EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Determined 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 7AAA of the Act relevantly provides that the Minister may, by legislative instrument, determine that, for the purposes of the Act, specified goods are therapeutic goods, or are therapeutic goods when used, advertised, or presented for supply in a particular way. The specified goods do not include goods that are declared not to be therapeutic goods under an order in force under section 7, or excluded goods that are covered by a determination under subsection 7AA(1) or (2) of the Act. The effect of a determination under section 7AAA is that the specified goods are subject to the regulatory framework for therapeutic goods under the Act.

The *Therapeutic Goods (Determined Goods) Determination 2024* (the Determination) is made under section 7AAA of the Act. The Determination determines that specified goods, including specified goods when used, advertised, or presented for supply in a particular way, are therapeutic goods 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*, *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 section 7AAA of the Act. The Determination determines that specified goods, including specified goods when used, advertised, or presented for supply in a specified way, are therapeutic goods for the purposes of the Act.

The Determination determines one item in the table in Schedule 1. That item specifies that goods containing nicotine for human use are therapeutic goods, with some exceptions. The exceptions are tobacco prepared and packed for smoking, foods that contain naturally occurring nicotine and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2023*. Nicotine is present in tobacco and naturally occurring in certain foods. However, tobacco prepared and packed for smoking, foods containing naturally occurring nicotine and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2023* are not intended to be determined to be therapeutic goods.

By contrast, goods containing nicotine for human use that are determined to be therapeutic goods include, but are not limited to, vaping goods (including heat-not-burn products), nicotine pouches, nicotine pearls, nicotine sachets, nicotine toothpicks and nicotine gummies. These goods are determined for the avoidance of doubt to be therapeutic goods irrespective of their nicotine concentration, dosage form, route of administration, presentation, indications or other claims.

This reflects the Department's long-standing policy and practice in relation to the regulatory status of these goods. Notwithstanding the Department's policy and practice, the Determination is made to remove any doubt about whether these goods are in fact therapeutic goods.

The effect of the Determination is to provide certainty that goods containing nicotine for human use are subject to the regulatory framework for therapeutic goods under the Act. Accordingly, such goods must be included in the Australian Register of Therapeutic Goods to be lawfully imported, exported, manufactured or supplied, unless subject to an exemption, approval or authority under the Act. In addition, requirements relating to compliance with applicable standards, manufacturing principles and advertising controls apply.

Statutory pre-conditions

Subsection 7AAA(2) provides that, before making a determination under this section, the Minister must have regard to the following matters:

(a) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;
(b) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;
(c) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

The Minister may also have regard to any other relevant matter.

These matters have been considered by the delegate in making the Determination. In summary, the Determination is made on the basis that goods that contain nicotine have the potential to harm the health of members of the public if not regulated under this Act. Goods containing nicotine are goods for which controls relating to quality, safety, efficacy and performance should be applied. The Determination applies irrespective of the therapeutic claims made in relation to the goods.

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.

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, 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 Determination is a disallowable legislative Instrument for the purposes of the *Legislation Act 2003* and commences at the same time as Parts 1 to 3 of Schedule 1 to 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 (Determined Goods) Determination 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Determined 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 section 7AAA of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Definitions

This section provides definitions for terms used in the Determination. In particular, the term 'tobacco product' is defined to have the same meaning as in section 9 of the *Public Health (Tobacco and Other Products) Act 2023.*

Section 5 – Goods determined to be therapeutic goods

This section provides that the goods specified in Schedule 1 are determined to be therapeutic goods for the purposes of the Act. Further, the goods specified in column 2 of Schedule 2, when used, advertised, or presented for supply in a way specified in column 3, are determined to be therapeutic goods for the purposes of the Act.

Schedule 1 – Therapeutic goods

The table in Schedule 1 sets out the goods that are determined to be therapeutic goods for the purposes of the Act.

Item 1 of the table in Schedule 1 specifies goods containing nicotine for human use (including but not limited to vaping goods), other than tobacco prepared and packed for smoking, foods that contain naturally occurring nicotine, and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2023*.

The note to this item provides that vaping goods include heat-not-burn products.

The effect of this item is to provide certainty that goods containing nicotine for human use, other than those excepted, are determined to be therapeutic goods for the purposes of the Act and are therefore subject to the therapeutic goods regulatory scheme. The item puts beyond doubt that goods containing nicotine for human use (including but not limited to vaping goods) are therapeutic goods for the purposes of the Act. The position in this item reflects the Department's long-standing policy and practice concerning vaping goods. Notwithstanding the Department's policy and practice, the item is made to remove any doubt that, unless excepted, goods containing nicotine for human use are therapeutic goods.

Tobacco prepared and packed for smoking, foods containing only naturally occurring nicotine and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2024* contain nicotine for human use. However, these products are not intended to be subject to the therapeutic goods regulatory scheme under the Act. Goods such as nicotine pouches, nicotine pearls, nicotine sachets, nicotine toothpicks and nicotine gummies (regardless of whether these goods contain tobacco, synthetic nicotine or naturally occurring nicotine extracts) will be covered by item 1 of the table in Schedule 1 and are therefore determined to be therapeutic goods, consistent with the current position on how such goods containing nicotine for human use are regulated under the Act.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Determined 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 legislative instrument

Section 7AAA of the Act relevantly provides that the Minister may, by legislative instrument, determine that, for the purposes of the Act, specified goods are therapeutic goods, or are therapeutic goods when used, advertised, or presented for supply in a particular way. The specified goods do not include goods that are declared not to be therapeutic goods under an order in force under section 7, or excluded goods that are covered by a determination under subsection 7AA(1) or (2) of the Act. The effect of a determination under section 7AAA is that the specified goods are subject to the regulatory framework for therapeutic goods under the Act.

The *Therapeutic Goods (Determined Goods) Determination 2024* (the Determination) is a legislative instrument made under section 7AAA of the Act. The Determination determines that specified goods, including specified goods when used, advertised, or presented for supply in a particular way, are therapeutic goods 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*, *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 section 7AAA of the Act. The Determination determines that specified goods, including specified goods when used, advertised, or presented for supply in a specified way, are therapeutic goods for the purposes of the Act.

The Determination determines one item in the table in Schedule 1. That item specifies that goods containing nicotine for human use are therapeutic goods, with some exceptions. The exceptions are tobacco prepared and packed for smoking, foods that contain naturally occurring nicotine and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2023*. Nicotine is present in tobacco and naturally occurring in certain foods. However, tobacco prepared and packed for smoking, foods containing naturally occurring nicotine and tobacco products that are permanently banned under Chapter 4 of the *Public Health (Tobacco and Other Products) Act 2023* are not intended to be determined to be therapeutic goods.

By contrast, goods containing nicotine for human use that are determined to be therapeutic goods include, but are not limited to, vaping goods (including heat-not-burn products), nicotine pouches, nicotine pearls, nicotine sachets, nicotine toothpicks and nicotine gummies. These goods are

determined for the avoidance of doubt to be therapeutic goods irrespective of their nicotine concentration, dosage form, route of administration, presentation, indications or other claims.

This reflects the Department's long-standing policy and practice in relation to the regulatory status of these goods, and removes any doubt about whether these goods are in fact therapeutic goods. The effect of the Determination is that goods containing nicotine for human use are subject to the regulatory framework for therapeutic goods under the Act. Accordingly, such goods must be included in the Australian Register of Therapeutic Goods to be lawfully imported, exported, manufactured or supplied, unless subject to an exemption, approval or authority under the Act. In addition, requirements relating to compliance with applicable standards, manufacturing principles and advertising controls apply.

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 vaping reforms and providing certainty about the regulatory status of goods containing nicotine. Goods that contain nicotine that are not regulated as therapeutic goods may pose a risk to the Australian public. This is due to the negative health effects that may arise from the supply of goods containing nicotine that are not regulated as therapeutic goods. The Determination promotes the right health by putting beyond doubt that regulatory requirements under the Act are imposed on goods that contain nicotine in the interests of public health and safety.

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.