EXPLANATORY STATEMENT

Customs (Prohibited Imports) Regulations 1956

Customs (Prohibited Imports) (Vaping Goods) Approval 2023

The *Customs Act 1901* ("the Act") concerns customs related functions and is the legislative authority that sets out the customs requirements for the importation, and exportation of goods to and from Australia.

Subsection 270(1) of the Act provides, in part that the Governor-General may make regulations not inconsistent with the Act, prescribing all matters, which by the Act are required or permitted to be prescribed or as may be necessary or convenient to be prescribed for giving effect to the Act.

Subsection 50(1) of the Act provides that the Governor-General may, by regulation, prohibit the importation of goods into Australia. This power may be exercised by prohibiting the importation of goods absolutely or in compliance with certain conditions or restrictions. Subsection 50(2)(c) of the Act provides that the power in subsection 50(1) to make regulations prohibiting the import of goods into Australia may be exercised by prohibiting the importation of goods unless specified conditions or restrictions are met.

Subregulation 5A(1) of the *Customs (Prohibited Imports) Regulations 1956* ("the Regulations") prohibits the import of vaping goods unless the importer holds both a licence to import vaping goods and a permission to import vaping goods, that was granted by a prescribed authority under the Regulations, if none of the exemptions to the prohibition in subregulations 5A(2) to (4) apply.

The *Customs (Prohibited Imports) (Vaping Goods) Approval 2023* ("the Approval Instrument") is made in contemplation of commencement of its enabling provision, subregulation 5A(5) of the Regulations, relying on section 4 of the *Acts Interpretation Act 1901*. Subregulation 5A(5) will allow the Minister to approve, by legislative instrument, the importation into Australia of vaping goods that meets one or more of the following conditions or restrictions:

- the vaping goods are specified in, or included in a class of vaping goods specified in, the approval;
- the vaping goods are imported in a form (including a concentration) specified in the approval;
- the vaping goods are imported by a person, or class of persons, specified in the approval;
- the vaping goods do not exceed a value or amount specified in the approval;
- the vaping goods are imported in a way, or by a means, specified in the approval.

The purpose of the Approval Instrument is to approve the importation of vaping goods by certain persons in particular circumstances where the vaping goods are not for use in the general community and the importation therefore does not pose any risk to public health.
Specifically, the Approval Instrument will approve the importation into Australia of vaping goods that are imported by:

- a person who is a member of a group of persons who are visiting Australia to participate in a national or international sporting event, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia;
- a person who is a member of a group of persons, being members of the military forces of another country who are visiting Australia for military training, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia;

- a person who is a member of a group of persons, being a group that includes a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia; or

The Approval Instrument complements the existing exemptions under the *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002* that apply in relation to the importation of therapeutic goods by the above persons.

The Approval Instrument also approves the importation into Australia of vaping goods by a police officer for the purposes of criminal investigation or law enforcement, including criminal prosecution.

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 as new and amended delegated instruments under the *Therapeutic Goods Act 1989*. 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 the 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 *Therapeutic Goods Act 1989* 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.

Consultation

Consultation was not undertaken specifically for the Approval Instrument as this instrument is consequential to the making of the *Customs Legislation Amendment (Vaping) Regulations 2023*, which form part of a broader Commonwealth Government initiative to address the risks posed by vaping to children and adolescents in Australia, while preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision.

The Therapeutic Goods Administration ("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 Approval Instrument are set out in **Attachment A.**

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

An impact analysis ("IA") was prepared on the proposed reforms 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 Approval Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act* 2003 and commences immediately after the commencement of the *Customs Legislation Amendment (Vaping Goods) Regulations 2023* ("the Amendment Regulations"). However, the Instrument of Approval does not commence at all if the Amendment regulations do not commence.

Attachment A

Details for the *Customs (Prohibited Imports) (Vaping Goods) Approval 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Customs (Prohibited Imports) (Vaping Goods) Approval 2023* ("the Approval Instrument").

Section 2 – Commencement

This section provides that the Approval Instrument commences at the same time as the commencement of the *Customs Legislation Amendment (Vaping Goods) Regulations 2023* ("the Amendment Regulations". However, the Approval Instrument 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 Approval Instrument is subregulation 5A(5) of the Amendment Regulations.

Section 4 – Definitions

This section provides that the term "police officer" has the same meaning as subsection 4(2) of the *Customs Act 1901*.

Section 5 – Approval of vaping goods

The section approves the importation into Australia of vaping goods that are imported by:

- a person who is a member of a group of persons who are vising Australia to participate in a national or international sporting event, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia;
- a person who is a member of a group of persons, being members of the military forces of another country who are visiting Australia for military training, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia;
- a person who is a member of a group of persons, being a group that includes a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business, who is responsible for the medical treatment of the persons in the group and is responsible for the control and custody of the vaping goods while the group is in Australia ; or
- by a police officer for the purposes of criminal investigation or law enforcement (including criminal prosecution).

Attachment B

Statement of Compatibility with Human Rights

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

Customs (Prohibited Imports) (Vaping Goods) Approval 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 the legislative instrument

The purpose of the *Customs (Prohibited Imports) (Vaping Goods) Approval 2023* ("the Approval Instrument") is to ensure that vaping goods are approved for importation when imported by certain persons.

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 as 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 the 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 *Therapeutic Goods Act 1989* 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 Approval Instrument is consequential to the making of the *Customs Legislation Amendment (Vaping) Regulations 2023*, which form part of a broader Commonwealth Government initiative to address the risks posed by vaping to children and adolescents in Australia, while preserving legitimate

patient access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision.

The purpose of the Approval Instrument is to provide approvals for importations of vaping goods by specified persons in particular circumstances. The Approval Instrument is limited in scope to particular persons. Specifically, the Approval Instrument approves the importation of vaping goods by a person that is a member of a foreign military or sporting group, or a group including a Head of State, where the person is responsible for the medical treatment of members of that group and for the custody and control of the vaping goods while they are in Australia. The Approval Instrument also approves importations by police officers for law enforcement purposes.

Human rights implications

The Instrument of Approval 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 measure 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.

By making vaping goods prohibited imports and only permitting their importation in certain circumstances, the Amendment Regulations engage and enhance the right to enjoy the highest standard of physical and mental health outcomes. The Approval Instrument engages this right by confining the approval in a way that ensures the vaping goods that are approved are not for supply in the general community. The approval in relation to police officers for law enforcement purposes also enhances the right to enjoy the highest standard of physical and mental health outcomes by supporting investigation activities and enforcement of laws in Australia designed to protect the community from the harms of vaping.

Conclusion

The Approval 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.