

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024

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

Division 1 in Part 4A-2 of the Act establishes offences and civil penalties for the importation, manufacture, supply and commercial possession of vaping goods. These offence and civil penalty provisions prohibit such activities unless an exception specified in the relevant provision authorises such activities in relation to specified persons, specified vaping goods, and when carried out in specified circumstances. The intent of these provisions is to deter trade in illicit vaping goods, arrest the alarming increase in the use of vaping products in Australia, particularly among youth and young adults, and prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

The exceptions to the offences and civil penalty provisions specify legitimate persons who may import, manufacture, supply and possess vaping goods, being persons who are generally authorised or permitted under Commonwealth or state and territory legislation to be lawfully involved in the therapeutic goods supply chain. For persons, vaping goods, and specified activities that are not generally covered by specific statutory authorisations or permissions, new sections 41R and 41RC of the Act are designed to provide a separate lawful basis for the Minister (section 41R) and the Secretary of the Department of Health and Aged Care (section 41RC) to authorise certain activities associated with specified vaping goods by certain persons in specified circumstances.

Section 41R of the Act provides a mechanism by which the Minister can determine the supply or possession of specified vaping goods by specified persons in specified circumstances, in practice principally where this may not otherwise be authorised under other relevant statutory provisions and where the supply or possession relates to a legitimate dealing with therapeutic vaping goods as part of the supply chain for such products.

Relevantly, section 41R of the Act provides that the Minister may, by legislative instrument, determine that specified vaping goods, or a specified class of vaping goods, may be supplied or possessed in Australia:

- by a specified person, or a specified class of persons;
- in the circumstances (if any) specified in the determination; and
- subject to the conditions (if any) specified in the determination.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Determination) is made under section 41R of the Act. In effect, this Determination authorises certain persons to possess and supply vaping goods in certain circumstances, where those persons would not otherwise be specifically authorised, approved or permitted under Commonwealth and state and territory laws. Such persons may include transporters, persons involved in the storage of vaping goods, persons involved in waste disposal and management, wholesale representatives, and import and export agents.

Some of the items provided in the Determination are time limited to enable the disposal or depletion of existing stock of vaping goods where supply was previously lawful under Commonwealth and state or territory laws.

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* (the CPI Regulations), the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). 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 broader and more extensive reforms to the regulation of vaping goods, principally to prohibit the importation, manufacture, supply, commercial possession and advertisement of vaping goods in Australia unless certain requirements under the Act are met. Therapeutic vaping goods that meet regulatory requirements for therapeutic goods under the Act will continue to be available where clinically appropriate. The reforms align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Purpose

The Determination is made under section 41R of the Act. Its purpose is to determine specified vaping goods, or specified classes of vaping goods, that may be supplied or possessed in Australia, and specified persons, or specified classes of persons, who may possess or supply those goods. The Determination also specifies the circumstances in which those persons may do so, and any applicable conditions that must be complied with. The effect of the Determination is that a person covered by its terms will not commit relevant offences or contravene civil penalty provisions in Chapter 4A of the Act relating to the supply or possession of a vaping good, provided the person does so in accordance with the Determination.

Incorporation by reference

The Determination incorporates, by reference, the following legislative instruments:

- the CPI Regulations made under the *Customs Act 1901*; and
- the TG Regulations and MD Regulations, made under the Act.

These legislative instruments 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 the Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023, which conveyed Ministers' collective commitment to enhancing the regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023.

The feedback received in connection with this consultation informed the development of the Amendment Act and related regulations and other legislative instruments, including the Determination. Further informal consultation, including for instance with health practitioners, was also undertaken in late 2023 and in 2024, and has further informed the development of the reforms.

Other details

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

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

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

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

Details of the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Determination).

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Definitions

This section provides definitions for terms used in the Determination. These include ‘Act’, ‘approved importer’, ‘authorised disposer’, ‘authority’, ‘commercial premises’, ‘CPI Regulations’, ‘destroy’, ‘notified vaping goods’, ‘MD Regulations’, ‘medicinal cannabis products’, ‘permitted cannabis wholesaler’, ‘permitted exporter’, ‘permitted health practitioner’, ‘permitted importer’, ‘permitted manufacturer’, ‘permitted recipient’, ‘permitted wholesale supplier’, ‘Regulations’, ‘therapeutic cannabis vaping good’, and ‘visiting group’.

The note to this section also makes it clear that expressions used in the Determination have the same meaning as in the Act. These include ‘commercial quantity’, ‘current Poisons Standard’, ‘Customs officer’, ‘essential principles’, ‘health practitioner’, ‘included in the Register’, ‘nurse practitioner’, ‘pharmacist’, ‘Register’, ‘registered goods’, ‘Secretary’, ‘sponsor’, ‘supply’, ‘vaping goods’ and ‘vaping substance’.

Section 5 – Circumstances in which specified vaping goods may be possessed

This section provides that, in relation to each item in the table in Schedule 1, the specified vaping goods, or specified class of vaping goods, determined in column 2, may be possessed by a specified person or a specified class of persons, determined in column 3, in the circumstances specified in column 4 and subject to the conditions, if any, specified in column 5.

Section 6 – Circumstances in which specified vaping goods may be possessed and supplied

This section provides that, in relation to each item in the table in Schedule 2, the specified vaping goods, or specified class of vaping goods, determined in column 2, may be possessed and supplied by a specified person or a specified class of persons determined in column 3, in the circumstances specified in column 4 and subject to the conditions, if any, in column 5.

Schedule 1 – Possession of specified vaping goods

This Schedule specifies for each item, vaping goods, the persons who may possess those vaping goods, the circumstances in which those persons may do so, and the applicable conditions (if any).

Item 1 – Amnesty for personal use by individuals

Item 1 of the table provides for a 12-month amnesty, until 30 June 2025, in relation to the possession of vaping goods by individuals for personal use, or use by a person under their care, in the circumstances specified in the item. It applies to vaping goods that are possessed by an individual on or before 30 June 2025 in the following circumstances:

- the person owns the goods for use by the person or another person in the person’s care;
- the person is not engaged in, and has at no time after 1 July 2024 been engaged in, the commercial importation, exportation, manufacture, wholesale supply or retail supply of vaping goods (whether as an owner, employee, contractor or other person engaged in these kinds of activities);
- the goods are not beneficially owned by, or under the control of, a body corporate;
- the goods are not possessed or stored in or at a retail premises or a commercial premises, where ‘retail premises’ is defined broadly in subsection 41QD(10) of the Act and ‘commercial premises’ is defined broadly in section 4 of the Determination; and
- the person possesses less than five times the commercial quantity of the kind of vaping goods.

The commercial quantities are specified in regulation 10N of the *Therapeutic Goods Regulations 1990* (the TG Regulations) as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid. These quantities will be repealed and replaced on 1 October 2024 with 9 vaping devices, 60 vaping accessories and 400mL of vaping substance that is a liquid. Therefore, the effect of specifying that the quantity of vaping goods must be less than five times the commercial quantity of the kind of vaping goods is that the quantities that may be possessed must, before 1 October 2024, be less than 70 vaping devices, 450 vaping accessories and 3,000mL of vaping substance that is liquid, and after 1 October 2024, less than 45 vaping devices, 300 accessories and 2,000mL of vaping substance that is a liquid.

Item 2 – Members of a visiting group

Item 2 applies to the possession of vaping goods by a person who is a member of a ‘visiting group’. This item permits the possession by persons in visiting groups of vaping goods that were imported by an approved importer (see item 3 of Schedule 2 to the Determination for the authorisation for the supply and possession of vaping goods by an approved importer) in accordance with an approval under subregulation 5A(5) of the CPI Regulations and the goods were given to the person by the approved importer.

Item 3 – Possession for purpose of export

Item 3 applies to certain kinds of vaping goods that are possessed on or before 31 December 2024 by a person who obtained the goods in the course of their exportation business (including export business owners and their employees) in specified circumstances. Those circumstances include that the goods must have been imported into Australia by that person or received from one of a specified class of persons involved in the lawful vaping goods supply chain (such as a permitted wholesale supplier).

The item is subject to a number of conditions including transportation, storage, delivery and record keeping requirements and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

Item 4 – Storage services

Item 4 applies to vaping goods that are possessed on or before 30 September 2024 by a person engaged in the business of providing storage facilities, including storage facility owners and their employees and contractors, where the person storing the vaping goods is one of the following specified class of persons who may need to engage storage facilities to store large quantities of vaping goods, such as a permitted importer, a permitted exporter, a permitted wholesale supplier, a permitted

recipient or a permitted cannabis wholesaler. Additionally, the goods must be stored in accordance with a written agreement between the parties.

The item is subject to a number of conditions including storage and record keeping requirements and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

The item applies to possession only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess the goods in the circumstances covered by this item.

Item 5 – Waste disposers

Item 5 applies to vaping goods that are possessed on or before 30 September 2024 by a person who holds a licence or written authorisation issued under a law of a state or territory, which authorises the person to destroy or dispose of waste (including, for example, employees or contractors authorised under a licence granted to a corporation) in specified circumstances. Those circumstances include that the goods must be possessed for the sole purpose of lawful destruction (defined in section 4 of the Determination as to render a thing unusable and unidentifiable), and that the person did not provide any payment or other consideration for the goods.

The item is subject to a number of conditions including while the goods are in the person's possession, the goods must be clearly marked for destruction; the goods must be destroyed as soon as practicable; storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

The item applies to possession only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess vaping goods in the circumstances covered by this item.

Item 6 – Medical or scientific research

Item 6 applies to vaping goods that are possessed on or before 30 September 2024 by a laboratory or testing facility that is engaged in bona fide medical or scientific research or testing of vaping goods in specified circumstances, including matters relating to the credentials of the laboratory or testing facility and the goods having been lawfully imported or manufactured and supplied to the person.

The item is subject to a number of conditions including the goods must not be used for any purpose other than medical or scientific research or testing, and must not be used in or on humans; storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

Schedule 2 – Possession and supply of specified vaping goods

This Schedule specifies for each item, vaping goods, the persons who may possess and supply those vaping goods, the circumstances in which those persons may do so, and the applicable conditions (if any).

Item 1 – Amnesty for individual possession and supply for disposal

This item provides a 12-month amnesty, until 30 June 2025, in relation to the personal possession and supply of vaping goods for the sole purpose of lawful disposal in the circumstances specified in the item, including that the quantity is less than five times the commercial quantity and that the person is not engaged in, and has at no time after 1 July 2024 been engaged in, the commercial importation, exportation, manufacture, wholesale supply or retail supply of vaping goods.

The item is subject to the conditions that the person must only supply the goods to another person that the person reasonably believes is an authorised disposer who will lawfully destroy the goods, and must not supply the goods in return for any payment or other consideration for the goods.

The commercial quantities are specified in regulation 10N of the TG Regulations as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid. These quantities will be repealed and replaced on 1 October 2024 with 9 vaping devices, 60 vaping accessories and 400mL of vaping substance that is a liquid. Therefore, the effect of specifying that the quantity of vaping goods must be less than five times the commercial quantity of the kind of vaping goods is that the quantities that may be possessed must, before 1 October 2024, be less than 70 vaping devices, 450 vaping accessories and 3,000mL of vaping substance that is liquid, and after 1 October 2024, less than 45 vaping devices, 300 accessories and 2,000mL of vaping substance that is a liquid.

Item 2 – Goods imported under a traveller exemption

Item 2 applies to the possession of vaping goods by a person entering Australia on board a ship or aeroplane where the importation meets the requirements of the traveller's exemption, including the relevant quantity limits, under either subregulation 5A(2) or paragraph 5(2)(b) of the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations). The item also applies to the supply of such goods by the importer, subject to the condition that the supply is only to a person under the care of the importer and who was on board the same ship or aircraft as the importer, and the goods are supplied for use in connection with the treatment of that person.

Item 3 – Person responsible for the treatment of a visiting group

Item 3 applies to the possession and supply by a person who has imported vaping goods pursuant to an approval under subregulation 5A(5) of the CPI Regulations.

The *Customs (Prohibited Imports) (Vaping Goods) Approval 2023* is an instrument made under subregulation 5A(5) of the CPI Regulations that is currently in force and approves the importation of vaping goods by members responsible for the medical treatment of groups of persons (defined in section 4 as 'visiting groups'). This includes:

- members of the military forces of another country who are visiting Australia for military training;
- groups of persons visiting Australia to participate in a national or international sporting event;
- groups of persons comprising a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country who are visiting Australia on official business ('visiting groups').

The effect of this item is that members responsible for the medical treatment of persons in visiting groups may possess, and supply to those persons, vaping goods that were imported in accordance with the *Customs (Prohibited Imports) (Vaping Goods) Approval 2023* or another approval made under subregulation 5A(5) of the CPI Regulations, which specifies a group of persons. The item is subject to conditions, including that the goods are only supplied to members of the visiting group, that unused goods are destroyed or removed at the end of the visit, and that the importer keeps records and produces the records on request by a customs officer or a person who is an authorised officer for the purposes of a provision of Part 5 of the TG Regulations or an authorised person for the purposes of section 41FN of the Act.

Item 4 – Surrender of vaping goods by businesses

This item provides a 3-month surrender scheme, until 30 September 2024, for businesses that possess at least twenty times the commercial quantity of vaping goods where the goods were manufactured by the person in Australia, or obtained by them in the course of their importation, exportation, wholesale supply, retail supply, transportation or storage business. To partake in the scheme, businesses are

required to notify the Department at a specified email address before 1 August 2024 of their intention to surrender the goods, and the business must comply with the conditions specified in the item.

The commercial quantities are specified in regulation 10N of the TG Regulations as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid. These quantities will be repealed and replaced on 1 October 2024 with 9 vaping devices, 60 vaping accessories and 400mL of vaping substance that is a liquid. This means that to be eligible for the business surrender scheme before 1 October 2024, a business would need to possess at least 280 vaping devices, 1800 accessories or 12,000mL of vaping substance that is a liquid, and after 1 October 2024 a business would need to possess at least 180 vaping devices, 1,200 accessories or 8,000mL of vaping substance that is a liquid.

The circumstances in which the business surrender scheme apply are that:

- immediately before 1 July 2024, the goods were in the person's possession or control and the importation or manufacture, supply, and possession of the goods was done in accordance with all applicable laws of the Commonwealth, a state or a territory;
- before 1 August 2024, the person must have notified the Department at vapereturn@health.gov.au that the person intends to surrender the goods to the Department;
- the goods are supplied to the Department for the purpose of surrender in accordance with a direction of an officer of the Department.

The item is subject to a number of conditions, including the person must supply the goods in accordance with a direction of the officer of the Department (such as a direction concerning transportation or any other process required to facilitate supply); the person must, if requested to do so by the Department, provide relevant information; storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

The purpose of this item is to ensure that businesses, such as retailers, who have been operating lawfully prior to 1 July 2024 and hold significant quantities of vaping goods that can no longer be lawfully supplied as at 1 July 2024 can make appropriate arrangements in a timely manner for the surrender of those goods.

Item 5 – Possession of small commercial quantities by businesses for the purpose of disposal

This item provides a 3-month amnesty, until 30 September 2024, in specified circumstances for businesses that possess no more than twenty times the commercial quantity of vaping goods where the goods were manufactured by the person in Australia, or obtained by them in the course of their importation, exportation, wholesale supply, retail supply, transportation or storage business.

The commercial quantities are specified in regulation 10N of the TG Regulations as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid, and apply until 30 September 2024. This means that the item applies in relation to quantities of up to 280 vaping devices, 1,800 accessories or 12,000mL of vaping substance that is a liquid.

The circumstances in which this item applies are that:

- immediately before 1 July 2024, the goods were in the business's possession or control and the importation or manufacture, possession and supply of the goods was done in accordance with all applicable laws of the Commonwealth, a state or a territory; and
- the person possesses no more than twenty times the commercial quantity of vaping goods and the goods are possessed for the sole purpose of supply to another person that the person reasonably believes is an authorised disposer and will lawfully destroy the goods.

An 'authorised disposer' is defined in section 4 of the Determination to mean a person who holds a licence or written authorisation issued under a law of a state or territory which authorises the person to destroy or dispose of waste, or an authority with functions relating to waste destruction or disposal.

The item is subject to a number of conditions including the person must supply the goods other than to another person that the person reasonably believes is an authorised disposer; the person must not supply the goods in return for any payment or other consideration for the goods; storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

The purpose of this item is to ensure that businesses, such as retailers, who have been operating lawfully prior to 1 July 2024 and hold a quantity of vaping goods that is no more than twenty times the commercial quantity and no longer be lawfully possessed and supplied as at 1 July 2024, can make appropriate arrangements in a timely manner for the disposal and destruction of such stock.

Item 6 – Possession and supply of vaping goods in the legitimate supply chain and export of vaping goods

Item 6 provides for a 3-month period (until 30 September 2024) for importation, wholesale supply or retail supply business to possess and supply vaping goods to specified persons in the legitimate supply chain where the importation, manufacture, possession and any supply of the goods before 1 July 2024 was lawful. Businesses possessing more than twenty times the commercial quantity of such goods immediately prior to 1 July 2024 must notify the Department at a specified e-mail address by 1 August 2024 to be covered by this item.

The item applies to vaping goods that are possessed and supplied by a person who obtained the goods in the course of their importation, wholesale supply or retail supply business (including business owners and their employees) in the following circumstances:

- the goods were imported into, or manufactured in, Australia before 1 July 2024, and the importation, manufacture, possession and any supply of the goods was done in accordance with all applicable laws of the Commonwealth, a state or a territory;
- the goods must be possessed for the purpose of supply to one of a specified class of persons involved in the lawful vaping goods supply chain (namely, a permitted recipient, a permitted wholesale supplier, a person outside Australia, or a permitted exporter than the person reasonably believes will export the goods before 1 January 2025 and will not use the goods, or supply them to any person in Australia);
- the goods must only be supplied in accordance with a written agreement between the person and the receiver of the goods, and
- the person must notify the Department by 1 August 2024 if they possessed more than twenty times the commercial quantity of the kind of vaping goods immediately prior to 1 July 2024.

The item is subject to several conditions including vaping goods that are supplied to a permitted recipient (such as supply to a pharmacist) must comply with applicable standards or the essential principles; storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

The commercial quantities are specified in regulation 10N of the TG Regulations as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid. This means that, if a relevant person possessed at least 280 vaping devices, 1,800 accessories or 12,000mL of vaping substance that is a liquid immediately prior to 1 July 2024, the person would need to notify the Department.

This item has two purposes. The first is to provide for the return through the legitimate supply chain of vaping goods that were previously lawful so that the goods can be surrendered or exported.

The second purpose is to facilitate the supply by retailers to pharmacists of vaping goods that have been lawfully imported or manufactured and supplied by wholesale before 1 July 2024, noting that general retailers can no longer supply vaping goods to consumers from 1 July 2024. It is a condition that where goods are supplied to a permitted recipient (which includes a pharmacist) the goods must

comply with applicable standards or the essential principles (as applicable). Retailers who hold vaping goods that do not comply applicable standards or the essential principles may not supply the goods to permitted recipients, but may supply it to other persons in the legitimate supply chain that are specified in the item.

The item applies to possession and supply only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess and supply the goods in the circumstances covered by this item.

Item 7 – Wholesale supply of notified vaping goods that do not contain nicotine (including devices) and medicinal cannabis substances

Item 7 applies to the possession and supply prior by a person engaged in the business of importation or wholesaling of notified vaping goods (other than goods that contain a substance included in a schedule to the current Poisons Standard), therapeutic cannabis vaping goods, or vaping substances that are medicinal cannabis products or medicines that contain synthetic cannabis.

The circumstances in which this item applies are that:

- the goods are possessed by the person for the sole purpose of supply to a permitted recipient, a permitted cannabis wholesaler or a permitted wholesale supplier ('receiver');
- the goods are supplied by the person to a receiver;
- if the goods are therapeutic cannabis vaping goods, the person reasonably believes that the goods were lawfully imported into, or manufactured in, Australia and supplied to the person, and that the goods are included in the Australian Register of Therapeutic Goods or approved for supply under subsection 41HB(1) of the Act or authorised for supply under subsection 41HC(1) of the Act;
- if the goods are vaping substances that are medicinal cannabis products or medicines that contain synthetic cannabis, the person reasonably believes that the goods were lawfully imported into, or manufactured in, Australia and supplied to the person, and that the goods are included in the Australian Register of Therapeutic Goods or are exempt from the operation of Part 3-2 of the Act under regulation 12A of the TG Regulations, approved for supply under subsection 19(1) of the Act or authorised for supply under subsection 19(5) or 19(7A) of the Act;
- if the goods include a substance included in Schedule 4 or 8 to the current Poisons Standard - the person is authorised or licenced under a law of the relevant state or territory to possess and supply the Schedule 4 or 8 substances for the purpose of wholesale supply (as applicable).

The item is subject to several conditions including the goods must only be supplied to a receiver in accordance with a written agreement between the person and the receiver; transportation, delivery, storage and record keeping requirements; and a requirement to notify the police if there is a suspicion that the goods have been lost or stolen.

This item has two purposes. The first is to provide for the wholesale supply of therapeutic vaping devices and vaping devices used to administer medicinal cannabis, as well as therapeutic vaping substances that do not contain a scheduled substance, by persons who are not licenced or authorised under a law of a state or territory to supply substances included in Schedule 4 to the Poisons Standard and consequently will not satisfy the exceptions to the offences and civil penalties in Chapter 4A of the Act that apply in relation to the possession and supply of vaping goods. The item applies to possession and supply of such goods only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess and supply such goods in the circumstances covered by this item.

The second purpose is to provide for the wholesale supply of vaping substances that are medicinal cannabis products or medicines that contain synthetic cannabis, by persons who are licenced or authorised under a law of a state or territory to supply substances included in Schedule 4 or 8 (as

applicable) to the Poisons Standard. The exceptions to the offences and civil penalty provisions in the Act do not apply to these goods and consequently it is necessary to specify persons that may supply such goods. The determination of these goods is not time limited because persons supplying these substances are already required to be licenced or authorised under state or territory law and it is not intended that such persons will be required to seek a consent under section 41RC of the Act to supply the goods.

Item 8 – Nicotine manufacture

Item 8 applies to nicotine in solution that is possessed and supplied by the holder of a manufacturing licence under Part 3-3 of the Act that authorises the manufacture of vaping goods ('licence holder'). The circumstances in which this item applies are that:

- the possession and supply occurs on or before 30 September 2024;
- the goods were manufactured by the licence holder in Australia; and
- if, immediately before 1 July 2024, the licence holder possessed more than twenty times the commercial quantity, the licence holder notified the Department at vapereturn@health.gov.au by 1 August 2024.

The commercial quantities are specified in regulation 10N of the TG Regulations as 14 vaping devices, 90 vaping accessories and 600mL of vaping substance that is a liquid. This means that, if the licence holder possessed more than 280 vaping devices, 1,800 accessories or 12,000mL of vaping substance immediately prior to 1 July 2024 that is a liquid, the person would need to notify the Department.

This item is subject to the conditions including that the goods may only be supplied to a person who is the holder of a licence under Part 3-3 of the Act that authorises the manufacture of vaping goods; the goods must be manufactured in compliance with the licence holder's licence.

The authorised possession and supply by a person under this item are time lime limited and apply only to possession and supply that occurs on or before 30 September 2024. After that date, it is intended that a licence holder will need to seek a consent under section 41RC of the Act to possess and supply the goods in the circumstances covered by this item. This allows relevant persons to be given adequate time to apply for a section 41RC consent for the possession and supply of nicotine for manufacture.

Item 9 – licenced and permitted importer exception

Item 9 applies to vaping substances that are possessed and supplied by the holder of a licence and permit under subregulation 5(5) of the CPI Regulations that applies to those goods. This item applies where the licence holder imports the goods in accordance with paragraphs 5(1)(a) to (d) of the CPI Regulations. Goods imported in accordance with paragraphs 5(1)(a) to (d) of the CPI Regulations will be ineligible to be notified vapes, because those goods will not meet the requirements of the standard that applies to therapeutic vaping goods. In practice, the goods to which this item will generally apply are vapes containing medicinal cannabis.

This item is subject to the following conditions: the goods may only be supplied to a permitted recipient, a permitted wholesale supplier, or a permitted cannabis wholesaler; and the person must, if requested to do so by the Department, provide certain kinds of information.

Item 10 – Transportation services to facilitate supply chains and export

Item 10 applies to specified classes of vaping goods (namely, notified vaping goods, therapeutic cannabis vaping goods, and vaping substances that are a medicinal cannabis product or a medicine that contains synthetic cannabis), which are possessed and supplied on or before 30 September 2024 by a person engaged in the business of providing transportation services (including transportation service owners and their employee drivers, and self-employed drivers) in certain circumstances.

Those circumstances are that the goods must be sent from one of a specified classes of persons involved in the lawful vaping goods supply chain (namely a ‘sender’, being one of a specified classes of people (such as a permitted wholesale supplier, a permitted cannabis wholesaler or a permitted importer) to another specified class of person involved in the chain (namely a ‘receiver’, being a permitted wholesale supplier, a permitted cannabis wholesaler, a permitted recipient or a permitted exporter), and where this is done in accordance with a written agreement between the person and either the sender or receiver.

The item is subject to conditions including in relation to ensuring that the goods are only supplied to a receiver or a receiver’s agent or employee, keeping a record of the written agreement and description of the goods, complying with state or territory laws relating to the handling of any substances included in Schedule 8 to the current Poisons Standard, ensuring certain safeguards are in place in relation to storage and transportation of the vaping goods, notification of police if the person reasonably suspects that the vaping goods have been lost or stolen and providing relevant information to the Department on request.

The item applies to possession only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess the goods in the circumstances covered by this item.

Item 11 – Transportation services to facilitate disposal

Item 11 applies to vaping goods that are possessed and supplied on or before 30 September 2024 by a person engaged in the business of providing transportation services (including transportation service owners and their employee drivers, and self-employed drivers) in certain circumstances, including that the goods must be transported and delivered only in accordance with a written agreement between the person and either an authorised disposer of vaping goods or a third party who the person reasonably believes is engaging their transportation services to facilitate the lawful destruction of the goods, and that the person reasonably believes the authorised disposer will lawfully destroy the goods.

The item is subject to conditions including for instance in relation to keeping a copy of the written agreement and a description of the vaping goods, complying with state or territory laws relating to the handling of any substances included in Schedule 8 to the current Poisons Standard, ensuring certain safeguards are in place in relation to storage and transportation of the vaping goods, notification of police if the person reasonably suspects that the vaping goods have been lost or stolen and providing relevant information to the Department on request.

The item applies to possession only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess the goods in the circumstances covered by this item.

Item 12 – Permitted health practitioner supply of cannabis vaping goods and substances

Item 12 applies to the possession and supply by a ‘permitted health practitioner’ of therapeutic cannabis vaping goods and vaping substances that are medicinal cannabis vaping products or a medicine that contains synthetic cannabis to a patient where the goods are either included in the Australian Register of Therapeutic Goods or are for supply under one of the access pathways under the Act for lawfully accessing unapproved therapeutic goods. A ‘permitted health practitioner’ is defined in section 4 as a person mentioned in subsection 41QB(10) of the Act, which in turn is defined as a pharmacist, or a medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occur. The ‘permitted health practitioner’ may only supply the goods to an ultimate consumer, or a person that the practitioner reasonably believes is lawfully obtaining the goods on behalf of the ultimate consumer (for example, a parent on behalf of their child).

The item is subject to the condition that, if the goods include a substance included in Schedule 8 to the current Poisons Standard, the person must comply with the requirements under the law of the relevant state or territory that apply to the possession and supply of Schedule 8 substances. A further condition is that the goods are stored in a part of the premises to which the public does not have access. This condition is of relevance to therapeutic cannabis vaping goods which, by definition, do not include substances and accordingly are not subject to the laws of the relevant state or territory applying to Schedule 4 or 8 substances.

Item 13 – Clinical trials

Item 13 applies to the possession and supply of vaping goods in connection with a clinical trial, on or before 30 September 2024. Specifically, it applies to possession and supply of vaping goods, by the sponsor of the goods, or the sponsor, or principal investigator, of a clinical trial, where:

- the goods are the subject of an approval under the Clinical Trial Application (CTA) Scheme, or an exemption under the Clinical Trial Notification (CTN) Scheme; and
- the person possesses the goods for the sole purpose of supplying the goods to the sponsor, or principal investigator, of a clinical trial or a participant enrolled in the clinical trial, as the case may be.

This item is subject to conditions, including that the vaping goods are only supplied to the persons as provided for in the circumstances, that the person complies with the CTA or CTN schemes and all applicable state and territory laws relating to the possession, testing and supply of any substances included in Schedule 8 to the current Poisons Standard that may be possessed and supplied in reliance on this item.

The item applies to possession and supply only on or before 30 September 2024. After that date, it is intended that a person will need to seek a consent under section 41RC of the Act to possess or supply the goods in the circumstances covered by this item.

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—Possession and Supply) Determination 2024

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

Overview of the Legislative Instrument

Division 1 in Part 4A-2 of the Act establishes a number of offences and civil penalties for the importation, manufacture, supply and commercial possession of vaping goods. These offence and civil penalty provisions prohibit such activities unless an exception specified in the relevant provision authorises such activities in relation to specified persons, vaping goods and when carried out in specified circumstances. The intent of these provisions is to deter trade in illicit vaping goods, arrest the alarming increase in the use of vaping products in Australia, particularly among youth and young adults, and prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

The exceptions to the offences and civil penalty provisions specify legitimate activities and persons who are generally authorised or permitted under Commonwealth and state and territory legislation to be lawfully involved in the therapeutic goods supply chain. For those persons, vaping goods, and specified activities that are not generally covered by specific statutory authorisations or permission, new sections 41R and section 41RC of the Act are designed to provide a separate lawful basis for the Minister, or the Secretary of the Department of Health and Aged Care, to authorise the possession or supply of specified vaping goods by certain persons in specified circumstances, subject to appropriate safeguards.

Section 41R of the Act provides a mechanism by which the Minister can determine the supply or possession of specified vaping goods by certain people, in circumstances where this may not be authorised under other relevant statutory provisions.

Purpose

The *Therapeutic Goods (Possession and Supply of Vaping Goods) Determination 2024* (the Determination) is made under section 41R of the Act. This Determination authorises persons to possess and supply vaping goods in certain circumstances, where those persons who not otherwise be specifically authorised, approved or permitted under Commonwealth and state and territory laws. Thus, this Determination allows, in specified circumstances and subject to compliance with specified conditions, classes of persons including transporters, persons involved in storage of goods, wholesale representatives, persons involved in waste disposal and management and import and export agents to possess, or to possess and supply, vaping goods.

Human rights implications

The Determination engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (the ICESCR) 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 ICCR).

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

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

The Determination promotes the right to health by ensuring that legitimate activities involving the supply and possession of therapeutic vaping goods by persons who are not generally covered by specific approvals, permissions or authorisations under Commonwealth and state and territory laws continue to be lawfully allowed. This ensures that intermediate actors in the lawful supply chain may continue to carry on activities that promote legitimate patient access to therapeutic vaping goods for smoking cessation or the management of nicotine dependence. In addition, this Determination also allows for temporary possession and supply of vaping goods for disposal or export where such goods should no longer be made available to the public in Australia because these goods do not comply with enhanced regulatory requirements.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCR 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. Limitations must be reasonable and necessary in the circumstances, as well as proportionate to the objectives that the limitations seek to achieve.

The Determination authorises specified persons to possess and supply specified vaping goods, but only in circumstances (and subject to any conditions) that are also specified in the Determination. In some instances, these include that the person possessing or supply the vaping goods must notify police if that person reasonably suspects that any of the goods have been lost or stolen, and must, if requested to do so by the Department, provide relevant information about, principally, the goods, the

person's possession of the goods and any other persons involved in such activities and must, in relation to a person engaged in the business of providing storage facilities, keep a record of the goods (including the relevant amount or quantity of the goods stored), the name and address of the person who has engaged the person's storage services (the storer) and the written agreement between the person and the storer.

The majority of information required to be provided to the Department, or maintained as part of a record, as part of complying with the Determination will be business related information rather than personal information. However, the Determination engages the right to protection against arbitrary and unlawful interferences with privacy because it is anticipated that in a small number of instances, persons may be engaged in unlawful dealings with vaping goods or may be dealing with vaping goods as part of the lawful supply chain for handling of therapeutic vaping goods but doing so as a small business, meaning that their business records may necessarily involve disclosing personal information such as their name.

The requirements relating to notification of police, and to provide information to the Department or to maintain specified kinds of records, are necessary, targeted and proportionate to the need to ensure that the Determination only authorises the lawful supply chain to handle therapeutic vaping goods and does not inadvertently permit the possession or supply of unlawful vapes, particularly as these vapes may pose a range of potentially very serious safety risks to consumers.

Conclusion

The Determination is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR, engages the right to privacy in Article 17 of the ICESCR in a measured, proportionate way as outlined above and otherwise does not raise any other human rights issues.