EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods—Advertising) Authorisation 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).

Chapter 4A of the Act sets out the regulatory framework for vaping goods that are imported into, manufactured and supplied in Australia. Subsection 41P of the Act provides that the term 'vaping goods' means goods that are, or are presented in such a way as to represent that they are, vaping substances, vaping accessories or vaping devices, as well as goods determined by the Minister to be vaping goods.

Subsection 42DZC(1) of the Act provides that the Secretary may, by legislative instrument, authorise the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods. Subsection 42DZC(4) provides that an authorisation under this section may be subject to conditions specified in the instrument. Subsection 42DZC(5) provides that, without limiting subsection (4), conditions in an authorisation of advertising may relate to any of the following:

- the nature of the audience to which the advertising is targeted;
- the form of the advertising;
- the content of the advertising;
- representations or information on:
  - the labels of specified vaping goods or a specified class of vaping goods; or
  - the packages in which specified vaping goods or a specified class of vaping goods are contained; or
  - any material included with the package in which specified vaping goods or a specified class of vaping goods are contained.

Relevantly, subsection 3(1) of the Act provides that advertise, in relation to therapeutic goods or vaping goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design is on the label of the goods, the package in which the goods are contained, or on any material included with the package in which the goods are contained.

Importantly, a person who advertises, or causes the advertising of vaping goods that are not covered by an authorisation under section 42DZC, or despite having an authorisation, the advertising does not comply with requirements or conditions specified in the authorisation, may be committing an offence or contravening a civil penalty provision in sections 42DZD and 42DZE of the Act.

The *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024* (the Authorisation) is made under section 42DZC of the Act. The Authorisation authorises the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods for the purposes of the advertising of such goods or classes of goods in appropriate circumstances and subject to conditions.

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

Under Part 4A of the Act, the advertising of vaping goods is prohibited to protect consumers, including vulnerable audiences such as youth and young adults, from the unethical and overtly promotional advertising of vaping goods. This prohibition reflects the health risks associated with vaping, and the significant increase in the uptake of vaping, particularly by young people, in the last few years. However, there may be some legitimate circumstances where controlled advertising may be appropriate, including for example, advertising directed exclusively to a medical practitioner that relates to the safe and effective use of the goods, and advertising that is on the label of a vaping good.

Advertising is also an essential component of the supply chain for vaping goods. It enables relevant persons within the supply chain to communicate necessary information about the price, availability, and characteristics of the goods. The ability to share such information within the lawful supply chain is critical to ensure that each person within the supply chain may make informed decisions about the types of goods to be stocked, and ultimately supplied to the patient.

The Authorisation made under section 42DZC of the Act, authorises the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods, subject to specified conditions. The purpose of the Authorisation is to authorise the advertising of vaping goods in certain limited circumstances, and subject to strict controls, to support the provision of information relating to the price, availability, safety and effective use of the vaping goods that are supplied in the lawful supply chain.

The Authorisation does this by authorising advertising of notified vaping goods in relation to the following kinds of advertising:

- advertising that is on the label of notified vaping goods, on the package in which notified vaping goods are contained and on any material included with the package in which notified vaping goods are contained;
- advertising that is directed exclusively to a medical practitioner, a nurse practitioner, a pharmacist or a practice manager or purchasing officer for such persons;
- advertising that is directed exclusively to and between persons engaged in the business of wholesale supply and retail supply of notified vaping goods;
- advertising that is advice or information given directly to a patient by a medical practitioner, nurse practitioner or pharmacist, in relation to the treatment of that patient for smoking cessation or the management of nicotine dependence.

The Authorisation also authorises advertising that is, or forms part of a Commonwealth or State health campaign in relation to vaping goods generally.

Relevantly, 'notified vaping goods' is defined in the Authorisation to mean one or more vaping goods that are exempt under item 15 in the table in Schedule 5A to the TG Regulations or item 2.17 in the table in Schedule 4 to the MD Regulations, in relation to which the sponsor has given a sponsor notice; and is not the subject of determination by the Secretary, published on the Department's website, that the supply of the goods should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not apply with a standard applicable to the goods.

The Authorisation also authorises advertising of medicinal cannabis vaping goods. Medicinal cannabis vaping goods are defined in subsection 4(1) to mean one or more therapeutic cannabis vaping goods as defined in the MD Regulations or vaping substances that are a medicinal cannabis

product or a medicine that contains synthetic cannabis. The following advertising is authorised in relation to medicinal cannabis vaping goods:

- advertising that is on the label of the medical cannabis vaping goods, on the package in which the medicinal cannabis vaping goods are contained and on any material included with the package in which the medicinal cannabis vaping goods are contained;
- advertising that is directed exclusively to persons mentioned in subsections 42AA(1) and (2) of the Act;
- advertising that is advice or information given directly to a patient by a person mentioned in paragraphs 42AA(1)(a) and (aa) or subsection 42AA(2) of the Act in the course of treatment of that patient.

In addition, the Authorisation allows for the advertising of vaping goods generally that is, or forms part of, one or more Commonwealth, State or Territory health campaign. These campaigns are defined in subsection 4(1) of the Authorisation to mean those conducted, funded or approved by a Commonwealth, or State or Territory government.

Each of the authorised advertisements concerning notified vaping goods and medicinal cannabis vaping goods are subject to conditions that are specified in the Authorisation. These conditions are intended to limit the kinds of information that may be included in the advertising and the form in which the advertising may be published or disseminated.

The effect of the Authorisation is to enable legitimate advertising of vaping goods to ensure that information relating to the safe and appropriate use of the goods may be communicated through the lawful supply chain and to the ultimate consumer.

Incorporation by reference

The Authorisation incorporates by reference, the following legislative instruments:

- *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*, which sets out minimum safety and performance requirements for certain vaping devices.

- *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*, which specifies requirements for the quality and safety of medicinal cannabis products.

- *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, which specifies requirements for the quality and safety of therapeutic vaping goods.

- *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*, which specifies requirements relating to the advertising of therapeutic goods.

Each of these documents are incorporated as in force from time to time, in accordance with paragraph 14(1)(a) of the *Legislation Act 2003* (the Legislation Act). These instruments are freely available on the Federal Register of Legislation at www.legislation.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 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. The Working Group had several meetings in 2024, which provided a forum in the consultation and discussion of various matters that form of the national vaping reform, including enforcement.

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 Authorisation. 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.

On 17 May 2024, a third, targeted consultation was conducted through the membership of the TGA Consultative Committee, a permanent non-statutory consultation forum with industry professional and consumer bodies involved in the manufacture, use and consumption of therapeutic goods. Feedback recommending restrictions on the advertising of vaping goods to health professionals was received from bodies representing those professionals.

The Senate Community Affairs and Legislation Standing Committee inquiry into the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, received submissions from various stakeholders, which included suggestions to restrict the advertising of vaping goods. These submissions informed the drafting of the Authorisation.

Other details

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

The Authorisation 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 Authorisation 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 commences. However, the Authorisation does not commence at all if the Amendment Act does not commence.

ATTACHMENT A

Details of the *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024* (the Authorisation).

Section 2 – Commencement

This section provides that the Authorisation commences at the same time as Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commences. However, the Authorisation 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 Authorisation is section 42DZC of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Definitions

This section provides the definitions of key terms used in the Authorisation, including 'Commonwealth health campaign', 'medicinal cannabis product', 'medicinal cannabis vaping goods', 'notification ID number', 'notified vaping goods', 'prohibited representation' 'restricted representation', 'sponsor notice', 'State health campaign' and 'therapeutic cannabis vaping good'.

This section also notes that a number of terms used in the Authorisation, including 'advertise', 'essential principles', 'indications', 'label', 'medical practitioner', 'nurse practitioner', 'pharmacist', 'sponsor', State', 'therapeutic goods', 'Therapeutic Goods Advertising Code', 'vaping goods' and 'vaping substance' are defined in subsection 3(1) of the Act, and therefore have the same meaning as in the Act.

Section 5 - Authorisation

This section provides that, for section 42DZC of the Act, in relation to each item in the tables in Parts 1 and 2 of Schedule 1, the advertising, or class of advertising specified in column 2, of vaping goods specified in column 3 are authorised, subject to the conditions (if any) specified in column 4.

Schedule 1 – Authorisation

Schedule 1 contains two parts:

- Part 1 specifies, for the purposes of section 5 of the Authorisation, the advertising of notified vaping goods that is authorised, and the conditions that apply to such authorisation; and
- Part 2 specifies, for the purposes of section 5 of the Authorisation, the advertising of medicinal cannabis vaping goods that is authorised, and the conditions that apply to such authorisation.

Relevantly, the term 'notified vaping goods' is defined in the Authorisation to mean one or more vaping goods that are exempt under item 15 in the table in Schedule 5A to the TG Regulations or item 2.17 in the table in Schedule 4 to the MD Regulations, in relation to which the sponsor has given a sponsor notice; and not the subject of determination by the Secretary, published on the Department's website, that the supply of the goods should cease because the Secretary is satisfied that the supply of

the goods compromises public health and safety or the goods do not apply with a standard applicable to the goods.

The advertising of notified vaping goods that is authorised in the items in the table in Part 1 of Schedule 1 is as follows:

- advertising that is:
  - on the label of the notified vaping goods; or
  - on the package in which the notified vaping goods are contained; or
  - on any material included with the package in which the notified vaping goods are contained;
- advertising that is directed exclusively to one or more of the following persons:
  - a medical practitioner;
  - a nurse practitioner;
  - a pharmacist; or
  - a practice manager or purchasing officer of a medical practitioner, a nurse practitioner or a pharmacist;
- advertising directed exclusively to and between persons who are engaged in the business of wholesale supply and retails supply of the notified vaping goods in accordance with:
  paragraph (h) of item 15 of Schedule 5A to the TG Regulations; or
  paragraph (g) of item 2.17 of Schedule 4 to the MD Regulations.
- advertising that is advice or information given directly to a patient, by one or more of the following persons, in the course of the treatment of the patient for smoking cessation or the management of nicotine dependence:
  - a medical practitioner;
  - a nurse practitioner; or
  - a pharmacist.

Part 1 also authorises advertising that is, or forms part of a Commonwealth or State health campaign for vaping goods generally.

The authorisation of the above advertising is subject to relevant conditions as specified in column 4. For example, the conditions applying the advertising of notified vaping goods include that the advertising must:

- only contain representations or information relating to one or more of the following:
  - the availability and price of the vaping goods;
  - information necessary for the safe and effective use of the vaping goods;
  - information about the vaping goods, including the indications or intended purposes, ingredients, formulation, composition, design specification or presentation;
- comply with the requirements for therapeutic goods specified in Part 3 of the Therapeutic Goods Advertising Code, as if that Part applied to the vaping goods;
- not contain a prohibited representation or restricted representation, as if one or more of those representations applied to the vaping goods; and
- not contain endorsements or testimonials about vaping goods.

These conditions are intended to limit the kinds of information that may be included in the advertising and the form in which the advertising may be published or disseminated. These limitations are critical to ensuring that advertising of vaping goods is appropriate, and only contains accurate information about the goods necessary to support their safe and effective use.

The term 'medicinal cannabis vaping goods' is defined in section 4 of the Authorisation to mean one or more therapeutic cannabis vaping goods or vaping substances that are a medicinal cannabis product or a medicine that contains synthetic cannabis. Therapeutic cannabis vaping good is defined in the MD Regulations and means a therapeutic cannabis vaping device or a therapeutic cannabis vaping device accessory.

The advertising of medicinal cannabis vaping goods authorised in the items in the table in Part 2 of Schedule 1 is limited to:

- advertising that is:
    - on the label of the medicinal cannabis vaping good; or
    - on the package in which the medicinal cannabis vaping goods are contained; or
    - on any material included with the package in which the medicinal cannabis vaping goods are contained;
- advertising that is directed exclusively to one or more persons mentioned in subsections 42AA(1) or (2) of the Act; and
- advertising that is advice or information given directly to a patient, by a person mentioned in paragraphs 42AA(1)(a) and (aa), or subsection 42AA(2) of the Act in the course of treatment of that patient.

Advertising that is on the label of the medicinal cannabis vaping goods, the package in which the goods are contained and any material included with such a package is subject to conditions specified in that item.

Authorising the above types of advertising is intended to reflect the status quo that applied to the advertising of medicinal cannabis vaping goods prior to the amendments made by the Amendment Act.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Vaping Goods—Advertising) Authorisation 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 the legislative instrument

Chapter 4A of the Act sets out the regulatory framework for vaping goods that are imported into, manufactured and supplied in Australia. Subsection 41P of the Act provides that the term 'vaping goods' means goods that are, or are presented in such a way as to represent that they are, vaping substances, vaping accessories or vaping devices, as well as goods determined by the Minister to be vaping goods.

Subsection 42DZC(1) of the Act provides that the Secretary may, by legislative instrument, authorise the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods. Subsection 42DZC(4) provides that an authorisation under this section may be subject to conditions specified in the instrument. Subsection 42DZC(5) provides that without limiting subsection (4), conditions in an authorisation of advertising may relate to any of the following:

- the nature of the audience to which the advertising is targeted;
- the form of the advertising;
- the content of the advertising;
- representations or information on:
  - the labels of specified vaping goods or a specified class of vaping goods; or
  - the packages in which specified vaping goods or a specified class of vaping goods are contained; or
  - any material included with the package in which specified vaping goods or a specified class of vaping goods are contained.

Relevantly, subsection 3(1) of the Act provides that advertise, in relation to therapeutic goods or vaping goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design is on the label of the goods, the package in which the goods are contained, or on any material included with the package in which the goods are contained.

Importantly, a person who advertises, or causes the advertising of vaping goods that are not covered by an authorisation under section 42DZC, or despite having an authorisation, the advertising does not comply with requirements or conditions specified in the authorisation, may be committing an offence or contravening civil penalty provision in sections 42DZD and 42DZE of the Act.

The *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024* (the Authorisation) is made under section 42DZC of the Act. The Authorisation authorises the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods for the purposes of the advertising of such goods or classes of goods in appropriate circumstances and subject to conditions.

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

Under Part 4A of the Act, the advertising of vaping goods is prohibited to protect consumers, including vulnerable audiences such as youth and young adults, from the unethical and overtly promotional advertising of vaping goods. This prohibition reflects the health risks associated with vaping, and the significant increase in the uptake of vaping, particularly by young people, in the last few years. However, there may be some legitimate circumstances where controlled advertising may be appropriate, including for example, advertising directed exclusively to a medical practitioner that relates to the safe and effective use of the goods, and advertising that is on the label of a vaping good.

Advertising is also an essential component of the supply chain for vaping goods. It enables relevant persons within the supply chain to communicate necessary information about the price, availability and characteristics of the goods. The ability to share such information within the lawful supply chain is critical to ensure that each person within the supply chain may make informed decisions about the types of goods to be stocked, and ultimately supplied to the patient.

The Authorisation made under section 42DZC of the Act, authorises the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods, subject to specified conditions. The purpose of the Authorisation is to authorise the advertising of vaping goods in certain limited circumstances, and subject to strict controls, to support the provision of information relating to the price, availability, safety and effective use of the vaping goods that are supplied in the lawful supply chain.

The Authorisation does this by authorising advertising of notified vaping goods in relation to the following kinds of advertising:

- advertising that is on the label of notified vaping goods, on the package in which notified vaping goods are contained and on any material included with the package in which notified vaping goods are contained;
- advertising that is directed exclusively to a medical practitioner, a nurse practitioner, a pharmacist or a practice manager or purchasing officer for such persons;
- advertising directed exclusively to and between persons engaged in the business of wholesale supply and retail supply of notified vaping goods;
- advertising that is advice or information given directly to a patient by a medical practitioner, nurse practitioner or pharmacist, in relation to the treatment of that patient for smoking cessation or the management of nicotine dependence.

The Authorisation also authorises advertising that is, or forms part of a Commonwealth or State health campaign in relation to vaping goods generally.

Relevantly, 'notified vaping goods' is defined in the Authorisation to mean one or more vaping goods that are exempt under item 15 in the table in Schedule 5A to the TG Regulations or item 2.17 in the table in Schedule 4 to the MD Regulations, in relation to which the sponsor has given a sponsor notice; and is not the subject of determination by the Secretary, published on the Department's website, that the supply of the goods should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not apply with a standard applicable to the goods.

The Authorisation also authorises advertising of medicinal cannabis vaping goods. A medicinal cannabis vaping good is defined in subsection 4(1) to mean a therapeutic cannabis vaping good as defined in the MD Regulations or a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis. The following advertising is authorised in relation to medicinal cannabis vaping goods:

- advertising that is on the label of the medical cannabis vaping goods, on the package in which the medical cannabis vaping goods are contained and on any material included with the package in which the medical cannabis vaping goods are contained;
- advertising that is directed exclusively to persons mentioned in subsections 42AA(1) and (2) of the Act;
- advertising that is advice or information given directly to a patient by a person mentioned in paragraphs 42AA(1)(a) and (aa) or subsection 42AA(2) of the Act in the course of treatment of that patient.

In addition, the Authorisation allows for the advertising of vaping goods generally that is, or forms part of, one or more Commonwealth, State or Territory health campaign. These campaigns are defined in subsection 4(1) of the Authorisation to mean those conducted, funded or approved by a Commonwealth, or State or Territory government.

Each of the authorised advertisements concerning notified vaping goods and medicinal cannabis vaping goods are subject to conditions that are specified in the Authorisation. These conditions are intended to limit the kinds of information that may be included in the advertising and the form in which the advertising may be published or disseminated.

The effect of the Authorisation is to enable legitimate advertising of vaping goods to ensure that information relating to the safe and appropriate use of the goods may be communicated through the lawful supply chain and to the ultimate consumer.

Human rights implications

The Authorisation engages two human rights and freedoms recognised in the instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, the right to freedom of opinion and expression and the right to health.

Right to freedom of opinion and expression

The Authorisation contains conditions that seek to limit the audience to whom vaping goods may be advertised and the form and content of such advertising. In doing so, the Authorisation engages the right to freedom of opinion and expression in Article 19 of the International Convention on Civil and Political Rights (the ICCPR). Article 19(2) provides that everyone shall have the right to freedom of expression, including the right to seek, receive and impart information orally or through a range of media.

Article 19(3) provides that the exercise of these rights may be subject to restrictions as are provided by law and are necessary for (among other things) the protection of public health. The Human Rights Committee of the United Nations has expressed the view that for a limitation to be 'necessary' imposes a burden of justification on government agencies to demonstrate that any restrictive measures are proportionate.

The restrictions on the form and content of the advertising of notified vaping goods, and the limitations on the persons to whom such advertising may be directed, are necessary to arrest the uptake of vaping, particularly by young people, and to protect public health. The Authorisation seeks to ensure that advertising contains only information necessary to support the safe and effective use of

vaping goods where those goods are necessary for the therapeutic use by a person. As such, any limitation on the right to freedom of expression is necessary to protect public health, and are proportionate in the circumstances.

Right to health

The Authorisation also 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 standard 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 Authorisation takes positive steps to promote the right to health by supporting the reforms to the regulation of vapes. The Authorisation enables legitimate advertising of notified vaping goods and medicinal cannabis vaping goods in specified, confined, circumstances, to support the lawful movement of therapeutic vaping goods through the lawful supply chain and to ensure that health professionals and patients may receive appropriate information that is necessary for the safe and effective use of the goods and to make appropriate clinical decisions.

Conclusion

The Authorisation is compatible with human rights because it engages the right to freedom of opinion and expression and falls within the exemption set out in Article 19(3) of the ICCPR, promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.