



Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023

I, Anthony Lawler, as delegate of the Minister for Health and Aged Care, make the following Order.

Dated 15 December 2023

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Schedules.....	1
Schedule 1—Amendments	2
<i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021</i>	2
Schedule 2—Amendments	10
<i>Therapeutic Goods (Exempt Monographs) Determination 2021</i>	10

1 Name

This instrument is the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*.

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.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	At the same time as the commencement of the <i>Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023</i> . However, this instrument does not commence at all if the <i>Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023</i> does not commence.	

Note: This table relates only to the provisions of this instrument as originally made.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 sections 3C and 10 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Standard for Nicotine Vaping Products) (TGO 110) Order 2021

1 Subsection 1(1)

Omit “*Nicotine Vaping Products*”, substitute “*Therapeutic Vaping Goods*”.

2 Section 4 (in the note)

Insert:

(aa) essential principles;

3 Section 4 (at the end of the note)

Add:

; (j) standard;

(k) supply;

(l) therapeutic goods.

4 Section 4 (definition of *finished product*)

Repeal the definition (including the notes).

5 Section 4 (definition of *flavour*)

Repeal the definition.

6 Section 4

Insert:

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

MDSO means the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*.

Note: MDSO is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

7 Section 4 (definition of *nicotine vaping product*)

Repeal the definition (including the notes).

8 Section 4 (definition of *other ingredient*)

Repeal the definition.

9 Section 4 (definition of *stated content*)

Omit “in a nicotine vaping product on the label of that product”, substitute “on a label”.

10 Section 4

Insert:

therapeutic vaping device has the same meaning as in the MD Regulations.

therapeutic vaping device accessory has the same meaning as in the MD Regulations.

therapeutic vaping kit has the same meaning as in the Regulations.

therapeutic vaping pack has the same meaning as in the Regulations.

therapeutic vaping substance has the same meaning as in the Regulations.

therapeutic vaping substance accessory has the same meaning as in the Regulations.

11 Section 5

Repeal the section, substitute:

5 Standard

The matters specified in this instrument constitute a standard for the following:

- (a) therapeutic vaping substances;
- (b) therapeutic vaping substance accessories;
- (c) therapeutic vaping kits;
- (d) goods in a therapeutic vaping pack.

12 Section 6

Repeal the section (including the notes), substitute:

6 Application

(1) Subject to subsection (2), this instrument applies to:

- (a) therapeutic vaping substances;
- (b) therapeutic vaping substance accessories;
- (c) therapeutic vaping kits;
- (d) goods in a therapeutic vaping pack;

that are finished products and the only indications for the goods are use for smoking cessation or the management of nicotine dependence.

(2) This instrument does not apply to:

- (a) registered goods; or
- (b) goods manufactured in, or imported into, Australia for export only; or
- (c) therapeutic goods mentioned in item 1A of Schedule 5 to the Regulations where those goods are carried by the importer as a passenger on a ship or aircraft; or

Note 1: Item 1A of Schedule 5 to the Regulations relates to therapeutic vaping substance, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack that are imported for use in the treatment of the traveller or another traveller in their care.

- (d) therapeutic goods mentioned in item 16 of Schedule 5A to the Regulations; or

Note 2: Item 16 of Schedule 5A to the Regulations relates to nicotine in solution as a starting material for use in the manufacture of a therapeutic vaping substance, therapeutic vaping substance accessory or any other therapeutic good.

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- (e) components or articles mentioned in item 2.18 of Part 2 of Schedule 4 to the MD Regulations; or

Note 3: Item 2.18 of Part 2 of Schedule 4 to the MD Regulations relates to components or articles imported for use in the manufacture of therapeutic vaping devices or therapeutic vaping device accessories.

- (f) therapeutic goods mentioned in items 4, 8, 10, 11, or 12 of Schedule 5A to the Regulations, subject to compliance with conditions specified in those items.

Note 4: Items 4, 8, 10, 11 and 12 of Schedule 5A to the Regulations relate to therapeutic goods that are imported by particular persons or are part of the medical supplies of a visiting ship or aircraft.

13 Part 2 (heading)

Repeal the heading, substitute:

Part 2—Therapeutic vaping substances and therapeutic vaping substance accessories

14 Subsection 7(1)

Omit “nicotine vaping product”, substitute “therapeutic vaping substance or therapeutic vaping substance that contains nicotine”.

15 Subsection 7(2)

Omit “nicotine vaping product”, substitute “therapeutic vaping substance or therapeutic vaping substance accessory”.

16 After subsection 7(2)

Insert:

- (2A) A therapeutic vaping substance or therapeutic vaping substance accessory that does not contain nicotine must not contain any active ingredient.

17 Subsection 7(3)

Omit “nicotine vaping product”, substitute “therapeutic vaping substance or therapeutic substance accessory”.

18 After subsection 7(3)

Insert:

Flavour

- (4) A therapeutic vaping substance or therapeutic vaping substance accessory may only contain ingredients or components that produce the taste or smell that a reasonable person would associate with:
- (a) mint or menthol flavour; or
 - (b) tobacco flavour.
- (5) A therapeutic vaping substance or therapeutic substance accessory must not contain ingredients or components that produce a combination of flavours.

Note: Examples of flavour combinations that are not permitted include cherry mint, chocolate mint and tobacco mint.

19 Section 8

Repeal the section (including the notes), substitute:

8 Labels

- (1) A therapeutic vaping substance or therapeutic vaping substance accessory must be labelled in accordance with this section.
- (2) Where a therapeutic vaping substance or therapeutic vaping substance contains nicotine, then the information specified in an item in the table in Part 1 of Schedule 2 must be:
 - (a) on or attached to the container or the primary pack of a therapeutic vaping substance or therapeutic vaping substance accessory; or
 - (b) supplied with the container or the primary pack of a therapeutic vaping substance or therapeutic vaping substance accessory.

Note 1: A label, in relation to therapeutic goods, is the display of printed information on or attached to the goods, on or attached to the container or primary pack in which the goods are supplied, or supplied with such a container or pack: see subsection 3(1) of the Act.

Note 2: Labels include displays of printed information on stickers placed over the container or primary pack of therapeutic goods, and information sheets supplied with the container or primary pack of therapeutic goods.

Example: A therapeutic vaping substance or therapeutic vaping substance accessory that contains nicotine complies with this subsection if the information specified in items 1 and 2 of Part 1 to Schedule 2 is printed on a sticker placed over the container of the substance or substance accessory and the information specified in item 3 of Part 2 to Schedule 2 is printed on an information sheet supplied with that container.

- (3) Where a therapeutic vaping substance or therapeutic vaping substance accessory does not contain nicotine, then the information specified in an item in the table in Part 2 of Schedule 2 must be:
 - (a) on or attached to the container or the primary pack of a therapeutic vaping substance or therapeutic vaping substance accessory; or
 - (b) supplied with the container or the primary pack of a therapeutic vaping substance or therapeutic vaping substance accessory.

Note 1: A label, in relation to therapeutic goods, is the display of printed information on or attached to the goods, on or attached to the container or primary pack in which the goods are supplied, or supplied with such a container or pack: see subsection 3(1) of the Act.

Note 2: Labels include displays of printed information on stickers placed over the container or primary pack of therapeutic goods, and information sheets supplied with the container or primary pack of therapeutic goods.

Example: A therapeutic vaping substance or therapeutic vaping substance accessory that does not contain nicotine complies with this subsection if the information specified in items 1 and 2 of Part 2 to Schedule 2 is printed on a sticker placed over the container of the substance or substance accessory, and the information specified in item 3 of Part 2 to Schedule 2 is printed on an information sheet supplied with that container.

- (3) All of the information that is displayed on the label of a therapeutic vaping substance or therapeutic vaping substance accessory must be:
 - (a) in English; and

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- (b) legible; and
 - (c) visible and not obscured; and
 - (d) durable.

20 Section 9

Omit “nicotine vaping product” (wherever occurring), substitute “therapeutic vaping substance or therapeutic vaping substance accessory”.

21 Section 10

Omit “nicotine vaping product” (wherever occurring), substitute “therapeutic vaping substance or therapeutic vaping substance accessory”.

22 Subsection 10(3)

Omit “item 1”, substitute “item 1A”.

23 Subsection 11(1)

Omit “nicotine vaping product”, substitute “therapeutic vaping substance or therapeutic vaping substance accessory that contains nicotine”.

24 After section 11

Insert:

12 Therapeutic vaping substance accessories

A therapeutic vaping substance accessory must comply with the following:

- (a) for a therapeutic vaping substance accessory that, if it did not contain a therapeutic vaping substance, would be a therapeutic vaping device accessory to which the MDSO ordinarily applies—either:
 - (i) the MDSO; or
 - (ii) the essential principles;
- (b) for a therapeutic vaping substance accessory that, if it did not contain a therapeutic vaping substance, would be a therapeutic vaping device accessory to which the MDSO does not ordinarily apply—the essential principles.

Part 3—Therapeutic vaping kits

13 Goods in a therapeutic vaping kit

Each therapeutic vaping substance and therapeutic vaping substance accessory in a therapeutic vaping kit must comply with Part 2.

Part 4—Therapeutic vaping packs

14 Goods in a therapeutic vaping pack

Therapeutic vaping substances and therapeutic vaping substance accessory

- (1) Each therapeutic vaping substance or therapeutic vaping substance accessory in therapeutic vaping pack must comply with Part 2.

Therapeutic vaping device, therapeutic vaping device accessory and therapeutic vaping substance accessory

- (2) Each good in a therapeutic vaping pack, other than a therapeutic vaping substance, must comply with the following:
 - (a) for a therapeutic vaping device or therapeutic vaping device accessory to which the MDSO ordinarily applies—either:
 - (i) the MDSO; or
 - (ii) the essential principles;
 - (b) for a therapeutic vaping device or therapeutic vaping device accessory to which the MDSO does not ordinarily apply—the essential principles.

Part 5—Transitional provisions

15 Transitional

- (1) In this section:

former TGO 110 means the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*, as in force immediately before the commencement of the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*.

- (2) Despite the amendments made by the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*, the former TGO 110 continues to apply in relation to therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, and goods in therapeutic vaping packs that are imported or manufactured before 1 March 2024.
- (3) Subsection (2) ceases to apply on 1 July 2024.

25 Schedule 2

Repeal the Schedule, substitute:

Schedule 2—Labelling information

Note: See section 8.

Part 1—Therapeutic vaping substances and accessories that contain nicotine

Labelling information	
Column 1	Column 2
Item	Information
1	a list of ingredients contained in the therapeutic vaping substance or therapeutic vaping substance accessory as follows: <ul style="list-style-type: none"> (a) the name of each active ingredient; and (b) the name of each other ingredient, other than the ingredients or components of a flavour; and (c) where the product contains mint or menthol flavour, or tobacco flavour: <ul style="list-style-type: none"> (i) the word “flavour” or a description that includes the word “flavour” (such as “mint flavour”); or (ii) the name of each ingredient or component producing that flavour
2	the concentration of nicotine contained in the therapeutic vaping substance or therapeutic vaping substance accessory as follows: <ul style="list-style-type: none"> (a) where the nicotine is in base form—the base form concentration of nicotine in mg/mL; or (b) where the nicotine is in salt form— the equivalent base form concentration of nicotine in mg/mL
3	the following warning statements: <ul style="list-style-type: none"> (a) “KEEP OUT OF REACH OF CHILDREN”; and (b) “Avoid contact with eyes”; and (c) “Avoid contact with skin”

Part 2—Therapeutic vaping substances and accessories that do not contain nicotine

Labelling information	
Column 1	Column 2
Item	Information
1	a list of ingredients contained in the therapeutic vaping substance or therapeutic vaping substance accessory as follows: <ul style="list-style-type: none"> (a) the name of each ingredient, other than the ingredients or components of a flavour; and (b) where the product contains mint or menthol flavour, or tobacco flavour: <ul style="list-style-type: none"> (i) the word “flavour” or a description that includes the word “flavour” (such as “mint flavour”); or (ii) the name of each ingredient or component producing that flavour
2	a statement that the therapeutic vaping substance or therapeutic vaping substance accessory does not contain nicotine <p style="margin-left: 40px;">Note The statement may be in the form of words or alphanumerical characters, for example “zero-nicotine”, “0% nicotine” or “0 mg/mL</p>

Labelling information	
Column 1	Column 2
Item	Information
	nicotine”.
3	the following warning statement: (a) “KEEP OUT OF REACH OF CHILDREN”

Schedule 2—Amendments

Therapeutic Goods (Exempt Monographs) Determination 2021

1 Section 4 (definition of *nicotine vaping product*)

Repeal the definition.

2 Section 4

Insert:

regulations means the *Therapeutic Goods Regulations 1990*.

3 Section 4 (definition of *TGO 110*)

Omit “*Nicotine Vaping Products*”, substitute “*Therapeutic Vaping Goods*”.

4 Section 4

Insert:

therapeutic vaping substance has the same meaning as in Regulations.

therapeutic vaping substance accessory has the same meaning as in Regulations.

5 Schedule 1 (table item 1, column 4)

Omit “*nicotine vaping product*”, substitute “*therapeutic vaping substance or therapeutic vaping substance accessory*”.