

# Possession and supply of vaping goods in Australia

Guidance on the legal instrument: *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* 

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#### Introduction

The *Therapeutic Goods Act 1989* (TG Act) strictly regulates vaping goods in Australia. It prohibits the importation, manufacture, supply, advertising, and commercial possession of any vaping good unless an exception applies. There are significant penalties for non-compliance. A person who fails to comply with these restrictions may be prosecuted for an offence or subject to civil penalty proceedings.

Where an exception applies to a particular activity, that activity is **not** unlawful. These exceptions provide defences to a particular person against the application of particular offences or civil penalty provisions.

Most of the exceptions are set out in the TG Act itself. However, the TG Act also provides for exceptions to be set out in a legal instrument made by the Minister (or a delegate).

The legal instrument is made under section 41R of the TG Act <u>Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024</u>) (the Possession and Supply Determination). It sets out additional circumstances in which a person will not be acting unlawfully or in breach of relevant offences or civil penalty provisions relating to possessing and supplying vaping goods.

This guidance provides an overview of who may possess (and in some instances, also supply) specified vapes, under the <u>Possession and Supply Determination</u>.

The majority of these exceptions are transitional. That is, they are time limited.

They provide additional time for people to:

- surrender unlawful vaping goods to the TGA (a minimum quantity applies);
- transport, store or dispose of vapes;
- export unlawful vapes; and
- other limited activities.

Permanent exceptions to the offences or civil penalty provisions apply in very limited circumstances, such as for visiting foreign dignitaries permitted to import vaping goods in accordance with the Australian customs legislation.

Strict conditions apply to all exceptions. Where a person is relying upon an exception in the determination for their possession or supply of vaping goods, credible evidence must be produced upon request to demonstrate compliance with the relevant requirements and conditions. Where evidence is not produced, the goods and associated activity will be treated as unlawful and enforcement action may be taken.

Where appropriate, future determinations made under section 41R of the TG Act may provide permanent exceptions for possessing and supplying vaping goods as appropriate to support the lawful supply of therapeutic vaping goods for patients seeking to quit smoking or manage their nicotine dependence. Where the exceptions with limited transitional periods are not extended under section 41R of the TG Act, further authorisation through a consent granted under section 41RC of the TG Act, or authorisation from States or Territory (if appropriate), may need to be obtained.

# Guidance on the application of the *Therapeutic* Goods (Vaping Goods—Possession and Supply) Determination 2024

# Background to the relevant offences and civil penalty provisions

#### The offences and civil penalty provisions

The possession and supply of vaping goods is strictly controlled. New offences and civil penalties under Part 4A of the TG Act commenced on 1 July 2024 in relation to the importation, manufacture, supply, commercial possession and advertising of vaping goods.

The relevant offence and penalty provisions for this guidance are:

- section 41QC Possessing at least a commercial quantity of vaping goods
- section 41QD Possessing less than a commercial quantity of vaping goods on retail premises
- section 41QB Supplying vaping goods.

## Possessing at least a commercial quantity of vaping goods (section 41QC)

Section 41QC of the TG Act prohibits the possession by a person of at least a 'commercial quantity' of a vaping good, subject to limited exceptions.

- The commercial quantities specified in the *Therapeutic Goods Regulations 1990* from 1 July to 30 September 2024 are:
  - 14 vaping devices
  - o 90 vaping accessories
  - 600mL of vaping substance that is a liquid.
- The commercial quantities from 1 October 2024 are:
  - 9 vaping devices
  - 60 vaping accessories
  - 400mL of vaping substance that is a liquid.

The exceptions to the offence and civil penalty provisions, as outlined in section 41QC of the TG Act, apply to:

- individuals possessing vaping goods that were lawfully supplied to them and are for their personal use, and the quantity is less than 5 times the 'commercial quantity' as set out above;
- persons involved in the legitimate pharmaceutical supply chain who possess vaping goods
  that are included in the Australian Register of Therapeutic Goods, are notified vaping goods
  or goods covered by this Determination (see Types of vaping goods covered by the
  Determination);

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- persons possessing vaping goods covered by the Possession and Supply Determination
- persons who are granted a consent under section 41RC of the TG Act to possess particular vaping goods.

The maximum penalties that will apply are up to 7 years in jail for each offence and/or up to \$2.191 million for each contravention by an individual and \$21.91 million for each contravention in respect of each unit of the quantity of vaping goods vaping goods possessed by a corporation.

## Possessing less than a commercial quantity of vaping goods on retail premises (section 41QD)

Section 41QD of the TG Act prohibits a retailer in relation to retail premises (including a retail worker) from possessing less than a commercial quantity of vaping goods on the retail premises. A retailer means:

- · an owner, lessee or occupier of retail premises in Australia
- a person conducting a business or undertaking at, or in connection or association with, retail premises in Australia
- · a director, officer or agent of a person referred to above
- a person performing work in any capacity (including, but not limited to, an employee or a contractor) for, or on behalf of, a person referred to above at, or in connection or association with, retail premises in Australia.

Retail premises are premises from which goods or services are available for supply, or are supplied, to a consumer, or that are used in connection with the supply of goods or services to a consumer, whether or not the premises are used wholly or predominantly for that purpose.

The exceptions to section 41QD apply to:

- pharmacists and other persons who are licenced under state or territory law to supply
  prescription medicines, in relation to the possession of vaping goods that are included in the
  Australian Register of Therapeutic Goods or are notified vaping goods (see Types of vaping
  goods covered by the Determination)
- persons possessing vaping goods in circumstances specified in the <u>Possession and Supply</u> Determination
- persons who are granted consent under section 41RC of the TG Act
- individuals possessing a quantity of vaping goods that were lawfully supplied for their personal use of not more than:
  - o 2 vaping devices
  - o 4 vaping accessories
  - 60mL of vaping substance that is a liquid.

The maximum penalties that will apply are up to 12 months in jail for each offence and/or up to \$313,000 for each contravention by an individual and \$3.13 million for each contravention in respect of each unit of the quantity of vaping goods vaping goods possessed by a corporation.

#### Supplying vaping goods (section 41QB)

Section 41QB of the TG Act prohibits a person from supplying vaping goods, subject to limited exceptions.

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The exceptions to section 41QB apply to:

- persons involved in the legitimate pharmaceutical supply chain who supply vaping goods that
  are included in the Australian Register of Therapeutic Goods, are notified vaping goods or
  goods covered by this Determination (see Types of vaping goods covered by the
  Determination)
- persons supplying vaping goods in circumstances specified in the <u>Possession and Supply</u> Determination
- persons who are granted consent under section 41RC of the Act to supply vaping goods.

The maximum penalties that will apply are up to 7 years in jail for each offence and/or up to \$2.191 million for each contravention by an individual and \$21.91 million for contravention in respect of each unit of the quantity of vaping goods vaping goods possessed by a corporation.

### **About this guidance**

#### **Key concepts**

#### 'Possession' and 'supply'

The <u>Possession and Supply Determination</u> separately provides for exception for 'Possession' (Schedule 1) and 'Possession and Supply' (Schedule 2).

#### Types of vaping goods covered by the Determination

Some items in the Possession and Supply Determination apply to specified types of vaping goods:

- notified vaping goods means vaping goods that have been notified to the TGA as complying with applicable requirements under the TG Act
  - A list of notified vaping goods is at <u>List of notified vapes | Therapeutic Goods</u>
     <u>Administration (TGA)</u>. If the Secretary makes a determination that a vaping good that has been notified should no longer be supplied because it compromises public health and safety or the goods do not conform with an applicable standard applicable, it is no longer a 'notified vaping good'.
- therapeutic cannabis vaping goods means therapeutic cannabis vaping devices or therapeutic cannabis vaping device accessories, as defined in the *Therapeutic Goods* (*Medical Devices*) Regulations 2002. These definitions apply only in relation to goods that are designed or intended only for use with medicinal cannabis
- medicinal cannabis vaping goods incorporates both therapeutic cannabis vaping goods and vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis
- **vaping goods** is a generic term that applies to all vaping goods, regardless of whether they can be lawfully supplied under the Act.

#### Persons covered by the Determination

Some items in the <u>Possession and Supply Determination</u> apply only to specific persons. The following definitions apply:

• an authorised disposer means:

- 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
- an authority of the Commonwealth, a State or a Territory that has functions relating to waste destruction or disposal.
- a **member of a visiting group** means a person who is a member of 'visiting group' as set out in the *Customs (Prohibited Imports) (Vaping Goods) Approval 2023*. It includes persons visiting Australia as part of an international sporting group, military forces of another country who are visiting Australia for military training, and groups that include a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business.

#### • a permitted exporter means:

- a person engaged in the business of exportation to whom the Secretary has given a consent under subsection 41RC(1) of the Act to possess the vaping goods
- o a person who obtained the goods in the course of their exportation business, and
  - possesses the goods for the sole purpose of exporting the goods from Australia, and
  - imported the goods, or received the goods from a permitted importer, a permitted supplier, a permitted recipient, or from a person supplying vaping goods for the purpose of export in the circumstances in item 6 or 10 of Schedule 2 to the Determination.
- a permitted health practitioner means a pharmacist, or a medical practitioner or nurse
  practitioner who is licenced or authorised under a law of the State or Territory in which the
  supply occurs to supply prescription medicines.
- a permitted importer means a person authorised under regulation 5 or 5A of the <u>Customs</u>
   (<u>Prohibited Imports</u>) <u>Regulations 1956</u> (the CPI Regulations) to import vaping goods, who is
   not already an approved importer
- a **permitted manufacturer** means a person who:
  - holds a licence under Part 3-3 of the TG Act that authorises the manufacture of the vaping goods at the manufacturing site where the manufacture occurs
  - is the holder of a conformity assessment document that applies to the vaping goods
  - holds a consent under subsection 41RC(1) to manufacture the vaping goods, and the manufacture is carried out in accordance with the consent.

#### a permitted recipient means:

- a wholesaler, pharmacist, medical practitioner or nurse practitioner who is licenced or authorised under a law of the State or Territory in which the person carries on a business, practises or is employed to supply prescription medicines
- a person engaged in the business of manufacture, wholesale supply or retail supply to whom the Secretary has given a consent under subsection 41RC(1) of the Act to possess the vaping goods
- o an importation, exportation, manufacturing, wholesale supply, retail supply, transportation or storage business who possesses or supplies vaping goods in the circumstances in items 4, 5 or 6 in the table in Schedule 2. These circumstances include that the importation or manufacture, supply, and possession of the goods immediately before 1 July 2024 was done in accordance with all applicable laws of the Commonwealth, a State or a Territory.

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- a **permitted supplier** means a person who:
  - holds a licence and permit granted under the Customs (Prohibited Imports Regulations)
     1956 to import the vaping goods, or is otherwise permitted under those regulations to import the vaping goods
  - o holds a licence under Part 3-3 of the Act to manufacture the vaping goods
  - holds a conformity assessment document that applies to the vaping goods
  - is a wholesaler who is licenced or authorised under a law of the State or Territory to supply prescription medicines and the supply occurs in accordance with the licence or authority
  - is engaged in the business of importation, manufacture, wholesale supply or retail supply and to whom the Secretary has given a consent under subsection 41RC(1) of the Act to supply the vaping goods
  - is engaged in the business of importation or wholesale supply and who possesses or supplies vaping goods in the circumstances in item 7 in the table in Schedule 2. These circumstances include that the goods are possessed for the sole purpose of supplying the goods to a permitted recipient or a permitted supplier.

#### Circumstances in which vaping goods may be possessed

Circumstances in which vaping goods may be possessed (rather than both possessed and supplied) are specified in Schedule 1 to the Determination.

The circumstances that are specified in Schedule 1 include possession for or by:

- personal use by an individual or for the use of someone in that person's care time limited
- members of a 'visiting group' from overseas, such as foreign dignitaries or international sporting groups
- export businesses who obtained the goods in the course of that business and for the purpose of exporting the vaping goods from Australia - time limited
- storage businesses storing lawful vaping goods as part of the pharmaceutical supply chain time limited
- waste disposal businesses possessing vaping goods for disposal time limited
- laboratories and testing facilities possessing goods for medical or scientific research or testing
   time limited.

These exceptions are subject to conditions and other requirements. More detail follows.

#### Possession for personal use

Item 1 of Schedule 1 to the Determination permits, until 30 June 2025, the possession of vaping goods by individuals for personal use, or use by a person under their care, in the following circumstances:

- the person owns the goods for use by the person or another person in the person's care
- the person is not engaged in, and has at no time after 1 July 2024 been engaged in, the commercial importation, exportation, manufacture, wholesale supply or retail supply of vaping goods (whether as an owner, employee, contractor or other person engaged in these kinds of activities)

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- the goods are not beneficially owned by, or under the control of, a body corporate
- the goods are not possessed or stored in or at a 'retail premises' or a 'commercial premises', which are defined as follows:
  - a retail premises means a premises from which goods or services are available for supply, or are supplied, to a consumer, or that are used in connection with the supply of goods or services to a consumer (whether or not the premises are used wholly or predominantly for that purpose).
  - o a commercial premises means premises:
    - from which goods or services are available for supply, or are supplied, to a person other than a consumer
    - that are used in connection with the supply of goods or services to a person other than a consumer
    - from which goods are imported, exported or manufactured
    - that are used in connection with the importation, exportation or manufacture of goods
    - whether or not the premises are used wholly or predominantly for that purpose.
- the person possesses less than the following quantities:
  - from 1 July 2024 to 30 September 2024:
    - 70 vaping devices
    - 450 vaping accessories, and
    - 3,000mL of vaping substance that is liquid
  - o from 1 October 2024 to 30 June 2025:
    - 45 vaping devices
    - 300 accessories, and;
    - 2,000mL of vaping substance that is a liquid.

#### Members of a visiting group

Item 2 of Schedule 1 to the Determination permits the possession of vaping goods by a person who is a **member of a visiting group** as set out in the <u>Customs (Prohibited Imports) (Vaping Goods)</u>
<u>Approval 2023</u>.

The goods may be possessed by the person in the group where they were given to the person by an approved importer. The importer must be an approved importer under subregulation 5A(5) of the *Customs (Prohibited Imports) Regulations 1956.* 

#### Possession by exporters

Item 3 of Schedule 1 to the Determination permits <u>exportation businesses</u>, before 1 January 2025, to possess vaping goods for the sole purpose of export.

The exception is subject to several conditions and requirements.

For this exception to apply, all of the following must be met:

• the goods are held by the person before 1 January 2025 for the sole purpose of export

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- the person imported the goods into Australia or received the goods from a permitted importer, a permitted supplier, a permitted recipient or a person supplying vaping goods in accordance with Item 6 or 10 of Schedule 2 to the Determination
- the goods must be in the persons possession at all times and clearly labelled for export
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- the person must keep a record of the quantity and description of each type of good
- the person must retain a copy of the receipt provided by the person who delivered the goods for at least 12 months
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with
- the person must retain a record of the date the goods were exported, the quantity and description of each type of vaping good, and the method of export, signed and dated
- if the person reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the offence or civil penalty provision does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions and requirements. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Storage of therapeutic vaping goods by storage businesses

Item 4 of Schedule 1 to the Determination permits <u>storage businesses</u> to possess vaping goods for storage purposes, until 30 November 2024, when doing so on behalf of a business who can lawfully trade in therapeutic vaping goods.

The exception applies to **notified vaping goods** and **medicinal cannabis vaping goods only**, where the storage is on behalf of:

- a person who obtained vaping goods in the course of their exportation business (see item 3 of Schedule 1 to the Determination for further details)
- a person who obtained vaping goods in the course of their importation, wholesale supply or retail supply business or manufactured the goods in Australia (see item 6 of Schedule 2 to the Determination for further details)
- a person engaged in the business of importation or supply of notified vaping goods other than goods that contain a substance included in a Schedule to the Poisons Standard, or are therapeutic cannabis vaping goods (see item 7 of Schedule 2 to the Determination for further details)
- a person who is a holder of a licence under Part 3-3 of the TG Act that authorises the manufacture of nicotine in solution (Item 8 of Schedule 2 to the Determination)

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- a person who is the holder of either a licence and permit under sub regulation 5(5) of the CPI Regulations or the holder of licence under Part 3-3 of the TG Act, in relation to goods that are or contain medicinal cannabis vaping substances (including synthetic cannabis) (see item 9 of Schedule 2 to the Determination for further details)
- a permitted importer
- a permitted exporter
- a permitted supplier
- a permitted recipient.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met by the storage business:

- the goods must be stored in accordance with a written agreement between the person and the party who engaged the person
- the written agreement must be kept by the storage business, along with a record of the
  quantity and description of the goods that includes the name and address of the person who
  owns the goods and is storing them with the storage business
- these records must be maintained for at least 12 months after the day the goods are removed from storage
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with in relation to the storage of Schedule 8 substances
- if the storage business reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the offence does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Waste disposal businesses possessing goods for disposal

Item 5 of Schedule 1 to the Determination permits <u>waste disposal businesses</u> to possess vaping goods, until 30 November 2024, for the sole purpose of destruction. The exception also applies to an agent or employee of the waste disposal business.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met by the waste disposal business:

• the business must hold a license or written authorisation issued by a state or territory which authorises the business to destroy or dispose of waste

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- the business must not have provided any type of payment for the vaping goods. This includes payment in any form, not only Australian or foreign currency, for example an exchange of goods or services
- a record must be kept of the quantity and description of each type of good
- the business must retain a copy of the receipt provided by the person who delivered the goods, for at least 12 months
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with in relation to the possession and destruction of Schedule 8 substances
- the business must retain, for at least 12 months after the day that the goods are destroyed, a
  record of the date the goods were destroyed, the quantity of goods destroyed, a description of
  the goods destroyed, the method of destruction, with the name and signature of the person
  recording the information
- if the waste disposal business reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the to the offence or civil penalty provisions does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

## Possession of vaping goods for bona fide medical or scientific research or testing

Item 6 of Schedule 1 to the Determination permits the possession of vaping goods by a person engaged in bona fide medical or scientific research or testing, until 30 November 2024.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met:

- the business or person must be:
  - o a laboratory accredited by the National Association of Testing Authorities
  - o a laboratory or testing facility operated by a university or hospital
  - a person engaged by a business above to conduct medical or scientific research or testing at the laboratory
- the research or testing must occur solely in the facility listed above
- the research or testing must not involve research or testing in or on humans
- the goods must have been lawfully imported into or manufactured in Australia and supplied to the laboratory
- the vaping goods must not be used for any other purpose

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- a record must be kept of the quantity and description of each type of good
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with in relation to the possession and testing of Schedule 8 substances
- the business or person must retain, for at least 12 months after the day that the goods are destroyed, a record of the date the goods were destroyed, the quantity of goods destroyed, a description of the goods destroyed, the method of destruction, with the name and signature of the person recording the information
- if the business reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the offence or civil penalty provision does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions and requirements. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

# Circumstances in which vaping goods may be possessed and supplied

The circumstances in Schedule 2 to the Determination permit a person to possess and supply certain vaping goods in specified circumstances. These include:

- personal possession of a specified amount of vaping goods and supply for disposal of those goods - time limited
- goods lawfully imported under the traveller's exemption under the CPI Regulations
- goods held by a person responsible for the treatment of a visiting group, such as the team doctor for a visiting sporting group
- surrender of vaping goods by businesses time limited
- disposal of small quantities of vaping goods by businesses time limited
- possessing vaping goods for supply to specified persons time limited
- supply of **notified vaping goods** that do not include Scheduled poisons and medical devices used to vape medicinal cannabis time limited
- liquid nicotine that is manufactured in Australia time limited
- medicinal cannabis substances
- transportation services to facilitate lawful therapeutic supply chains and export time limited
- transportation services to facilitate lawful disposal time limited

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- medicinal cannabis vaping goods for supply under the Special Access Scheme and Authorised Prescriber scheme
- vaping goods for use in clinical trials time limited.

These exceptions are subject to conditions and requirements. More detail follows.

#### Personal possession and supply for disposal

Item 1 of Schedule 2 to the Determination provides a 12-month amnesty, until 30 June 2025, in relation to the personal possession and supply of a quantity of vaping goods for the sole purpose of lawful disposal.

The person possessing the goods must not be engaged in, or at any time after 1 July 2024 have been engaged in, the commercial importation, exportation, manufacture, wholesale supply or retail supply of vaping goods.

The circumstances in which the goods may be supplied by the individual under this exception is limited to lawful disposal. The person must not supply the goods to anyone other than an **authorised disposer**.

The person must not supply the goods to the **authorised disposer** in return for any type of payment from the **authorised disposer**. This includes payment in any form, not only Australian or foreign currency, for example an exchange of goods or services.

The quantity of goods that may be possessed and supplied for disposal must be less than the following quantities:

- from 1 July 2024 to 30 September 2024:
  - 70 vaping devices
  - 450 vaping accessories
  - o 3,000mL of vaping substance that is liquid
- from 1 October 2024 to 30 June 2025:
  - 45 vaping devices
  - o 300 accessories
  - o 2,000mL of vaping substance that is a liquid.

If any of these conditions are not met the exception to the offence does not apply.

#### Goods imported under a traveller's exemption

Item 2 of Schedule 2 to the Determination applies to the possession of vaping goods by a person entering Australia on board a ship or aeroplane.

The goods must be imported with the person in accordance with the requirements of the traveller's exemption, including the relevant quantity limits, under either subregulation 5A(2) or paragraph 5(2)(b) of the *Customs (Prohibited Imports) Regulations 1956.* 

The goods must not be supplied to any other person unless all of the following apply:

- the person was on the same ship or aeroplane
- the goods are supplied for the treatment of the other person and that person is under the care of the person supplying the goods to them.

If any of these conditions are not met the exception to the offence does not apply.

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#### Goods held by a person responsible for the treatment of a visiting group

Item 3 of Schedule 2 to the Determination applies to the possession and supply by a person who has entered Australia on board a ship or aeroplane as part of a visiting group.

The importation of the goods must have been approved under subregulation 5A(5) of the <u>Customs</u> (*Prohibited Imports*) Regulations 1956.

The exception is subject to conditions and requirements.

For this exception to apply, all of the following must also be met:

- the goods must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group
- any portion of the goods that are unused at the end of the visit must be destroyed or removed from Australia
- the person must:
  - carry a list, in English, of the quantity and type of goods imported
  - o keep a record of the use of the goods while the group is in Australia
  - produce the list or record for inspection at the request of customs officers or a relevant authorised person for the purposes of section 41FN of the TG Act.

If any of these conditions are not met the exception to the offence does not apply.

#### Business surrender scheme

Item 4 of Schedule 2 to the Determination provides for a business surrender scheme under which retail and other businesses can surrender vaping goods to the Commonwealth.

The exception applies to vaping goods obtained in the course of importation, exportation, wholesale supply, retail supply, manufacture, transportation or storage business, where those goods were lawful prior to 1 July 2024. These vaping goods would include those goods that general retailers could lawfully supply prior to 1 July 2024 (eg zero nicotine vapes that did not make therapeutic claims) and certain products that could previously only be sold in pharmacies but that do not meet the current standards under the TG Act (eg certain flavours of nicotine vapes).

The scheme applies where the business possesses, for the sole purpose of surrendering the goods to the Therapeutic Goods Administration, at least 20 times the commercial quantity of vaping goods.

The relevant minimum quantity limits are:

- 280 vaping devices
- 1,800 accessories
- 12,000mL of vaping substance that is a liquid.

If you are uncertain whether the goods you hold qualify for the business surrender scheme, please enquire via email <a href="mailto:vapereturn@health.gov.au">vapereturn@health.gov.au</a>.

To be eligible for the exception, the business must notify the Therapeutic Goods Administration **before 1 September 2024**, at <a href="mailto:vapereturn@health.gov.au">vapereturn@health.gov.au</a> that they intend to surrender the goods. The TGA will make arrangements with the business for collection.

The following conditions also apply:

- the person must provide the information required by the TGA about the goods, including but not limited to:
  - the person in possession of or supplying the goods to the TGA

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- o relevant contact details of the person or other persons involved in such activity
- o description of the goods including quantity, type and description
- o location of the goods
- o any other relevant information about the goods
- the goods must be stored in an area that is locked or otherwise secured and not accessible
  by a person who is not authorised to access that area, including any members of the public
- the person must keep and maintain a record of all goods in the person's possession, including the amount or quantity of goods and a description of the goods
- the person must supply the goods in accordance with any direction from an officer of the TGA
  or Department (including any direction relating to transport or any other process required to
  facilitate supply to the TGA).
- if the business or person reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day.

#### Disposal of small quantities of vaping goods by businesses

Item 5 of Schedule 2 to the Determination permits certain businesses to organise for disposal of small quantities of vaping goods that were lawful prior to 1 July 2024. These vaping goods would include those goods that general retailers could lawfully supply prior to 1 July 2024 (eg zero nicotine vapes that did not make therapeutic claims) and certain products that could previously only be sold in pharmacies but that do not meet the current standards under the TG Act (eg certain flavours of nicotine vapes).

The item applies to vaping goods obtained in the course of importation, exportation, wholesale supply, retail supply, manufacture, transportation or storage business.

A maximum limit applies. These limits are:

- 280 vaping devices
- 1,800 accessories
- 12,000mL of vaping substance that is a liquid.

The exception is subject to conditions and requirements. For this exception to apply, all of the following must also be met:

- the goods must not be supplied to anyone other than an authorised disposer who will lawfully destroy the goods
- the person must not supply the goods in return for any type of payment. This includes payment in any form, not only Australian or foreign currency, for example an exchange of goods or services
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with in relation to the possession and supply of Schedule 8 substances
- the business must keep and maintain a record of all goods in their possession, including the amount or quantity of goods and a description of the goods

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- if the business reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the offence or civil penalty does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Possessing vaping goods for supply to specified persons

Item 6 of Schedule 2 to the Determination permits the possession and supply of goods that were lawful prior to 1 July 2024, until 30 November 2024, by a person who obtained the goods in the course of their importation, wholesale supply or retail supply business, or where they manufactured the goods. It allows people who now hold non-compliant stock to sell those products into the pharmacy supply chain if the products meet relevant TGA standards or to sell the products overseas and export them.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met:

- the goods must have been imported into or manufactured in Australia before 1 July 2024, in accordance with Commonwealth, state and territory laws
- the goods are possessed by the business or person for the sole purpose of supply to:
  - o a **permitted recipient** (see Persons covered by the Determination)
  - o a **permitted supplier** (see Persons covered by the Determination)
  - another person outside of Australia
  - a permitted exporter (see Persons covered by the Determination), that the person reasonably believes:
    - will lawfully export the goods from Australia before 1 January 2025, and
    - will not use the goods or supply the goods to any person in Australia
- the vaping goods must be supplied to one of the people above in accordance with a written agreement
- if, immediately before 1 July 2024, the person possessed more than:
  - 280 vaping devices
  - 1,800 accessories
  - 12,000mL of vaping substance that is a liquid

the person must notify the Department of that fact at vapereturn@health.gov.au **before**1 September 2024

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- if the goods are supplied to a '**permitted recipient**', the goods must comply with applicable TGA product standards<sup>1</sup> and the essential principles<sup>2</sup>
- a record must be kept of the quantity and description of each type of good
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- if the goods contain a substance included in Schedule 8 of the Australian Poisons Standard, all relevant state and territory laws must be complied with in relation to the possession, supply and export of Schedule 8 substances
- during transportation:
  - o the person must not leave the goods unattended, other than in a secure area
  - the person must take all reasonable steps to ensure that the goods are stored and transported in accordance with the instructions provided by the receiver or in accordance with the label of the goods
- in the course of supply to the receiver:
  - the goods must be delivered to the street address stated in the written agreement
  - the person must not leave the goods at the street address unless they obtain a written receipt from the receiver
- the business must retain, for at least 12 months after the day of supply:
  - o the written receipt provided at the time of supply
  - a description of the goods, including quantity, supplied to the receiver
  - o the written agreement
- if the business reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty provision does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

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<sup>&</sup>lt;sup>1</sup> TGO 110 at Federal Register of Legislation - Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021.. The MDSO (Federal Register of Legislation - Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023).

<sup>&</sup>lt;sup>2</sup> Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002.* 

#### Possession and supply of notified vaping goods that do not contain Scheduled poisons and medical devices used to vape medicinal cannabis

Item 7 of Schedule 2 to the Determination applies, until 30 November 2024, to persons engaged in the business of importation and supply.

Its application is limited to:

- notified vaping goods that do not contain any substance included in a schedule to the Australian Poisons Standard - Nicotine is a scheduled substance
- therapeutic cannabis vaping goods i.e. medical devices used to vape medicinal cannabis.

The exception is subject to several conditions and requirements.

- for this exception to apply, all of the following must be met:
  - o the possession and supply must have occurred on or before 30 November 2024
  - the goods are possessed by the person for the sole purpose of supply, and are supplied to, a **permitted recipient** or a **permitted supplier** (see Persons covered by the Determination)
- if the goods are therapeutic cannabis vaping goods, the goods are only supplied to a
  permitted recipient or permitted supplier if they are included in the Australian Register of
  Therapeutic Goods
- if the goods are **therapeutic cannabis vaping goods** that are not included in the Australian Register of Therapeutic Goods, that they are supplied to a receiver who is not engaged in the business of wholesale supply
- the goods must only be supplied to a receiver in accordance with a written agreement between the person and the receiver
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- the person must keep and maintain a record of all goods in the person's possession, including the amount or quantity of goods and a description of the goods
- during transportation the person must not leave the goods unattended, other than in a secure
  area, and must take all reasonable steps to ensure that the goods are stored and transported
  in accordance with the instructions that are provided by the receiver or specified on the label
  of the goods
- the goods must be delivered to the street address stated in the written agreement
- the person must not leave the goods at the street address unless the person obtains a written receipt for the delivery of the goods from the receiver
- the business must retain, for at least 12 months after the day of supply:
  - the written receipt provided at the time of supply
  - o a description of the goods, including quantity, supplied to the receiver
  - o the written agreement
- if the business or person reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day

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• the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty provision does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Liquid nicotine that is manufactured in Australia

Item 8 of Schedule 2 to the Determination provides for the holder of a manufacturing licence (under Part 3-3 of the TG Act) that authorises the manufacture of vaping goods (licence holder) to possess and supply, before 30 November 2024, liquid nicotine that it manufactured in Australia.

Liquid nicotine is a 'vaping substance' even if it is not intended for use with a vaping device.

Liquid nicotine that is <u>lawfully</u> imported into Australia will be a **notified vaping good** and may consequently be covered by the exceptions in the TG Act that apply to **notified vaping goods**.

Liquid nicotine that is manufactured in Australia, however, is not eligible to be a **notified vaping good** and this item permits its possession and supply in specified circumstances.

The circumstances in which this item applies are when:

- the liquid nicotine was manufactured by the licence holder in Australia
- if, immediately before 1 July 2024, the licence holder possessed more than 20 times the commercial quantity, being more than 12,000mL of liquid nicotine, the licence holder has notified the Department at vapereturn@health.gov.au by 1 September 2024
- the goods may only be supplied to a person who is the holder of a licence under Part 3-3 of the Act that authorises the manufacture of vaping goods
- the goods must be manufactured in compliance with the licence holder's licence
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty contravention does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Medicinal cannabis substances

Item 9 of Schedule 2 to the Determination applies to goods that are or contain a vaping substance that is a medicinal cannabis product, or a medicine that contains synthetic cannabis.

These vaping substances are ineligible to be **notified vaping goods** because they will not meet the requirements of the product standard that applies to therapeutic vaping goods.

This item applies to a person who holds a licence and permit under regulation 5 of the *Customs* (*Prohibited Imports*) Regulations 1956 that applies to vaping goods, or the holder of a manufacturing license under Part 3-3 of the TG Act.

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The item only applies to goods imported in accordance with paragraphs 5(1)(a) to (d) of the *Customs* (*Prohibited Imports*) Regulations 1956 or to goods manufactured in Australia under a manufacturing license under Part 3-3 of the TG Act.

This item is subject to the following conditions:

- the goods may only be supplied to a 'permitted health practitioner' (see Persons covered by the Determination)
- the person must comply with the relevant requirements under state or territory legislation that apply to the possession and supply of Schedule 4 or Schedule 8 medicines.
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met, the exception to the application of the offence or civil penalty provision does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Transportation services to facilitate therapeutic supply chains and export

Item 10 of Schedule 2 to the Determination applies to **notified vaping goods** and **medicinal cannabis vaping goods** only, that are possessed and supplied on or before 30 November 2024 by a person engaged in the business of providing transportation services.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met:

- the goods must be being transported on behalf of one of the following persons:
  - a person who obtained vaping goods in the course of their exportation business (see item 3 of Schedule 1 to the Determination for further details)
  - a person who obtained vaping goods in the course of their importation, wholesale supply or retail supply business or manufactured the goods in Australia (see item 6 of Schedule 2 to the Determination for further details)
  - a person engaged in the business of importation or supply of notified vaping goods other than goods that contain a substance included in a Schedule to the Poisons Standard, or are therapeutic cannabis vaping goods (see item 7 of Schedule 2 to the Determination for further details)
  - a person who is a holder of a licence under Part 3-3 of the TG Act that authorises the manufacture of nicotine in solution (Item 8 of Schedule 2 to the Determination)
  - a person who is the holder of either a licence and permit under sub regulation 5(5) of the CPI Regulations or the holder of licence under Part 3-3 of the TG Act, in relation to goods that are or contain medicinal cannabis (including synthetic cannabis) vaping substances (see item 9 of Schedule 2 to the Determination for further details)
  - a permitted importer
  - o a permitted supplier
- the goods must be being transported to a permitted supplier, a permitted recipient or a permitted exporter only

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- the transportation must be in accordance with a written agreement between the person and either the sender or receiver
- the person must not supply the goods other than to a person that they reasonably believe is the receiver in the written agreement
- while the goods are in the person's possession the person must possess evidence of the
  written agreement and the person must keep and maintain a record of all goods in the
  person's possession, including the quantity and description of the goods
- if the goods contain a substance included in Schedule 8 to the Australian Poisons Standard, the person must comply with all applicable laws of the state or territory that apply to the possession, supply, and transportation of a Schedule 8 substance
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- during transportation the person must not leave the goods unattended, other than in a secure
  area, and must take all reasonable steps to ensure that the goods are stored and transported
  in accordance with the instructions that are provided by the receiver or specified on the label
  of the goods
- the goods must be delivered to the street address stated on the packaging of the goods or in the written agreement
- the person must not leave the goods at the street address unless the person obtains a written receipt for the delivery of the goods from the receiver
- the business must retain, for at least 12 months after the day of delivery:
  - the written receipt provided at the time of delivery
  - o a description of the goods, including quantity, delivered
  - $\circ \quad \text{the written agreement.} \\$
- if the business or person reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty contravention does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

#### Transportation services to facilitate lawful disposal

Item 11 of Schedule 2 to the Determination applies to vaping goods that are possessed and supplied on or before 30 November 2024 by a person engaged in the business of providing transportation services.

This item facilitates transportation through the supply chain of vaping goods that can no longer be lawfully supplied in Australia and are being transported solely for the purpose of disposal by an **authorised disposer**.

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The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met:

- the goods are possessed by the person for the sole purpose of delivering the goods to an authorised disposer (see Persons covered by the Determination)
- delivery is in accordance with a written agreement between the person and an authorised disposer, or with a third party who possesses the goods that the person reasonably believes is engaging the person's transportation services to facilitate the lawful destruction of the goods by an authorised disposer
- the person reasonably believes the authorised disposer will lawfully destroy the goods
- while the goods are in the person's possession the person must possess evidence of the
  written agreement, and the person must keep and maintain a record of all goods in the
  person's possession, including the quantity and a description of the goods
- if the goods contain a substance included in Schedule 8 to the Australian Poisons Standard, the person must comply with all applicable laws of the state or territory that apply to the possession, supply, and transportation of a Schedule 8 substance
- the goods must be stored in an area that is locked and not accessible by a person who is not authorised to access that area, including any members of the public
- during transportation, the person must not leave the goods unattended, other than in a secure
  area, and must take all reasonable steps to ensure that the goods are stored and transported
  in accordance with the instructions that are provided by the authorised disposer or on the
  label of the goods
- the goods must be delivered to the street address stated on the packaging of the goods or in the written agreement
- the person must not leave the goods at the street address unless the person obtains a written receipt for the delivery of the goods from the **authorised disposer**
- the business or person must retain, for at least 12 months after the day of delivery:
  - the written receipt provided at the time of delivery
  - o a description of the goods, including quantity, delivered
  - o the written agreement
- if the business or person reasonably suspects that any of the goods have been lost or stolen, they must notify the police in that state or territory as soon as practical, which must be before the end of the next business day
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty provisions does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

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## Medicinal cannabis vaping goods for supply under the Special Access Scheme and Authorised Prescriber scheme

Item 12 of Schedule 2 to the Determination applies to the possession and supply by a **permitted health practitioner** of **therapeutic cannabis vaping goods** where the goods are either registered in the Australian Register of Therapeutic Goods or are for supply under one of the access pathways under the TG Act for unapproved therapeutic goods.

The **permitted health practitioner** may only supply the goods to an ultimate consumer, or a person that the practitioner believes is lawfully obtaining the goods on behalf of the ultimate consumer (for example, a parent on behalf of their child).

The exception is subject to the following conditions:

- if the goods include a substance included in Schedule 8 to the Australian Poisons Standard, the person must comply with the requirements under state or territory law that apply to the possession and supply by a health practitioner of Schedule 8 substances
- the goods must be stored in a part of the premises to which the public does not have access.

This item is not time-limited as **permitted health practitioners** are already licenced or authorised under state or territory law to supply prescription medicines and as such are suitable persons to possess and supply medicinal cannabis vaping goods where clinically appropriate.

#### Vaping goods for use in clinical trials

Item 13 of Schedule 2 to the Determination applies to the possession and supply of vaping goods by the sponsor of the goods, or the sponsor or principal investigator of a clinical trial, on or before 30 November 2024.

The exception is subject to several conditions and requirements. For this exception to apply, all of the following must be met:

- the goods must be the subject of an approval under the Clinical Trial Application (CTA)
   Scheme, or an exception under the Clinical Trial Notification (CTN) Scheme
- the vaping goods must only be supplied to:
  - o if the person is the sponsor of the goods—the clinical trial sponsor
  - if the person is the sponsor or principal investigator of the clinical trial—a participant enrolled in the trial
- the person must comply with any condition imposed in relation to the approval or exception
- if the goods include a substance included in Schedule 8 to the Australian Poisons Standard, the person must comply with the requirements of the relevant state or territory law that apply to the possession, testing and supply of Schedule 8 substances
- the business or person must, upon request, provide any information that the department requires about the goods, the person's possession of the goods, and any other persons involved in the activities, and any other matter that the department determines is relevant.

If any of these conditions are not met the exception to the application of the offence or civil penalty provisions does not apply.

Credible evidence must be produced upon request to demonstrate compliance with the conditions. Where credible evidence is not produced, the goods will be treated as unlawful and enforcement action may be taken.

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#### **Time limits**

The majority of exceptions under the <u>Possession and Supply Determination</u> are transitional. That is, they are time limited.

They provide additional time for people to:

- surrender unlawful vaping goods to the TGA (a minimum quantity applies)
- transport, store or dispose of vapes subject to conditions
- · export unlawful vapes
- · and other limited activity.

Where the time limit for an exception ceases, the exception to the application of the offence or civil penalty provisions does not apply. The goods will be unlawful and enforcement action may be taken.

#### **Critical dates for time-limited exceptions:**

#### 1 July 2024 - previously lawful goods

A number of exceptions provide for goods which were lawful under Commonwealth, state and territory laws prior to 1 July 2024 but which ceased to be lawful on 1 July 2024.

- Item 4, Sch 2 business surrender scheme for importers, exporters, wholesalers, retailers, manufacturers, and transport and storage businesses with large quantities of previously lawful vaping goods which have ceased to be lawful.
- Item 5, Sch 2 disposal scheme for importers, exporters, wholesalers, retailers, manufacturers and transport and storage businesses for small quantities of previously lawful vaping goods which have ceased to be lawful.
- Item 6, Sch 2 possessing previously lawful vaping goods which have ceased to be lawful for supply prior to 30 September 2024 to specified persons.
- Item 8, Sch 2 liquid nicotine manufactured lawfully in Australia.

In addition, the exceptions for personal possession of vaping goods require the person not to be engaged in commercial importation, exportation, manufacture, wholesale supply or retail supply of vaping goods from 1 July 2024.

#### 1 September 2024 – notifying TGA of large quantities of vaping goods

Three exceptions require businesses to notify the Department (TGA) <u>before 1 September 2024</u> that the business possesses large quantities of vaping goods.

- Item 4, Sch 2 business surrender scheme for importers, exporters, wholesalers, retailers, manufacturers, and transport and storage businesses with large quantities of previously lawful vaping goods which have ceased to be lawful.
- Item 6, Sch 2 possessing previously lawful vaping goods which have ceased to be lawful for supply prior to 30 September 2024 to specified persons
- Item 8, Sch 2 liquid nicotine manufactured lawfully in Australia.

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#### 30 November 2024

A number of exceptions provide that possession, or possession and supply, must occur on or before 30 November 2024. While the majority of exceptions are aimed towards allowing time for the transport, storage, surrender, disposal or export of pre-existing stocks of vaping goods, some items are included to allow relevant persons sufficient time to apply for individual consent for possession, and supply if appropriate, from the Secretary under section 41RC of the TG Act.

- Item 4, Sch 1 persons engaged in the business of providing storage facilities
- Item 5, Sch 1 persons licensed under s/t law authorising disposal of waste
- Item 6, Sch 1 persons engaged in bona fide medical or scientific research or testing of vaping goods
- Item 4, Sch 2 surrender scheme for importers, exporters, wholesalers, retailers, manufacturers and transport and storage businesses with large quantities of previously lawful vaping goods which have ceased to be lawful
- Item 5, Sch 2 disposal scheme for importers, exporters, wholesalers, retailers, manufacturers and transport and storage businesses for small quantities of previously lawful vaping goods which have ceased to be lawful.
- Item 6, Sch 2 possessing previously lawful vaping goods which have ceased to be lawful for supply prior to 30 September 2024 to specified persons
- Item 7, Sch 2 notified vaping goods containing scheduled substances or cannabis vaping goods to receivers
- Item 8, Sch 2 liquid nicotine manufactured lawfully in Australia.
- Item 10, Sch 2 transportation services to facilitate therapeutic supply chains and export
- Item 11, Sch 2 transportation services to facilitate lawful disposal
- Item 13, Sch 2 vaping goods for use in clinical trials

#### 1 January 2025 – export of previously lawful vaping goods

• Item 6, Sch 2 – possessing previously lawful vaping goods which have ceased to be lawful for supply prior to 30 September 2024 to specified persons. **Permitted exporters** must lawfully export these goods prior to 1 January 2025.

# What happens when the exception reaches the end of its specified time period and expires?

Future determinations, made under section 41R of the TG Act, may provide permanent exceptions for possessing and supplying vaping goods as appropriate to support the lawful supply of therapeutic vaping goods for patients seeking to quit smoking or manage their nicotine dependence.

Alternatively, consent may be sought from the Secretary under section 41RC of the TG Act. This may allow for possession and supply of vaping goods an individual basis. This consent mechanism will be established soon.

Some offences also provide exceptions for a limited number of persons licenced or authorised under state or territory law to possess medicines containing substances included in Schedule 4 (which will subsequently change to Schedule 3) to the Poisons Standard. You will need to contact your relevant state or territory for information about how to obtain such an authorisation or licence.

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### **Enquiries**

- It is recognised that the transitional arrangements for vaping goods are complex. This is necessary to ensure tight control over vaping goods that have become unlawful on 1 July 2024 and to ensure they are not accessible by Australian consumers during the process of surrender, disposal or export in accordance with the determination.
- For questions in relation to your particular circumstances please write to <a href="https://www.nvp.au">NVP@health.gov.au</a>.

## **Version history**

Version	Description of change	Author	Effective date
V1.0	Original publication	Vaping Implementation and Enforcement Branch	19/07/2024

### **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia Email: <a href="mailto:info@tga.gov.au">info@tga.gov.au</a> Phone: 1800 020 653 Fax: 02 6203 1605

Web: tga.gov.au