

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 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”).

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply specified therapeutic goods, or classes of such goods, for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and the specified conditions, if any, are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations, if any, prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedules 8, 9 or 10 to the Poisons Standard.

Health practitioners who supply therapeutic goods pursuant to rules made under subsection 19(7A) are required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act.

These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia and overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (“the Register”), or not otherwise the subject of an exemption, approval or authority under the Act.

The *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022* (“the Principal Rules”) are made under subsection 19(7A) of the Act. The Principal Rules specify health practitioners, medicines, circumstances and conditions for the purposes of subsection 19(7A) of the Act.

The *Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023* (“the Amendment Rules”) is made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act. The Amendment Rules amend the Principal Rules to include the authorised supply of certain therapeutic vaping goods by specified health practitioners under certain conditions, where supply is indicated for smoking cessation or the management of nicotine dependence. The Amendment Rules also make minor amendments to update the reference to the SAS Guidelines in the Principal Rules, the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022*.

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 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, if made, 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 Rules are made under subsection 19(7A) of the Act. The Principal Rules specify health practitioners, medicines, circumstances and conditions for the purposes of subsection 19(7A) of the Act. The Principal Rules, and subsections 19(7A) to (7D) of the Act, support the operation of the Special Access Scheme – Category C (“SAS C”) pathway. The SAS C pathway provides immediate access to unapproved therapeutic goods, where certain circumstances exist, and certain conditions are met. Supply of goods under the SAS C pathway must be notified to the TGA within 28 days of the supply.

The Amendment Rules amend the Principal Rules to enable medical practitioners and nurse practitioners to supply therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, and goods in a therapeutic vaping pack to patients who are 16 years of age or over, for use in smoking cessation or the management of nicotine dependence. Such supply is subject to certain specified conditions, including that the practitioner informs the patient that the goods are not included in the Register, obtains informed consent from the patient and supplies the goods in accordance with good medical practice.

The goods that are specified in the Amendment Rules are those that are the subject of a notice under item 15 in Schedule 5A to the Regulations and are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations. This is to ensure that the goods are accessed through the SAS C pathway meet minimum standards for safety and quality.

The effect of the Amendment Rules is to enable a medical practitioner or nurse practitioner to supply the specified goods to their patients, 16 years of age or older, without the pre-approval or authority from the Secretary. This facilitates legitimate patient access to the goods for use in smoking cessation or the treatment of nicotine dependence.

Incorporation by reference

SAS Guidance

The Amendment Rules incorporate by reference the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023) (“the SAS Guidance”), which is published by the TGA. This document provides guidance for health practitioners and sponsors involved in providing patients with access to therapeutic goods that are not included in the Register (and are not otherwise the subject of an exemption, approval or authority under the Act) through the Special Access Scheme. It outlines the various access pathways and the regulatory obligations when accessing and supplying such therapeutic goods.

The Amendment Rules incorporate the SAS Guidance as in force or existing at 1 January 2024, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* (“the Legislation Act”), which permits a legislative instrument to incorporate a document (that is not an Act or legislative instrument) as it exists at, or before, the time the instrument commences. The SAS Guidance is available for free from the TGA website and may be accessed at www.tga.gov.au.

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

The Amendment Rules are 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 Rules, on the OIA website at: oia.pmc.gov.au/.

The Amendment Rules are a disallowable legislative instrument for the purposes of the Legislation Act and commence at the same time as the commencement of the *Therapeutic Goods Amendment (Vaping) Regulations 2023* (“the Amendment Regulations”). However, the Amendment Rules do not commence at all if the Amendment Regulations do not commence.

Details of the *Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023* (“the Amendment Rules”).

Section 2 – Commencement

This section provides that the Amendment Rules commence at the same time as the commencement of the *Therapeutic Goods Amendment (Vaping) Regulations 2023* (“the Amendment Regulations”). However, the Amendment Rules do 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 Rules is subsections 19(7A), 32CM(7A) and 41HC(6) 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 Rules are made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Rules is amended as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Rules has effect according to its terms.

The Amendment Rules make amendments to the:

- *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022* (“the Principal Rules”);
- *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* (“the Biologicals Rules”);
- and
- *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022* (“the Medical Devices Rules”).

Schedule 1 – Amendments

Therapeutic Goods (Medicines—Authorised Supply) Rules 2022.

Item 1 – Section 1

This item makes a minor amendment to update the name of the Principal Rules to reflect that the instrument authorises certain health practitioners to supply specified goods that are either medicines or other therapeutic goods for use in the treatment of their patients. Other therapeutic goods are therapeutic goods that are not medicines, medical devices or biologicals.

Item 2 – Section 4 (at the end of the note)

This item makes a minor amendment to the note in section 4 of the Principal Rules to clarify that the term ‘therapeutic goods’ has the same meaning as in the Act.

Items 3 and 5 – Section 4

These items introduce new definitions in section 4 of the Principal Rules, including definitions of ‘nurse practitioner’, ‘therapeutic vaping pack’ and ‘therapeutic vaping substance’.

Item 4 – Section 4 (definition of *SAS Guidance*)

This item repeals and substitutes the definition of ‘SAS Guidance’ in section 4 of the Principal Rules to reflect that ‘SAS Guidance’ means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023), as in force or existing on 1 January 2024.

Item 6 – After section 5

This item introduces new section 5A to the Principal Rules. New section 5A authorises the supply of certain therapeutic vaping goods by a health practitioner who is a medical practitioner or a nurse practitioner (“the treating practitioner”), or by a health practitioner to a patient of a treating practitioner, with reference to certain matters specified in new Schedule 1A (as introduced by item 7 below).

Subsection 5A(1) provides that a treating practitioner is authorised to supply a therapeutic good that is within the class of therapeutic goods specified column 2 of an item in the table in Schedule 1A, to a patient of that practitioner, where the circumstances specified in that subsection are met. Those circumstances include that the conditions specified in subsection 5A(2) are met and that patient is 16 years of age or over.

Similarly, subsection 5A(3) provides that a health practitioner is authorised to supply a therapeutic good that is within the class of therapeutic goods specified column 2 of an item in the table in Schedule 1A, to a patient of a treating practitioner, provided that the supply is requested by the treating practitioner and the other circumstances specified in that subsection are met. These include that the conditions specified in subsection 5A(4) are satisfied.

Item 7 – After Schedule 1

This item introduces new Schedule 1A to the Principal Rules.

Schedule 1A specifies the goods for the purposes of new section 5A with reference to the class of goods, dosage form, route of administration and indication in relation to those goods. For example, item 1 in the table in Schedule 1A, authorises the supply of certain therapeutic vaping substances and therapeutic vaping substance accessories that contain nicotine as the only active ingredient, in a solid or liquid dosage form. These goods are inhaled and indicated for smoking cessation or the management of nicotine dependence.

The items in new Schedule 1A also include therapeutic vaping substances and therapeutic vaping substance accessories that do not contain any active ingredients, therapeutic vaping kits and goods in a therapeutic vaping pack. These goods are identified as being the subject of a notice under item 15 in Schedule 5A to the Regulations and not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations. This is to ensure that the goods that may be accessed under the SAS C pathway as a consequence of the Amendment Rules are those that have been notified to the Secretary as having met minimum quality and safety standards.

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

Item 8 – Section 4 (definition of SAS Guidance)

This item repeals and substitutes the definition of ‘SAS Guidance’ in section 4 of the Biologicals Rules to reflect that ‘SAS Guidance’ means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023), as in force or existing on 1 January 2024.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

Item 9 – Section 4 (definition of SAS Guidance)

This item repeals and substitutes the definition of ‘SAS Guidance’ in section 4 of the Medical Devices Rules to reflect that ‘SAS Guidance’ means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023), as in force or existing on 1 January 2024.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 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

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply specified therapeutic goods, or classes of such goods, for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and the specified conditions, if any, are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations, if any, prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedules 8, 9 or 10 to the Poisons Standard.

Health practitioners who supply therapeutic goods pursuant to rules made under subsection 19(7A) are required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act.

These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia and overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (“the Register”), or not otherwise the subject of an exemption, approval or authority under 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 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 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 SAS C pathway 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, if made, 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 Rules are made under subsection 19(7A) of the Act. The Principal Rules specify health practitioners, medicines, circumstances and conditions for the purposes of subsection 19(7A) of the Act. The Principal Rules, and subsections 19(7A) to (7D), support the operation of the Special Access Scheme – Category C (“SAS C”) pathway. The SAS C pathway provides immediate access to unapproved therapeutic goods, where certain circumstances exist, and certain conditions are met. Supply of goods under the SAS C pathway must be notified to the TGA within 28 days of the supply.

The Amendment Rules amend the Principal Rules to enable medical practitioners and nurse practitioners to supply therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, and goods in a therapeutic vaping pack to patients who are 16 years of age or over, for use in smoking cessation or the management of nicotine dependence. Such supply is subject to certain specified conditions, including that the practitioner informs the patient that the goods are not included in the Register, obtains informed consent from the patient and supplies the goods in accordance with good medical practice.

The goods that are specified in the Amendment Rules are those that are the subject of a notice under item 15 in Schedule 5A to the Regulations and are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations. This is to ensure that the goods that are accessed through the SAS C pathway meet minimum standards for safety and quality.

The effect of the Amendment Rules is to enable a medical practitioner or nurse practitioner to supply the specified goods to their patients, 16 years of age or older, without pre-approval or authority from the Secretary. This facilitates legitimate patient access to goods for use in smoking cessation or the treatment of nicotine dependence.

Human rights implications

The Amendment Rules engage 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 Rules take 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 substances or therapeutic vaping substance accessories to persons who require such goods for smoking cessation or the management of nicotine dependence under the supervision of an appropriate 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 about 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 Rules take positive steps to promote the right to health by enabling health practitioners to supply certain therapeutic vaping goods to patients for smoking cessation or the management of nicotine dependence. This means that a practitioner will be able to supply unregistered therapeutic vaping substances or therapeutic vaping substance accessories by way of notification (within 28 days after the supply) rather than having to seek approval or authority prior to the supply; thus, facilitating timely availability to Australian patients. Such supply is subject to certain conditions, including that the practitioner informs the patient that the goods are not included in the Register, obtains informed consent and supplies in accordance with good medical practice.

Conclusion

The Amendment Rules are compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.