

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2025

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, or to otherwise lawfully deal with vaping goods for legitimate purposes. 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 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, transportation, storage, disposal, destruction and medical and scientific research and testing 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 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, or other legitimate activities involving the possession or supply of vaping goods (such as transportation, storage, disposal, destruction or medical or scientific research or testing), 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 2025* (the Amendment Determination), similarly made under section 41R of the Act, amends the Principal Determination, principally to specify additional circumstances in which vaping goods may be lawfully possessed or supplied, and to extend several items authorising possession or supply until 31 December 2025.

Purpose

The Principal Determination, made under section 41R of the Act, determines 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 Amendment Determination, also made under section 41R of the Act, amends the Principal Determination, principally to specify two new additional circumstances in which vaping goods may be lawfully possessed or supplied by relevant persons, and to extend the period in which goods may be possessed or supplied by relevant persons until 31 December 2025.

In particular, the Amendment Determination introduces new items 14 and 15 in Schedule 2 to the Principal Determination to determine that vaping goods may be possessed or supplied by specified persons in specified circumstances.

New item 14 authorises the possession and supply of vaping goods by an authority (as defined in section 4 of the Principal Determination), or an agent or employee of an authority, for a number of purposes including the investigation of potential non-compliance with Commonwealth or state and territory laws, and the surrender, seizure, forfeiture, transportation, storage, destruction or disposal of vaping goods.

New item 15 authorises the possession and supply of vaping goods by a person who is a party to a contract with an authority to transport, store, destroy or dispose of vaping goods, and certain persons associated with the contractor, for the sole purpose of performing that contract.

The effect of the Amendment Determination is that persons covered by these new items will not, subject to compliance with the terms of those items, commit relevant offences or contravene civil penalty provisions in Chapter 4A of the Act relating to the supply or possession of a vaping good.

The Amendment Determination also makes minor amendments to extend the period of time that items 4, 5 and 6 in Schedule 1, and items 7, 8, 10 and 11 in Schedule 2 to the Principal Determination apply until 31 December 2025. Extending the timeframe in which goods may be possessed or supply by relevant persons under these items is intended to provide additional time for consultation and implementation of an on-going scheme of exemptions.

Consultation

In late February and early March 2025, the TGA undertook targeted consultation with states and territories and a broad group of Australian logistics (transport, disposal and storage) providers through established consultative forums in relation to the new items introduced by the Amendment Determination. No concerns were raised by stakeholders.

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**.

The Office of Impact Analysis has advised that the preparation of an impact analysis in relation to the Amendment Determination is not required (OIA25-09278).

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 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2025* (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(3) 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 – Section 4 (definition of *authority*)

This item repeals the definition of ‘authority’ in section 4 of the Principal Determination and replaces it with a revised definition that removes the words ‘with functions relating to vaping goods, therapeutic goods, health, law enforcement or waste disposal’.

The purpose of this amendment is to remove the unnecessary limitation on the types of authorities that are captured under the definition for the purposes of the Principal Determination. For example, authorities with functions in relation to education may need to possess or supply vaping goods for the purposes of confiscating vaping goods from students. The revised definition also supports the operation of new table items 14 and 15 as introduced below, which rely on the definition of ‘authority’ in the Principal Determination.

Items 2 and 4 – Schedule 1 (table item 4, column 4, paragraph (a) and table item 6, column 4, paragraph (a))

These items amend the date in table items 4 and 6 in Schedule 1 to the Principal Determination, on or before which possession of specified vaping goods may occur, from 31 March 2025 to 31 December 2025. This extends the application of these items by 9 months.

Extending the timeframe in which goods may be possessed by relevant persons under this item is intended to provide the TGA with additional time to consult with relevant persons to determine the on-going need of these exemption.

Item 3 – Schedule 1 (table item 5, column 4, paragraph (a))

This item amends the date in table item 5 in Schedule 1 to the Principal Determination, on or before which possession may occur, from 31 January 2025 to 31 December 2025. Extending the timeframe in which goods may be possessed by relevant persons under this item is intended to provide the TGA with additional time to consult with those persons to determine the on-going need of this exemption.

Items 5, 6, 7 and 8 – Schedule 2 (table item 7, column 4, paragraph (a), table item 8, column 4, paragraph (a), table item 10, column 4, paragraph (a), and table item 11, column 4, paragraph (a))

These items amend the date in table items 7, 8, 10 and 11 in Schedule 2 to the Principal Determination, on or before which possession or supply of specified vaping goods may occur, from 31 March 2025 to 31 December 2025. This extends the application of these items by 9 months.

Extending the timeframe in which goods may be possessed or supplied by relevant persons under these items is intended to provide the TGA with additional time to consult with relevant persons to determine the on-going need for these exemptions.

Item 9 – Schedule 2 (table item 13, column 4, subparagraph (b)(ii) (second occurring))

This item makes a minor amendment to correct an erroneous duplication of subparagraph (b)(ii) in column 4 of table item 13 in Schedule 2 to the Principal Determination. The amendment corrects the numbering of the relevant subparagraph from (b)(ii) to (b)(iii).

Item 10 – Schedule 2 (at the end of the table)

This item introduces new table items 14 and 15 in Schedule 2 to the Principal Declaration.

Item 14 – Possession and supply by an authority

New table item 14 permits an authority (as defined in section 4 of the Principal Determination), and agents or employees of an authority, to possess and supply vaping goods in specified circumstances. Relevantly, ‘authority’ in section 4 of the Principal Determination (as amended above), means a Commonwealth authority, a department of State of the Commonwealth or a State, a department or administrative unit of the Public Service of a Territory, or an authority of the Commonwealth, a State or Territory (including a local council or other body responsible for local government).

The specified circumstances in which possession and supply is authorised under this item include for the purpose of facilitating, or in connection with: an investigation as to whether the applicable laws of the Commonwealth, a State or a Territory have been complied with; proceedings in respect of which the vaping goods may afford evidence; surrender, seizure, forfeiture, transportation, storage, destruction or disposal of the vaping goods; and bona fide medical or scientific research or testing of vaping goods.

In circumstances involving supply under this item, the person supplying the vaping goods must reasonably believe that the recipient can lawfully possess the vaping goods under the Act and all other applicable laws of the Commonwealth, a State or a Territory, and that the vaping goods will not be used by any person. This is intended to ensure that subsequent possession facilitated by this item is lawful and for legitimate purposes only.

Where vaping goods are possessed or supplied by an agent or employee of an authority under this item, the permitted circumstances are limited to where that agent or employee is acting solely in their official capacity. This is intended to prevent vaping goods being possessed or supplied for illegitimate purposes by agents or employees of authorities and will assist with managing the risk of vaping goods being diverted to the illicit market.

It is intended that this item will have ongoing application, and as such it is not time limited.

Item 15 – Possession and supply by persons contracted or subcontracted by an authority

New table item 15 permits persons contracted by an authority (for example, logistics providers) and their agents or employees to transport, store, destroy or dispose of vaping goods, to possess and supply vaping goods for the sole purpose of performance of the contract between the person and the authority. The item similarly applies to persons (including agents or employees) subcontracted by a person contracted by an authority to provide those services under the contract.

In circumstances involving supply under this item, the person supplying the vaping goods must reasonably believe that the recipient can lawfully possess the vaping goods under the Act and all other applicable laws of the Commonwealth, a State or a Territory, and that the vaping goods will not be used by any person. This is intended to ensure that subsequent possession facilitated by this item is lawful and for legitimate purposes only.

Where vaping goods are possessed or supplied by an agent or employee of a contractor or subcontractor under this item, the permitted circumstances are limited to where that agent or employee is acting solely in their capacity as an agent or employee of the contractor or subcontractor. This is intended to prevent vaping goods being possessed or supplied for illegitimate purposes by those agents or employees and will assist with managing the risk of vaping goods being diverted to the illicit market.

It is intended that this item will have ongoing application, and as such it is not time limited.

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 2025

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, or to otherwise lawfully deal with vaping goods for legitimate purposes. 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 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, transportation, storage, disposal, destruction and medical and scientific research and testing 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 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, or other legitimate activities involving the possession or supply of vaping goods (such as transportation, storage, disposal, destruction or medical or scientific research or testing), 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.

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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 2025* (the Amendment Determination), similarly made under section 41R of the Act, amends the Principal Determination, principally to specify additional circumstances in which vaping goods may be lawfully possessed or supplied, and to extend several items authorising possession or supply until 31 December 2025.

Purpose

The Principal Determination, made under section 41R of the Act, determines 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 Amendment Determination, also made under section 41R of the Act, amends the Principal Determination, principally to specify two new additional circumstances in which vaping goods may be lawfully possessed or supplied by relevant persons, and to extend the period in which goods may be possessed or supplied by relevant persons until 31 December 2025.

In particular, the Amendment Determination introduces new items 14 and 15 in Schedule 2 to the Principal Determination to determine that vaping goods may be possessed or supplied by specified persons in specified circumstances.

New item 14 authorises the possession and supply of vaping goods by an authority (as defined in section 4 of the Principal Determination), or an agent or employee of an authority, for a number of purposes including the investigation of potential non-compliance with Commonwealth or state and territory laws, and the surrender, seizure, forfeiture, transportation, storage, destruction or disposal of vaping goods.

New item 15 authorises the possession and supply of vaping goods by a person who is a party to a contract with an authority to transport, store, destroy or dispose of vaping goods, and certain persons associated with the contractor, for the sole purpose of performing that contract.

The effect of the Amendment Determination is that persons covered by these new items will not, subject to compliance with the terms of those items, commit relevant offences or contravene civil penalty provisions in Chapter 4A of the Act relating to the supply or possession of a vaping good.

The Amendment Determination also makes minor amendments to extend the period of time that items 4, 5 and 6 in Schedule 1, and items 7, 8, 10 and 11 in Schedule 2 to the Principal Determination apply until 31 December 2025. Extending the timeframe in which goods may be possessed or supplied by relevant persons under these items is intended to provide additional time for consultation and implementation of an on-going scheme of exemptions.

Human rights implications

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

Right to health

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health* (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Determination promotes the right to health by ensuring that legitimate activities involving the supply and possession of vaping goods by persons who are not generally covered by

specific approvals, permissions or authorisations under Commonwealth and state and territory laws are permitted. The exemptions ensure that intermediate actors, such as local councils and logistics providers, may carry on activities associated with legitimate patient access to therapeutic vaping goods for smoking cessation or the management of nicotine dependence. They also support the detection, surrender, disposal and destruction of potentially harmful illicit vaping goods.

Conclusion

The Amendment Determination is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR, and otherwise does not raise any other human rights issues.