

Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 15 July 2024

Nicholas Henderson Acting Deputy Secretary Health Products Regulation Group Department of Health and Aged Care



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1 Name

This instrument is the *Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024.*

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

ote: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 41R of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024

1 Section 4 (definition of permitted cannabis wholesaler)

Repeal the definition.

2 Section 4 (definition of permitted exporter)

Repeal the definition, substitute:

permitted exporter, in relation to vaping goods, means:

- (a) 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; or
- (b) a person specified in column 3 of item 3 in the table in Schedule 1; or
- (c) a person specified in column 3 of items 4 or 5 in the table in Schedule 2.

3 Section 4 (definition of permitted importer)

Repeal the definition, substitute:

permitted importer, in relation to vaping goods, means a person authorised under regulation 5 or 5A of the CPI Regulations to import the vaping goods, other than an approved importer.

4 Section 4 (definition of permitted recipient)

Repeal the definition, substitute:

permitted recipient, in relation to vaping goods, means:

- (a) a person mentioned in paragraph 41QB(8)(b) of the Act; or
- (b) 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; or
- (c) a person specified in column 3 of items 4, 5 or 6 in the table in Schedule 2.

5 Section 4 (definition of permitted wholesale supplier)

Repeal the definition, substitute:

permitted supplier, in relation to vaping goods, means:

- (a) a person mentioned in paragraphs 41QB(7)(a), (b), (c) or (d) of the Act; or
- (b) a person engaged in the business of importation, manufacture, wholesale supply or retail supply to whom the Secretary has given a consent under subsection 41RC(1) of the Act to supply the vaping goods; or
- (c) a person specified in column 3 of item 7 in the table in Schedule 2.

6 Schedule 1 (table item 3, column 4, subparagraph (b)(ii))

Repeal the subparagraph, substitute:

(ii) received the goods from:

2

- (A)a permitted importer;
- (B) a permitted supplier;
- (C) a permitted recipient; or
- (D)a person supplying vaping goods in accordance with item 6 or 10 of Schedule 2 to this Determination

7 Schedule 1 (table item 4, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

8 Schedule 1 (table item 4, column 4, subparagraph (b)(iii))

Repeal the subparagraph, substitute:

(iii) a permitted importer, a permitted exporter, a permitted supplier or a permitted recipient;

9 Schedule 1 (table item 5, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

10 Schedule 1 (table item 6, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

11 Schedule 2 (table item 4, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

12 Schedule 2 (table item 4, column 4, paragraph (c))

Repeal the paragraph, substitute:

- (c) the person:
 - (i) possesses at least 20 times the commercial quantity of the kind of vaping goods; and
 - (ii) possesses the goods for the sole purpose of surrendering the goods to the Department; and
 - (iii) notified the Department, before 1 September 2024, at vapereturn@health.gov.au that the person intends to surrender the goods to the Department;

13 Schedule 2 (table item 5, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

14 Schedule 2 (table item 6, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

15 Schedule 2 (table item 6, column 4, subparagraph (d)(ii))

Repeal the subparagraph, substitute:

(ii) a permitted supplier; or

16 Schedule 2 (table item 6, column 4, subparagraph (e)(ii))

Repeal the subparagraph, substitute:

(ii) a permitted supplier; or

17 Schedule 2 (table item 6, column 4, paragraph (g))

Omit "1 August 2024", substitute "1 September 2024".

18 Schedule 2 (table item 7)

Repeal the item, substitute:

- 7 one or more of the following:
 - (a) notified vaping goods, other than goods that contain a substance included in a Schedule to the current Poisons Standard;
 - (b) therapeutic cannabis vaping goods

a person engaged in the business of importation or supply all of the following:

- (a) the possession and supply occurs on or before 30 November 2024;
- (b) the goods are possessed by the person for the sole purpose of supplying the goods to a permitted recipient or a permitted supplier (receiver);
- (c) in the case of goods mentioned in paragraph (a) of column 2—the goods are supplied by the person to a receiver;
- (d) in the case of goods mentioned in paragraph (b) of column 2 that are entered in the Register—the goods are supplied by the person to a receiver;
- (e) in the case of goods
 mentioned in paragraph (b) of
 column 2 that are not entered
 in the Register—the goods
 are supplied by the person to
 a receiver who is not a person
 engaged in the business of
 wholesale supply

all of the following:

- (a) the goods must only be supplied to a receiver in accordance with a written agreement between the person and the receiver;
- (b) the goods must be stored:
 - (i) in an area, or a receptacle in an area, that is locked or otherwise secured in a way that is designed to prevent access to the area or receptacle by a person who is not authorised to access the area or receptacle; and
 - (ii) in an area the person reasonably believes a member of the public could not access without permission from the person;
- (c) the person must keep and maintain a record of all goods in the person's possession, including:
 - (i) the amount or quantity of goods; and
 - (ii) a description of the goods;
- (d) during transportation:
 - (i) the person must not leave the goods unattended, other than in a secure area; and
 - (ii) the person must take all reasonable steps to ensure that the goods are stored and transported in accordance with the instructions (if any) that are provided by the receiver, or that are specified on the label of the goods;
- (e) the goods must be delivered to the street address stated in the written agreement referred to in paragraph (a);
- (f) 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, or a person purportedly acting on behalf of, the receiver;

- (g) the person must retain, for a period of no less than 12 months after the day on which supply of the goods occurs:
 - (i) the written receipt, or a copy of the written receipt;
 - (ii) a description of the goods (including the amount or quantity of goods) delivered;and
 - (iii) the written agreement, or a copy of the written agreement;
- (h) if the person reasonably suspects that any of the goods have been lost or stolen, the person must notify police in the State or Territory in which the person suspects the goods were lost or stolen:
 - (i) as soon as practicable; and
 - (ii) before the end of the next business day;
- (i) the person must, if requested to do so by the Department, provide any information that the Department requires about:
 - (i) the goods;
 - (ii) the person's possession or supply of the goods, and any other persons involved in such activities: and
 - (iii) any other matter that the Department determines is relevant

19 Schedule 2 (table item 8, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

20 Schedule 2 (table item 8, column 4, paragraph (c))

Omit "1 August 2024", substitute "1 September 2024".

21 Schedule 2 (table item 9)

Repeal the item, substitute:

goods that are or contain a vaping substance that is a medicinal cannabis

a person who

(a) the holder of a licence and permit

the goods are:

- (a) imported in accordance with paragraphs 5(1)(a) to (d) of the CPI Regulations; or
- (b) manufactured in Australia under a licence granted under

all of the following:

- (a) the goods may only be supplied to a permitted health practitioner;
- (b) the person must, if requested to do so by the Department, provide any information that the

product or a
medicine that
contains
synthetic
cannabis

granted under subregulat ion 5(5) of the CPI Regulations that applies to the vaping goods; or (b) the holder

of a

licence

under

the Act

Part 3-3 of

Part 3-3 of the Act

Department requires about:

- (i) the goods;
- (ii) the person's possession or supply of the goods, and any other persons involved in such activities; and
- (iii) any other matter that the Department determines is relevant;
- (c) if the goods contain a substance included in Schedule 4 to the current Poisons Standard—the person must comply with all applicable laws of the State or Territory that apply to the possession and supply of a substance to which Schedule 4 of the current Poisons Standard applies;
- (d) if the goods contain a substance included in Schedule 8 to the current Poisons Standard—the person must comply with all applicable laws of the State or Territory that apply to the possession and supply of a substance to which Schedule 8 of the current Poisons Standard applies

22 Schedule 2 (table item 10, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

23 Schedule 2 (table item 10, column 4, subparagraph (b)(iii))

Repeal the subparagraph, substitute:

(iii) a permitted supplier or a permitted importer;

24 Schedule 2 (table item 10, column 4, paragraph (c))

Omit "a permitted wholesale supplier, a permitted cannabis wholesaler,", substitute "a permitted supplier,".

25 Schedule 2 (table item 11, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".

26 Schedule 2 (table item 13, column 4, paragraph (a))

Omit "30 September 2024", substitute "30 November 2024".