

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 3) 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 such time that an appropriate on-going consent scheme is determined to be implemented and adopted by industry.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 3) 2024* (the Amendment Determination) is similarly made under section 41R of the Act. It amends the Principal Determination, principally to remove conditions relating to the production, seizure and inspection of documents and information, and conditions requiring persons to notify state or territory police when vaping goods are suspected to be lost or stolen, from several items in Schedules 1 and 2 to the Principal Determination. The Amendment Determination also makes minor amendments to extend the period during which the goods may be supplied or possessed in certain circumstances.

## 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 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 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 Customs 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 second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, domestic 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 third stage of the Government's vaping reforms comprised amendments to the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024*, the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022*, the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, and the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*. These amendments commenced on 1 October 2024, and include the following:

- establishing a new 'pharmacist only model' pathway for accessing notified therapeutic vaping goods. Under this pathway, subject to state and territory government requirements, therapeutic vaping goods containing a nicotine concentration of 20mg/mL or less may be supplied by a pharmacist without prescription, where clinically appropriate, to adults aged 18 years or over; and
- introducing strengthened product standards for therapeutic vaping goods that are for use in smoking cessation or the management of nicotine dependence, including restrictions on the formulation of vaping substances, reducing allowable nicotine concentrations, imposing more stringent technical product requirements and enhancing labelling and packaging requirements.

## Purpose

The Principal Determination is made under section 41R of the Act 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 Amendment Determination amends the Principal Determination, principally to address concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation (SSCSDL) in relation to the broad discretionary and coercive nature of conditions relating to the production, seizure and inspection of documents and information and include the requirement for persons to notify state or territory police when vaping goods are suspected to be lost or stolen. In particular, the Amendment Determination amends the Principal Determination by repealing the following conditions:

- paragraphs (g) and (h) in column 5 of item 3 of Schedule 1;
- paragraphs (d) and (f) in column 5 of item 4 of Schedule 1;
- paragraphs (h) and (i) in column 5 of item 5 of Schedule 1;
- paragraphs (f) and (g) in column 5 of item 6 of Schedule 1;
- subparagraph (c)(iii) in column 5 of item 3 of Schedule 2;
- paragraphs (a) and (f) in column 5 of item 4 of Schedule 2;
- paragraphs (f) and (g) in column 5 of item 5 of Schedule 2;
- paragraphs (a) and (i) in column 5 of item 6 of Schedule 2;
- paragraphs (h) and (i) in column 5 of item 7 of Schedule 2;
- paragraph (c) in column 5 of item 8 of Schedule 2;
- paragraph (b) in column 5 of item 9 of Schedule 2;
- paragraphs (i) and (j) in column 5 of item 10 of Schedule 2;
- paragraphs (h) and (i) in column 5 of item 11 of Schedule 2;
- paragraph (d) in column 5 of item 13 of Schedule 2.

The Amendment Determination also amends item 5 of Schedule 1 and item 4 of Schedule 2 to the Principal Determination to extend the period in which goods may be supplied or possessed by relevant persons under these items from 30 November 2024 to 31 January 2025. This amendment is intended

to provide additional time for goods to be collected from business participating in the business surrender scheme and provided to an authorised disposer for subsequent destruction.

The Amendment Determination also makes a small number of other minor consequential and editorial amendments.

### **Consultation**

Consultation was not undertaken in relation to the making of the Amendment Determination as the amendments made by the Amendment Determination principally address the concerns raised by the SSCSDL, provide additional time in which relevant persons may supply or possess certain vaping goods for the purposes of surrendering to the Department, and otherwise make minor editorial amendments or corrections.

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, such as 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 principally address concerns raised by the SSCSDL or are otherwise minor and machinery in nature. An IA was separately prepared in relation to the Government's reforms to the regulation of vapes, considering 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/](http://oia.pmc.gov.au/).

The Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

**Details of the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 3) 2024***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 3) 2024* (the Amendment Determination).

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on the day after it is registered on the Federal Register of Legislation.

**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).

**Items 1 and 4 – Schedule 1 (table item 3, column 5, at the end of subparagraph (f)(v) and table item 4, column 5, at the end of paragraph (e))**

These items make minor editorial amendments to remove the semi-colon at the end of subparagraph (f)(v) in column 5 of item 3 and paragraph (e) in column 5 of item 4 of Schedule 1 to the Principal Determination, consequential to the amendments made to those items below.

**Items 2, 3 and 5 – Schedule 1 (table item 3, column 5, paragraphs (g) and (h), table item 4, column 5, paragraphs (d) and (f))**

These items amend items 3 and 4 of Schedule 1 to the Principal Determination to address concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation Committee (SSCSDL).

Item 2 repeals paragraphs (g) and (h) in column 5 of item 3 of Schedule 1 to the Principal Determination.

Items 3 and 5 repeal paragraphs (d) and (f) in column 5 of item 4 of Schedule 1 to the Principal Determination.

**Item 6 – Schedule 1 (table item 5, column 4, paragraph (a))**

Under item 5 of Schedule 1 to the Principal Determination, vaping goods may be possessed 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 and subject to specified conditions.

This item amends the date in paragraph (a) in column 4 of item 5 of Schedule 1 to the Principal Determination, on or before which possession for the purpose of disposal may occur, from 30 November 2024 to 31 January 2025. This extends the application of this item by two months, providing additional time during which vaping goods may be provided to, and possessed by an authorised disposer for subsequent destruction.

**Items 7 and 9 – Schedule 1 (table item 5, column 5, at the end of subparagraph (g)(v) and table item 6, column 5, at the end of subparagraph (e)(v))**

These items make minor editorial amendments to remove the semi-colon at the end of subparagraph (g)(v) in column 5 of item 5 and subparagraph (e)(v) in column 5 of item 6 of Schedule 1 to the Principal Determination, consequential to the amendments made to those items below.

**Items 8 and 10 – Schedule 1 (table item 5, column 5, paragraphs (h) and (i) and table item 6, column 5, paragraphs (f) and (g))**

These items amend items 5 and 6 of Schedule 1 to the Principal Determination to address concerns raised by the SSCSDL.

Item 8 repeals paragraphs (h) and (i) in column 5 of item 5 of Schedule 1 to the Principal Determination.

Item 10 repeals paragraphs (f) and (g) in column 5 of item 6 of Schedule 1 to the Principal Determination.

**Item 11 – Schedule 2 (table item 3, column 5, at the end of subparagraph (c)(ii))**

This item makes a minor editorial amendment to remove the semi-colon at the end of subparagraph (c)(ii) in column 5 of item 3 of Schedule 2 to the Principal Determination, consequential to the amendments made to those items below.

**Items 12, 14 and 16 – Schedule 2 (table item 3, column 5, subparagraph (c)(iii) and table item 4, column 5, paragraphs (a) and (f))**

These items amend items 3 and 4 of Schedule 2 to the Principal Determination to address concerns raised by the SSCSDL.

Item 12 repeals subparagraphs (c)(iii) in column 5 of item 3 of Schedule 2 to the Principal Determination.

Items 14 and 16 repeal paragraphs (a) and (f) in column 5 of item 4 of Schedule 2 to the Principal Determination.

### **Item 13 – Schedule 2 (table item 4, column 4, paragraph (a))**

Item 4 of Schedule 2 to the Principal Determination authorises the supply and possession of vaping goods by certain businesses in specified circumstances, including where possession of vaping goods had been lawful prior to 1 July 2024. Subject to specified conditions, the item enables these businesses to arrange for the surrender of those goods to the Department. In practice, this is referred to as the ‘business surrender scheme’.

This item amends the date in paragraph (a) in column 4 of item 4 of Schedule 2 to the Principal Determination, on or before which possession or supply by certain business that are part of the business surrender scheme, may occur from 30 November 2024 to 31 January 2025. This extends the application of this item by two months.

### **Items 15, 17, 20 and 22 – Schedule 2 (table item 4, column 5, at the end of paragraph (e), table item 5, column 5, at the end of subparagraph (e)(ii), table item 6, column 5, at the end of subparagraph (h)(iii) and table item 7, column 5, at the end of subparagraph (g)(iii))**

These items make minor editorial amendments to remove the semi-colon from the end of paragraph (e) in column 5 of item 4, subparagraph (e)(ii) in column 5 of item 5, subparagraph (h)(iii) in column 5 of item 6 and subparagraph (g)(iii) in column 5 of item 7 of Schedule 2 to the Principal Determination, consequential to the amendments made to those items below.

### **Items 18, 19, 21 and 23 – Schedule 2 (table item 5, column 5, paragraphs (f) and (g), table item 6, column 5, paragraphs (a) and (i) and table item 7, column 5, paragraphs (h) and (i))**

These items amend items 5, 6 and 7 of Schedule 2 to the Principal Determination to address concerns raised by the SSCSDL.

Item 18 repeals paragraphs (f) and (g) in column 5 of item 5 of Schedule 2 to the Principal Determination.

Items 19 and 21 repeal paragraphs (a) and (i) in column 5 of item 6 of Schedule 2 to the Principal Determination.

Item 23 repeals paragraphs (h) and (i) in column 5 of item 7 of Schedule 2 to the Principal Determination.

### **Item 24 – Schedule 2 (table item 8, column 4, at the end of paragraph (a))**

This item makes a minor editorial amendment to remove the erroneous reference to ‘30 March 2025’ in paragraph (a) in column 4 of item 8 and replace it with ‘31 March 2025’.

### **Item 25 – Schedule (table item 8, column 5, at the end of paragraph (b))**

This item makes a minor editorial amendment to remove the semi-colon at the end of paragraph (b) in column 5 of item 8 of Schedule 2 to the Principal Determination, consequential to the amendments made to that item below.

### **Items 26 and 27 – Schedule 2 (table item 8, column 5, paragraph (c) and table item 9, column 5, paragraph (b))**

These items amend items 8 and 9 of Schedule 2 to the Principal Determination to address concerns raised by the SSCSDL.

Item 26 repeals paragraphs (c) in column 5 of item 8 of Schedule 2 to the Principal Determination.



Item 27 repeals paragraph (b) in column 5 of item 9 of Schedule 2 to the Principal Determination.

**Item 28 – Schedule 2 (table item 9, column 5, paragraph (c))**

This item makes a minor editorial amendment to replace the reference to ‘Schedule 4 of the current Poisons Standards applies’ with ‘Schedule 4 to the current Poisons Standard applies’ in paragraph (c) in column 5 of item 9 of Schedule 2 to the Principal Determination.

**Items 29, 31 and 33 – Schedule 2 (table item 10, column 5, at the end of subparagraph (h)(iii), table item 11, column 5, at the end of subparagraph (g)(iii) and table item 13, column 5, at the of paragraph (c))**

These items make minor editorial amendments to remove the semi-colon from the end of subparagraph (h)(iii) in column 5 of item 10, subparagraph (g)(iii) in column 5 of item 11 and paragraph (c) in column 5 of item 13 of Schedule 2 to the Principal Determination, consequential to the amendments made to those items below.

**Items 30, 32 and 34 – Schedule 2 (table item 10, column 5, paragraphs (i) and (j), table item 11, column 5, paragraphs (h) and (i) and table item 13, column 5, paragraph (d))**

These items amend items 10, 11 and 13 of Schedule 2 to the Principal Determination to address concerns raised by the SSCSDL.

Item 30 repeals paragraphs (i) and (j) in column 5 of item 10 of Schedule 2 to the Principal Determination.

Item 32 repeals paragraphs (h) and (i) in column 5 of item 11 of Schedule 2 to the Principal Determination.

Item 34 repeals paragraph (d) in column 5 of item 13 of Schedule 2 to the Principal Determination.

## 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 (No. 3) 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 such time that an appropriate on-going consent scheme is determined to be implemented and adopted by industry.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 3) 2024* (the Amendment Determination) is similarly made under section 41R of the Act. It amends the Principal Determination, principally to remove conditions relating to the production, seizure and inspection of documents and information, and conditions requiring persons to notify state or territory police when vaping goods are suspected to be lost or stolen, from several items in Schedules 1 and 2 to the Principal Determination. The Amendment Determination also makes minor amendments to extend the period during which the goods may be supplied or possessed in certain circumstances.

## 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 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 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 Customs 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 second stage of reforms to the regulation of vaping goods, principally to prohibit the importation, domestic 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 third stage of the Government's vaping reforms comprised amendments to the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024*, the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022*, the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, and the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*. These amendments commenced on 1 October 2024, and include the following:

- establishing a new 'pharmacist only model' pathway for accessing notified therapeutic vaping goods. Under this pathway, subject to state and territory government requirements, therapeutic vaping goods containing a nicotine concentration of 20mg/mL or less may be supplied by a pharmacist without prescription, where clinically appropriate, to adults aged 18 years or over; and
- introducing strengthened product standards for therapeutic vaping goods that are for use in smoking cessation or the management of nicotine dependence, including restrictions on the formulation of vaping substances, reducing allowable nicotine concentrations, imposing more stringent technical product requirements and enhancing labelling and packaging requirements.

## Purpose

The Principal Determination is made under section 41R of the Act 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 Amendment Determination amends the Principal Determination, principally to address concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation (SSCSDL) in relation to the broad discretionary and coercive nature of conditions relating to the production, seizure and inspection of documents and information and include the requirement for persons to notify state or territory police when vaping goods are suspected to be lost or stolen. In particular, the Amendment Determination amends the Principal Determination by repealing the following conditions:

- paragraphs (g) and (h) in column 5 of item 3 of Schedule 1;
- paragraphs (d) and (f) in column 5 of item 4 of Schedule 1;
- paragraphs (h) and (i) in column 5 of item 5 of Schedule 1;
- paragraphs (f) and (g) in column 5 of item 6 of Schedule 1;
- subparagraph (c)(iii) in column 5 of item 3 of Schedule 2;
- paragraphs (a) and (f) in column 5 of item 4 of Schedule 2;
- paragraphs (f) and (g) in column 5 of item 5 of Schedule 2;
- paragraphs (a) and (i) in column 5 of item 6 of Schedule 2;
- paragraphs (h) and (i) in column 5 of item 7 of Schedule 2;
- paragraph (c) in column 5 of item 8 of Schedule 2;
- paragraph (b) in column 5 of item 9 of Schedule 2;
- paragraphs (i) and (j) in column 5 of item 10 of Schedule 2;
- paragraphs (h) and (i) in column 5 of item 11 of Schedule 2;
- paragraph (d) in column 5 of item 13 of Schedule 2.

The Amendment Determination also amends item 5 of Schedule 1 and item 4 of Schedule 2 to the Principal Determination to extend the period in which goods may be supplied or possessed by relevant persons under these items from 30 November 2024 to 31 January 2025. This amendment is intended

to provide additional time for goods to be collected from business participating in the business surrender scheme and provided to an authorised disposer for subsequent destruction.

The Amendment Determination also makes a small number of other minor consequential and editorial amendments.

### **Human rights implications**

As the Amendment Determination principally addresses concerns raised by the SSCSDL, extends for the timeframe in which vaping goods may be supplied or possessed by certain persons by two months, and otherwise makes a small number of editorial amendments, 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.