

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment 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, commercial possession, advertising 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 relating to the importation, manufacture, supply and commercial possession of vaping goods. The offence and civil penalty provisions prohibit such conduct unless an exception specified in the relevant provision of the Act applies. 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. These persons are authorised or permitted under Commonwealth or state and territory legislation to be lawfully involved in the therapeutic goods supply chain. The exceptions include reference to persons, vaping goods and activities covered by a determination or consent under sections 41R and 41RC of the Act. These sections 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 determine or authorise the supply or possession of specified vaping goods by certain persons in specified circumstances, subject to appropriate safeguards.

In contrast to other exceptions to offences and civil penalty provisions in the Act, the exceptions reflected in a legislative instrument made under section 41R of the Act (or a consent under section 41RC) may be highly detailed, technical in nature and, in some cases, transitional. The purpose of these exceptions is to specify the persons who may legitimately supply or possess vaping goods in complex circumstances that are not reflected in the Act. As a significant number of persons play a legitimate role in the importation, exportation, manufacture, wholesale and retail supply of vaping goods outside the circumstances reflected in the Act the circumstances reflected in the legislative instrument made under section 41R are necessarily detailed to mitigate the risk of diversion and to ensure appropriate oversight by the Department of the supply and possession of vaping goods by persons in the pharmaceutical wholesale and retail supply chains who are not already expressly permitted by the exceptions in the Act.

The regulation of vaping goods is complex, being subject to both Commonwealth and state and territory laws. Commonwealth delegated legislation (such as controls in the *Customs (Prohibited Imports) Regulations 1956*) and state and territory laws may change from time to time.

It is therefore considered necessary and appropriate to provide a basis in which the Minister may authorise the supply and possession of certain vaping goods in a legislative instrument made under section 41R of the Act, to enable sufficient flexibility to specify appropriate circumstances in which vaping goods may be lawfully supplied or possessed, and to deal with unintended situations that arise because of the complex interaction between, or changes to, these laws.

Essentially, section 41R of the Act provides a mechanism by which the Minister may determine the circumstances in which specified vaping goods may be supplied or possessed by specified persons. In practice, these circumstances occur where supply or possession relates to a legitimate dealing with

therapeutic vaping goods as part of the supply chain for such products and the person is not ordinarily covered by a statutory exception expressly outlined in the Act.

Specifically, 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 Principal Determination) is made under section 41R of the Act. In effect, the Principal Determination authorises certain persons to supply or possess vaping goods in certain circumstances, where those persons would not otherwise be permitted to do so. 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.

The Principal Determination is driven by public health objectives principally to ensure that:

- unused stock of unlawful vaping goods in the community at the commencement of the vaping reforms may be surrendered, exported, disposed, or destroyed in controlled circumstances that minimise the risk of diversion; and
- the Department has oversight of the supply and possession of lawful vaping goods by certain persons in the pharmaceutical wholesale or retail supply chains who do not otherwise hold a licence or authority to do so; and
- adequate protection is afforded to certain specified persons where the supply or possession of vaping goods without a licence or other authority for a bespoke reason outweighs the public health and safety concerns, such as supply or possession for scientific research or testing.

Some of the items provided in the Principal Determination are time limited to enable the disposal or depletion of existing stock of vaping goods where supply or possession of those goods was lawful under Commonwealth and state or territory laws prior to the commencement of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*. Limiting the time in which those items are available is intended to ensure:

- appropriate enforcement action is available for the possession and supply of unlawful vapes following the sunset of the instrument; and
- the lawful supply and possession of certain vaping goods by certain persons in the supply chain who otherwise do not have a licence or authority to do so, until a consent scheme is implemented and adopted by industry.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024* (the Amendment Determination) is similarly made under section 41R of the Act. It amends the Principal Determination principally to:

- extend the notification requirements, by one month, that apply to specified persons intending to surrender vaping goods to the Department of Health and to persons possessing a particular commercial quantity of vaping goods;
- extend the expiration of the application of some items relating to supply and possession from 30 September 2024 to 30 November 2024; and

- make minor amendments to defined terms and ensure consistency with the regulatory framework in Chapters 3 and 4 of the Act in relation to the supply of medicinal cannabis vaping goods.

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. 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 did not meet 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 were 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, commenced on 1 July 2024, and implemented 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.

The Principal Determination includes several items that apply to the supply and possession of vaping goods until 30 September 2024. The purpose of these items was to implement transitional arrangements for persons to divest themselves of vaping goods that can no longer be lawfully possessed and supplied, and for persons involved in the supply chain for legitimate therapeutic vapes to continue their involvement until further authority is made available under sections 41R or 41RC of the Act or, in relation to registered or notified vaping goods, until the person is duly licenced or authorised under the law of a state or territory to supply or possess goods containing substances included in Schedule 4 to the Poisons Standard. On 1 October 2024, amendments to the Act take effect under which persons who are licenced or authorised under the law of a state or territory to supply or possess goods containing substances included in Schedule 3, rather than Schedule 4, to the Poisons Standard, will fall within exceptions to the offences and civil penalty provisions in Chapter 4A in relation to the supply and possession of registered or notified vaping goods.

The Principal Determination includes a definition and several references to a 'permitted cannabis wholesaler', the intent of which was to apply to wholesalers of vaping substances that are or contain medicinal cannabis. However, as there are no vaping substances containing medicinal cannabis that are included in the Australian Register of Therapeutic Goods (Register), medicinal cannabis vaping substances are, in practice, imported, or manufactured in Australia, and held under the 'direct control' exemptions in items 1 or 2 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (TG Regulations). Under those exemptions, such goods must remain under the direct control of the sponsor, and although the services of third-party transporters and storage facilities may be engaged by sponsors in connection with the distribution of such goods, the supply of the goods by wholesale is prohibited under section 21 of the Act.

The Principal Determination also includes references to wholesale supply of 'therapeutic cannabis vaping goods', which is a defined term in the *Therapeutic Goods (Medical Devices) Regulations 2002* (MD Regulations) that applies to medical devices used to vape medical cannabis. There are a small number of medical devices used to vape medical cannabis that are included in the Register. The remainder of these goods that are imported into Australia are imported under the direct control exemption in item 2.1 of Part 2 of Schedule 4 to the MD Regulations and the supply of such goods by wholesale is prohibited under section 41MK of the Act.

The references in the Principal Determination to wholesale supply of medicinal cannabis vaping goods do not limit such supply to goods that are included in the Register and as such, are broader than what is permitted under Chapters 3 and 4 of the Act in relation to the wholesale supply of such goods.

Purpose

The Principal 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 Principal 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 Principal Determination.

The purpose of the Amendment Determination is principally to give relevant stakeholders adequate time to notify the Department about their intention to surrender or export specified vaping goods by extending the date by which a notification must be made from 1 August 2024 to 1 September 2024, and to extend the period for relevant persons to supply or possess vaping goods from 30 September 2024 to 30 November 2024. This will allow specified persons additional time to make the necessary arrangements and, where necessary, for further authorisation to be made available under section 41R or section 41RC of the Act for the lawful supply or possession of the goods.

The amendments are also intended to ensure consistency with the regulatory framework in Chapters 3 and 4 of the Act in relation to the *wholesale* supply of vaping goods that are or contain medicinal cannabis or a medicine that contains synthetic cannabis. That is, to permit such supply only in relation to goods that are included in the Register, and to ensure that wholesale supply is not permitted under Chapter 4A of the Act where the direct control exemptions apply to the goods.

The references to wholesale supply of such goods in the Principal Determination have the effect that the offences and civil penalties in Chapter 4A of the Act do not apply in relation to the possession and wholesale supply of those goods in the circumstances specified in the Principal Determination. However, neither the Principal Determination nor the Amendment Determination affect the operation of the offences in sections 21 and 41MK of the Act, which apply separately to prohibit the wholesale supply of medicinal cannabis vaping goods that are not included in the Register and are not otherwise exempt, approved or authorised.

Consultation

Consultation was not undertaken because the purpose of the Amendment Determination is simply to provide further time for stakeholders to transition to the new regulatory framework for vaping goods, to better reflect the regulatory framework in Chapters 3 and 4 that applies to medicinal cannabis vaping goods, and to provide greater specificity of the persons covered by the Principal Determination. Significant consultation was separately undertaken in relation to the Government's vaping reform measures, which included the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*, related regulations and other legislative instruments, including the Principal Determination.

Other details

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

The Amendment 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 not prepared in relation to the Amendment Determination as the amendments are minor and machinery in nature. An IA was separately prepared in relation to the Government's reforms to the regulation of vapes, taking into account the feedback received from stakeholders throughout the consultation (OBPR23-03933). The IA has been published on the Office of Impact Analysis' website at: oia.pmc.gov.au/.

The Amendment Determination is a disallowable legislative instrument for the purposes of the Legislation Act and commences the day after it is registered on the Federal Register of Legislation.

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

Section 1 – Name

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

Section 2 – Commencement

This section provides that the Amendment Determination commences on the day after it is registered.

Section 3 – Authority

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

Subsection 33(1) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Determination is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned. Any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Principal Determination).

Item 1 – definition of ‘permitted cannabis wholesaler’

Item 1 repeals the definition of ‘permitted cannabis wholesaler’, which under the Principal Determination applies to wholesalers of medicinal cannabis vaping substances. As there are no such goods included in the Register, the wholesale supply of these goods is not permitted under Chapter 3 of the Act. Consequently, references to, and a definition of, such a person is not required in the Principal Determination. References to ‘permitted cannabis wholesaler’ in the relevant items in Schedules 1 and 2 of the Principal Determination have also been omitted.

Item 2 – definition of ‘permitted exporter’

Item 2 repeals the definition of ‘permitted exporter’ and replaces it with a definition that substitutes the reference in paragraph (b) to ‘persons covered by a determination under section 41R of the Act in relation to vaping goods possessed by the person in the course of their export business’, with a reference to ‘a person specified in column 3 of item 3 in the table in Schedule 1 or column 3 of items 4 or 5 in the table in Schedule 2’. The substituted reference is intended to provide greater specificity as to the persons covered by the definition. Minor amendments are also made to the chapeau and paragraph (a) that do not change the meaning of the term.

Item 3 – definition of ‘permitted importer’

Item 3 repeals the definition of ‘permitted importer’ and replaces it with a definition that adds the words ‘in relation to vaping goods’ and ‘the’. The purpose of this amendment is to clarify that a person is only covered by the definition in relation to goods the importation of which is authorised under regulation 5 or 5A of the CPI Regulations.

Item 4 – definition of ‘permitted recipient’

Item 4 repeals the definition of ‘permitted recipient’ and replaces it with a definition that:

- deletes references to a person in relation to whom a consent under subsection 41RC(1) of the Act is given in the course of their practice as a health practitioner, a nurse practitioner and a pharmacist and a health practitioner, a nurse practitioner or a pharmacist who is covered by a determination under section 41R. These references are not required because a health practitioner, nurse practitioner and pharmacist is already covered by paragraph (a) of the definition.
- substitutes the reference in paragraph (c) to ‘persons covered by a determination under section 41R of the Act in relation to vaping goods possessed by the person in the course of the person’s importation, manufacturing, wholesale supply or retail supply business’ with a reference to ‘a person specified in column 3 of items 4, 5 or 6 in the table in Schedule 2’. The substituted reference is intended to provide greater specificity as to the persons covered by the definition.

Item 5 – definition of ‘permitted wholesale supplier’

Item 5 repeals the definition of ‘permitted wholesale supplier’ and replaces it with a definition that:

- substitutes the identification of the person as a ‘permitted supplier’. This more accurately reflects the persons falling within the definition, which includes retail suppliers.
- amends the order of the wording in paragraph (b) but does not change its meaning.
- substitutes the reference to ‘a person covered by a determination under section 41R of the Act in relation to vaping goods supplied by them in the course of their importation, manufacturing, wholesale supply or retail supply business’ with a reference to ‘a person specified in column 3 of item 7 in the table in Schedule 2’. The substituted reference is intended to provide greater specificity as to the persons covered by the definition.

Item 6 – references to a permitted cannabis wholesaler and permitted wholesale supplier

Item 6 repeals subparagraph (b) (ii) in column 4 of item 3 of Schedule 1 and substitutes it with a new subparagraph (b) (ii) to delete a reference to a ‘permitted cannabis wholesaler’. This reference is not required because the meaning of the term is a person who supplies medicinal cannabis vaping substances by wholesale, and as there are no such goods included in the Register, the wholesale supply of these goods is prohibited under Chapter 3 of the Act.

The substituted definition also substitutes ‘permitted wholesale supplier’ with ‘permitted supplier’ to reflect the new label for the term (see item 5).

Item 7 – possession by storage facilities on or before specified date

Item 7 amends the date in table item 4 of Schedule 1 on or before which possession may occur, from 30 September 2024 to 30 November 2024. This extends the application of this item by two months. In practice this item may apply to storage facilities in two circumstances. Firstly, it may apply in relation to the possession of registered or notified vaping goods that would ordinarily fall within the exceptions to the offences and civil penalties in Chapter 4A but for the storage facility not being licenced or authorised to possess medicines containing substances included in Schedule 4 to the Poisons Standard. Facilities intending to store such goods after 30 November 2024 will need to be licenced or authorised under state or territory law to possess medicines containing substances included

in Schedule 3 to the Poisons Standard, or will need further authorisation under section 41R (if available) or section 41RC of the Act to possess the relevant vaping goods.

Facilities intending to store vaping goods that are not registered or notified after 30 November 2024 will need further authorisation under section 41R (if available) or section 41RC of the Act to possess the relevant vaping goods.

Item 8 – references to a permitted cannabis wholesaler and permitted wholesale supplier

Item 8 amends subparagraph (b) (iii) in column 4 of table item 4 of Schedule 1 to delete a reference to a ‘permitted cannabis wholesaler’. This reference is not required because the meaning of the term is a person who supplies medicinal cannabis vaping substances by wholesale, and as there are no such goods included in the Register, the wholesale supply of these goods is prohibited under Chapter 3 of the Act.

This item also substitutes ‘permitted wholesale supplier’ with ‘permitted supplier’ to reflect the new label for the term (see item 5).

Item 9 – possession by waste disposal facilities on or before specified date

Item 9 amends the date in table item 5 of Schedule 1 on or before which possession for the purpose of disposal may occur, from 30 September 2024 to 30 November 2024. This extends the application of this item by two months.

In practice this item may apply to waste disposal facilities in two circumstances. Firstly, it may apply in relation to the possession of registered or notified vaping goods that would ordinarily fall within the exceptions to the offences and civil penalties in Chapter 4A but for the waste disposal facility not being licenced or authorised to possess medicines containing substances included in Schedule 4 to the Poisons Standard. Facilities intending to engage in disposal of such goods after 30 November 2024 will need to be licenced or authorised under state or territory law to possess medicines containing substances included in Schedule 3 to the Poisons Standard, or will need further authorisation under section 41R (if available) or section 41RC of the Act to possess the relevant vaping goods.

Secondly, it may apply in relation to the possession of vaping goods that are not registered or notified. Facilities intending to store vaping goods that are not registered or notified after 30 November 2024 will need further authorisation under section 41R (if available) or section 41RC of the Act to possess the relevant vaping goods.

Item 10 – possession by persons engaged in medical or scientific research on or before specified date

Item 10 amends the date in table item 5 of Schedule 1 on or before which possession may occur for the purpose of bona fide medical or scientific research from 30 September 2024 to 30 November 2024. This extends the application of this item by two months.

In practice the persons to whom this item applies are likely to be licenced or authorised under state or territory law to possess medicines containing substances included in Schedule 4 to the Poisons Standard, and the possession by such persons of registered or notified vaping goods will fall within the exceptions to the offences and civil penalty provisions in Chapter 4A. Consequently, this item is more likely to be applicable in relation to the possession by such persons of vaping goods that are not registered or notified. Persons covered by this item will not be able to possess the relevant vaping goods after 30 November 2024 (even where the person possesses the goods with the intention of engaging in bona fide research relating to the goods) unless these persons have further authorisation under section 41R (if available) or section 41RC of the Act.

Items 11 and 12 – notification, possession and supply under business surrender scheme on or before specified date

Items 11 and 12 amend table item 4 of Schedule 2 to:

- change the date by which business must notify the Department that the person intends to surrender the goods to the Department from 1 August 2024 to 1 September 2024; and
- change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024.

This provides one additional month for business to make the necessary notification, and two additional months during which possession and supply for the purpose of surrender is lawful.

Item 13 – possession and supply by businesses for the purpose of disposal

Item 13 amends table item 5 of Schedule 2 to change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024. This provides two additional months during which possession and supply for the purpose of surrender is lawful.

Items 14-17 – possession and supply through the pharmaceutical supply chain

Items 14-17 amend table item 6 of Schedule 2 to:

- change the date by which business must notify the Department (if applicable) that, immediately before 1 July 2024, the person possessed more than 20 times the commercial quantity.
- change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024.
- substitute references in column 4 to a ‘permitted wholesale supplier’ to a ‘permitted supplier’ to reflect the amended label for this term (see item 5).

This provides one additional month for business to make the necessary notification, and two additional months during which possession and supply is lawful.

Item 18 – wholesale supply of notified vaping goods (including devices) and medical devices used to vape medicinal cannabis

Item 18 repeals table item 7 of Schedule 2 and substitutes it with a new item. The purpose of amended item 7 is to provide, until 30 November 2024, for the possession and wholesale supply of notified vaping goods other than goods that contain a substance included in a Schedule to the current Poisons Standard, and therapeutic cannabis vaping goods that are included in the Register, in the circumstances specified in the item. As these goods do not include substances that are included in the Register, wholesalers of these goods may not be authorised or licenced under state or territory law to supply goods containing substances included in Schedule 4 to the Poisons Standard and consequently may not fall within the exceptions to the offences and civil penalty provisions in Chapter 4A of the Act. After 30 November 2024, it is intended that any person who is not authorised or licenced under state or territory law to supply goods containing substances included in Schedule 3 to the Poisons Standard, will require further authorisation under section 41R (if available) or section 41RC of the Act to possess and supply such goods.

The amended item differs from item 7 in the Principal Determination in the following respects:

- it does not apply to medicinal cannabis vaping substances. These goods are omitted from this item, which applies to a person engaged in the business of importation or wholesale supply, for two reasons:
 - these goods are separately covered by item 9 of Schedule 2;
 - the wholesale supply of these goods is prohibited under Chapter 3 of the Act, as there are no such goods included in the Register;
- it applies in relation to the possession and supply on or before 30 November 2024 – item 7 in the Principal Determination applied on an ongoing basis in relation to the possession and

supply of medicinal cannabis vaping substances (which are no longer covered by this item), and until 30 September 2024 in relation to notified vaping goods other than goods that contain a substance included in a Schedule to the current Poisons Standard, and therapeutic cannabis vaping goods. This provides two additional months during which possession and wholesale supply in the specified circumstances is lawful. After 30 November 2024, further authorisation under the Act will be required if the person is possessing or supplying medical devices used to vape medicinal cannabis, or if the person is possessing or supplying notified vaping goods and is not licenced or authorised under state or territory law to possess and supply substances included in Schedule 3 to the Poisons Standard;

- possession for the sole purpose of supplying the goods to a permitted cannabis wholesaler has been deleted;
- references to the reasonable belief of the importer or wholesaler that medicinal cannabis vaping substances or medical devices used to vape medicinal cannabis are included in the Register or have been approved for supply under an access pathway for unapproved goods have been deleted. This is because under the direct control exemptions such a belief is not required prior to supply;
- references to compliance with requirements under state or territory law that apply to possession of goods containing substances included in Schedule 4 or 8 to the Poisons Standard have been deleted, because the amended item applies only to goods that do not contain such substances;
- in relation to therapeutic cannabis vaping goods, the circumstances are that the goods are either included in the Register, or, for goods that are not included in the Register, they are supplied to a person who is not engaged in the business of wholesale supply. This has been added to reflect the prohibition in section 41MK of the Act on the wholesale supply of medical devices that are not included in the Register and are not otherwise exempt, authorised or approved.

Items 19 and 20 – nicotine in solution that is manufactured in Australia

Items 19 and 20 amend column 4 of table item 8 of Schedule 2 to:

- change the date by which business must notify the Department (if applicable) that, immediately before 1 July 2024, the person possessed more than 20 times the commercial quantity of nicotine in solution. The new date is 1 August 2024; and
- change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024.

This provides one additional month for business to make the necessary notification, and two additional months during which possession and supply is lawful. After 30 November 2024, lawful possession or supply of nicotine in solution that is manufactured in Australia would require further authorisation under section 41R (if available) or section 41RC of the Act.

Item 21– possession and supply of medicinal cannabis vaping substances

Item 21 repeals table item 9 of Schedule 2 and substitutes it with a new item. The purpose of amended item 9 is to provide for the possession and supply of vaping substances that are medicinal cannabis products or medicines that contain synthetic cannabis that have been imported, or manufactured in Australia, and are held under the direct control of sponsors until they are supplied to a permitted recipient.

The amended item differs from item 9 in the Principal Determination in the following respects:

- it applies to ‘goods that are or contain a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis’. This amendment is made because the purpose of the item is to apply to medicinal cannabis vaping substances and their containers that are either imported under regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*, or are lawfully manufactured in Australia pursuant to a licence under Chapter 3-3 of the Act;

- it includes references to persons who manufacture medicinal cannabis vaping substances and their containers under a licence under Part 3-3 of the Act and the goods being manufactured by such a person. This extends the operation of the exemption to domestically manufactured goods;
- it deletes references to a permitted wholesale supplier and a permitted cannabis wholesaler, because the goods to which the item applies cannot be supplied via wholesale;
- it substitutes the list of persons to whom the goods may be supplied with a ‘permitted health practitioner’. This reflects the prohibition on wholesale supply of medicinal cannabis substances, and the requirements that supply of goods held under the direct control exemptions only be to a person who can lawfully supply the goods to a patient under an exemption, approval or authority under the Act;
- it includes references to compliance with requirements under state or territory law that apply to possession of goods containing substances included in Schedule 4 or 8 to the Poisons Standard, because the goods to which the item applies contain such substances.

Items 22 - 24 – transport of notified vaping goods and medicinal cannabis vaping goods through the pharmaceutical supply chain

Item 22 amends column 4 of table item 10 of Schedule 2 to change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024. This provides two additional months during which possession and supply by a person engaged in the business of transporting goods is lawful. After 30 November 2024, further authorisation under the Act will be required if the person is possessing or supplying medicinal cannabis vaping goods, or if the person is possessing or supplying notified vaping goods and is not licenced or authorised under state or territory law to possess and supply substances included in Schedule 3 to the Poisons Standard.

Items 23 and 24 amend item 10 of Schedule 1 to delete references to a ‘permitted cannabis wholesaler’. These references are not required because the meaning of the term is a person who supplies medicinal cannabis vaping substances by wholesale, and as there are no such goods included in the Register, the wholesale supply of these goods is prohibited under Chapter 3 of the Act. These items also substitute ‘permitted wholesale supplier’ with ‘permitted supplier’ to reflect the new label for the term (see item 5).

Item 25– transport of vaping goods for the purpose of disposal

Item 25 amends table item 11 of Schedule 2 to change the date on or before which possession and supply must occur, from 30 September 2024 to 30 November 2024. This provides two additional months during which possession and supply by a person engaged in the business of transporting goods is lawful.

Item 26 – clinical trials

Item 26 amends table item 13 of Schedule 2 to change the date on or before which possession and supply must occur from 30 September 2024 to 30 November 2024. This provides two additional months during which possession and supply in the context of an approved or exempt clinical trial is lawful. After 30 November 2024, further authorisation under the Act will be required if the person is possessing or supplying vaping goods that are not notified vaping goods, or if the person is possessing or supplying notified vaping goods and is not licenced or authorised under state or territory law to possess and supply substances included in Schedule 3 to the Poisons Standard.

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) Amendment 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 offences and civil penalties relating to the importation, manufacture, supply and commercial possession of vaping goods. The offence and civil penalty provisions prohibit such conduct unless an exception specified in the relevant provision of the Act applies. 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. These persons are authorised or permitted under Commonwealth or state and territory legislation to be lawfully involved in the therapeutic goods supply chain. The exceptions include reference to persons, vaping goods and activities covered by a determination or consent under sections 41R and 41RC of the Act. These sections 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 determine or authorise the supply or possession of specified vaping goods by certain persons in specified circumstances, subject to appropriate safeguards.

In contrast to other exceptions to offences and civil penalty provisions in the Act, the exceptions reflected in a legislative instrument made under section 41R of the Act (or a consent under section 41RC) may be highly detailed, technical in nature and, in some cases, transitional. The purpose of these exceptions is to specify the persons who may legitimately supply or possess vaping goods in complex circumstances that are not reflected in the Act. As a significant number of persons play a legitimate role in the importation, exportation, manufacture, wholesale and retail supply of vaping goods outside the circumstances reflected in the Act the circumstances reflected in the legislative instrument made under section 41R are necessarily detailed to mitigate the risk of diversion and to ensure appropriate oversight by the Department of the supply and possession of vaping goods by persons in the pharmaceutical wholesale and retail supply chains who are not already expressly permitted by the exceptions in the Act.

The regulation of vaping goods is complex, being subject to both Commonwealth and state and territory laws. Commonwealth delegated legislation (such as controls in the *Customs (Prohibited Imports) Regulations 1956*) and state and territory laws may change from time to time.

It is therefore considered necessary and appropriate to provide a basis in which the Minister may authorise the supply and possession of certain vaping goods in a legislative instrument made under section 41R of the Act, to enable sufficient flexibility to specify appropriate circumstances in which vaping goods may be lawfully supplied or possessed, and to deal with unintended situations that arise because of the complex interaction between, or changes to, these laws.

Essentially, section 41R of the Act provides a mechanism by which the Minister may determine the circumstances in which specified vaping goods may be supplied or possessed by specified persons. In practice, these circumstances occur where supply or possession relates to a legitimate dealing with

therapeutic vaping goods as part of the supply chain for such products and the person is not ordinarily covered by a statutory exception expressly outlined in the Act.

Specifically, 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 Principal Determination) is made under section 41R of the Act. In effect, the Principal Determination authorises certain persons to supply or possess vaping goods in certain circumstances, where those persons would not otherwise be permitted to do so. 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.

The Principal Determination is driven by public health objectives principally to ensure that:

- unused stock of unlawful vaping goods in the community at the commencement of the vaping reforms may be surrendered, exported, disposed, or destroyed in controlled circumstances that minimise the risk of diversion; and
- the Department has oversight of the supply and possession of lawful vaping goods by certain persons in the pharmaceutical wholesale or retail supply chains who do not otherwise hold a licence or authority to do so; and
- adequate protection is afforded to certain specified persons where the supply or possession of vaping goods without a licence or other authority for a bespoke reason outweighs the public health and safety concerns, such as supply or possession for scientific research or testing.

Some of the items provided in the Principal Determination are time limited to enable the disposal or depletion of existing stock of vaping goods where supply or possession of those goods was lawful under Commonwealth and state or territory laws prior to the commencement of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*. Limiting the time in which those items are available is intended to ensure:

- appropriate enforcement action is available for the possession and supply of unlawful vapes following the sunset of the instrument; and
- the lawful supply and possession of certain vaping goods by certain persons in the supply chain who otherwise do not have a licence or authority to do so, until a consent scheme is implemented and adopted by industry.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024* (the Amendment Determination) is similarly made under section 41R of the Act. It amends the Principal Determination principally to:

- extend the notification requirements, by one month, that apply to specified persons intending to surrender vaping goods to the Department of Health and to persons possessing a particular commercial quantity of vaping goods;
- extend the expiration of the application of some items relating to supply and possession from 30 September 2024 to 30 November 2024; and

- make minor amendments to defined terms and ensure consistency with the regulatory framework in Chapters 3 and 4 of the Act in relation to the supply of medicinal cannabis vaping goods.

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. 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 did not meet 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 were 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, commenced on 1 July 2024, and implemented 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.

The Principal Determination includes several items that apply to the supply and possession of vaping goods until 30 September 2024. The purpose of these items was to implement transitional arrangements for persons to divest themselves of vaping goods that can no longer be lawfully possessed and supplied, and for persons involved in the supply chain for legitimate therapeutic vapes to continue their involvement until further authority is made available under sections 41R or 41RC of the Act or, in relation to registered or notified vaping goods, until the person is duly licenced or authorised under the law of a state or territory to supply or possess goods containing substances included in Schedule 4 to the Poisons Standard. On 1 October 2024, amendments to the Act take effect under which persons who are licenced or authorised under the law of a state or territory to supply or possess goods containing substances included in Schedule 3, rather than Schedule 4, to the Poisons Standard, will fall within exceptions to the offences and civil penalty provisions in Chapter 4A in relation to the supply and possession of registered or notified vaping goods.

The Principal Determination includes a definition and several references to a 'permitted cannabis wholesaler', the intent of which was to apply to wholesalers of vaping substances that are or contain medicinal cannabis. However, as there are no vaping substances containing medicinal cannabis that are included in the Australian Register of Therapeutic Goods (Register), medicinal cannabis vaping substances are, in practice, imported, or manufactured in Australia, and held under the 'direct control' exemptions in items 1 or 2 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (TG Regulations). Under those exemptions, such goods must remain under the direct control of the sponsor, and although the services of third-party transporters and storage facilities may be engaged by sponsors in connection with the distribution of such goods, the supply of the goods by wholesale is prohibited under section 21 of the Act.

The Principal Determination also includes references to wholesale supply of 'therapeutic cannabis vaping goods', which is a defined term in the *Therapeutic Goods (Medical Devices) Regulations 2002* (MD Regulations) that applies to medical devices used to vape medical cannabis. There are a small number of medical devices used to vape medical cannabis that are included in the Register. The remainder of these goods that are imported into Australia are imported under the direct control exemption in item 2.1 of Part 2 of Schedule 4 to the MD Regulations and the supply of such goods by wholesale is prohibited under section 41MK of the Act.

The references in the Principal Determination to wholesale supply of medicinal cannabis vaping goods do not limit such supply to goods that are included in the Register and as such, are broader than what is permitted under Chapters 3 and 4 of the Act in relation to the wholesale supply of such goods.

Purpose

The Principal 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 Principal 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 Principal Determination.

The purpose of the Amendment Determination is principally to give relevant stakeholders adequate time to notify the Department about their intention to surrender or export specified vaping goods by extending the date by which a notification must be made from 1 August 2024 to 1 September 2024, and to extend the period for relevant persons to supply or possess vaping goods from 30 September 2024 to 30 November 2024. This will allow specified persons additional time to make the necessary arrangements and, where necessary, for further authorisation to be made available under section 41R or section 41RC of the Act for the lawful supply or possession of the goods.

The amendments are also intended to ensure consistency with the regulatory framework in Chapters 3 and 4 of the Act in relation to the *wholesale* supply of vaping goods that are or contain medicinal cannabis or a medicine that contains synthetic cannabis. That is, to permit such supply only in relation to goods that are included in the Register, and to ensure that wholesale supply is not permitted under Chapter 4A of the Act where the direct control exemptions apply to the goods.

The references to wholesale supply of such goods in the Principal Determination have the effect that the offences and civil penalties in Chapter 4A of the Act do not apply in relation to the possession and wholesale supply of those goods in the circumstances specified in the Principal Determination. However, neither the Principal Determination nor the Amendment Determination affect the operation of the offences in sections 21 and 41MK of the Act, which apply separately to prohibit the wholesale supply of medicinal cannabis vaping goods that are not included in the Register and are not otherwise exempt, approved or authorised.

Human rights implications

As the Amendment Determination extends the timeframes for industry stakeholders to opt-in to transitional arrangements and amends references to wholesale supply, which is a business transaction only that does not affect supply to the final recipient of the goods, the Amendment Determination does not engage any applicable rights or freedoms.

Conclusion

The Amendment Determination is compatible with human rights because it does not raise any human rights issues.