EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2024

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

Section 41BD of the Act provides the meaning of 'medical device' for the purposes of the Act. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v). Those purposes include, for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection 41BD(2B), is also a medical device. Subsection 41BD(2B) of the Act provides that the Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles for the purposes of paragraph 41BD(1)(ab) of the Act.

The *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* (the Principal Instrument) is made under subsection 41BD(2B) of the Act. The Principal Instrument specifies a number of classes of instruments, apparatus, appliances, software, implants, reagents, materials and other articles to be medical devices for the purposes of the Act.

The *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2024* (the Amendment Instrument) amends the Principal Instrument to specify that articles or components that are, or are likely to be taken to be, for use in the manufacture of therapeutic cannabis vaping goods, other than fasteners, such as bolts, nuts and screws, are medical devices for the purposes of the Act.

Background

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

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

therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

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

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

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

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

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

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

The Amendment Act commenced on 1 July 2024, and implements the second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, domestic 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 for therapeutic goods 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.

The third stage of the Government's vaping reforms comprised amendments to the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024*, the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022*, the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, and the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*. These amendments commenced on 1 October 2024, and include the following:

- establishing a new 'pharmacist only model' pathway for accessing notified therapeutic vaping goods. Under this pathway, subject to state and territory government requirements, therapeutic vaping goods containing a nicotine concentration of 20mg/mL or less may be supplied by a pharmacist without prescription, where clinically appropriate, to adults aged 18 years or over; and

- introducing strengthened product standards for therapeutic vaping goods that are for use in smoking cessation or the management of nicotine dependence, including restrictions on the formulation of vaping substances, reducing allowable nicotine concentrations, imposing more stringent technical product requirements and enhancing labelling and packaging requirements.

The Amendment Act is further supported by amendments to the TG Regulations and the MD Regulations made by the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) which implemented a number of measures to give effect to the second stage of the reforms to the regulation of vaping goods.

Relevantly, item 6 of Schedule 1 to the Amendment Regulations amended item 2.18 of Part 2 of Schedule 4 to the MD Regulations, with effect from 1 July 2024, to include a reference to therapeutic cannabis vaping goods in the column that specifies the goods to which the exemption in that item applies.

The effect of this amendment is that medical devices that are articles or components for use in the manufacture of therapeutic cannabis vaping goods may be lawfully imported, subject to compliance with conditions specified in that item.

Purpose

The Principal Instrument is made under subsection 41BD(2B) of the Act. The Principal Instrument specifies that particular classes of instruments, apparatus, appliances, materials or other articles are medical devices for the purposes of the Act.

The effect of an instrument made under subsection 41BD(2B) of the Act is that particular classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles are specified to be medical devices and therefore subject to regulation under Chapter 4 of the Act. Chapter 4 includes regulatory requirements that are appropriate for medical devices, including requirements for conformity assessment certification for quality management systems and compliance with the essential principles. However, there may be uncertainty as to whether certain therapeutic goods are or are not medical devices for the purposes of the Act. An instrument under subsection 41BD(2B) provides clarity on the regulatory arrangements applying to particular goods.

The Amendment Instrument is made under subsection 41BD(2B) of the Act, and makes a minor amendment to item 7 in Schedule 1 to the Principal Instrument to specify that articles and components that are, or are likely to be taken to be, for use in the manufacture of therapeutic cannabis vaping goods, including for example, mouthpieces, heating elements and batteries are medical devices for the purposes of the Act. This amendment compliments the amendments made to item 2.18 of Part 2 of Schedule 4 to the MD Regulations, by making it clear that such articles and components are medical devices, and therefore subject to the regulatory requirements under Chapter 4 of the Act.

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 a 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 further 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.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023.

The feedback received in connection with this consultation informed the development of the Amendment Act and related regulations and other legislative instruments, including the Determination. Further informal consultation, including for instance with health practitioners, was also undertaken in late 2023 and in 2024, and has further informed the development of the reforms.

Other details

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

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

An impact analysis (IA) was prepared on the proposed reforms to the regulation of vapes, taking into account the feedback received from stakeholders throughout the consultations. The Office of Impact Analysis (OIA) determined that the IA was consistent with good practice and met Australian Government best practice regulation requirements (OBPR23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

The Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2024*

Section 1 – Name

This section provides that the name of the instrument is *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2024* (the Amendment Instrument).

Section 2 – Commencement

This section provides that the Amendment Instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is subsection 41BD(2B) of the *Therapeutic Goods Act 1989* (the Act).

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

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* (the Principal Instrument).

Item 1 – Section 4

This item introduces the definitions of ‘therapeutic cannabis vaping good’ in section 4 of the Principal Instrument.

The definition of ‘therapeutic cannabis vaping good’ has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). That is, a therapeutic cannabis vaping device or a therapeutic cannabis vaping device accessory.

Item 2 – Schedule 1 (table item 7)

This item amends item 7 in the table in Schedule 1 to the Principal Instrument to include a reference to ‘therapeutic cannabis vaping goods’.

The effect of this item is that the articles or components specified in item 7 (i.e. mouthpieces, coils or batteries) that are (or are likely to be) for use in the manufacture of a therapeutic cannabis vaping good are medical devices for the purpose of the Act and are therefore subject to the regulatory requirements under Chapter 4.

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 Devices—Specified Articles) Amendment Instrument 2024

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

Overview of legislative instrument

Section 41BD of the Act provides the meaning of 'medical device' for the purposes of the Act. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v). Those purposes include, for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

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pharmacist without prescription, where clinically appropriate, to adults aged 18 years or over; and

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Human rights implications

The Amendment Instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable 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.

The Amendment Instrument supports the right to health by clarifying that articles or components for use in the manufacture of therapeutic cannabis vaping goods are medical devices for the purposes of the Act, reducing the risk of confusion and providing greater certainty, for both industry and consumers, of the regulatory status of such articles or components.

The amendments made by the Amendment Instrument also assists industry in understanding their regulatory requirements and responsibilities, including where relevant, the minimum standards that such goods are required to meet. The application of minimum regulatory requirements to these goods provides consumers with a degree of assurance as to the quality, safety and performance of such goods.

Conclusion

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