EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods) Determination 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. It also provides for the establishment and maintenance of a national system of controls for the importation, manufacture, supply and export of vaping goods. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health and Aged Care (the Department).

Section 41P of the Act sets out definitions for a number of key terms including the term *vaping goods*. This term encompasses goods that may be characterised as a vaping substance, a vaping accessory or a vaping device, and goods that are presented in such a way as to represent that the goods are a *vaping accessory*, *vaping device* or *vaping substance*. Broadly:

- a *vaping accessory* is a cartridge, capsule, pod or other vessel that is for use in, or with, a vaping device;
- a *vaping device* is a device—whether or not it is filled with a vaping substance—that generates or releases, or is intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user;
- a *vaping substance* means nicotine in solution in any concentration, or any liquid or other substance for use in or with a vaping device, and includes a container (other than a vaping accessory or vaping device) in which such a liquid or substance is present.

However, the definition of *vaping goods* also encompasses goods that are, or are included in a class of goods that are, determined to be vaping goods under subsection 41P(3) of the Act. Subsection 41P(3) provides that the Minister may, by legislative instrument, determine that specified goods or specified classes of goods, or those goods when used, advertised or presented for use or supply in a particular way, are or are not vaping goods for the purposes of the Act. The effect of this provision is to enable the Minister to clarify whether specified goods or classes of goods are, or are not, regulated as vaping goods under the Act.

The *Therapeutic Goods (Vaping Goods) Determination 2024* (the Determination) is made under subsection 41P(3) of the Act. The purpose of the Determination is to determine that therapeutic goods that contain nicotine in a liquid form, which are included in the Register, are not vaping goods if the goods are for:

- oromucosal or transdermal administration; and
- use as an aid in withdrawal either from tobacco smoking or nicotine vaping.

Background

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

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

goods for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

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

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

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

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

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

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

The Amendment Act, commencing on 1 July 2024, 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 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.

Purpose

The Determination is made under subsection 41P(3) of the Act. It determines, for the purposes of the Act, specified classes of goods that are not vaping goods.

Specifically, the Determination determines that therapeutic goods that contain nicotine in a liquid form, which are included in the Register, are not vaping goods and are therefore not subject to the controls in Chapter 4A of the Act, if the goods are:

- oromucosal or transdermal administration; and for
- use as an aid in the withdrawal either from tobacco smoking or nicotine vaping.

The purpose of this Determination is to exclude some common nicotine replacement therapies that contain nicotine in solution from the controls of Chapter 4A of the Act, which apply to vaping goods, in circumstances where the goods are included in the Register.

It is appropriate to exclude these goods from the controls in Chapter 4A of the Act to ensure their continued availability outside pharmacy settings for persons seeking access to nicotine replacement therapy goods. Such goods are unrelated to the harms of vaping, and the quantities of nicotine in solution contained therein are small enough such that the goods are unlikely to be diverted for illicit purposes. These goods have been evaluated by the TGA for quality, safety and efficacy prior to inclusion in the Register. To ensure that such goods can continue to be supplied outside pharmacy settings in accordance with scheduling requirements, the Minister may make a determination that these goods are not vaping goods for the purposes of the Act.

Incorporation by reference

The Determination incorporates, by reference, the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110). TGO 110 is a legislative instrument made under section 10 of the Act. It specifies requirements for the quality and safety of therapeutic vaping goods.

TGO 110 is incorporated as in force from time to time, in accordance with paragraph 14(1)(a) of the *Legislation Act 2003* (the Legislation Act). TGO 110 is freely available on the Federal Register of Legislation at www.legislation.gov.au.

Consultation

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook 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 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 holding 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.

The TGA also consulted Consumer Healthcare Products Australia concerning the description of the goods to be included in the Determination and no concerns were raised.

Other details

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

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

An impact analysis (IA) was prepared on the proposed reforms relating to the regulation of vapes, (OBPR23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

The Determination is a disallowable legislative instrument for the purposes of the Legislation Act and commences at the same time as Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commences. However, the Determination does not commence at all if the Amendment Act does not commence.

Attachment A

Details of the *Therapeutic Goods (Vaping Goods) Determination 2024*

Section 1 - Name

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods) Determination 2024* (the Determination).

Section 2 - Commencement

This section provides that the Determination commences at the same time as Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commences. However, the Determination does not commence at all if the Amendment Act does not commence. The Amendment Act received Royal Assent on 27 June 2024 and commences on 1 July 2024.

Section 3 - Authority

This section provides that the legislative authority for making the Determination is subsection 41P(3) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 - Definitions

This section provides definitions for terms used in the Determination, including 'Act', 'nicotine' and 'TGO 110'.

The note to this section also makes it clear that a number of expressions used in the Determination have the same meaning as in the Act. These include 'advertise', 'manufacture', 'presentation', 'Register', 'supply', and 'therapeutic goods'.

Section 5 - Specified goods—vaping goods

Subsection (1) of this section provides that the goods or classes of goods specified in Part 1 of Schedule 1 are determined to be vaping goods.

Subsection (2) of this section provides that for each item of the table in Part 2 of Schedule 1, the goods or classes of goods specified in column 2, when used, advertised, or presented for use or supply in a way specified in column 3, are determined to be vaping goods.

Section 6 - Specified goods—not vaping goods

Subsection (1) of this section provides that the goods or classes of goods specified in Part 1 of Schedule 2 are determined not to be vaping goods.

Subsection (2) of this section provides that for each item of the table in Part 2 of Schedule 2, the goods or classes of goods specified in column 2, when used, advertised, or presented for use or supply in a way specified in column 3, are determined not to be vaping goods.

Schedule 1 – Vaping goods

This Schedule specifies vaping goods in two parts, both which have intentionally been left blank. Part 1 is reserved for use in future to specify goods or classes of goods that are vaping goods. Part 2 is reserved for use in future to specify goods or classes of goods that, when used, advertised, or presented for use or supply in a particular way, are determined to be vaping goods.

Schedule 2 – Not vaping goods

This Schedule specifies goods that are not vaping goods in two parts.

Part 1 of this Schedule specifies goods or classes of goods that are not vaping goods. Its effect is to determine that therapeutic goods that contain nicotine in a liquid form and which are included in the Australian Register of Therapeutic Goods (the Register), are not vaping goods if the goods are for:

- oromucosal or transdermal administration; and
- use as an aid in withdrawal either from tobacco smoking or nicotine vaping.

Part 2 of this Schedule has intentionally been left blank. It is reserved for use in future to specify goods or classes of goods that, when used, advertised, or presented for use or supply in a particular way, are determined to not to be vaping goods.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Vaping Goods) Determination 2024

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

Overview of the Legislative Instrument

Section 41P of the Act sets out definitions for a number of key terms including the term *vaping goods*. This term encompasses goods that may be characterised as a vaping substance, a vaping accessory or a vaping device, and goods that are presented in such a way as to represent that the goods are, a *vaping accessory*, *vaping device* or *vaping substance*.

However, the definition of *vaping goods* also encompasses goods that are, or are included in a class of goods that are, determined to be vaping goods under subsection 41P(3) of the Act. Subsection 41P(3) provides that the Minister may, by legislative instrument, determine that specified goods or specified classes of goods, or those goods when used, advertised or presented for use or supply in a particular way, are or are not vaping goods for the purposes of the Act. The effect of this provision is to enable the Minister to clarify whether specified goods or classes of goods are, or are not, regulated as vaping goods under the Act.

The *Therapeutic Goods (Vaping Goods) Determination 2024* (the Determination) is made under subsection 41P(3) of the Act. The purpose of the Determination is to determine that therapeutic goods that contain nicotine in a liquid form, which are included in the Register, are not vaping goods if the goods are for:

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Background

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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.

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The Amendment Act, commencing on 1 July 2024, 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 for therapeutic good 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 Determination is made under subsection 41P(3) of the Act. It determines, for the purposes of the Act, specified classes of goods that are not vaping goods.

Specifically, the Determination determines that therapeutic goods that contain nicotine in a liquid form, which are included in the Register, are not vaping goods and are therefore not subject to the controls in Chapter 4A of the Act, if the goods are for:

- oromucosal or transdermal administration; and
- use as an aid in the withdrawal either from tobacco smoking or nicotine vaping.

The purpose of this Determination is to exclude some common nicotine replacement therapies that contain nicotine in solution from the controls of Chapter 4A of the Act, which apply to vaping goods, in circumstances where the goods are included in the Register.

It is appropriate to exclude these goods from the controls in Chapter 4A of the Act to ensure their continued availability outside pharmacy settings for persons seeking access to nicotine replacement therapy goods. Such goods are unrelated to the harms of vaping, and the quantities of nicotine in solution contained therein are small enough such that the goods are unlikely to be diverted for illicit purposes. These goods have been evaluated by the TGA for quality, safety and efficacy prior to inclusion in the Register. To ensure that such goods can continue to be supplied outside pharmacy settings in accordance with scheduling requirements, the Minister may make a determination that these goods are not vaping goods for the purposes of the Act.

Human rights implications

The Determination 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 Determination takes positive steps to promote the right to health by supporting the reforms to the regulation of vapes, and by allowing consumers to be able to access goods with established safety and quality information for use as an aid in withdrawal either from tobacco smoking or nicotine vaping in a wider variety of supply chains such as supermarkets. Without this Determination, these goods which are currently available from supermarkets and pharmacies would only be available from pharmacies. As such, the Determination supports access for Australian consumers to these products to assist with their endeavours to quit smoking or vaping.

Conclusion

The Determination 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.