EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment (Vaping) 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 7AA of the Act relevantly provides that the Minister may, by legislative instrument, determine that specified goods are excluded goods for the purposes of the Act. The effect of a determination under section 7AA is to exclude the specified goods from the operation of the Act.

The *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024* (the Amendment Determination) amends the Principal Determination to repeal a saving provision, relating to certain vaping devices, which is no longer intended to continue to apply on the commencement of this Amendment Determination. The effect of the amendment is that goods that were previously excluded goods under item 16 prior to the repeal of item 16 on 1 January 2024, and were manufactured or imported before 1 March 2024, are no longer excluded goods and will be subject to the regulatory scheme under 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 Principal Determination, which is made under section 7AA of the Act, determines specified goods, including specified vaping goods when used, advertised, or presented for supply in a specified way, to be excluded goods for the purposes of the Act.

Item 16 of the table in Schedule 1 to the Principal Determination was repealed by the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*. Item 16 had the effect of excluding vaping devices from the therapeutic goods framework, other than vaping devices intended to be used exclusively for the vaporisation and administration of a medicine. The effect of the repeal of item 16 was that vaping devices, other than vaping device intended to be used exclusively for the vaporisation and administration of a medicine, were no longer excluded goods for the purpose of the Act, and became subject to the therapeutic goods regulatory scheme.

In addition to repealing item 16 of the table in Schedule 1 to the Principal Determination, the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023* also introduced section 7. That section provided that item 16 of the table in Schedule 1 to the Principal Determination,

as in force immediately before the repeal of that item, continues to apply to goods covered by that item that were imported or manufacturer before 1 March 2024.

The Amendment Determination amends the Principal Determination to repeal section 7 of the Principal Determination. The effect of the Amendment Determination is that vaping devices, other than vaping devices intended to be used exclusively for the vaporisation and administration of a medicine, that were imported or manufactured before 1 March 2024 will no longer be excluded goods for the purposes of the Act.

All vaping devices will be subject to the regulatory framework in the Act, including the new vaping goods regulatory framework under Chapter 4A of the Act. Vaping devices for therapeutic use will need to meet the applicable regulatory requirements under the therapeutic goods legislation to be lawfully imported, manufactured or supplied in Australia, whether or not those devices may be used for other purposes.

Statutory pre-conditions

Subsection 7AA(3) 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.

These matters have been considered by the delegate in making the Amendment Determination. In summary, section 7 is repealed on the basis that vaping devices have the potential to harm the health of members of the public if not regulated under the Act. This is because vaping devices, and vaping device accessories, are integral to the administration, dosage and volume of the vaping substance that may be inhaled directly by the user. Further, vaping devices, and vaping device accessories, contain components, such as heating elements and batteries, for which controls relating to quality, safety and performance should be applied. The effect of the repeal would therefore be to ensure that the vaping reforms apply to vaping devices and vaping device accessories, whether or not those devices are intended to administer medicines exclusively, and whether or not they were manufactured or imported prior to 1 March 2024 when the first tranche of vaping regulatory reforms came into effect. Also, the goods in question are therapeutic goods. It is appropriate that they be regulated under the Act and there is no other regulatory scheme that could appropriately manage the risks associated with their use.

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 Amendment 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 Determination are set out in **Attachment A**.

The Amendment 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. (OBPR23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

The Amendment 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 *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commences. However, the Amendment Determination does not commence at all if the Amendment Act does not commence.

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

This section provides that the Amendment Determination commences at the same time as the substantive provisions (Parts 1 to 3 of Schedule 1) of 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 Amendment Determination is section 7AA 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 Determination 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 Determination is amended as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination).

Item 1 – Section 7

This item repeals section 7 of the Principal Determination, which sets out a savings provision relating to the repeal of item 16 of the table in Schedule 1 to the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*

Section 7 provides that item 16 of the table in Schedule 1, as in force immediately before the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*, continues to apply to goods covered by the item that are imported or manufactured before 1 March 2024.

Item 16 referred to vaping devices, other than vaping devices that are intended, by the person under whose name the device is or is to be supplied, to be used exclusively for the vaporisation and administration of a medicine, including vaporiser nicotine. The previously excluded vaping devices under item 16 include e-cigarette and vaping devices that are not for therapeutic purposes, or are used for both therapeutic and non-therapeutic purposes.

The effect of this amendment to repeal section 7 is that vaping devices that were excluded goods under item 16 of the table in Schedule 1 prior to its repeal and were imported or manufactured before 1 March 2024, will no longer be excluded goods under the Act. From the commencement of this instrument, all vaping devices that were previously excluded goods because of the operation of section 7 will no longer be excluded goods and will be regulated under the Act as therapeutic 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 (Excluded Goods) Amendment (Vaping) 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 7AA of the *Therapeutic Goods Act 1989* (the Act) relevantly provides that the Minister may, by legislative instrument, determine that specified goods are excluded goods for the purposes of the Act. The effect of a determination under section 7AA is to exclude the specified goods from the operation of the Act.

The *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024 (the Amendment Determination) amends the Principal Determination to repeal a saving provision, relating to certain vaping devices, which is no longer intended to continue to apply on the commencement of this Amendment Determination. The effect of the amendment is that goods that were previously excluded goods under item 16 prior to the repeal of item 16 on 1 January 2024, and were manufactured or imported before 1 March 2024, are no longer excluded goods and will be subject to the regulatory scheme under 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 Principal Determination, which is made under section 7AA of the Act, determines specified goods, including specified vaping goods when used, advertised, or presented for supply in a specified way, to be excluded goods for the purposes of the Act.

Item 16 of the table in Schedule 1 to the Principal Determination was repealed by the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*. Item 16 had the effect of excluding vaping devices from the therapeutic goods framework, other than vaping devices intended to be used exclusively for the vaporisation and administration of a medicine. The effect of the repeal of item 16 was that vaping devices, other than vaping device intended to be used exclusively for the vaporisation and administration of a medicine, were no longer excluded goods for the purpose of the Act, and became subject to the therapeutic goods regulatory scheme.

In addition to repealing item 16 of the table in Schedule 1 to the Principal Determination, the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023* also introduced section 7. That section provided that item 16 of the table in Schedule 1 to the Principal Determination, as in force immediately before the repeal of that item, continues to apply to goods covered by that item that were imported or manufacturer before 1 March 2024.

The Amendment Determination amends the Principal Determination to repeal section 7 of the Principal Determination. The effect of the Amendment Determination is that vaping devices, other than vaping devices intended to be used exclusively for the vaporisation and administration of a medicine, that were imported or manufactured before 1 March 2024 will no longer be excluded goods for the purposes of the Act.

All vaping devices will be subject to the regulatory framework in the Act, including the new vaping goods regulatory framework under Chapter 4A of the Act. Vaping devices for therapeutic use will need to meet the applicable regulatory requirements under the therapeutic goods legislation to be lawfully imported, manufactured or supplied in Australia, whether or not those devices may be used for other purposes.

Human rights implications

The Amendment 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 Amendment Determination takes positive steps to promote the right to health by repealing provisions that had the effect of continuing to exclude certain vaping devices from the operation of the Act. The continued exclusion of such goods from the therapeutic goods regulatory scheme could

pose a risk to the Australian public. This is due to the negative health effects that may arise from the inhalation of vaping substances of unknown origin and otherwise the risks of vapes overheating, igniting or exploding. This instrument promotes the right to health by imposing regulatory requirements on vaping devices to support their safety and performance.

Conclusion

This legislative 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.