

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024*

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

Section 41R of the Act relevantly 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; and
- in the circumstances (if any) specified in the determination; and
- subject to the conditions (if any) specified in the determination.

Section 41R of the Act provides a mechanism by which the Minister can determine the supply or possession of specified vaping goods by specified persons in specified circumstances. In practice, this principally covers circumstances where supply or possession may not be authorised under other relevant statutory provisions and where the supply or possession relates to a legitimate dealing with therapeutic vaping goods as part of the supply chain for such products. The effect of an instrument made under section 41R of the Act is that a person covered by its terms will not commit relevant offences or contravene civil penalty provisions in Chapter 4A of the Act relating to the supply or possession of a vaping good, provided the person does so in accordance with the terms of the instrument.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Principal Determination) is made under section 41R of the Act. It 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. Such persons 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 also specifies the circumstances in which those persons may do so, and any applicable conditions that must be complied with.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024* (the Amendment Determination), also made under section 41R of the Act, amends the Principal Determination, principally to clarify that disposable cannabis vapes and pre-filled medicinal cannabis cartridges may be possessed or supplied in the circumstances specified in the relevant items in the Principal Determination.

### **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.

Relevantly, under item 4 in Schedule 1, and items 10 and 12 in Schedule 2 to the Principal Determination, the vaping goods that may be supplied and/or possessed include ‘vaping substances that are medicinal cannabis products or medicines that contain synthetic cannabis’. However, the use of this wording to describe the goods means that disposable cannabis vapes or pre-filled medicinal cannabis cartridges for use with a medical device, which can lawfully be imported as controlled drugs

under regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*, would not be covered by these items.

The Amendment Determination amends the Principal Determination to correct this unintended error, with the effect of ensuring that disposable cannabis vapes and pre-filled medicinal cannabis cartridges, will continue to be available in the circumstances specified in the Principal Determination, as such goods are not intended to be affected by the Government's broader vaping reforms.

The Amendment Determination replaces table item 4 of Schedule 2 to the Principal Determination (which is more commonly known as the 'business surrender scheme exception') with a new item 4. The amendments to item 4 principally expand the scope of the business surrender scheme exception from applying only to goods possessed immediately before 1 July 2024, by the person relying on the exception (the relevant person) to also include goods possessed at that time by another person (other than an ultimate consumer of the goods) to whom the relevant person had lawfully supplied the goods.

This amendment is intended to reduce compliance burden by permitting, for example, a wholesaler who lawfully supplied vaping goods to a retailer to access the business surrender scheme in relation to those goods, rather than the retailer (if they possess the requisite quantity of vaping goods) having to access the scheme separately.

The Amendment Determination also makes minor amendments to:

- extend the period of time in which the goods specified in items 4 and 6 in Schedule 1 and items 7, 10 and 11 in Schedule 2 to the Principal Determination may be possessed or supplied from 30 November 2024 to 31 March 2025;
- correct a small number of typographical errors;
- update nomenclature used in the instrument for consistency across items; and
- to include conjunctions in a number of items in both Schedule 1 and Schedule 2, to assist with clarity and readability of the instrument.

## Consultation

Consultation was not undertaken in relation to the making of the Amendment Determination as the purpose of the Amendment Determination is simply to clarify the types of specified goods covered by specific items in the Principal Determination and make other minor amendments that are machinery in nature.

Significant consultation was separately undertaken in relation to the Government's vaping reform measures, which included the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*, related regulations and other legislative instruments, including the Principal Determination.

## Other details

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

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

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

The Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 1 October 2024.

**Details of the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024* (the Amendment Determination).

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on 1 October 2024.

**Section 3 – Authority**

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

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

**Section 4 – Schedules**

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

**Schedule 1 – Amendments**

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

**Item 1 – Schedule 1 (table item 3, column 4, subparagraph (b)(i))**

This item makes a minor editorial amendment to replace the comma with a semi-colon at the end of subparagraph (b)(i) in column 4 of item 3 in Schedule 1 to the Principal Determination.

**Item 2 – Schedule 1 (table item 3, column 4, at the end of sub-subparagraphs (b)(ii)(A) to (C))**

This item makes a minor editorial amendment to add the conjunction ‘or’ to the end of sub-subparagraphs (b)(ii)(A) to (C) in column 4 of item 3 in Schedule 1 to the Principal Determination.

This amendment is intended to assist with readability by making it clear that the matters specified in those sub-subparagraphs are intended to operate disjunctively.

**Item 3 – Schedule 1 (table item 3, column 5, paragraph (e))**

This item makes a minor editorial amendment to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraph (e) of column 5 in item 3 in Schedule 1 to the Principal Determination.

**Item 4 – Schedule 1 (table item 3, column 5, at the end of subparagraphs (f)(i) to (iii) and (h)(i))**

This item makes a minor editorial amendment to add the conjunction ‘and’ to the end of subparagraphs (f)(i) to (iii) and (h)(i) in column 5 of item 3 in Schedule 1 to the Principal Determination.

This amendment is intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

**Item 5 – Schedule 1 (table item 4, column 2, paragraph (b))**

This item repeals paragraph (b) in column 2 of item 4 in Schedule 1 and substitutes it with a new paragraph (b) to refer to ‘goods that are or contain a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis’.

This amendment has the effect that disposable cannabis vapes and pre-filled medicinal cannabis cartridges for use with a medical device will continue to be available in circumstances specified in item 4 in Schedule 1 to the Principal Determination.

**Items 6 and 12 – 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 may occur, from 30 November 2024 to 31 March 2025. This extends the application of these items by four months.

**Items 7, 9, 11, 14 and 16 – Schedule 1 (table item 4, column 5, at the end of subparagraphs (c)(i) and (f)(i), table item 5, column 5, at the end of subparagraphs (g)(i) to (iii) and (i)(i) and table item 6, column 5, at the end of subparagraphs (a)(i), (e)(i) to (iii) and (g)(i))**

Items 7, 9, 11, 14 and 16 make minor editorial amendments to add the conjunction ‘and’ to the end of subparagraphs (c)(i) and (f)(i) in column 5 of table item 4, subparagraphs (g)(i) to (iii) and (i)(i) in column 5 of item 4, and subparagraphs (a)(i), (e)(i) to (iii) and (g)(i) in column 5 of item 6 in Schedule 1 to the Principal Determination.

These amendments are intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

**Items 8, 10 and 15 – Schedule 1 (table item 4, column 5, paragraph (e), table item 5, column 5, paragraph (f) and table item 6, column 5, paragraph (d))**

These items make minor editorial amendments to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraph (e) of column 5 in item 4, paragraph (f) of column 5 in item 5, and paragraph (d) of column 5 in item 6 in Schedule 1 to the Principal Determination.

**Item 13 – Schedule 1 (table item 6, 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 item 6 in Schedule 1 to the Principal Determination.

**Item 17 – Schedule 2 (table item 2, column 5)**

This item makes a minor editorial amendment to correct formatting of the point in time definition of ‘(receiver)’ in column 5 of item 2 in Schedule 2 to the Principal Determination.

### **Item 18 – Schedule 2 (table item 3, column 3)**

This item makes a minor editorial amendment to replace the words ‘an approved importer’ with the words ‘a person’ in column 3 of item 3 in Schedule 2 to the Principal Determination.

### **Item 19 – Schedule 2 (table item 4)**

This item repeals table item 4 in Schedule 2 to the Principal Determination (commonly known as the ‘business surrender scheme exception’) and substitutes it with a new item.

The new table item principally replaces paragraph (b) in column 4 to include vaping goods which were, immediately before 1 July 2024, in the possession or control of:

- the person relying on the item (*relevant person*) (which is consistent with the version of item 4 in the Principal Determination); or
- another person to whom the relevant person had supplied the goods, in circumstances where the other person was not the ultimate consumer of the goods.

The addition of the latter category of persons is intended to reduce compliance burden by permitting, for example, a wholesaler who lawfully supplied vaping goods to a retailer to access the business surrender scheme in relation to those goods, rather than the retailer (if they possess the requisite quantity of vaping goods) having to access the scheme separately. The retailer can supply the vaping goods to the wholesaler for the purpose of facilitating business surrender under table item 6 in Schedule 2 to the Principal Determination.

New item 4 also includes minor editorial amendments, such as the inclusion of the conjunction ‘and’ where appropriate.

### **Items 20, 24 and 27 – Schedule 2 (table item 5, column 4, at the end of subparagraphs (b)(i), table item 6, column 5, at the end of subparagraph (a)(i) and table item 6, column 5, at the end of subparagraphs (g)(i) and (ii) and (h)(i))**

Items 20, 24 and 27 make minor editorial amendments to add the conjunction ‘and’ to the end of subparagraph (b)(i) in column 4 of item 5 and subparagraphs (a)(i), (g)(i) and (ii) and (h)(i) in column 5 of item 6 in Schedule 2 to the Principal Determination.

These amendments are intended to assist with readability by making it clear that the matters specified in relevant subparagraphs are intended to operate conjunctively.

### **Item 21 – Schedule 2 (table item 5, column 5, paragraph (c))**

This item makes a minor editorial amendment to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraph (c) of column 5 in item 5 in Schedule 2 to the Principal Determination.

### **Item 22 – Schedule 2 (table item 6, column 4, at the end of paragraph (b))**

This item makes a minor editorial amendment to remove the unnecessary conjunction ‘and’ at the end of paragraph (b) in column 4 of item 6 in Schedule 2 to the Principal Determination.

### **Item 23 – Schedule 2 (table item 6, column 4, at the end of subparagraphs (e)(i) to (iii))**

This item makes a minor editorial amendment to remove the unnecessary conjunction ‘or’ at the end of subparagraphs (e)(i) to (iii) in column 4 of item 6 in Schedule 2 to the Principal Determination.

### **Items 25 and 26 – Schedule 2 (table item 6, column 5, paragraph (b))**

These items make minor editorial amendments to paragraph (b) in column 5 of item 6 in Schedule 2 to the Principal Determination.

Item 25 removes an erroneous space following the emerald between the words ‘current Poisons Standard’ and ‘the person’.

Item 26 replaces the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’.

### **Item 28 – Schedule 2 (table item 6, column 5, subparagraph (h)(iii))**

This item replaces the incorrect reference to ‘Column 5’ in subparagraph (h)(iii) in column 5 of item 6 in Schedule 2 to the Principal Determination with a reference to ‘column 4’.

### **Item 29 – Schedule 2 (table item 7, column 4, paragraph (a))**

This item amends the date in table item 7 in Schedule 2 to the Principal Determination, on or before which possession may occur, from 30 November 2024 to 31 March 2025. This extends the application of this item by four months.

### **Item 30 – Schedule 2 (table item 7, column 4, paragraphs (d) and (e))**

This item makes a minor technical amendment to substitute the references ‘entered’ in paragraphs (d) and (e) in column 4 of item 7 in Schedule 2 to ‘included’ to reflect that therapeutic cannabis vaping goods are ‘included in the Register’.

### **Items 31 and 33 – Schedule 2 (table item 7, column 5, at the end of subparagraphs (g)(i) and (i)(i) and table item 9, column 5, at the end of subparagraph (b)(i))**

Items 31 and 33 make minor editorial amendments to add the conjunction ‘and’ to the end of subparagraphs (g)(i) and (i)(i) in column 5 of item 7 and subparagraph (b)(i) in column 5 of item 9 in Schedule 2 to the Principal Determination.

These amendments are intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

### **Item 32 – Schedule 2 (table item 8)**

This item repeals item 8 in the table in Schedule 2 to the Principal Determination and replaces it with a new item 8 which extends the application of the item by four months, from 30 November 2024 to 31 March 2025 and otherwise makes amendments to assist with clarifying requirements, and improve readability of that item.

New item 8 differs from the previous item in the following aspects:

- introduces the point in time definition of ‘relevant licence holder’ in column 3;
- replaces references to ‘the person’ with ‘relevant licence holder’ in columns 4 and 5;
- reorders some of the conditions specified in column 5, for clarity.

### **Item 34 – Schedule 2 (table item 9, column 5, paragraphs (c) and (d))**

This item makes a minor editorial amendment to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraphs (c) and (d) in column 5 of item 9 in Schedule 2 to the Principal Determination.

### **Items 35 – Schedule 2 (table item 10, column 2, paragraph (c))**

This item repeals paragraph (c) in column 2 of item 10 in Schedule 2 and substitutes a new paragraph (c) to refer to ‘goods that are or contain a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis’.

This amendment has the effect that disposable cannabis vapes and pre-filled medicinal cannabis cartridges for use with a medical device will continue to be available in circumstances specified in item 4 in Schedule 1 to the Principal Determination.

### **Item 36 – Schedule 2 (table item 10, column 4, paragraph (a))**

This item amends column 4 of table item 10 in Schedule 2 to the Principal Determination to change the date on or before which possession and supply of notified and registered vaping goods must occur from 30 November 2024 to 31 March 2025. This provides four additional months during which possession and supply by a person engaged in the business of transporting goods is lawful.

### **Items 37, 39 and 41 – Schedule 2 (table item 10, column 5, at the end of subparagraphs (b)(i) and (h)(i) and (j)(i), and table item 11, column 4, at the end of sub-subparagraph (c)(i)(B))**

Items 37, 39 and 41 make minor editorial amendments to add the conjunction ‘and’ to the end of subparagraphs (b)(i), (h)(i) and (j)(i) in column 5 of item 10 and sub-subparagraph (c)(i)(B) in column 4 of item 11 in Schedule 2 to the Principal Determination.

These amendments are intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

### **Items 38 and 42 – Schedule 2 (table item 10, column 5, paragraph (c) and table item 11, column 5, paragraph (b))**

Items 38 and 42 make minor editorial amendment to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraph (c) in column 5 of item 10 and paragraph (b) in column 5 of item 11 in Schedule 2 to the Principal Determination.

### **Item 40 – Schedule 2 (table item 11, column 4, paragraph (a))**

This item amends the date in table item 11 in Schedule 2 to the Principal Determination, on or before which possession may occur, from 30 November 2024 to 31 March 2025. This extends the application of this item by four months.

### **Item 43 – Schedule 2 (table item 11, column 5, paragraph (e))**

This item makes a minor editorial amendment to substitute the reference to ‘Column 4’ in paragraph (e) in column 5 of item 11 in Schedule 2 with ‘column 4’.

### **Item 44 – Schedule 2 (table item 11, column 5, at the end of subparagraphs (g)(i) and (i)(i))**

This item makes a minor editorial amendment to add the conjunction ‘and’ to the end of subparagraphs (g)(i) and (i)(i) in column 5 of item 11 in Schedule 2 to the Principal Determination.

This amendment is intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

### **Item 45 – Schedule 2 (table item 12, column 2, paragraph (b))**



This item repeals paragraph (b) in column 2 of item 12 in Schedule 2 and substitutes a new paragraph (b) to refer to ‘goods that are or contain a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis’.

This amendment has the effect that disposable cannabis vapes and pre-filled medicinal cannabis cartridges for use with a medical device will continue to be available in circumstances specified in item 4 in Schedule 1 to the Principal Determination.

**Items 46, 49 and 50 – Schedule 2 (table item 12, column 4, at the end of subparagraphs (a)(i) and (ii), table item 13, column 4, at the end of subparagraph (c)(i) and table item 13, column 5, at the end of subparagraph (a)(i))**

Items 46, 49 and 50 make minor editorial amendments to add the conjunction ‘or’ to the end of subparagraphs (a)(i) and (ii) in column 4 of item 12, subparagraph (c)(i) in column 4 of item 13 and subparagraph (a)(i) in column 5 of item 13 in Schedule 2 to the Principal Determination.

These amendments are intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate disjunctively.

**Items 47 and 51 – Schedule 2 (table item 12, column 5, paragraph (a) and table item 13, column 5, paragraph (c))**

These items make minor editorial amendments to replace the reference to ‘Schedule 8 of the current Poisons Standard’ with ‘Schedule 8 to the current Poisons Standard’ in paragraph (a) in column 5 of item 12 and paragraph (c) in column 5 of item 13 in Schedule 2 to the Principal Determination.

**Item 48 – Schedule 2 (table item 13, column 4, paragraph (a))**

This item repeals paragraph (a) in column 4 of item 13 in Schedule 2 to the Principal Determination.

This amendment is intended to remove the requirement that vaping goods must have been possessed or supplied in the context of an approved or exempt clinical trial on or before 30 November 2024. Specifically, it will have ongoing application to the possession and supply of vaping goods, by the sponsor of the goods, or the sponsor or principal investigator, of a clinical trial, where the goods are the subject of an approval under the TGA’s Clinical Trial Approval (CTA) scheme or a valid notification under the Clinical Trial Notification (CTN) scheme.

**Item 52 (table item 13, column 5, at the end of subparagraph (d)(i))**

This item makes a minor editorial amendment to add the conjunction ‘and’ to the end of subparagraph (d)(i) in column 5 of item 13 in Schedule 2 to the Principal Determination.

This amendment is intended to assist with readability by making it clear that the matters specified in the relevant subparagraphs are intended to operate conjunctively.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024*

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

#### Overview of the Legislative Instrument

Section 41R of the Act relevantly 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; and
- in the circumstances (if any) specified in the determination; and
- subject to the conditions (if any) specified in the determination.

Section 41R of the Act provides a mechanism by which the Minister can determine the supply or possession of specified vaping goods by specified persons in specified circumstances. In practice, this principally covers circumstances where supply or possession may not be authorised under other relevant statutory provisions and where the supply or possession relates to a legitimate dealing with therapeutic vaping goods as part of the supply chain for such products. The effect of an instrument made under section 41R of the Act is that a person covered by its terms will not commit relevant offences or contravene civil penalty provisions in Chapter 4A of the Act relating to the supply or possession of a vaping good, provided the person does so in accordance with the terms of the instrument.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Principal Determination) is made under section 41R of the Act. It 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. Such persons 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 also specifies the circumstances in which those persons may do so, and any applicable conditions that must be complied with.

The *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination (No. 2) 2024* (the Amendment Determination), also made under section 41R of the Act, amends the Principal Determination, principally to clarify that disposable cannabis vapes and pre-filled medicinal cannabis cartridges may be possessed or supplied in the circumstances specified in the relevant items in the Principal Determination.

#### 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.

Relevantly, under item 4 in Schedule 1, and items 10 and 12 in Schedule 2 to the Principal Determination, the vaping goods that may be supplied and/or possessed include ‘vaping substances

that are medicinal cannabis products or medicines that contain synthetic cannabis'. However, the use of this wording to describe the goods means that disposable cannabis vapes or pre-filled medicinal cannabis cartridges for use with a medical device, which can lawfully be imported as controlled drugs under regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*, would not be covered by these items.

The Amendment Determination amends the Principal Determination to correct this unintended error, with the effect of ensuring that disposable cannabis vapes and pre-filled medicinal cannabis cartridges, will continue to be available in the circumstances specified in the Principal Determination, as such goods are not intended to be affected by the Government's broader vaping reforms.

The Amendment Determination replaces table item 4 of Schedule 2 to the Principal Determination (which is more commonly known as the 'business surrender scheme exception') with a new item 4. The amendments to item 4 principally expand the scope of the business surrender scheme exception from applying only to goods possessed immediately before 1 July 2024, by the person relying on the exception (the relevant person) to also include goods possessed at that time by another person (other than an ultimate consumer of the goods) to whom the relevant person had lawfully supplied the goods.

This amendment is intended to reduce compliance burden by permitting, for example, a wholesaler who lawfully supplied vaping goods to a retailer to access the business surrender scheme in relation to those goods, rather than the retailer (if they possess the requisite quantity of vaping goods) having to access the scheme separately.

The Amendment Determination also makes minor amendments to:

- extend the period of time in which the goods specified in items 4 and 6 in Schedule 1 and items 7, 10 and 11 in Schedule 2 to the Principal Determination may be possessed or supplied from 30 November 2024 to 31 March 2025;
- correct a small number of typographical errors;
- update nomenclature used in the instrument for consistency across items; and
- to include conjunctions in a number of items in both Schedule 1 and Schedule 2, to assist with clarity and readability of the instrument.

### **Human rights implications**

As the Amendment Determination simply corrects an erroneous description of the vaping goods covered by item 4 of Schedule 1 and items 10 and 12 of Schedule to the Principal Determination, and otherwise makes a small number of editorial amendments, the Amendment Determination does not engage any applicable rights or freedoms.

### **Conclusion**

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