EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 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 41BD of the Act provides the meaning of 'medical device' for the purposes of the Act. Subsection 41BD(1) provides a broad definition of 'medical device', which includes instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, specified under subsections 41BD(2A) and (2B) of the Act.

Subsection 41BD(3) of the Act provides that the Secretary may, by legislative instrument, declare that a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, are not medical devices for the purposes of the Act. A declaration under this subsection does not prevent articles from being therapeutic goods. If articles meet the definition of therapeutic goods, it has the effect that therapeutic goods declared to not be medical devices are regulated as therapeutic goods under Chapter 3 of the Act instead of being regulated under Chapter 4 of the Act as medical devices.

The *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* ("the Principal Declaration") is a legislative instrument made under subsection 41BD(3) of the Act. The Principal Declaration declares that a number of articles are not medical devices for the purposes of the Act.

The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* ("the Amendment Declaration") amends the Principal Declaration to specify that certain other therapeutic goods are not medical devices for the purposes of the Act.

The therapeutic goods that are specified in the Amendment Declaration to not be medical devices are:

- articles that are intended to administer *a therapeutic good*, rather than a medicine, in such a way that the therapeutic good and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable;
- therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack; and
- therapeutic vaping substance accessories.

The effect of the Amendment Declaration is that those goods specified in the instrument are not regulated under Chapter 4 of the Act, and are instead regulated under Chapter 3 of the Act.

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 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 Declaration is made under subsection 41BD(3) of the Act. The Principal Declaration declares particular instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or particular classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, not to be medical devices for the purposes of the Act.

The effect of an instrument under subsection 41BD(3) of the Act is that therapeutic goods declared not to be a medical device are not regulated under Chapter 4 of the Act, and are instead regulated under Chapter 3 of the Act. Chapter 4 includes regulatory requirements that are appropriate for medical devices, including requirements for conformity assessment certification for quality management systems and compliance with the essential principles. However, the regulatory framework for medical devices may not be appropriate for certain therapeutic goods, or there may be uncertainty as to whether certain therapeutic goods are or are not medical devices for the purposes of the Act. An instrument under subsection 41BD(3) provides clarity on the regulatory arrangements applying to particular therapeutic goods and provides a mechanism for therapeutic goods to be regulated under Chapter 3 of the Act where that would be more appropriate for the goods.

The Amendment Declaration amends the Principal Declaration by declaring certain articles not to be medical devices for the purpose of the Act. The Amendment Declaration confirms that the following articles are not medical devices for the purpose of the Act:
- therapeutic vaping devices that are for use as a single integral unit with a therapeutic good for the vaporisation and administration of that therapeutic good, and are not reusable. For

example, pre-filled, disposable therapeutic vaping devices that contain a therapeutic vaping substance;
- therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack; and
- therapeutic vaping substance accessories.

The purpose of this amendment is to clarify the regulation that applies to these therapeutic vaping goods and therapeutic vaping devices. The effect of the Amendment Declaration is to ensure that certain vaping devices are instead regulated under Part 3-2 of the Act, not Chapter 4. This measure addresses uncertainty about the proper characterisation of certain vaping devices and ensures uniformity of regulation of therapeutic vaping devices or therapeutic vaping device accessories in therapeutic vaping packs, and therapeutic vaping substance accessories that contain a therapeutic vaping substance. Further, the amendments provide that where a device is supplied with a therapeutic good as a single integral unit for the administration of the therapeutic good, even where that therapeutic good is not a medicine (and would be another therapeutic good), such goods are regulated under Chapter 3 of the Act. The Amendment Declaration does not specify therapeutic vaping devices or therapeutic vaping device accessories as these devices, supplied as devices alone, will continue to be regulated under Chapter 4.

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 Declaration are set out in **Attachment A**.

The Amendment Declaration 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 Declaration on the OIA website at: oia.pmc.gov.au/.

The Amendment Declaration 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 Declaration does not commence at all if the Amendment Regulations do not commence.

Attachment A

Details of the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023*

Section 1 – Name

This section provides that the name of the instrument is *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* ("the Amendment Declaration").

Section 2 – Commencement

This section provides that the Amendment Declaration commences at the same time as the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* ("the Amendment Regulations"). However, the Amendment Declaration 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 Declaration is subsection 41BD(3) 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 Declaration 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 Declaration is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Declaration has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* ("the Principal Declaration").

Item 1 – Section 4 (paragraph (b) of the note)

This item makes a minor amendment to the note in section 4 of the Principal Declaration to clarify that the term 'therapeutic good' has the same meaning as in the Act.

Item 2 – Section 4

This item introduces new definitions in section 4 of the Principal Declaration, including definitions of 'therapeutic vaping device', 'therapeutic vaping device accessory', 'therapeutic vaping pack' and 'therapeutic vaping substance accessory'. All terms are defined to have the same meaning as in the *Therapeutic Goods Regulations 1990* ("the Regulations") and the *Therapeutic Goods (Medical Devices) Regulations 2002* ("the MD Regulations").

The definition of 'therapeutic vaping substance accessory' provides that this term has the same meaning as in the Regulations. That is, a cartridge, capsule, pod or other vessel that contains a therapeutic vaping substance (for example, nicotine) and is designed or intended to be used in or with a therapeutic vaping device.

The definition of ‘therapeutic vaping device’ provides that this term has the same meaning as in the MD Regulations. That is, a vaping device, other than a disposable vape or a therapeutic cannabis vaping device. Relevantly, the Regulations define a ‘vaping device’ as a device that generates or releases (or is 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.

Item 3 – Schedule 1 (table item 3)

This item makes a minor amendment to repeal and replace item 3 in the table in Schedule 1 to the Principal Declaration. The amendment is intended to clarify that non-reusable articles that are for use in combination with a therapeutic good, whether or not the therapeutic good is a medicine, as a single integral unit intended to administer that therapeutic good, are not medical devices for the purposes of the Act. This item would include, for example, a disposable therapeutic vape.

The effect of this amendment is that non-reusable vaping devices that contain a vaping substance that is intended to be for therapeutic use, but that does not meet the definition of medicine in the Act, are declared not to be medical devices, and are therefore regulated as therapeutic goods under Chapter 3 of the Act. Such goods would include, for example, a disposable therapeutic vape that is indicated for smoking cessation or the management of nicotine dependence and does not contain any active ingredient.

Item 4 – Schedule 1 (at the end of the table)

This item introduces items 10 and 11 to the table in Schedule 1 to the Principal Declaration to declare that therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack, and therapeutic vaping substance accessories, are not medical devices. The effect of this amendment is that such goods are regulated under Chapter 3 of the Act, instead of being regulated under Chapter 4 of the Act as medical devices.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Articles that are Not Medical Devices) 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 41BD of the Act provides the meaning of 'medical device' for the purposes of the Act. Subsection 41BD(1) provides a broad definition of 'medical device', which includes instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, specified under subsections 41BD(2A) and (2B) of the Act.

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- articles that are intended to administer a therapeutic good, rather than a medicine, in such a way that the therapeutic good and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable;
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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 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 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 Declaration is made under subsection 41BD(3) of the Act. The Principal Declaration declares particular instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or particular classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, not to be medical devices for the purposes of the Act.

The effect of an instrument under subsection 41BD(3) of the Act is that therapeutic goods declared to not be a medical device are not regulated under Chapter 4 of the Act, and are instead regulated under Chapter 3 of the Act. Chapter 4 includes regulatory requirements that are appropriate for medical devices, including requirements for conformity assessment certification for quality management systems and compliance with the essential principles. However, the regulatory framework for medical devices may not be appropriate for certain therapeutic goods, or there may be uncertainty as to whether certain therapeutic goods are or are not medical devices for the purposes of the Act. An instrument under subsection 41BD(3) provides clarity on the regulatory arrangements applying to particular therapeutic goods and provides a mechanism for therapeutic goods to be regulated under Chapter 3 of the Act where that would be more appropriate for the goods.

The Amendment Declaration amends the Principal Declaration by declaring certain articles not to be medical devices for the purpose of the Act. The Amendment Declaration confirms that the following articles are not medical devices for the purpose of the Act:
- therapeutic vaping devices that are for use as a single integral unit with a therapeutic good for the vaporisation and administration of that therapeutic good, and are not reusable. For example, this would apply to pre-filled disposable therapeutic vaping devices that contain a therapeutic vaping substance;
- therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack; and
- therapeutic vaping substance accessories.

The purpose of this amendment is to clarify the regulation that applies to these therapeutic vaping goods and therapeutic vaping devices. The effect of the Amendment Declaration is to ensure that certain vaping devices are instead regulated under Part 3-2 of the Act, not Chapter 4. This measure addresses uncertainty about the proper characterisation of certain vaping devices and ensures uniformity of regulation of therapeutic vaping devices or therapeutic vaping device accessories in

therapeutic vaping packs, and therapeutic vaping substance accessories that contain a therapeutic vaping substance. Further, the amendments provide that where a device is supplied with a therapeutic good as a single integral unit for the administration of the therapeutic good, even where that therapeutic good is not a medicine, and would be an other therapeutic good, such goods are regulated under Chapter 3 of the Act. The Amendment Declaration does not specify therapeutic vaping devices or therapeutic vaping device accessories as these devices, supplied as devices alone, will continue to be regulated under Chapter 4.

Human rights implications

The Amendment Declaration 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.

The Amendment Declaration 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 these 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.

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 Declaration promotes and supports the right to health by specifying that certain vaping devices are not medical devices for the purposes of the Act, reducing the risk of confusion, and providing greater certainty, for both industry and consumers around the regulatory status of vaping devices. This is designed to assist industry in understanding their regulatory requirements and responsibilities and provides the public with a level of assurance as to the safety of such devices and the standards that apply to these goods.

Conclusion

The Amendment Declaration 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.