

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 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).

Section 61 of the Act provides that the Secretary may release to the public, and to certain organisations, bodies, or authorities, specified kinds of therapeutic goods information and vaping goods information. Relevantly, subsection 61(1) of the Act defines, for the purpose of section 61:

- ‘therapeutic goods information’ as information in relation to therapeutic goods that is held by the Department and relates to the performance of the Department’s functions; and
- ‘vaping goods information’ as information in relation to vaping goods that is held by the Department and relates to the performance of the Department’s functions.

Under subsection 61(5AA) of the Act, the Secretary may release specified therapeutic goods information, for a specified purpose, to a person, body or authority that is, or is of a kind, specified under subsection 61(5AB) of the Act. Subsection 61(5AB) provides that, for the purpose of subsection 61(5AA), the Minister may, by legislative instrument, specify one or more kinds of persons, bodies or authorities (or a person, body or authority), kinds of therapeutic goods information and purposes.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

Subsection 61(7A) provides that the Secretary may release vaping goods information of a kind specified under subsection 61(7B) to persons, bodies or authorities that are (or are of a kind) also specified under that subsection, for a purpose or purposes specified under that subsection. Subsection 61(7B) provides that, for the purpose of subsection 61(7A), the Minister may, by legislative instrument, specify one or more kinds of persons bodies or authorities (or a person, body or authority), kinds of vaping goods information and purposes.

Under subsection 61(7C) of the Act, the Secretary may release to the public vaping goods information of a kind specified under subsection 61(7D). Subsection 61(7D) provides that the Minister may, by legislative instrument, specify kinds of vaping goods information for the purpose of subsection 61(7C).

The *Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 2024* (the Instrument) is a legislative instrument made under subsections 61(5AB), (5D), (7B) and (7D) of the Act.

The Instrument specifies, for the purposes of subsections 61(5AA) and (7A) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may

release to specified persons, bodies or authorities, and the purpose for which that information may be released. The persons, bodies and authorities specified in the Instrument include Commonwealth or State departments; departments or administrative units of the Public Service of a Territory; and Commonwealth, state or territory authorities, with functions relating to therapeutic goods, vaping goods, health, revenue or law enforcement.

Under subsection 61(5AB), the Instrument specifies that therapeutic goods information relating to one or more therapeutic vaping goods, therapeutic vaping kits, goods in a therapeutic vaping pack and therapeutic cannabis vaping goods may be released. The Instrument provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under subsection 61(7B), the Instrument specifies that vaping goods information relating to one or more vaping goods may be released. The Instrument similarly provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under both provisions, the Instrument authorises release to those persons, bodies and authorities for the purpose of supporting compliance and enforcement activities relating to the importation, exportation, manufacture, supply, possession or advertising of the relevant kinds of goods.

The Instrument also specifies, for the purposes of subsections 61(5C) and (7C) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to the public. These include, among other things, information about black market vaping goods and therapeutic vaping goods, which are suspected of having been unlawfully supplied, to protect the consumers and the broader public from unsafe goods.

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 Instrument is made under subsections 61(5AB), (5D), (7B) and (7D) of the Act. It specifies, for the purposes of subsections 61(5AA) and (7A) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to specified persons, bodies or authorities, and the purpose for which that information may be released. The Instrument also specifies, for the purposes of subsections 61(5C) and (7C) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to the public under subsections 61(5D) and 61(7D) of the Act, respectively.

The Instrument provides, for the purposes of subsections 61(5AA) and (7A) of the Act, the persons, bodies and authorities to whom information may be released include Commonwealth or State departments; departments or administrative units of the Public Service of a Territory; and Commonwealth, state or territory authorities, with functions relating to therapeutic goods, vaping goods, health, revenue or law enforcement.

Under subsection 61(5AB), the Instrument specifies that therapeutic goods information relating to one or more therapeutic vaping goods, therapeutic vaping kits, goods in a therapeutic vaping pack and therapeutic cannabis vaping goods may be released. The Instrument provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under subsection 61(7B), the Instrument specifies that vaping goods information relating to one or more vaping goods may be released. The Instrument similarly provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under both provisions, the Instrument authorises release to those persons, bodies and authorities for the purpose of supporting compliance and enforcement activities relating to the importation, exportation manufacture, supply, possession or advertising of the relevant kinds of goods.

Release of the specified kinds of therapeutic goods information and vaping goods information to these bodies or authorities is necessary and critical to address the growing public health problem associated with vaping. The bodies and authorities that are, or are of a kind, specified in the Instrument play a pivotal role in the application and enforcement of the Government's vaping reforms.

For example, the ATO is responsible for investigating money laundering that may be associated with the supply of unlawful vaping goods, and otherwise enforcing tobacco excises that may be applicable to goods to which the Instrument applies. Additionally, the Australian Border Force is responsible for seizing unlawful vaping goods at the border, and officers of state and territory authorities with functions relating to therapeutic goods, health, revenue or law enforcement are empowered to carry out enforcement powers under the vaping reforms.

The Instrument also authorises the release of certain therapeutic goods information and vaping goods information to the public. The publication of information relating to therapeutic vaping goods and other vaping goods is critical to ensure that Australians (including consumers, patients, pharmacists and health practitioners) are aware of information about, for example, the safety, quality, efficacy or performance of lawfully supplied or acquired therapeutic vaping goods, and safety risks or enforcement activities related to unlawful vaping goods.

This Instrument enables the release of a wide range of information relating to therapeutic vaping goods and other vaping goods consistent with the *Privacy Act 1988*. This may include, for example:

- providing safety alerts to the public about the dangers associated with the use of particular vaping goods (for example, the contamination of vaping goods with high levels of toxic substances) to ensure that users are informed about such risks and are able to take steps to avoid a threat to their health by not using products for which such alerts are made;
- informing Commonwealth, state and territory health authorities or law enforcement bodies about vaping goods, which have been, or are suspected of having been, imported, manufactured or supplied in contravention of the Act; or
- informing the public about decisions or actions taken under the Act or its regulations in relation to vaping goods, such as information about enforcement action taken against the suppliers of prohibited vaping goods.

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

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

An impact analysis (IA) was prepared on the proposed reforms relating to the regulation of vapes, taking into account the feedback received from stakeholders throughout the consultations. (OBPR23-03933). The IA has been published on the OIA website at: oia.pmc.gov.au/.

The Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences at the same time as Parts 5 to 11 of the Amendment Act commence. However, the Instrument does not commence at all if the Amendment Act does not commence.

Details of the *Therapeutic Goods (Information Specification— Therapeutic Vaping Goods and Vaping Goods) Instrument 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 2024* (the Instrument).

Section 2 – Commencement

This section provides that the Instrument commences at the same time as Parts 5 to 11 of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) commence. However, the Instrument 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 Instrument is subsections 61(5AB), (5D), (7B) and (7D) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Definitions

This section provides definitions for several terms used in the Instrument. These include ‘relevant therapeutic vaping good’, ‘therapeutic goods information’, ‘vaping goods information’.

The definition of ‘authority’ is intended to cover a very broad range of government authorities across the Commonwealth, States and Territories, including ‘Commonwealth authorities’ as defined in subsection 3(1) of the Act, Departments of State, administrative units, and authorities (including local councils), which have functions relating to vaping goods, therapeutic goods, health, revenue or law enforcement. Those functions may be on a statutory, executive or other basis. Additionally, the words ‘relating to’ are intended to have wide operation and encompass functions that have an indirect, but relevant, connection with the specified matters. For example, functions relating to therapeutic goods is intended to extend to the provision of those goods to those providing services in the public health system.

This section also notes that a number of terms used in the Instrument have the meaning given in subsection 3(1) of the Act, including ‘advertise’, ‘Commonwealth authority’, ‘corresponding State law’, ‘Secretary’, ‘supply’, ‘therapeutic goods’ and ‘vaping goods’.

Subsections 4(2) and (3) supplement the definitions in the Instrument by providing that references to the terms ‘testing’ and ‘sample’ in this Instrument are to be construed broadly.

Section 5 — Release of therapeutic goods information

Subsection (1) of this section provides that, for the purposes of subsection 61(5AA) of the Act, in relation to each item in the table in Schedule 1 to the Instrument, the kinds of therapeutic goods

information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Subsection (2) of this section provides that, for the purpose of subsection 61(5C) of the Act, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 2 to the Instrument may be released to the public.

Section 6 – Release of vaping goods information

Subsection (1) of this section provides that for the purposes of subsection 61(7A) of the Act, in relation to each item in the table in Schedule 3 to the Instrument, the kinds of vaping goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Subsection (2) of this section provides that, for the purpose of subsection 61(7C) of the Act, the kinds of vaping goods information specified in column 2 of the table in Schedule 4 to the Instrument may be released to the public.

Section 7 – Repeals

This section provides that each instrument that is specified in Schedule 5 to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Instrument has effect according to its terms. In effect, the *Therapeutic Goods (Information Specification— Therapeutic Vaping Goods and Vaping Devices) Instrument 2023* is repealed.

Schedule 1—Release of therapeutic goods information to a person, body or authority

For subsection 5(1) of the Instrument, this Schedule specifies kinds of therapeutic goods information, the persons, bodies and authorities to whom that information may be released, and purposes for which the information may be released.

Item 1 of the table in Schedule 1 specifies:

- in column 2, the information that may be released by the Secretary is information about one or more relevant therapeutic vaping goods, including but not limited to the following—
 - particulars of the relevant therapeutic vaping good, including strength, formulation, composition, design specification or presentation;
 - information about the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the relevant therapeutic vaping good, including information about the identity or conduct of:
 - the sponsor, wholesaler, supplier, advertiser or possessor of the relevant therapeutic vaping good;
 - persons involved, or apparently involved, in the actual, attempted, suspected or proposed importation, exportation, manufacture, advertising, possession or supply of the relevant therapeutic vaping good;
 - information about compliance with requirements under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law, including (but not limited to) information relating to the following:
 - any relevant exemption, consent, authority, approval, permit, permission, licence, determination or other authorisation (a relevant authorisation);
 - any information held by the Department relating to a relevant authorisation;

- compliance with customs legislation;
- any decision or action taken under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law in relation to a relevant therapeutic vaping good, including (but not limited to) the following:
 - surveillance, search, seizure, forfeiture, destruction or recall of a relevant therapeutic vaping good;
 - the commencement, progress or result of a civil penalty proceeding, a criminal prosecution or a proceeding seeking an injunction in relation to any act or omission related to a relevant therapeutic vaping good;
- information about testing, and the corresponding results, of a sample of a relevant therapeutic vaping good;
- information about an ingredient, component, reagent, material or other article that is intended to be or is suspected of being used in the manufacture of a relevant therapeutic vaping good; and
- in column 3, the persons, bodies or authorities to whom the specified therapeutic goods information may be released is an authority, which is defined in subsection 4(1) of the Instrument; and
- in column 4, the purposes for which the Secretary may release the specified therapeutic goods information to the specified recipients is to support cooperation, and to otherwise seek or provide assistance, in monitoring, compliance and enforcement activities under Commonwealth, State or Territory law relating to the importation, manufacture, supply, possession or advertising of the relevant therapeutic vaping goods.

Schedule 2—Release of therapeutic goods information to the public

This Schedule specifies, for the purpose of subsection 5(2) of the Instrument, the kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5D) of the Act.

Item 1 of the table in Schedule 2 specifies information relating to one or more relevant therapeutic vaping goods, that are the subject of an exemption, consent, authority, approval, licence, determination or other authorisation under the Act and any instrument made under the Act or customs legislation. This information includes:

- details of a relevant therapeutic vaping good, or a sample of the good, including strength, formulation, composition, design, specification or presentation;
- details of the sponsor, supplier or advertiser of a relevant therapeutic vaping good;
- the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a relevant therapeutic vaping good, or the withdrawal of a relevant therapeutic vaping good from supply in Australia;
- any information held by the Department relating to an authorisation or application for a relevant authorisation relating to a relevant therapeutic vaping good;
- compliance with requirements under the Act and any instruments made under the Act, including the details of any review undertaken by the Department in relation to the compliance of a relevant therapeutic vaping good with these requirements;
- information relating to an adverse event which is, or may be associated with, the use of a relevant therapeutic vaping good;
- information relating to testing, and the results of testing, of a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including information relating to the quality, safety or efficacy of the good;
- information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, including safety alerts or recall actions about

actual or potential dangers or health risks associated with the use of a relevant therapeutic vaping good;

- the safe use of a relevant therapeutic vaping good;
- information relating to the appropriate disposal of a relevant therapeutic vaping good;
- information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being used in the manufacture of a relevant therapeutic vaping good.

Item 2 of the table in Schedule 2 specifies information relating to one or more relevant therapeutic vaping goods that are or have been, or are suspected of being or having been, imported into, exported from, manufactured or supplied in, Australia, including (but not limited to) the following:

- details about a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including strength, formulation, composition, design specification or presentation;
- details of the actual or apparent sponsor, supplier or advertiser of a relevant therapeutic vaping good;
- the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a relevant therapeutic vaping good, including details about the location and premises where the relevant therapeutic vaping goods have been supplied, stored or otherwise dealt with;
- information relating to an adverse event which is, or may be associated with, the use of a relevant therapeutic vaping good;
- information relating to testing, and the results of testing, of a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including information relating to the quality, safety or efficacy of the good;
- information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, or patient safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a relevant therapeutic vaping good;
- information relating to the appropriate disposal of a relevant therapeutic vaping good;
- information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a relevant therapeutic vaping good.

Schedule 3 – Release of vaping goods information to a person, body or authority

For subsection 6(1) of the Instrument, this Schedule specifies kinds of vaping goods information, the persons, bodies and authorities to whom that information may be released, and purposes for which the information may be released.

Item 1 of the table in Schedule 3 specifies:

- in column 2, the information that may be released by the Secretary is information about one or more vaping goods, including but not limited to the following—
 - particulars of the vaping good, including strength, formulation, composition, design specification or presentation;
 - information about the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the vaping good, including information about the identity or conduct of:
 - the sponsor, wholesaler, supplier, advertiser or possessor of the vaping good;
 - persons involved, or apparently involved, in the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the vaping good;

- information about compliance with requirements under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law, including (but not limited to) information relating to the following:
 - o any relevant exemption, consent, authority, approval, permit, permission, licence, determination or other authorisation (a relevant authorisation);
 - o any information held by the Department relating to a relevant authorisation;
 - o compliance with customs legislation;
- any decision or action taken under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law in relation to a vaping good;
- monitoring, compliance or enforcement activity conducted, or proposed to be conducted, in relation to a vaping good, including (but not limited to) the following:
 - o surveillance, search, seizure, forfeiture, destruction or recall of a vaping good;
 - o the commencement, progress or result of a civil penalty proceeding, a criminal prosecution seeking an injunction in relation to any act or omission related to a vaping good;
- information about testing, and the corresponding results, of a sample of a vaping good;
- information about an ingredient, component, reagent, material or other article that is intended to be or is suspected of being used in the manufacture of a vaping good.
- in column 3, the persons, bodies or authorities to whom the specified vaping goods information may be released is an authority, which is defined in subsection 4(1) of the Instrument; and
- in column 4, the purposes for which the Secretary may release the specified vaping goods information to the specified recipients is to support cooperation, and otherwise to seek or provide assistance, in monitoring, compliance and enforcement activities under Commonwealth, State or Territory law relating to the importation, manufacture, supply, possession, or advertising of vaping goods.

Schedule 4 – Release of vaping goods information to the public

This Schedule specifies, for the purpose of subsection 6(2) of the Instrument, the kinds of vaping goods information that the Secretary may release to the public under subsection 61(7B) of the Act.

Item 1 of the table in Schedule 4 specifies information relating to one or more vaping goods that are the subject of an exemption, consent, authority, approval, licence, determination or a relevant authorisation under the Act and any instrument made under the Act or the customs legislation. This information includes:

- details of a vaping good, or a sample of a vaping good, including strength, formulation, composition, design, specification or presentation;
- details of the sponsor, supplier or advertiser of a vaping good;
- the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a vaping good, or the withdrawal of a vaping good from supply in Australia;
- any information held by the Department relating to an authorisation or application for a relevant authorisation relating to a vaping good;
- compliance with requirements under the Act and any instruments made under the Act, including the details of any review undertaken by the Department in relation to the compliance of a vaping good with these requirements;
- information relating to an adverse event which is, or may be associated with, the use of a vaping good;

- information relating to testing, and the results of testing, of a vaping good, or a sample of a vaping good, including information relating to the quality, safety or efficacy of the good;
- information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a vaping good;
- the safe use of a vaping good;
- information relating to the appropriate disposal of a vaping good;
- information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a vaping good.

Item 2 of the table in Schedule 4 specifies information relating to one or more vaping goods that are or have been, or are suspected of being or having been, imported into, exported from, manufactured, supplied or possessed in, Australia, including (but not limited to) the following:

- details about a vaping good, or a sample of a vaping good, including strength, formulation, composition, design specification or presentation;
- details of the actual or apparent sponsor, supplier or advertiser of a vaping good;
- the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a vaping good, including details about the location and premises where the vaping goods have been supplied, stored or otherwise dealt with;
- information relating to an adverse event which is, or may be associated with, the use of a vaping good;
- information relating to testing, and the results of testing, of a vaping good, or a sample of a vaping good, including information relating to the quality, safety or efficacy of the good;
- information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, or patient safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a vaping good;
- information relating to the appropriate disposal of a vaping good;
- information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a vaping good.

Item 3 of the table in this Schedule specifies information about decisions or actions taken under the Act and any instruments made under the Act, in relation to one or more vaping goods.

Schedule 5 – Repeals

Schedule 5 repeals *Therapeutic Goods (Information Specification— Therapeutic Vaping Goods and Vaping Devices) Instrument 2023* such that the *Therapeutic Goods (Information Specification— Therapeutic Vaping Goods and Vaping Goods) Instrument 2024* operates instead.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 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

Section 61 of the Act provides that the Secretary may release to the public, and to certain organisations, bodies, or authorities, specified kinds of therapeutic goods information and vaping goods information. Relevantly, subsection 61(1) of the Act defines, for the purpose of section 61:

- ‘therapeutic goods information’ as information in relation to therapeutic goods that is held by the Department and relates to the performance of the Department’s functions; and
- ‘vaping goods information’ as information in relation to vaping goods that is held by the Department and relates to the performance of the Department’s functions.

Under subsection 61(5AA) of the Act, the Secretary may release specified therapeutic goods information, for a specified purpose, to a person, body or authority that is, or is of a kind, specified under subsection 61(5AB) of the Act. Subsection 61(5AB) provides that, for the purpose of subsection 61(5AA), the Minister may, by legislative instrument, specify one or more kinds of persons, bodies or authorities (or a person, body or authority), kinds of therapeutic goods information and purposes.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

Subsection 61(7A) provides that the Secretary may release vaping goods information of a kind specified under subsection 61(7B) to persons, bodies or authorities that are (or are of a kind) also specified under that subsection, for a purpose or purposes specified under that subsection. Subsection 61(7B) provides that, for the purpose of subsection 61(7A), the Minister may, by legislative instrument, specify one or more kinds of persons bodies or authorities (or a person, body or authority), kinds of vaping goods information and purposes.

Under subsection 61(7C) of the Act, the Secretary may release to the public vaping goods information of a kind specified under subsection 61(7D). Subsection 61(7D) provides that the Minister may, by legislative instrument, specify kinds of vaping goods information for the purpose of subsection 61(7C).

The *Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 2024* (the Instrument) is a legislative instrument made under subsections 61(5AB), (5D), (7B) and (7D) of the Act.

The Instrument specifies, for the purposes of subsections 61(5AA) and (7A) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to specified persons, bodies or authorities, and the purpose for which that information may be released. The persons, bodies and authorities specified in the Instrument include Commonwealth or State departments; departments or administrative units of the Public Service of a Territory; and Commonwealth, state or territory authorities, with functions relating to therapeutic goods, vaping goods, health, revenue or law enforcement.

Under subsection 61(5AB), the Instrument specifies that therapeutic goods information relating to one or more therapeutic vaping goods, therapeutic vaping kits, goods in a therapeutic vaping pack and therapeutic cannabis vaping goods may be released. The Instrument provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under subsection 61(7B), the Instrument specifies that vaping goods information relating to one or more vaping goods may be released. The Instrument similarly provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under both provisions, the Instrument authorises release to those persons, bodies and authorities for the purpose of supporting compliance and enforcement activities relating to the importation, exportation, manufacture, supply, possession or advertising of the relevant kinds of goods.

The Instrument also specifies, for the purposes of subsections 61(5C) and (7C) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to the public. These include, among other things, information about black market vaping goods and therapeutic vaping goods, which are suspected of having been unlawfully supplied, to protect the consumers and the broader public from unsafe goods.

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 Instrument is made under subsections 61(5AB), (5D), (7B) and (7D) of the Act. It specifies, for the purposes of subsections 61(5AA) and (7A) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to specified persons, bodies or authorities, and the purpose for which that information may be released. The Instrument also specifies, for the purposes of subsections 61(5C) and (7C) of the Act, the kinds of therapeutic goods information and vaping goods information respectively that the Secretary may release to the public under subsections 61(5D) and 61(7D) of the Act, respectively.

The Instrument provides, for the purposes of subsections 61(5AA) and (7A) of the Act, the persons, bodies and authorities to whom information may be released include Commonwealth or State departments; departments or administrative units of the Public Service of a Territory; and

Commonwealth, state or territory authorities, with functions relating to therapeutic goods, vaping goods, health, revenue or law enforcement.

Under subsection 61(5AB), the Instrument specifies that therapeutic goods information relating to one or more therapeutic vaping goods, therapeutic vaping kits, goods in a therapeutic vaping pack and therapeutic cannabis vaping goods may be released. The Instrument provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under subsection 61(7B), the Instrument specifies that vaping goods information relating to one or more vaping goods may be released. The Instrument similarly provides a non-exhaustive list of specific kinds of information related to these goods, which are authorised for release.

Under both provisions, the Instrument authorises release to those persons, bodies and authorities for the purpose of supporting compliance and enforcement activities relating to the importation, exportation manufacture, supply, possession or advertising of the relevant kinds of goods.

Release of the specified kinds of therapeutic goods information and vaping goods information to these bodies or authorities is necessary and critical to address the growing public health problem associated with vaping. The bodies and authorities that are, or are of a kind, specified in the Instrument play a pivotal role in the application and enforcement of the Government's vaping reforms.

For example, the ATO is responsible for investigating money laundering that may be associated with the supply of unlawful vaping goods, and otherwise enforcing tobacco excises that may be applicable to goods to which the Instrument applies. Additionally, the Australian Border Force is responsible for seizing unlawful vaping goods at the border, and officers of state and territory authorities with functions relating to therapeutic goods, health, revenue or law enforcement are empowered to carry out enforcement powers under the vaping reforms.

The Instrument also authorises the release of certain therapeutic goods information and vaping goods information to the public. The publication of information relating to therapeutic vaping goods and other vaping goods is critical to ensure that Australians (including consumers, patients, pharmacists and health practitioners) are aware of information about, for example, the safety, quality, efficacy or performance of lawfully supplied or acquired therapeutic vaping goods, and safety risks or enforcement activities related to unlawful vaping goods.

This Instrument enables the release of a wide range of information relating to therapeutic vaping goods and other vaping goods consistent with the *Privacy Act 1988*. This may include, for example:

- providing safety alerts to the public about the dangers associated with the use of particular vaping goods (for example, the contamination of vaping goods with high levels of toxic substances) to ensure that users are informed about such risks and are able to take steps to avoid a threat to their health by not using products for which such alerts are made;
- informing Commonwealth, state and territory health authorities or law enforcement bodies about vaping goods, which have been, or are suspected of having been, imported, manufactured or supplied in contravention of the Act; or
- informing the public about decisions or actions taken under the Act or its regulations in relation to vaping goods, such as information about enforcement action taken against the suppliers of prohibited vaping goods.

Human rights implications

The Instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR) and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

Right to health

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 vaping products takes positive steps to promote the right to health by supporting reforms to the regulation of vapes. These reforms will support the availability of safe therapeutic vaping goods to persons who require these goods for smoking cessation or the management of nicotine dependence, while ensuring that health and safety risks associated with unsafe black market vaping goods are abated.

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 or pharmacist supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The Instrument takes positive steps to promote the right to health by facilitating the release of therapeutic goods information principally relating to therapeutic vaping goods, therapeutic vaping kits, goods in a therapeutic vaping pack and therapeutic cannabis vaping device accessories, and vaping goods information principally relating to one of more vaping goods. The release of such information to kinds of persons, bodies or authorities including Commonwealth or State departments; departments or administrative units of a Territory Public Service; or Commonwealth, state or territory authorities, with functions relating to therapeutic goods, vaping goods, health, revenue or law enforcement ensures there is an effective compliance and enforcement scheme in place to identify and prevent the importation or supply of unlawful vaping goods that do not meet minimum standards for quality, safety and efficacy or performance. Information release and sharing under these provisions allow for early intervention and detection of the supply of non-compliant and unsafe therapeutic and other vaping goods to the public. This also ensures that supply is stopped immediately and the public is

warned early of any adverse health events in the use of non-compliant and unsafe therapeutic and non-therapeutic vaping goods.

Additionally, the publication of information relating to therapeutic vaping goods and other vaping goods is critical to ensure that Australians (including consumers, patients and health practitioners) are aware of information about, for example, the safety, quality, efficacy or performance of lawfully supplied or acquired therapeutic vaping goods, and safety risks or enforcement activities related to unlawful vaping goods.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence. It also prohibits unlawful attacks on a person's reputation. Limitations on the right to privacy must be according to law and not arbitrary, i.e. limitations must be reasonable and necessary in the particular circumstances, as well as proportionate to the objectives the limitations seek to achieve.

The information specified in the Instrument to be released to the public may include the name of the sponsor of the therapeutic vaping goods, which is the person who imports the goods into Australia, exports the goods from Australia, or manufactures the goods in Australia.

Although the sponsor is most often a company, the sponsor may be an individual, so it may be possible to identify an individual from the information published on the Therapeutic Goods Administration (TGA) website. The TGA, as part of the Australian Government Department of Health and Aged Care, is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Any use or disclosure of personal information would be consistent with the Privacy Act.

The collection and use of the information specified in the Instrument by the TGA, and its disclosure, is critically important in informing the public as to, for example, the compliance of therapeutic vaping goods with minimum safety, quality, efficacy or performance requirements for vaping goods, and health and safety risks of other kinds of vaping goods. In particular, it is important that the information about the sponsor of vaping goods is publicly available, to ensure patients and health practitioners are able to easily identify vaping goods that meet minimum requirements and can contact the sponsor if needed, vaping goods that pose health and safety risks and should not be used.

As such, the disclosure of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as the disclosure would be reasonable given it is appropriate and justified for the public to know the identity of a sponsor, even if the sponsor is an individual, and the disclosure would be necessary and proportionate to the objective of ensuring that therapeutic vaping goods imported or supplied in Australia meet minimum safety, quality, efficacy or performance requirements for such goods, and to reduce the public health and safety risks associated with other kinds of vaping goods.

Conclusion

The Instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and any engagement with the right to privacy in Article 17 of ICCPR is reasonable, necessary and proportionate.