EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023

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

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 2023* ("the Amendment Determination") amends the Principal Determination to remove the exclusion of certain vaping devices from the therapeutic goods regulatory scheme. The effect of this amendment is that vaping devices will no longer be excluded goods for the purposes of the Act, and therefore will be subject to the therapeutic goods regulatory scheme. The amendments provide for a two-month transitional arrangement through inclusion of a savings provision.

Background

The public health problem

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

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

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent

evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known.

Reforms to the regulation of vapes

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

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

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

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

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

The new framework will support the following public health objectives to:

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

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

Purpose

The 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 way, to be excluded goods for the purposes of the Act.

The Amendment Determination amends the Principal Determination to repeal item 16 of the table in Schedule 1 to the Principal Determination. That item 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 Amendment Determination is that vaping devices, other than vaping devices intended to be used exclusively for the vaporisation and administration of a medicine, will no longer be excluded goods for the purposes of the Act. This means that all vaping devices that are therapeutic goods will be subject to the therapeutic goods regulatory scheme.

Vaping devices are those that generate or release, or are designed or intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user. 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.

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, the item is repealed on the basis that therapeutic vaping devices have the potential to harm the health of members of the public if not regulated under this 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, that are used to administer medicines are regulated under the Act, whether or not those devices are intended to administer medicines exclusively.

From 1 March 2024, all therapeutic vaping devices and therapeutic vaping device accessories, whether imported or manufactured in Australia, will need to comply with applicable product standards. These standards will be enhanced over 2024 to address risks posed to users, particularly youth and young adults.

In addition, vaping devices that are not intended for therapeutic use will be prohibited from importation into Australia from 1 January 2024. Further, subject to the passage of legislative amendments, the domestic manufacture and supply of such products will also be prohibited later next year.

Consultation

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

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

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

Other details

Details of the 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. The Office of Impact Analysis ("OIA") determined that the IA was consistent with good practice and met Australian Government best practice regulation requirements (OBPR23-03933). The IA has been published, or will be published, prior to commencement of the Amendment Determination 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 the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* ("the Amendment Regulations"). However, the Amendment Determination does not commence at all if the Amendment Regulations do not commence.

Attachment A

Details of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023* ("the Amendment Determination").

Section 2 – Commencement

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

Section 3 – Authority

This section provides that the legislative authority for making the 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 – After section 6

This item introduces new section 7 to the Principal Determination, which sets out a savings provision relevant to the amendments made by amending item 2 of the Amendment Determination.

Section 7 provides that item 16 of the table in Schedule 1 to the Principal Determination, as in force immediately before the commencement of the Amendment Determination, continues to apply to goods covered by the item that are imported or manufactured before 1 March 2024.

The effect of this amendment is that vaping devices imported or manufactured before 1 March 2024 will continue to be exempt if such devices were exempt under item 16 of the table in Schedule 1 prior to its repeal. All therapeutic vaping devices manufactured or imported from 1 March 2024, are not excluded and must comply with the therapeutic goods framework.

Item 2 – Schedule 1 (table item 16)

This item repeals item 16 of the table in Schedule 1 to the Principal Determination. The effect of this amendment is that no therapeutic vaping devices will be excluded goods for the purposes of the Act. Therefore, all therapeutic vaping devices will be subject to the therapeutic goods framework.

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 2023

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

Overview of legislative instrument

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.

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Background

The public health problem

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

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

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

Reforms to the regulation of vapes

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

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

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

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

regulatory burden on practitioners, while maintaining regulatory oversight commensurate with the risk.

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

Purpose

The 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 way, to be excluded goods for the purposes of the Act.

The Amendment Determination amends the Principal Determination to repeal item 16 of the table in Schedule 1 to the Principal Determination. That item 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 Amendment Determination is that no therapeutic vaping devices will be excluded goods for the purposes of the Act. All therapeutic vaping devices will, therefore, be subject to the therapeutic goods framework.

Vaping devices are those that generate or release, or are designed or intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user. Therapeutic vaping devices will need to meet the applicable regulatory requirements under the therapeutic goods legislation to be lawfully imported, manufactured or supplied in Australia.

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

The Amendment Determination takes positive steps to promote the right to health by supporting the reforms to the regulation of vapes. These reforms 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. Restricting the domestic supply of non-therapeutic vapes, while still allowing for therapeutic use, strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to Australians combating smoking

addiction or nicotine dependence. Ensuring vapes are only accessed under health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The new framework will support the following public health objectives:

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

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

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

The Amendment 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.