EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023

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

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 4FD(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 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.

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 Order") is made under subsection 41CB(1) of the Act. The Order constitutes a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories that were excluded from the operation of the Act under item 16 of the table in Schedule 1 to the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Excluded Goods Determination") immediately prior to the repeal of that item. The effect of the Order is to provide an alternative means for sponsors and manufacturers of such devices to demonstrate that their devices comply with the essential principles identified in the Order.

Background

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes in Australia.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers access for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures are therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by youth and young adults.

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

Reforms to the regulation of vapes

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

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

In broad terms, the first stage of reforms will:

- prohibit the importation of disposable single use vapes, irrespective of therapeutic claims, subject to limited exceptions, from 1 January 2024;
- prohibit the importation of non-therapeutic vapes, irrespective of nicotine content, subject to limited exceptions, from 1 March 2024;

- introduce the requirement for importers to obtain a customs licence and permit to import therapeutic vapes, subject to limited exceptions, from 1 March 2024, with applications to be enabled from 1 January 2024;
- end the personal importation scheme for therapeutic vapes – the scheme will cease to operate on 1 March 2024, but the importation of disposable vapes will be prohibited from 1 January 2024;
- retain a limited traveller's exception that allows persons arriving in Australia by ship or plane to carry a limited quantity of vapes for their treatment or the treatment of someone travelling with them under their care – revisions to the traveller's exemption will commence on 1 March 2024 with restrictions on disposable vapes commencing 1 January 2024;
- introduce the requirement for importers and manufacturers to notify the Secretary that therapeutic vapes intended to be imported, or released for supply in Australia, comply with relevant product standards or essential principles, as the case may be – this requirement will commence on 1 March 2024, with notifications to be enabled from 1 January 2024;
- modify the exemptions relating to unregistered therapeutic vapes to require such goods to be supplied through prescription medicine supply chains to patients for smoking cessation or the management of nicotine dependence – this requirement will commence on 1 March 2024;
- make minor changes to relevant product standards to facilitate the introduction of the notification and permit schemes, introduce restrictions on flavours and ensure minimum standards for device components; and
- enable therapeutic vapes to be accessed by patients under the Special Access Scheme – Category C, to facilitate more timely access to unregistered therapeutic vapes and reduce regulatory burden on practitioners, while maintaining regulatory oversight commensurate with the risk.

These changes will be supplemented with amendments to the Act that are proposed to be introduced to Parliament next year. The amendments will strengthen domestic compliance and enforcement mechanisms to support the broader policy intent. Compliance and enforcement effort both within and between jurisdictions is essential to address the risk of vaping to population health.

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

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

Purpose

The Order is made under subsection 41CB(1) of the Act. The Order determines a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories that were excluded under item 16 of the table in Schedule 1 to the Excluded Goods Determination immediately prior to the repeal of that item. The effect of the Order is that devices that comply with the Order are to be treated as complying with all of the essential principles set out in Schedule 1 to the MD Regulations.

The purpose of the Order is to provide sponsors 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 Order does this by specifying that therapeutic vaping devices or therapeutic vaping device accessories that comply with one or more of the following matters, relating to the good, are to be treated as complying with all of the essential principles in Schedule 1 to the MD Regulations:

- ISO 9001 certification for the manufacture of the device issued by an IAF accredited body;
- ISO 13485 certification for the manufacture of the device issued by either:
    - an IAF accredited body;
    - a notified body;
    - an auditing organisation recognised by Health Canada;
    - an Australian conformity assessment body determined under the MD Regulations;
- a valid form of evidence establishing compliance with requirements for supply of consumer grade e-cigarettes including:
    - a marketing authorisation order granted by the United States Food and Drug Administration under the Premarket Tobacco Products Applications and Recordkeeping Requirements Rule; or
    - an authorisation from a member state of the European Union under EU Directive 2014/40/EU; or
    - publication in the United Kingdom Medicines & Healthcare products Regulatory Agency ECIG database, as in force from time to time, listing e-cigarette products notified under the *Tobacco and related Products Regulations and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020*;
- certification, licence, notification, or other approval, establishing compliance with requirements for supply of therapeutic goods, issued by:
    - the United States Food and Drug Administration; or
    - a notified body; or
    - a body designated by the United Kingdom Medicines & Healthcare products Regulatory Agency.

It is important to note that compliance with an order made under subsection 41CB(1) is not mandatory for sponsors of medical devices to which an 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.

Incorporation by reference

Subsection 41CB(3) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* ("the Legislation Act"), an order or variation of an order under the provision may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The Order incorporates the following documents by reference, with the intended manner of incorporation being as in force or existing from time to time:

- the *Therapeutic Goods (Excluded Goods) Determination 2018*, a legislative instrument that specifies certain goods to be excluded goods for the purposes of the Act. The Excluded Goods Determination is available for free from the Federal Register of Legislation and may be accessed at www.legislation.gov.au;
- *EU Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products*. This document is available for free from the EUR-lex website and may be accessed at www.eur-lex.europa.eu;
- the *Premarket Tobacco Products Applications and Recordkeeping Requirements Rule,* published by the United States Food and Drug Administration. This document is available for free from Federal Register website and may be accessed at www.federalregister.gov;

- the *Tobacco and related Products Regulations and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020*. This document is available for free at www.legislation.gov.uk.

The Order also incorporates the following international standards, with the intended manner of incorporation being as they exist from time to time:

- International Standard ISO 9001, *Quality Management Systems*;
- International Standard ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*.

ISO 9001and ISO 13485 are published at www.iso.org. However, these international standards are not publicly available for free. Rather, they can, by prior written arrangement where possible and without charge, be viewed by members of the public at the TGA office in Fairbairn, ACT. While these standards are not available for free, it is anticipated that the persons most affected by their adoption in the Order would likely be in possession of these standards. As important benchmarks for the safety of therapeutic goods and other consumer goods, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

Consultation

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook public consultation ("the 2022 consultation") on reforms to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through the Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023, which conveyed Ministers' collective commitment to enhancing regulation of vapes in Australia.

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

Other details

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

The 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 (OBPR23-03933). The IA has been published, or will be published, prior to commencement of the Order on the OIA website at: oia.pmc.gov.au/.

The Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences at the same time as the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* ("the Amendment Regulations"). However, the Order does not commence at all if the Amendment Regulations do not commence.

Attachment A

Details of the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* ("the Order").

Section 2 – Commencement

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

Section 3 – Authority

This section provides that the legislative authority for making the Order is subsection 41CB(1) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides the definitions for key terms used in the Order, including 'IAF accredited organisation', 'ISO 13485', 'ISO 9001', 'notified body', 'therapeutic vaping device', and 'therapeutic vaping device accessory'.

The definition of 'therapeutic vaping device' provides that this term has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* ("the MD Regulations"). That is, a therapeutic good that is a vaping device, other than a disposable vape or a therapeutic cannabis vaping device. Relevantly, the Regulations define a 'vaping device' as a device that generates or releases (or is designed or intended to generate or release), using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user.

The definition of 'therapeutic vaping device accessory' provides that this term has the same meaning as in the MD Regulations. That is, a therapeutic good that is an unfilled cartridge, capsule pod or other vessel designed or intended to contain a therapeutic vaping substance, is for use in a therapeutic vaping device and is refillable. A therapeutic vaping device accessory does not include a therapeutic cannabis vaping device accessory.

Relevantly, the Order provides that a 'notified body' means a body that has been designated by a member state of the European Union, and notified to the European Commission, or has been approved or designated by the United Kingdom Medicines & Healthcare products Regulatory agency, to assess the conformity of medical devices.

This section also notes that a number of terms used in the Order have the meaning given in subsection 3(1) of the Act, including, 'medical device standard' and 'therapeutic goods'.

Section 5 – Standard

This section provides that the Order constitutes a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories.

Section 6 – Application

This section provides that the Order applies to a therapeutic vaping device or a therapeutic vaping device accessory that:

- was excluded under item 16 of the table in Schedule 1 to the *Therapeutic Goods (Excluded Goods) Determination 2018*, as in force immediately before the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Order 2023* (which repeals item 16); and
- is intended by the person under whose name the device is or is to be supplied, only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence; and
- is imported or manufactured on or after 1 March 2024.

Section 7 – Medical device standard

Subsection 7(1) provides that the matters specified in Schedule 1 to the Order constitute a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories.

Subsection 7(2) makes it clear that therapeutic vaping devices and therapeutic vaping device accessories that comply with the standard in subsection 7(1) are treated as complying with all parts of the essential principles in Schedule 1 to the MD Regulations.

Schedule 1 – Medical device standard for vaping devices

Schedule 1 specifies, for the purposes of section 7 of the Order, that any one or more of the following matters relating to the goods, constitutes a standard for therapeutic vaping devices and therapeutic vaping device accessories:

- ISO 9001 certification for the manufacture of the device, issued by an IAF accredited body;
- ISO 13485 certification for the manufacture of the device, issued by either:
    - an IAF accredited body;
    - a notified body;
    - an auditing organisation recognised by Health Canada;
    - an Australian conformity assessment body determined under the Regulations;
- one of the following valid forms of evidence establishing compliance with requirements for supply of consumer grade e-cigarettes:
    - a marketing order granted by the United States Food and Drug Administration under the Premarket Tobacco Products Applications and Recordkeeping Requirements Rule (compliance with this form of evidence may be demonstrated by the good being published on the FDA's Premarket Tobacco Product Marketing Granted Orders website, or by providing a copy of the marketing order to the Therapeutic Goods Administration);
    - an authorisation from a member state of the European Union under EU Directive 2014/40/EU (this would include either a market authorisation letter of acknowledgement from a member state of the EU, translated to English (if required);
    - publication in the United Kingdom Medicines & Healthcare products Regulatory Agency ECIG database, as in force or existing from time to time, listing e-cigarette products notified under the *Tobacco and related Products Regulations and the Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020*;
- certification, licence, notification, establishing compliance with the requirements for supply of therapeutic goods, issued by:
    - the United States Food and Drug Administration (compliance with such requirements may be demonstrated through any relevant scheme including Pre-Market Approval or De Novo Premarket notification 510(K));
    - a notified body;

- a body designated by the United Kingdom Medicines & Healthcare products Regulatory Agency.

Therapeutic vaping devices and therapeutic vaping device accessories that comply with one or more of the above matters are treated as complying with all of the essential principles.

Attachment B

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) Order 2023

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

Overview of 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 4FD(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 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.

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 Order") is made under subsection 41CB(1) of the Act. The Order constitutes a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories that were excluded from the operation of the Act under item 16 of the table in Schedule 1 to the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Excluded Goods Determination") immediately prior to the repeal of that item. The effect of the Order is to provide an alternative means for sponsors and manufacturers of such devices to demonstrate that their devices comply with the essential principles identified in the Order.

Background

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes in Australia.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers access for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures are therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by youth and young adults.

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

Reforms to the regulation of vapes

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

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

In broad terms, the first stage of the reforms will:

- prohibit the importation of disposable single use vapes, irrespective of therapeutic claims, subject to limited exceptions, from 1 January 2024;

- prohibit the importation of non-therapeutic vapes, irrespective of nicotine content, subject to limited exceptions, from 1 March 2024;
- introduce the requirement for importers to obtain a customs licence and permit to import therapeutic vapes, subject to limited exceptions, from 1 March 2024, with applications to be enabled from 1 January 2024;
- end the personal importation scheme for therapeutic vapes – the scheme will cease to operate on 1 March 2024, but the importation of disposable vapes will be prohibited from 1 January 2024;
- retain a limited traveller's exception that allows persons arriving in Australia by ship or plane to carry a limited quantity of vapes for their treatment or the treatment of someone travelling with them under their care – revisions to the traveller's exemption will commence on 1 March 2024 with restrictions on disposable vapes commencing 1 January 2024;
- introduce the requirement for importers and manufacturers to notify the Secretary that therapeutic vapes intended to be imported, or released for supply in Australia, comply with relevant product standards or essential principles, as the case may be – this requirement will commence on 1 March 2024, with notifications to be enabled from 1 January 2024;
- modify the exemptions relating to unregistered therapeutic vapes to require such goods to be supplied through prescription medicine supply chains to patients for smoking cessation or the management of nicotine dependence – this requirement will commence on 1 March 2024;
- make minor changes to relevant product standards to facilitate the introduction of the notification and permit schemes, introduce restrictions on flavours and ensure minimum standards for device components; and
- enable therapeutic vapes to be accessed by patients under the Special Access Scheme – Category C, to facilitate more timely access to unregistered therapeutic vapes and reduce regulatory burden on practitioners, while maintaining regulatory oversight commensurate with the risk.

These changes will be supplemented with amendments to the Act that are proposed to be introduced to Parliament next year. The amendments will strengthen domestic compliance and enforcement mechanisms to support the broader policy intent. Compliance and enforcement effort both within and between jurisdictions is essential to address the risk of vaping to population health.

Purpose

The Order is made under subsection 41CB(1) of the Act. The Order determines a medical device standard for therapeutic vaping devices and therapeutic vaping device accessories that were excluded under item 16 of the table in Schedule 1 to the Excluded Goods Determination immediately prior to the repeal of that item. The effect of the Order is that devices that comply with the Order are to be treated as complying with all of the essential principles set out in Schedule 1 to the MD Regulations.

The purpose of the Order is to provide sponsors 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 Order does this by specifying that therapeutic vaping devices or therapeutic vaping device accessories that comply with one or more of the following matters, relating to the good, are to be treated as complying with all of the essential principles in Schedule 1 to the MD Regulations:

- ISO 9001 certification for the manufacture of the device issued by an IAF accredited body;
- ISO 13485 certification for the manufacture of the device issued by either:
    - an IAF accredited body;
    - a notified body;
    - an auditing organisation recognised by Health Canada;
    - an Australian conformity assessment body determined under the MD Regulations;
- a valid form of evidence establishing compliance with requirements for supply of consumer grade e-cigarettes including:

    - a marketing authorisation order granted by the United States Food and Drug Administration under the Premarket Tobacco Products Applications and Recordkeeping Requirements Rule; or
    - an authorisation from a member state of the European Union under EU Directive 2014/40/EU; or
    - publication in the United Kingdom Medicines & Healthcare products Regulatory Agency ECIG database, as in force from time to time, listing e-cigarette products notified under the *Tobacco and related Products Regulations and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020*;
- certification, licence, notification, or other approval, establishing compliance with requirements for supply of therapeutic goods, issued by:
    - the United States Food and Drug Administration; or
    - a notified body; or
    - a body designated by the United Kingdom Medicines & Healthcare products Regulatory Agency.

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

Human rights implications

The 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 young people and poses a major risk to population health and Australia's success in tobacco control.

The reforms to the regulation of vaping products takes positive steps to promote the right to health by supporting reforms to the regulation of vapes. These reforms will support the availability of therapeutic vaping goods to persons who require these goods for smoking cessation or the management of nicotine dependence, while ensuring that access is supervised by a health practitioner and that minimum standards for the safety and quality of therapeutic vaping goods are met.

Collectively, the reforms are intended to arrest the increasing uptake of recreational vaping, especially by youth and young adults. Restricting the domestic supply of non-therapeutic vapes while still allowing for therapeutic use strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to Australians combating smoking addiction or nicotine dependence. Ensuring vapes are only accessed under health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their

use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The new framework will support the following public health objectives:

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

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

The Order takes positive steps to promote the right to health by offering sponsors of medical devices that are therapeutic vaping devices or therapeutic vaping device accessories, which were previously excluded goods from the operation of the Act an alternative option for demonstrating compliance with the essential principles. This is to ensure that the device conforms with minimum safety principles, and performs and operates as intended by the manufacturer. However, it enables the continued supply of previously excluded goods that meet these minimum standards to prevent interruption of supply to patients and give sponsors and manufacturers time to meet the requirements of the essential principles. As such, the Order will assist in providing practitioners and patients with a level of assurance of the quality, safety and performance of therapeutic vaping devices and therapeutic vaping device accessories, while supporting their continued availability.

Conclusion

The 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.