

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024

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

Subsections 41QB(1) to (3) of the Act establish offences and a civil penalty provision that prohibit the supply of vaping goods in Australia other than where the exceptions specified in section 41QB apply. These exceptions include the ‘retail supply chain exception’ in subsections 41QB(9), (10) and (11). This exception is designed to cover specified kinds of persons engaged in the legitimate supply of vaping goods to persons who are the ultimate consumers of the goods, for legitimate therapeutic purposes.

Relevantly, one of the elements of the retail supply chain exception is that the vaping goods are supplied to a person for smoking cessation, the management of nicotine dependence or another indication determined by the Minister under section 41RA of the Act.

The *Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024* (the Determination) is a legislative instrument made under section 41RA of the Act. It determines, for the purposes of paragraph 41QB(11)(a), indications, other than smoking cessation or management of nicotine dependence, for which a person may be supplied a vaping good. The effect of determining these indications is that the supply of a vaping good for a determined indication will, provided all other elements of the retail supply chain exception in subsections 41QB(9) to (11) apply, ensure that there will be no commission of an offence or contravention of a civil penalty in connection with that supply.

Background

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

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

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

The Government's vaping reforms are being implemented in stages over 2024. The *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms comprised amendments to *the Customs (Prohibited Imports) Regulations 1956*, *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002*. These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.
- since 1 March 2024, stronger regulatory controls have applied to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

The Amendment Act, commencing on 1 July 2024, implements the second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, manufacture, supply, commercial possession and advertisement of vaping goods in Australia unless certain requirements under the Act are met. Therapeutic vaping goods that meet regulatory requirements for therapeutic goods under the Act will continue to be available where clinically appropriate. The reforms align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the *National Tobacco Strategy 2023-2030*.

Purpose

The Determination is made under section 41RA of the Act. It determines, for the purposes of paragraph 41QB(11)(a), indications, other than smoking cessation or the management of nicotine dependence, for which persons may use vaping goods that are supplied under established pathways for lawfully accessing unapproved therapeutic goods under the Act.

In relation to vaping goods that are intended to be used in a clinical trial, the indications that are determined are as follows:

- for goods approved under paragraph 19(1)(b) or paragraph 41HB(1)(e) of the Act—the indications specified in the approval;
- for goods exempt under item 3 of Schedule 5A to the Regulations or item 2.3 in Part 2 of Schedule 4 to the MD Regulations—the indications set out in the notice, about the trial and the therapeutic goods covered by the trial, referred to in that item.

This has the effect that a vaping good of any kind can be supplied for use in clinical trials, for indications other than smoking cessation or the management of nicotine addiction, and remain eligible for the supply chain exceptions in subsections 41QB(9) to (11) of the Act.

In relation to medicinal cannabis vaping goods and in relation to vaping substances that are a medicinal cannabis product or a medicine that contains synthetic cannabis, the indications that are determined are as follows:

- for goods that are included in the Australian Register of Therapeutic Goods (the Register)—the indications that are accepted in relation to the inclusion of the goods in the Register;
- for goods that are approved under subsection 19(1)(a) or subsection 41HB(1)(d) of the Act—the indications specified in the approval;
- for goods that are authorised for supply under subsection 19(5) or subsection 41HC(1) of the Act—the indications or intended purposes specified in the authorisation;
- for goods authorised for supply under rules made under subsection 19(7A) or subsection 41HC(6) of the Act—the indications specified in the rules;
- for goods that are exempt under regulation 12A of the Regulations or under regulation 7.2 of the MD Regulations (these provisions exempt therapeutic goods supplied on prescription to a person who is a Category A patient, being a person who is seriously ill, in specified circumstances)—use in the treatment of the person’s condition as set out in the statement referred to in subparagraph 12A(2)(a)(iii) of the Regulations or subparagraph 7.2(1)(b)(ii) of the MD Regulations (as applicable).

The effect of determining the above indications is that the supply of the vaping goods in connection with vaping medicinal cannabis will satisfy the requirements of paragraph 41QB(11)(a) of the Act, and consequently the supply will be eligible to meet the requirements of the supply chain exception in section 41QB, where the supply is for the determined indications. This has the effect that medicinal cannabis goods that are vaping goods can continue to be supplied under the established statutory pathways for unapproved goods for indications other than smoking cessation or the management of nicotine addiction.

Consultation

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

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

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback received in connection with this consultation informed the development of the Amendment Act and related regulations and other legislative instruments, including the Determination. Further informal consultation, including

for instance with health practitioners, was also undertaken in late 2023 and in 2024, and has further informed the development of the reforms.

Other details

Details of the Determination are set out in **Attachment A**.

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

An impact analysis (IA) was prepared on the proposed reforms relating to the regulation of vapes, taking into account the feedback received from stakeholders throughout the consultations. The Office of Impact Analysis (OIA) determined that the IA was consistent with good practice and met Australian Government best practice regulation requirements (OBPR23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

The Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences at the same time as Parts 1 to 3 of Schedule 1 to the Amendment Act. However, the Determination does not commence at all if the Amendment Act does not commence.

Details of the *Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024* (the Determination).

Section 2 – Commencement

This section provides that the Determination commences at the same time as the substantive provisions (Parts 1 to 3 of Schedule 1) of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commence. However, the Determination does not commence at all if the Amendment Act does not commence. The Amendment Act received Royal Assent on 27 June 2024 and commences on 1 July 2024.

Section 3 – Authority

This section provides that the legislative authority for making the Determination is section 41RA of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Definitions

This section provides definitions for a number of terms used in the Determination. These include ‘Act’, ‘intended purpose’, ‘medicinal cannabis products’, ‘MD Regulations’ and ‘Regulations’.

The note in this section also makes it clear that a number of expressions used in the Determination have the same meaning as in the Act. These include ‘included in the Register’, ‘indications’, ‘medical device’, ‘medical practitioner’, ‘medicine’, ‘Register’, ‘registered goods’, ‘therapeutic goods’, ‘vaping device’, ‘vaping goods’, and ‘vaping substance’.

Section 5 – Other indications for which vaping goods may be used

This section provides that for the purposes of paragraph 41QB(11)(a) of the Act, in relation to each item of the table in Schedule 1, the indications in column 3 are determined to be indications, other than smoking cessation or management of nicotine dependence, for which the vaping goods in column 2 may be used.

Schedule 1 – Other indications for which vaping goods may be used

This Schedule determines other indications for which specified kinds of vaping goods may be used.

Item 1 of the table in Schedule 1 provides that a vaping good may be used for the following:

- for goods approved under paragraph 19(1)(b) of the Act—the indications specified in the approval;
- for a medical device approved under paragraph 41HB(1)(e) of the Act—the intended purposes specified in the approval;
- for goods exempt under item 3 of Schedule 5A to the Regulations—the indications set out in the notice that is given in accordance with that item;
- for medical devices exempt under item 2.3 in Part 2 of Schedule 4 to the MD Regulations—the intended purpose set out in the notice that is given in accordance with that item.

Item 2 of the table in Schedule 1 provides that a medicinal cannabis vaping good may be used for the following:

- for a medical device included in the Register—the intended purpose accepted in relation to the inclusion of the medical device in the Register;
- for a medical device approved under subsection 41HB(1)(d) of the Act—the intended purpose specified in the approval;
- for a medical device authorised for supply under subsection 41HC(1) of the Act—the intended purpose specified in the authorisation;
- for a medical device authorised for supply under rules made under subsection 41HC(6) of the Act—the purpose specified in the rules;
- for medical devices exempt under regulation 7.2 of the MD Regulations, in relation to a person who is a Category A patient as defined in regulation 7.2—the use of the device in relation to the treatment of the person’s condition, as set out in the statement referred to in subparagraph 7.2(1)(b)(ii) of the MD Regulations.

Item 3 of the table in Schedule 1 provides that a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis may be used for the following:

- for registered goods—the indications that are accepted in relation to the inclusion of the goods in the Australian Register of Therapeutic Goods (the Register);
- for goods approved under subsection 19(1)(a) of the Act—the indication specified in the approval;
- for goods authorised for supply under subsection 19(5) of the Act—the indications specified in the authorisation;
- for goods authorised for supply under rules made under subsection 19(7A) of the Act—the indications specified in the rules;
- for goods exempt under regulation 12A of the Regulations, in relation to a person who is a Category A patient as defined in regulation 12A—the use of the good in relation to the treatment of the person’s condition, as set out in the statement referred to in subparagraph 12A(2)(a)(iii) of the Regulations.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024

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

Overview of legislative instrument

Subsections 41QB(1) to (3) of the Act establish offences and a civil penalty provision that prohibit the supply of vaping goods in Australia other than where the exceptions specified in section 41QB apply. These exceptions include the ‘retail supply chain exception’ in subsections 41QB(9), (10) and (11). This exception is designed to cover specified kinds of persons engaged in the legitimate supply of vaping goods to persons who are the ultimate consumers of the goods, for legitimate therapeutic purposes.

Relevantly, one of the elements of the retail supply chain exception is that the vaping goods are supplied to a person for smoking cessation, the management of nicotine dependence or another indication determined by the Minister under section 41RA of the Act.

The *Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024* (the Determination) is a legislative instrument made under section 41RA of the Act. It determines, for the purposes of paragraph 41QB(11)(a), indications, other than smoking cessation or management of nicotine dependence, for which a person may be supplied a vaping good. The effect of determining these indications is that the supply of a vaping good for a determined indication will, provided all other elements of the retail supply chain exception in subsections 41QB(9) to (11) apply, ensure that there will be no commission of an offence or contravention of a civil penalty in connection with that supply.

Background

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

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

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

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- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.
- since 1 March 2024, stronger regulatory controls have applied to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

The Amendment Act, commencing on 1 July 2024, implements the second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, manufacture, supply, commercial possession and advertisement of vaping goods in Australia unless certain requirements under the Act are met. Therapeutic vaping goods that meet regulatory requirements for therapeutic goods under the Act will continue to be available where clinically appropriate. The reforms align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the *National Tobacco Strategy 2023-2030*.

Purpose

The Determination is made under section 41RA of the Act. It determines, for the purposes of paragraph 41QB(11)(a), indications, other than smoking cessation or the management of nicotine dependence, for which persons may use vaping goods that are supplied under established pathways for lawfully accessing unapproved therapeutic goods under the Act.

In relation to vaping goods that are intended to be used in a clinical trial, the indications that are determined are as follows:

- for goods approved under paragraph 19(1)(b) or paragraph 41HB(1)(e) of the Act—the indications specified in the approval;

- for goods exempt under item 3 of Schedule 5A to the Regulations or item 2.3 in Part 2 of Schedule 4 to the MD Regulations—the indications set out in the notice, about the trial and the therapeutic goods covered by the trial, referred to in that item.

This has the effect that a vaping good of any kind can be supplied for use in clinical trials, for indications other than smoking cessation or the management of nicotine addiction, and remain eligible for the supply chain exceptions in subsections 41QB(9) to (11) of the Act.

In relation to medicinal cannabis vaping goods and in relation to vaping substances that are a medicinal cannabis product or a medicine that contains synthetic cannabis, the indications that are determined are as follows:

- for goods that are included in the Australian Register of Therapeutic Goods (the Register)—the indications that are accepted in relation to the inclusion of the goods in the Register;
- for goods that are approved under subsection 19(1)(a) or subsection 41HB(1)(d) of the Act—the indications specified in the approval;
- for goods that are authorised for supply under subsection 19(5) or subsection 41HC(1) of the Act—the indications or intended purposes specified in the authorisation;
- for goods authorised for supply under rules made under subsection 19(7A) or subsection 41HC(6) of the Act—the indications specified in the rules;
- for goods that are exempt under regulation 12A of the Regulations or under regulation 7.2 of the MD Regulations (these provisions exempt therapeutic goods supplied on prescription to a person who is a Category A patient, being a person who is seriously ill, in specified circumstances)—use in the treatment of the person’s condition as set out in the statement referred to in subparagraph 12A(2)(a)(iii) of the Regulations or subparagraph 7.2(1)(b)(ii) of the MD Regulations (as applicable).

The effect of determining the above indications is that the supply of the vaping goods in connection with vaping medicinal cannabis will satisfy the requirements of paragraph 41QB(11)(a) of the Act, and consequently the supply will be eligible to meet the requirements of the supply chain exception in section 41QB, where the supply is for the determined indications. This has the effect that medicinal cannabis goods that are vaping goods can continue to be supplied under the established statutory pathways for unapproved goods for indications other than smoking cessation or the management of nicotine addiction.

Human rights implications

The Determination engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

Vaping has been associated with a range of short-term health risks and its long-term health effects are still unknown. Vape marketing and use in the community has increased rapidly in recent years, particularly among youth and young adults and poses a major risk to population health and Australia’s success in tobacco control.

The reforms to the regulation of vapes support the availability of therapeutic vaping goods to persons who require such goods for smoking cessation or the management of nicotine dependence under the supervision of a health practitioner, and ensure the application of minimum quality and safety standards to vaping goods.

Collectively, the reforms are intended to arrest the increasing uptake of recreational vaping, especially by youth and young adults, and to strike an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to Australians combating smoking addiction or nicotine dependence. Ensuring vapes are only accessed under health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The Determination takes positive steps to promote the right to health by supporting the vaping and by ensuring that vaping goods can be lawfully supplied to persons, as part of a retail supply chain exception from offences and a civil penalty that may otherwise apply for supplying such goods, for determined indications. In particular, the Determination ensures that vaping goods used in connection with the inhalation of medicinal cannabis can continue to be supplied under established pathways that apply under the Act for accessing unapproved goods where clinically appropriate, and that clinical research into any vaping goods is not precluded by the controls in Chapter 4A of the Act.

Conclusion

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