, short-circuiting, and risk of explosion during use and recharging, where the therapeutic vaping device or therapeutic vaping device accessory is, or contains, a battery; and
- prevents leaks of the liquid or substance being vaporised; and
- ensures that all materials used in the inhalation pathway of the device, including any by-products or degradants, are biocompatible and the amount of harmful chemicals (such as heavy metals, volatile organic compounds, and other toxic substances) that the patient receives is less than the tolerable exposure limit below which there would be no appreciable risk to human health.

These additional design and construction requirements address particular safety and performance risks including by incorporating requirements for accurate emitted mass or dosage delivery of the medicine, safe temperatures of the external contact points of the device and preventing inadvertent activation of the device. There are further requirements to mitigate battery and usage related risks, and for child safety.

Item 6 – Name of the device

Item 6 of the table in Schedule 1 specifies matters relating to the name of a therapeutic vaping device or therapeutic vaping device accessory (including its brand name).

The name of a therapeutic vaping device or a therapeutic vaping device accessory must not be in any way attractive to children or adolescents and, whether expressly or by implication:

- suggest that the device:
 - is a food, beverage or cosmetic product; or
 - has health benefits other than its intended purpose, including healing, vitalising, natural, organic or rejuvenating properties; or
 - is safe, without harm or without side effects; or
- promote the use or supply of the device;
- exaggerate, or be likely to exaggerate, the efficacy or performance of the device;
- encourage, or be likely to encourage, inappropriate or excessive use of the device.

Compliance with these requirements will ensure that therapeutic vaping devices and therapeutic vaping device accessories do not include names that are in any way promotional or designed to attract young people or new users, misleading, suggesting any health benefit, or resembling a food or beverage.

Item 7 – Instructions for use

Item 7 of the table in Schedule 1 specifies matters relating to instructions for use.

A therapeutic vaping device or therapeutic vaping device accessory must be supplied with instructions for use that are:

- in English (noting the instructions may also be provided in any other language); and
- clearly legible; and
- supplied in paper or electronic format that is readily accessible to patients.

Where the instructions for use are supplied in an electronic format, a paper copy must be provided to a patient upon request and without charge.

The instructions for use must contain all of the following information, in a text size of at least 3 mm:

- the manufacturer's name, or trading name, and address;
- the intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used;
- the name of the device, brand name and model;
- the batch code, lot number or serial number that identifies the kind of medical device;
- any particular handling or storage requirements applying to the device, including recommended storage conditions;
- any warnings, restrictions or precautions that may apply in relation to the use of the device, including a statement that informs the patient or user to seek advice from a healthcare professional if the device is not functioning correctly;
- if applicable, information about the risks associated with button or coin batteries;
- any actions that need to be performed prior to using the device, including any preparatory actions for first-time use;
- information about how to use the device, including instructions for assembly;
- any cleaning requirements for the device;
- information about the replacement of the consumable components of the device during its expected lifetime, including the size and type of battery;

- either the expiry date for the device or the expected lifetime of the device, indicated as duration of use after the first use or the number of actuations before being discarded;
- any precautions a patient or user should take if there are risks associated with the disposal of the device, including instructions on how to dispose of the device or its parts or how to recycle used batteries.

These requirements broadly align with those of other medical devices and are intended to ensure that appropriate information in relation to the design and intended use of therapeutic vaping devices and therapeutic vaping device accessories is available to patients. These requirements will also support identification of a device in the case of an adverse event, and end of life disposal of the device and its batteries.

Item 8 – Labelling requirements for therapeutic vaping devices

Item 8 of the table in Schedule 1 specifies matters relating to the labels of therapeutic vaping devices, including that the device must be labelled with information that is:

- in English; and
- clearly legible; and
- printed in a manner that is durable; and
- in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour; and
- in a text colour that contrasts with the colour of the therapeutic vaping device.

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 device and does not, for example, rub off or fade off.

The label on the therapeutic vaping device must be either matte white or matte grey, unless required by an applicable standard to be another colour.

The label must contain the following information on the device itself:

- the sponsor’s name;
- the device name, brand name and model;
- the batch code, lot number or serial number that identifies the kind of medical device;
- the warning statement: “Risk of fire or explosion. Replace only with the same size and type of battery”.

The label must also contain the following information on the device itself, or on the packaging of the device if it is impracticable or inappropriate to be on the device itself:

- the address of the sponsor;
- the name and address of the manufacturer.

The information required to be on the label must be displayed in a text size of at least 3 mm.

Item 9 – Labelling requirements for therapeutic vaping device accessories

Item 9 of the table in Schedule 1 specifies matters relating to labels of therapeutic vaping device accessories, including that the accessory must be labelled with information that is:

- in English; and
- clearly legible; and
- printed in a manner that is durable; and
- in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour; and

- in a text colour that contrasts with the colour of the therapeutic vaping device.

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 device and does not, for example, rub off or fade off.

The label on the therapeutic vaping device accessory must be either matte white, matte grey or matte black, unless required by an applicable standard to be another colour.

The label must contain the following information on the therapeutic vaping device accessory itself:

- the device name and model
- the batch code, lot number or serial number that identifies the kind of medical device; and
- the warning statement: “Risk of fire or explosion. Replace only with the same size and type of battery”, if the device contains a battery (of any kind).

The label must also contain the following information on the therapeutic vaping device accessory itself, or on the packaging or instructions for use of the device if it is impracticable or inappropriate to be on the device itself:

- the brand name;
- the sponsor’s name;
- the address of the sponsor;
- the name and address of the manufacturer.

The information required to be on the label must be displayed in a text size of at least 1 mm.

The labelling requirements for therapeutic vaping devices and therapeutic vaping device accessories includes information for patients that is intended to support identification of the goods, support product recalls and compliance and enforcement action if required, and are broadly consistent with requirements for other medical devices.

Item 10 – Plain design and appearance

Item 10 of the table in Schedule 1 specifies matters relating to the appearance of a therapeutic vaping device and therapeutic vaping device accessory. In particular, a therapeutic vaping device must be predominantly either matte white or matte grey, and feature no more than 3 other matte colours or shades (including the colour or shade of any text) and a therapeutic vaping device 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 therapeutic vaping device or therapeutic vaping device accessory features a colour or shade other than matte white or matte grey, that colour must not be visible when the device is fully assembled for use. Colours, when used appropriately on a therapeutic vaping device or therapeutic vaping device accessory, can support usability of the device by clearly identifying how the device is to be assembled ready for use, or to identify which substances are to be used in therapeutic vaping device accessories. However, the use of colour in this way is not intended to impinge on the overall intention for the device to have a plain appearance to reduce the appeal to youth and address the risk of illegal diversion of these devices and accessories to youth or the black market.

A therapeutic vaping device or 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 device. 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 TGO 110 for a therapeutic vaping substance accessory.

Any information on a therapeutic vaping device or therapeutic vaping device accessory must be:

- in English; and
- clearly legible; and
- printed in a manner that is durable; and
- in a text colour that is matte grey or matte black, unless required by a relevant standard to be another colour; and
- in a text colour that contrasts with the colour of the therapeutic vaping device or therapeutic vaping device accessory.

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 device and does not, for example, rub off or fade off.

The therapeutic vaping device and therapeutic vaping device accessory must not display:

- any words, symbols, trademarks, images, figures, logos or emblems, that are in contravention of another provision of this standard; or
- any promotional statement, pictorial representation or design.

Additionally, a therapeutic vaping device or therapeutic vaping device accessory must not include any features designed to change the appearance of the device, including 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.

The design requirements for therapeutic vaping devices and therapeutic vaping device accessories, including through restriction of colours that are displayed on all exterior visible surfaces, are intended to reduce appeal to youth and address the risk of illegal diversion of these devices and accessories to youth or the black market.

Item 11 – Labelling and packaging requirements for primary packs

Item 11 specifies matters relating to the primary pack of a therapeutic vaping device or a therapeutic vaping device accessory.

A therapeutic vaping device and a therapeutic vaping device accessory must be supplied in a primary pack, where the label and primary pack are white.

Any text on the label or primary pack must be:

- in English; and
- clearly legible; and
- printed in a manner that is durable; and
- in a text colour that is matte grey or matte black, unless required by a relevant standard to be another colour.

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 device and does not, for example, rub off or fade off.

The label and primary pack must not contain the following:

- any feature that suggests, whether expressly or by implication, that the device has health benefits other than its intended purpose, including healing, vitalising, natural, organic, or rejuvenating properties;
- any words, symbols, trademarks, images, figures, logos or emblems, that are in contravention of another provision of this standard;
- any promotional statement, pictorial representation or design.

Additionally, the label and primary pack must not include any features designed to change the appearance of the packaging, including 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;
- removable tabs;
- fold out panels.

The label of the primary pack must also include the following warning statements:

- “KEEP OUT OF REACH OF CHILDREN”; and
- “WARNING CONTAINS BUTTON OR COIN BATTERY. HAZARDOUS IF SWALLOWED – SEE INSTRUCTIONS” (if applicable); and
- “RISK OF FIRE OR EXPLOSION. REPLACE ONLY WITH THE SAME SIZE AND TYPE OF BATTERY” (if applicable).

In addition to the requirements in paragraph (b), these warning statements must be in bold-face, sans serif, capital letters of uniform thickness and size.

Compliance with new labelling and packaging requirements for a primary pack mentioned above will ensure that the information for the appropriate use of therapeutic vaping devices and therapeutic vaping device accessories is available on the pack and reinforces the message that vapes are therapeutic goods and not recreational products.

Item 12 – Requirements relating to toxicological risk assessments

Item 12 specifies matters relating to toxicological risk assessments.

A therapeutic vaping device and a therapeutic vaping device accessory must be subject to, and supported by evidence of, a toxicological risk assessment of the emissions from the device, for the expected lifetime of the therapeutic vaping device or therapeutic vaping device accessory, that includes (but is not limited to) an assessment of all of the following, having regard to the generally acknowledged state of the art, to demonstrate that the toxicological risks have been minimised:

- the atomiser (or the part of the device that heats and vaporises the therapeutic vaping substance);
- all materials within the device that the therapeutic vaping substance and its vapour come in contact with;
- any leachable substances, contaminants and thermal degradation products from the device.

Requiring manufacturers of therapeutic vaping devices and therapeutic vaping device accessories to have conducted a toxicological risk assessment that is considered as part of compliance to ISO14971 (in accordance with item 2), seeks to mitigate, as far as practicable, the toxicological risks associated with inhaled vapour from the device, specifically where those risks relate to the therapeutic vaping device or therapeutic vaping device accessory.

The results of the toxicological risk assessment must be considered by the manufacturer of the therapeutic vaping devices and therapeutic vaping device accessories as part of their risk assessment process and compliance to ISO14971 (in accordance with item 2). Manufacturers of the therapeutic vaping devices and therapeutic vaping device accessories must also identify and implement risk controls and monitor the effectiveness of these risk controls, including in relation to the results of the toxicological risk assessment.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 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 legislative instrument

Under section 41C of the Act, the regulations may set out requirements for medical devices, to be known as the essential principles. The essential principles are important mandatory requirements or standards that apply to medical devices, and provide minimum benchmarks for the safety, design, quality and performance of medical devices. The essential principles are set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”).

The essential principles include, for example, requirements relating to the design and construction of medical devices, requirements that medical devices must perform in the way intended by the manufacturer, and requirements relating to their long-term safety and the chemical, physical and biological properties of materials used in a medical device.

Persons who apply to include a kind of medical device in the Australian Register of Therapeutic Goods (“the Register”) must certify, among other things, that the kind of medical device complies with the essential principles (paragraph 41FD(d) of the Act refers). Further, a kind of medical device may be cancelled from the Register if the Secretary is satisfied that such a certification is incorrect or is no longer correct (paragraph 41GN(1)(f) of the Act refers).

The Act also contains offences for importing, supplying or exporting a kind of medical device that does not comply with the essential principles (Division 1 of Part 4-11 of the Act refers).

Subsection 41CB(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a medical device standard for the kinds of medical devices identified in the order, and provides that medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in the standard. Subsection 41CB(2) provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

Section 41CC of the Act provides that, without limiting the scope of section 41CB, an order establishing a medical device standard for kinds of medical devices may be specified by reference to matters mentioned in paragraphs 41CC(1)(a) to (f) which include, for example, the safety or performance characteristics of the devices, a standard published by a standards organisation (subsection 41CC(2) of the Act provides further details on such organisations), or such other matters as the Minister thinks fit.

The *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (“the Principal Order”) is made under subsection 41CB(1) of the Act. The Principal Order constitutes a medical device standard for certain therapeutic vaping devices and therapeutic vaping device accessories. The effect of the Principal Order is to provide an alternative means for sponsors and manufacturers of such devices to demonstrate compliance with the essential principles.

The *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024* (“the Amendment Order”) is made under section 41CB of the Act. The Amendment Order amends the Principal Order to update the requirements that sponsors and manufacturers of therapeutic vaping devices and therapeutic vaping device accessories may comply with as an alternative means to demonstrate compliance with the essential principles. This includes strengthening the product specific standards for these devices, and updating the manufacturing requirements. The changes seek to further protect Australians, particularly young people, from the harmful effects of vaping and nicotine dependence, while enabling those with a legitimate need to access therapeutic vapes to continue to do so, where clinically appropriate.

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 use 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, has been 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, has been 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

The purpose of the Amendment Order is to strengthen the medical device standard for therapeutic vaping devices and therapeutic vaping device accessories by introducing further product-specific standards and updated manufacturing requirements for these devices.

The Principal Order provides sponsors and manufacturers of therapeutic vaping devices and therapeutic vaping device accessories that were previously excluded from the therapeutic goods framework with an alternative option for demonstrating compliance with the essential principles. The Principal Order specifies that therapeutic vaping devices or therapeutic vaping device accessories that comply with the matters in Schedule 1 to the Principal Order are to be treated as complying with all of the essential principles in Schedule 1 to the MD Regulations.

It is important to note that compliance with an order made under subsection 41CB(1) of the Act is not mandatory for sponsors of medical devices to which the order applies. Rather, such orders are designed to assist sponsors by providing an alternative mechanism that sponsors may elect to use for the purposes of demonstrating compliance with the essential principles.

The Amendment Order amends the Principal Order to strengthen the minimum requirements for the quality, safety and performance of therapeutic vaping devices and therapeutic vaping device accessories that were previously excluded goods and that are intended by the person under whose name the device is or is to be supplied only to administer or contain a therapeutic vaping substance for which the only indications are used for smoking cessation or the management of nicotine dependence.

The amendments made by the Amendment Order include:

- requiring compliance with international standards for the manufacture of the devices and application or risk management to the devices;
- requiring compliance with international standards and Australian regulatory requirements for batteries;
- requiring compliance with Australian Standards in relation to electrical charges for devices that are rechargeable;
- introducing minimum standards for the design and construction of the device to minimise risks to users, including risks of overheating, inadvertent actuation, variable dose delivery and leaking;

- imposing restrictions in relation to the name of the device, in particular the name of the device must not suggest that the good is a food, beverage or cosmetic product, and must not be attractive to children or adolescents;
- requiring instructions for use be supplied with the device;
- requiring a plain appearance and packaging;
- introducing new, comprehensive labelling and packing requirements, to better support the safe use of such device and to assist consumers and health practitioners to identify and understand their components; and
- introducing requirements for performance of a toxicological risk assessment of the emissions from the device.

The Amendment Order 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 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 standards 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 Order takes positive steps to promote the right to health by strengthening the product specific standards for therapeutic vaping devices and therapeutic vaping device accessories. The Amendment Order elevates the minimum requirements for the quality, safety and performance of these devices, to provide an assurance to medical practitioners and patients that therapeutic vaping devices and therapeutic vaping device accessories meet minimum safety, quality and performance requirements. The proposal to elevate the minimum standards of safety and quality of these goods is intended to curb the importation and supply of therapeutic vaping goods that present a risk to public health and safety. The Amendment Order seeks to further protect Australians, particularly young people, from the harmful effects of vaping and nicotine dependence, while enabling those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate.

Conclusion

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