



Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024

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

Dated 27 September 2024

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

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 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.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 October 2024.	1 October 2024

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

1 Section 4 (note)

Repeal the note, substitute:

Note 1: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) batch;
- (b) British Pharmacopoeia;
- (c) container;
- (d) essential principles;
- (e) European Pharmacopoeia;
- (f) manufacture;
- (g) medicine;
- (h) primary pack;
- (i) registered goods;
- (j) sponsor;
- (k) standard;
- (l) supply;
- (m) therapeutic goods;
- (n) United States Pharmacopoeia-National Formulary.

Note 2: The definition of *container* in the Act is as follows:

container, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.

Note 3: To avoid doubt, the container of a therapeutic vaping substance or therapeutic vaping substance accessory is the bottle, cartridge, capsule, pod or other vessel that contains the therapeutic vaping substance, and not the blister pack, strip pack or other wrapper in which the container is supplied.

2 Section 4

Insert:

batch number means a number, or a combination of letters, numerals, or symbols, which is given by the manufacturer to a batch of relevant goods or therapeutic vaping packs, to uniquely identify that batch.

Note: The batch number may be used to trace the batch through all stages of manufacture and distribution.

batch number prefix means the prefix that precedes the batch number, and consists of any words or symbols that clearly indicate that the information following those words or symbols is the batch number.

Note: Common forms of the batch number prefix include the following (either in capital letters, lower case letters or a combination of capital and lower case letters):

- (a) Batch number;
- (b) Batch no.;
- (c) Batch;
- (d) B;
- (e) (B);
- (f) B/N;

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- (g) Lot number;
 - (h) Lot No.;
 - (i) Lot.

capacity means the volume of the empty container.

contact details, in relation to a sponsor, means information that would enable a person to contact the sponsor and that:

- (a) includes the address of the principal place of business of the sponsor in Australia; and
- (b) may also include a telephone number, website or email address of the sponsor;

but is not a post office, cable, telegraphic or code address of the sponsor.

expiry date has the same meaning as in the Regulations.

expiry date prefix means the prefix that precedes the expiry date, and consists of any words or symbols that clearly indicate that the information following those words or symbols is the expiry date (other than words indicating that the goods may be used after that date, including ‘Best by’ and ‘Best before’).

Note: Common forms of the expiry date prefix include the following (either in capital letters, lower case letters or a combination of capital and lower case letters):

- (a) Expiry date;
- (b) Expiry;
- (c) Expires;
- (d) Exp. Date;
- (e) Exp;
- (f) Use by;
- (g) Use before.

fill volume means the volume of a therapeutic vaping substance that is present in a container.

flavouring agent means an ingredient or component, or mixture of ingredients or components, added to a therapeutic vaping substance or a therapeutic vaping substance accessory to:

- (a) provide flavour to the good; or
- (b) maintain the stability of the favour.

intermediate packaging means packaging which:

- (a) encloses one or more containers; and
- (b) is enclosed in a primary pack.

label means:

- (a) in relation to a relevant good—a display of printed information on, or attached to, any of the following:
 - (i) the container;
 - (ii) the intermediate packaging (if any);
 - (iii) the primary pack; and
- (b) in relation to a therapeutic vaping pack—a display of printed information on, or attached to, the pack.

main label means:

- (a) the label, or part of the label, that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and
- (b) if there are 2 or more labels:
 - (i) the label, or part of the label, where the name of the good is more or most conspicuously displayed; or
 - (ii) if the name of the good is equally more or most conspicuously displayed on more than one of those labels—each of the labels on which the name of the good is equally more or most conspicuously displayed.

menthol flavour means the taste or smell that a reasonable person would associate with menthol as a purified ingredient.

mint flavour means the taste or smell that a reasonable person would associate with herbaceous plants of a recognised species in the *Mentha* genus.

name, in relation to relevant goods and therapeutic vaping packs, means:

- (a) where the name of the goods has been registered under the *Trade Marks Act 1995*—the registered trade mark for the relevant goods; or
- (b) in any other case—the unique, invented, common or scientific name; that is assigned to the goods and that appears on one or more labels of the goods.

Poisons Information Centre contact information means information to enable a person to contact a Poisons Information Centre that includes:

- (a) the national telephone number for the Poisons Information Centre in Australia (13 11 26); or
- (b) the telephone number for another poisons information centre:
 - (i) that is attended by adequately trained staff for 24-hour emergency poisons information; and
 - (ii) where calls to the centre are logged and submitted for incorporation into the official collection of poisoning data.

relevant goods means any of the following:

- (a) a therapeutic vaping substance;
- (b) a therapeutic vaping substance accessory;
- (c) a therapeutic vaping kit.

relevant indications means one or both of the following:

- (a) in relation to a therapeutic vaping substance, a therapeutic vaping substance accessory or a therapeutic vaping kit, including a therapeutic vaping substance or therapeutic vaping substance accessory that is contained in a therapeutic vaping pack or therapeutic vaping kit—the use for smoking cessation or the management of nicotine dependence;
- (b) in relation to a therapeutic vaping device or a therapeutic vaping device accessory that is contained in a therapeutic vaping pack—the purpose to administer, or contain, a therapeutic vaping substance for which the only indication is use for smoking cessation or the management of nicotine dependence.

small container means a container that:

- (a) has a capacity of 25 mL or less; and
- (b) is not a very small container.

3 Section 4 (definition of *stated content*)

Repeal the definition, substitute:

stated content means the concentration of nicotine that is stated on the label to be present in a therapeutic vaping substance or therapeutic vaping substance accessory.

4 Section 4

Insert:

text size means the height of the following:

- (a) capital letters or lower case letters, including an ascender or descender;
- (b) numbers or numerals;
- (c) symbols.

tobacco flavour means the taste or smell that a reasonable person would associate with herbaceous plants of a recognised species in the *Nicotiana* genus.

very small container means a container that has a capacity of 5 mL or less.

5 Section 5

Repeal the section.

6 Before section 6

Insert:

Part 1A—Application

7 Section 6

Repeal the section, substitute:

6 Application

- (1) This instrument applies to the following goods for which the only indications are relevant indications:
 - (a) therapeutic vaping substances; and
 - (b) therapeutic vaping substance accessories; and
 - (c) therapeutic vaping kits; and
 - (d) goods in a therapeutic vaping pack;other than:
 - (e) registered goods; or
 - (f) goods manufactured in, or imported into, Australia for export only; or
 - (g) 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: 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.

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

Note: 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. Item 16 of Schedule 5A to the Regulations also relates to any other starting material that is an ingredient or component for use in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory.

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

Note: 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.

- (j) 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: 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.

- (2) To avoid doubt, this instrument applies to:

- (a) therapeutic vaping substances and therapeutic vaping substance accessories that are contained in a therapeutic vaping kit; and
(b) therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping device accessories and therapeutic vaping devices contained in a therapeutic vaping pack.

8 Parts 2, 3, 4 and 5

Repeal the Parts, substitute:

Part 2—General provisions

7 Name

- (1) The name of relevant goods must not:

- (a) be in any way attractive to children or adolescents; or
(b) whether expressly or by implication—
(i) suggest that the goods are a food, beverage or cosmetic product; or
(ii) suggest that the goods have health benefits, including healing, vitalising, natural, organic or rejuvenating properties; or
(iii) suggest that the goods are safe, without harm or without side effects; or
(iv) promote the use or supply of the goods; or
(v) exaggerate, or be likely to exaggerate, the efficacy or performance of the goods; or
(vi) encourage, or be likely to encourage, inappropriate or excessive use of the goods.

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- (2) Goods in a therapeutic vaping pack must only be supplied in a therapeutic vaping pack where the name of the pack complies with subsection (1) as if the pack were relevant goods.

8 Goods in a therapeutic vaping kit or therapeutic vaping pack

- (1) Each therapeutic vaping substance and therapeutic vaping substance accessory in a therapeutic vaping kit or a therapeutic vaping pack must:
- (a) be a finished product; and
 - (b) be indicated only for use for smoking cessation or the management of nicotine dependence; and
 - (c) conform with the requirements for therapeutic vaping substances and therapeutic vaping substance accessories specified in this instrument (as applicable).
- (2) Each therapeutic vaping device and therapeutic vaping device accessory in a therapeutic vaping pack must:
- (a) be a finished product; and
 - (b) be intended only to administer, or contain, a therapeutic vaping substance for which the only indication is use for smoking cessation or the management of nicotine dependence; and
 - (c) conform with the following:
 - (i) for a therapeutic vaping device or a therapeutic vaping device accessory to which the MDSO ordinarily applies—either the MDSO or the essential principles;
 - (ii) for a therapeutic vaping device or a therapeutic vaping device accessory to which the MDSO does not ordinarily apply—the essential principles.
- (3) The goods in a therapeutic vaping pack must all be:
- (a) therapeutic goods; or
 - (b) goods intended by the manufacturer of the goods to assist with the use of a therapeutic vaping device or therapeutic vaping device accessory.

Part 3—Ingredients

9 General requirements

All ingredients, other than flavouring agents that are not menthol, in a therapeutic vaping substance or a therapeutic vaping substance accessory must comply with one or more of the following:

- (a) the British Pharmacopoeia;
- (b) the European Pharmacopoeia;
- (c) the United States Pharmacopoeia-National Formulary.

10 Active ingredients

- (1) A therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine must contain nicotine as the only active ingredient.
- (2) The concentration of nicotine in a therapeutic vaping substance or a therapeutic vaping substance accessory must not be more than 50 mg/mL in solution (equivalent base form).
- (3) The concentration of nicotine in a therapeutic vaping substance or therapeutic vaping substance accessory must be not less than 90.0% and not more than 110.0% of the stated content.
- (4) A therapeutic vaping substance or a therapeutic vaping substance accessory that does not contain nicotine must not contain any other active ingredient.

11 Permitted ingredients

- (1) Subject to subsection (2), only those ingredients that are specified in column 2 of the table in Schedule 1 to this instrument may be used in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory.

Note 1: See section 15 for requirements relating to containers of therapeutic vaping substance accessories.

Note 2: To avoid doubt, this subsection applies to the manufacture of therapeutic vaping substances including those contained in a therapeutic vaping substance accessory.

- (2) For each item of the table in Schedule 1 to this instrument, the ingredient specified in column 2 must comply with the requirements (if any) specified in column 3.

12 Restricted substances

For each item of the tables in Parts 1, 2 and 3 of Schedule 2 to this instrument, the substance specified in column 2 must:

- (a) not be added to a therapeutic vaping substance or a therapeutic vaping substance accessory; and
- (b) if present in a therapeutic vaping substance or a therapeutic vaping substance accessory—be present at a concentration below the limit specified in column 3.

13 Flavour

- (1) A therapeutic vaping substance or a therapeutic vaping substance accessory may only contain flavouring agents that produce one of the following:
 - (a) menthol flavour;
 - (b) mint flavour;
 - (c) tobacco flavour.
- (2) For the avoidance of doubt, a therapeutic vaping substance or therapeutic substance accessory must not contain flavouring agents that produce a combination of flavours.

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

Part 4—Containers

14 Containers of therapeutic vaping substances

- (1) The container of a therapeutic vaping substance must have a fill volume that is not more than 60 mL.
- (2) The container of a therapeutic vaping substance must be predominantly either black, white, grey or clear, and feature not more than 4 other colours or shades, including the colour or shade of any text.

15 Containers of therapeutic vaping substance accessories

- (1) The container of a therapeutic vaping substance accessory must have a fill volume that is not more than 5 mL.
- (2) The container of 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 the MDSO or the essential principles, except the requirements relating to labelling and packaging;
 - (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, except the requirements relating to labelling and packaging.

Note: Requirements relating to labelling and packaging of a container of a therapeutic vaping substance accessory are specified in Part 5 of this instrument.

- (3) The following requirements apply to the container of a therapeutic vaping substance accessory:
 - (a) the container of a therapeutic vaping substance accessory must be predominantly either matte white, matte grey or matte black, and feature no more than 3 other matte colours or shades, including the colour or shade of any text;
 - (b) where the container of a therapeutic vaping device accessory features a colour or shade other than matte white or matte grey, that colour must not be visible when the therapeutic vaping device is fully assembled for use;
 - (c) the container of a therapeutic vaping device accessory may have a clear panel, which must be the smallest size that enables visibility of the amount of therapeutic vaping substance in the container.

Part 5—Labelling and packaging

Division 1—General

16 General requirements

- (1) The label, primary pack, intermediate packaging (if any) and container of a relevant good must comply with the requirements specified in this Division.
- (2) The information required to be included on the label of a relevant good must be:
 - (a) in English; and
 - (b) clearly legible; and
 - (c) printed in a manner that is durable; and
 - (d) in a colour that contrasts strongly with the background, except for the expiry date, expiry date prefix, batch number or batch number prefix, when that information is embossed or debossed and not printed.

17 Appearance

The label and primary pack, other than a primary pack that is a container, of a relevant good must be predominantly white, and feature no more than 4 other colours or shades, including the colour or shade of any text.

Note 1: Section 20 requires warning statements to be in black text. For the avoidance of doubt, black (required for the text of warning statements) is one of the 4 other colours or shades permitted by this section to be on the label or primary pack.

Note 2: Requirements relating to a primary pack that is a container are in Part 4 of this instrument.

18 Prohibited features

- (1) The label, primary pack, intermediate packaging (if any) and container of a relevant good must not contain the following:
 - (a) any feature that suggests, whether expressly or by implication, that the good:
 - (i) is a food, beverage or cosmetic product; or
 - (ii) has health benefits other than its indications, including healing, vitalising, natural, organic or rejuvenating properties;
 - (b) any words, symbols, trademarks, images, figures, logos or emblems that are in contravention of another provision of this instrument;
 - (c) any promotional statement, pictorial representation or design.
- (2) The label, primary pack, intermediate packaging (if any) and container of a relevant good must not include any features designed to change the appearance of the label, container or package, including, but not limited to, any of the following:
 - (a) heat activated inks;
 - (b) inks or embellishments designed to appear gradually over time;
 - (c) inks that appear fluorescent in certain light;
 - (d) panels designed to be scratched or rubbed to reveal an image or text.

19 Dispensing labels

The primary pack of a relevant good must include a minimum space of 70 mm x 30 mm for the dispensing label, unless precluded by the dimensions of the primary pack.

20 Warning statement panel

- (1) A warning statement panel must:
 - (a) be at least 30% of the total main label size; and
 - (b) display the following warning statement:
 - (i) “THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE”.
- (2) The text of the warning statement required by subsection (1) must:
 - (a) be in bold-face, sans serif, capital letters of uniform thickness and size; and
 - (b) be in black text on a white background; and
 - (c) be oriented in the same direction as the name of the good; and
 - (d) be of a such a size that the text fills, as much as possible, the background of the warning statement panel.

21 Child-resistant packaging

- (1) A therapeutic vaping substance or therapeutic vaping substance accessory must comply with the requirements specified in the following sections of TGO 95 (*child-resistant packaging requirements*):
 - (a) section 8 (general requirements); and
 - (b) where the product is in a reclosable package—section 9 (reclosable packages), other than subsection 9(6); and
 - (c) where the product is in a non-reclosable package—section 10 (non-reclosable packages).
- (2) A therapeutic vaping substance or therapeutic vaping substance accessory is taken to comply with the child-resistant packaging requirements if one of the following paragraphs applies:
 - (a) the product is packaged for supply in Canada and complies with the requirements in relation to child-resistant packaging specified in sections 50 to 54 of the Vaping Products Labelling and Packaging Regulations of Canada, as in force or existing from time to time;
 - (b) the product is packaged for supply in the European Union and complies with the requirements in relation to child-resistant packaging specified in Article 20(3)(g) of the *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014*, as in force or existing from time to time;
 - (c) the product is packaged for supply in New Zealand and complies with the requirements in relation to child-resistant packaging specified in regulations made under the *Smokefree Environments and Regulated Products Act 1990* (NZ), as in force or existing from time to time;
 - (d) the product is packaged for supply in the United Kingdom and complies with the requirements in relation to child-resistant packaging specified in

paragraph 36(7) of the *Tobacco and Related Products Regulations 2016* of the United Kingdom, as in force or existing from time to time;

- (e) the product is packaged for supply in the United States and complies with the requirements in relation to child-resistant packaging specified in 16 CFR § 1700.15 of the Poison prevention packaging standards of the United States, as in force or existing from time to time.

Note: To avoid doubt, a paragraph of this subsection only applies where the laws of the relevant jurisdiction specify requirements in relation to child-resistant packaging.

Division 2—Therapeutic vaping substances and therapeutic vaping substance accessories

Subdivision 2.1—Primary packs

22 Information to be included on the main label of a primary pack

- (1) The main label on the primary pack of a therapeutic vaping substance or a therapeutic vaping substance accessory must contain all of the information listed in column 2 of the following table.

Information to be included on main label of a primary pack	
Column 1	Column 2
Item	Information
1	the name of the good
2	for a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine—the word “nicotine” and the concentration of nicotine as follows: (a) where the nicotine is in base form—the base form concentration of nicotine in mg/mL; (b) where the nicotine is in single salt form—the equivalent base form concentration of nicotine in mg/mL, with the name of the salt form in brackets immediately after the word “nicotine”; Example: For a therapeutic vaping substance containing 15 mg/mL of nicotine lactate, with an equivalent base form concentration of 10 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as lactate) 10 mg/mL”. (c) where the nicotine is a combination of salt forms or a combination of salt and base forms—the total equivalent base form concentration of nicotine in mg/mL, with the names of all the forms of nicotine in brackets immediately after the word “nicotine” Example: For a therapeutic vaping substance containing 5 mg/mL of nicotine as benzoate salt and 15 mg/mL nicotine lactate, with an equivalent base form concentration of 12 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as benzoate and lactate) 12 mg/mL”.
3	for a therapeutic vaping substance or a therapeutic vaping substance accessory that does not contain nicotine—the concentration of nicotine in the form of “nicotine 0 mg/mL”

Information to be included on main label of a primary pack

Column 1 Column 2

Item Information

4	for a therapeutic vaping substance or therapeutic vaping substance accessory that is menthol flavour—the words “menthol flavour”
5	for a therapeutic vaping substance or a therapeutic vaping substance accessory that is mint flavour—the words “mint flavour”
6	for a therapeutic vaping substance or a therapeutic vaping substance accessory that is tobacco flavour—the words: (a) “tobacco flavour”; or (b) “classic flavour”
7	the fill volume in mL

- (2) The information required by subsection (1) must:
 - (a) be orientated in the same direction; and
 - (b) for the information mentioned in items 1 to 3—be displayed in a text size of at least 3 mm; and
 - (c) for all other text—be displayed in a text size of at least 1.5 mm.
- (3) The name of the good on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional words or images.
- (4) Where a therapeutic vaping substance or a therapeutic vaping substance accessory contains nicotine, the name of the good, the word “nicotine” and the concentration of nicotine must:
 - (a) appear as a cohesive unit by placing the word “nicotine” and the concentration of nicotine together in a single line of text immediately below the name of the good; and
 - (b) not be separated by additional words or images.
- (5) Where a therapeutic vaping substance or a therapeutic vaping substance accessory does not contain nicotine, the name of the good and concentration of nicotine must:
 - (a) appear as a cohesive unit by placing the words “nicotine 0 mg/mL” immediately below the name of the good; and
 - (b) not be separated by additional words or images.
- (6) Where a therapeutic vaping substance or a therapeutic vaping substance accessory contains nicotine, the main label on the primary pack must contain a warning statement panel as specified in section 20.

23 Information to be included on the label of a primary pack

- (1) The label on the primary pack of a therapeutic vaping substance or a therapeutic vaping substance accessory must contain all of the information listed in column 2 of the following table.

Information to be included on the label of a primary pack

Column 1 **Column 2**

Item **Information**

1	the name of each ingredient in the therapeutic vaping substance or the therapeutic vaping substance accessory
2	the batch number preceded by the batch number prefix
3	the expiry date preceded by the expiry date prefix
4	the name of the sponsor
5	the contact details of the sponsor
6	the storage conditions applicable to the therapeutic vaping substance or therapeutic vaping substance accessory
7	the words “Poisons Information Centre:” followed immediately by Poisons Information Centre contact information
8	the warning statements: (a) “Avoid contact with eyes and skin”; and (b) “Do not swallow”

- (2) The information required by subsection (1) must be displayed in a text size of at least 1.5 mm.

Subdivision 2.2—Intermediate packaging**24 Information to be included on the main label of intermediate packaging**

- (1) The main label on the intermediate packaging (if any) of a therapeutic vaping substance or a therapeutic vaping substance accessory must contain all of the information listed in column 2 of the following table.

Information to be included on main label of intermediate packaging

Column 1 **Column 2**

Item **Information**

1	the name of the good
2	for a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine—the word “nicotine” and the concentration of nicotine as follows: (a) where the nicotine is in base form—the base form concentration of nicotine in mg/mL; (b) where the nicotine is in single salt form—the equivalent base form concentration of nicotine in mg/mL, with the name of the salt form in brackets immediately after the word “nicotine”; Example: For a therapeutic vaping substance containing 15 mg/mL of nicotine lactate, with an equivalent base form concentration of 10 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as lactate) 10 mg/mL”. (c) where the nicotine is a combination of salt forms or a combination of salt and base forms—the total equivalent base form concentration of nicotine in mg/mL, with the names of all the forms of nicotine in brackets immediately after the word “nicotine”

Information to be included on main label of intermediate packaging

Column 1 **Column 2**

Item **Information**

Example: For a therapeutic vaping substance containing 5 mg/mL of nicotine as benzoate salt and 15 mg/mL nicotine lactate, with an equivalent base form concentration of 12 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as benzoate and lactate) 12 mg/mL”.

3	for a therapeutic vaping substance or a therapeutic vaping substance accessory that does not contain nicotine—the concentration of nicotine in the form of “nicotine 0 mg/mL”
4	the batch number preceded by the batch number prefix
5	the expiry date preceded by the expiry date prefix
6	all of the following warning statements: (a) for a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine—“THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE”; (b) “Keep out of reach of children”; (c) “Avoid contact with eyes and skin”; (d) “Do not swallow”

(2) The information required by subsection (1) must be displayed in a text size of at least 1.5 mm.

(3) The warning statement required by paragraph (a) in column 2 of item 6 in the table in subsection (1) must be displayed in capital letters.

Subdivision 2.3—Containers**25 Information to be included on the main label of a container**

- (1) This section applies to the main label of a container that is not a small container or a very small container.
- (2) Where the container of a therapeutic vaping substance is enclosed in a primary pack, the main label on the container must contain all of the information listed in column 2 of the following table.

Information to be included on main label of a container

Column 1 **Column 2**

Item **Information**

1	the name of the good
2	for a therapeutic vaping substance that contains nicotine—the word “nicotine” and the concentration of nicotine as follows: (a) where the nicotine is in base form—the base form concentration of nicotine in mg/mL;

Information to be included on main label of a container

Column 1 Column 2

Item Information

(b) where the nicotine is in single salt form—the equivalent base form concentration of nicotine in mg/mL, with the name of the salt form in brackets immediately after the word “nicotine”;

Example: For a therapeutic vaping substance containing 15 mg/mL of nicotine lactate, with an equivalent base form concentration of 10 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as lactate) 10 mg/mL”.

(c) where the nicotine is a combination of salt forms or a combination of salt and base forms—the total equivalent base form concentration of nicotine in mg/mL, with the names of all the forms of nicotine in brackets immediately after the word “nicotine”

Example: For a therapeutic vaping substance containing 5 mg/mL of nicotine as benzoate salt and 15 mg/mL nicotine lactate, with an equivalent base form concentration of 12 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as benzoate and lactate) 12 mg/mL”.

3 for a therapeutic vaping substance that does not contain nicotine—the concentration of nicotine in the form of “nicotine 0 mg/mL”

4 for a therapeutic vaping substance that is menthol flavour—the words “menthol flavour”

5 for a therapeutic vaping substance that is mint flavour—the words “mint flavour”

6 for a therapeutic vaping substance that is tobacco flavour—the words:

(a) “tobacco flavour”; or

(b) “classic flavour”

7 the fill volume in mL

- (3) The information required by subsection (1) must:
- (a) be orientated in the same direction; and
 - (b) for the information mentioned in items 1 to 3—be displayed in a text size of at least 3 mm; and
 - (c) for all other text—be displayed in a text size of at least 1.5 mm.
- (4) The name of the good on the main label of the container must be presented in a continuous, uninterrupted manner and not be broken up by additional words or images.
- (5) Where a therapeutic vaping substance contains nicotine, the name of the good, the word “nicotine” and the concentration of nicotine must:
- (a) appear as a cohesive unit by placing the word “nicotine” and the concentration of nicotine together in a single line of text immediately below the name of the good; and
 - (b) not be separated by additional words or images.
- (6) Where a therapeutic vaping substance does not contain nicotine, the name of the good and concentration of nicotine must:

- (a) appear as a cohesive unit by placing the words “nicotine 0 mg/mL” immediately below the name of the good; and
 - (b) not be separated by additional words or images.
- (7) Where a therapeutic vaping substance contains nicotine, the main label on the container must contain a warning statement panel as specified in section 20.

26 Information to be included on the label of a container

- (1) This section applies to the label of a container that is not a small container or very small container.
- (2) Where the container of a therapeutic vaping substance is enclosed in a primary pack, the label on the container must contain all of the information listed in column 2 of the following table.

Information to be included on the label of a container	
Column 1	Column 2
Item	Information
1	the name of each ingredient in the therapeutic vaping substance
2	the batch number preceded by the batch number prefix
3	the expiry date preceded by the expiry date prefix
4	the name of the sponsor
5	the contact details of the sponsor
6	the storage conditions applicable to the therapeutic vaping substance
7	the words “Poisons Information Centre:” followed immediately by Poisons Information Centre contact information
8	the warning statements: <ul style="list-style-type: none"> (a) “Avoid contact with eyes and skin”; and (b) “Do not swallow”

- (3) The information required by subsection (2) must be displayed in a text size of at least 1.5 mm.

27 Information to be included on the main label of a small container

- (1) Where a primary pack contains a therapeutic vaping substance which is enclosed in a small container, the main label on the small container must contain all of the information listed in column 2 of the following table.

Information to be included on main label of a small container	
Column 1	Column 2
Item	Information
1	the name of the good
2	for a therapeutic vaping substance that contains nicotine—the word “nicotine” and the concentration of nicotine as follows:

Information to be included on main label of a small container

Column 1 **Column 2**

Item **Information**

- (a) where the nicotine is in base form—the base form concentration of nicotine in mg/mL;
- (b) where the nicotine is in single salt form—the equivalent base form concentration of nicotine in mg/mL, with the name of the salt form in brackets immediately after the word “nicotine”;
- Example: For a therapeutic vaping substance containing 15 mg/mL of nicotine lactate, with an equivalent base form concentration of 10 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as lactate) 10 mg/mL”.
- (c) where the nicotine is a combination of salt forms or a combination of salt and base forms—the total equivalent base form concentration of nicotine in mg/mL, with the names of all the forms of nicotine in brackets immediately after the word “nicotine”
- Example: For a therapeutic vaping substance containing 5 mg/mL of nicotine as benzoate salt and 15 mg/mL nicotine lactate, with an equivalent base form concentration of 12 mg/mL nicotine, the statement of concentration required to be on the main label is “nicotine (as benzoate and lactate) 12 mg/mL”.

3	for a therapeutic vaping substance that does not contain nicotine—the concentration of nicotine in the form of “nicotine 0 mg/mL”
4	for a therapeutic vaping substance that is menthol flavour—the words “menthol flavour”
5	for a therapeutic vaping substance that is mint flavour—the words “mint flavour”
6	for a therapeutic vaping substance that is tobacco flavour—the words: (a) “tobacco flavour”; or (b) “classic flavour”
7	the fill volume in mL
8	for a therapeutic vaping substance that contains nicotine—the warning statement: “THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE”

- (2) The information required by subsection (1) must:
- (a) be orientated in the same direction; and
 - (b) for the information mentioned in items 1 to 3—be displayed in a text size of at least 2 mm; and
 - (c) for all other text—be displayed in a text size of at least 1.5 mm.
- (3) The name of the good on the main label of the small container must be presented in a continuous, uninterrupted manner and not be broken up by additional words or images.
- (4) The warning statement required by item 8 in the table in subsection (1) must be displayed in capital letters.

28 Information to be included on the label of a small container

- (1) Where a primary pack contains a therapeutic vaping substance which is enclosed in a small container, the label on the small container must contain all of the information listed in column 2 of the following table.

Information to be included on the label of a small container	
Column 1	Column 2
Item	Information
1	the batch number preceded by the batch number prefix
2	the expiry date preceded by the expiry date prefix
3	the name of the sponsor
4	the storage conditions applicable to the therapeutic vaping substance
5	all of the following warning statements: (a) “Avoid contact with eyes and skin”; (b) “Do not swallow”; (c) for a container that is less than 10 mL—“Keep out of reach of children”

- (2) The information required by subsection (1) must be displayed in a text size of at least 1.5 mm.

29 Information to be included on the main label of a very small container

- (1) Where a primary pack contains:
- (a) a therapeutic vaping substance which is enclosed in a very small container; or
 - (b) a therapeutic vaping substance accessory where the cartridge, capsule, pod or other vessel is a very small container;
- the main label on the very small container must contain all of the information listed in column 2 of the following table.

Information to be included on main label of a very small container	
Column 1	Column 2
Item	Information
1	the name of the good
2	for a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine—the word “nicotine” and the equivalent base form concentration of nicotine in mg/mL
3	for a therapeutic vaping substance or a therapeutic vaping substance accessory that does not contain nicotine—the concentration of nicotine in the form of “nicotine 0 mg/mL”
4	for a therapeutic vaping substance or a therapeutic vaping substance accessory that is menthol flavour—the words “menthol flavour”
5	for a therapeutic vaping substance or a therapeutic vaping substance accessory that is mint flavour—the words “mint flavour”
6	for a therapeutic vaping substance or a therapeutic vaping substance accessory that is tobacco flavour—the words:

Information to be included on main label of a very small container

Column 1 **Column 2**

Item **Information**

- (a) “tobacco flavour”; or
 - (b) “classic flavour”
-

7 the fill volume in mL

- (2) The information required by subsection (1) must:
- (a) be orientated in the same direction; and
 - (b) be displayed in a text size of at least 1 mm.

30 Information to be included on the label of a very small container

- (1) Where a primary pack contains:
- (a) a therapeutic vaping substance which is enclosed in a very small container; or
 - (b) a therapeutic vaping substance accessory where the cartridge, capsule, pod or other vessel is a very small container;
- the label on the very small container must contain all of the information listed in column 2 of the following table.

Information to be included on the label of a very small container

Column 1 **Column 2**

Item **Information**

1 the batch number preceded by the batch number prefix

2 the expiry date preceded by the expiry date prefix

- (2) The information required by subsection (1) must be displayed in a text size of at least 1 mm.

Division 3—Therapeutic vaping kits**31 General**

Each therapeutic vaping substance and therapeutic vaping substance accessory in a therapeutic vaping kit must be enclosed in a primary pack that complies with the labelling and packaging requirements specified in Division 2, other than section 19.

32 Information to be included on the main label of a therapeutic vaping kit

- (1) The main label of a therapeutic vaping kit must contain all of the information listed in column 2 of the following table.

Information to be included on main label of a therapeutic vaping kit	
Column 1	Column 2
Item	Information
1	the name of the therapeutic vaping kit
2	for each therapeutic vaping substance or therapeutic vaping substance accessory in the kit—the following information as stated on the main label of the primary pack of the good: (a) the name of the good; (b) the presence of nicotine (if applicable) and the equivalent base form concentration of nicotine in each good; (c) the fill volume in mL
3	for each therapeutic vaping substance or therapeutic vaping substance accessory in the kit that is menthol flavour, mint flavour or tobacco flavour—the flavour, as stated on the main label of the primary pack of the good

- (2) The information required by subsection (1) must:
- (a) be orientated in the same direction; and
 - (b) for the information mentioned in items 1 and 2—be displayed in a text size of at least 3 mm; and
 - (c) for all other text—be displayed in a text size of at least 1.5 mm.
- (3) The name of the good on the main label of the kit must be presented in a continuous, uninterrupted manner and not be broken up by additional words or images.
- (4) Where a therapeutic vaping kit contains a therapeutic vaping substance or a therapeutic vaping substance accessory that contains nicotine, the main label of the kit must contain a warning statement panel as specified in section 20.

33 Information to be included on the label of a therapeutic vaping kit

- (1) The label of a therapeutic vaping kit must contain all of the information listed in column 2 of the following table.

Information to be included on the label of a therapeutic vaping kit	
Column 1	Column 2
Item	Information
1	the batch number preceded by the batch number prefix
2	the expiry date preceded by the expiry date prefix
3	the name of the sponsor
4	the contact details of the sponsor

Information to be included on the label of a therapeutic vaping kit

Column 1 **Column 2**

Item **Information**

5	the storage conditions applicable to each therapeutic vaping substance or therapeutic vaping substance accessory in the kit
6	the words “Poisons Information Centre:” followed immediately by Poisons Information Centre contact information
7	the warning statements: (a) “Avoid contact with eyes and skin”; and (b) “Do not swallow”

- (2) The information required by subsection (1) must appear in a text size of at least 1.5 mm.

Division 4—Goods in a therapeutic vaping pack**34 General**

Goods in a therapeutic vaping pack must be supplied in a therapeutic vaping pack that complies with the labelling and packaging requirements for a primary pack specified in Division 1, as if the pack was a relevant good.

35 Information to be included on the main label of a therapeutic vaping pack

- (1) Goods in a therapeutic vaping pack must be supplied in a therapeutic vaping pack that contains all of the information listed in column 2 of the following table on the main label.

Information to be included on main label of a therapeutic vaping pack

Column 1 **Column 2**

Item **Information**

1	the name of the therapeutic vaping pack
2	for each therapeutic vaping substance or therapeutic vaping substance accessory in the pack—the following information as stated on the main label of the primary pack of the good: (a) the name of the good; (b) the presence of nicotine (if applicable) and the equivalent base form concentration of nicotine in each good; (c) the fill volume in mL
3	for each therapeutic vaping substance or therapeutic vaping substance accessory in the pack that is menthol flavour, mint flavour or tobacco flavour—the flavour, as stated on the main label of the primary pack of the good
4	for each therapeutic vaping device or therapeutic vaping device accessory in the pack—the name and model of the therapeutic vaping device or therapeutic vaping device accessory

- (2) The information required by subsection (1) must:

- (a) be orientated in the same direction; and
 - (b) for the information mentioned in item 1 and paragraph (a) in column 2 of item 2—be displayed in a text size of at least 3 mm; and
 - (c) for all other text—be displayed in a text size of at least 1.5 mm.
- (3) The name of the therapeutic vaping pack on the main label of the pack must be presented in a continuous, uninterrupted manner and not be broken up by additional words or images.
- (4) Goods in a therapeutic vaping pack that contain nicotine, must be supplied in a therapeutic vaping pack that contains a warning statement panel as specified in section 20 on the main label.

36 Information to be included on the label of a therapeutic vaping pack

- (1) Goods in a therapeutic vaping pack must be supplied in a therapeutic vaping pack that includes all of the information listed in column 2 of the following table on the label.

Information to be included on the label of a therapeutic vaping pack	
Column 1	Column 2
Item	Information
1	the batch number preceded by the batch number prefix
2	the expiry date preceded by the expiry date prefix
3	the name of the sponsor
4	the contact details of the sponsor
5	the name and address of the manufacturer
6	the storage conditions applicable to each good in the therapeutic vaping pack
7	the words “Poisons Information Centre:” followed immediately by Poisons Information Centre contact information
8	where the therapeutic vaping pack contains a therapeutic vaping substance or a therapeutic vaping substance accessory—the warning statements: <ul style="list-style-type: none"> (a) “Avoid contact with eyes and skin”; and (b) “Do not swallow”
9	where the therapeutic vaping pack contains a therapeutic vaping device or a therapeutic vaping device accessory—the warning statements: <ul style="list-style-type: none"> (a) “KEEP OUT OF REACH OF CHILDREN”; and (b) “RISK OF FIRE EXPLOSION. REPLACE ONLY WITH SAME SIZE AND TYPE BATTERY”; and (c) “WARNING CONTAINS BUTTON OR COIN BATTERY. HAZARDOUS IF SWALLOWED – SEE INSTRUCTIONS” (if applicable)

- (2) The information required by items 1 to 8 in subsection (1) must appear in a text size of at least 1.5 mm.
- (3) The warning statements required by item 9 in subsection (1) must:
 - (a) appear in a text size of at least 5 mm; and
 - (b) be in bold-face, sans serif, capital letters of uniform thickness and size.

Part 6—Information leaflet

37 General requirements

- (1) Relevant goods must be accompanied by:
 - (a) an information leaflet that is:
 - (i) enclosed within the packaging; or
 - (ii) on a surface of the packaging; or
 - (iii) affixed to a surface of the packaging; or
 - (b) instructions for accessing an information leaflet that is in electronic form, in the form of a PDF file or a HTML file.
- (2) An information leaflet must contain the headings specified in column 2 of an item in Schedule 3 to this instrument, followed immediately by the information specified in column 3 of that item.
- (3) The information in an information leaflet must be:
 - (a) in English; and
 - (b) clearly legible; and
 - (c) written in language that will easily be understood by patients.

Part 7—Application, saving and transitional provisions

38 Application, savings and transitional provisions

(1) In this section:

former TGO 110 means the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*, as in force immediately before the commencement of the *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024*.

(2) Despite the amendments made by the *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024*, 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:

- (a) imported or manufactured before 1 March 2025; and
- (b) supplied before 1 July 2025.

(3) This section ceases to apply on 1 July 2025.

9 Schedule 1

Repeal the Schedule, substitute:

Schedule 1—Permitted ingredients

Note: See section 11.

Permitted ingredients		
Column 1	Column 2	Column 3
Item	Ingredient	Requirements
1	flavouring agents that produce either: <ul style="list-style-type: none">(a) menthol flavour; or(b) mint flavour; or(c) tobacco flavour	all of the following: <ul style="list-style-type: none">(a) only the minimum number of flavouring agents that are necessary to produce the relevant flavour or maintain the stability of that flavour may be added to the therapeutic vaping substance or therapeutic vaping substance accessory;(b) flavouring agents must not contain any of the following:<ul style="list-style-type: none">(i) 2,3-pentanedione;(ii) acetoin;(iii) benzaldehyde;(iv) cinnamaldehyde;(v) diacetyl;(vi) any substance that, whether heated or unheated, would pose a risk to human health;

Permitted ingredients		
Column 1	Column 2	Column 3
Item	Ingredient	Requirements
		(c) any menthol in a flavouring agent must be at a concentration not more than 20 mg/mL
2	glycerol	
3	nicotine	
4	propylene glycol	
5	water	

10 Schedule 2

Repeal the Schedule, substitute:

Schedule 2—Restricted substances

Note: See section 12.

Part 1—Compounds

Restricted substances		
Column 1	Column 2	Column 3
Item	Ingredient	Limit
1	acetaldehyde	0.2 mg/mL
2	acrolein	0.022 mg/mL
3	diethylene glycol	1.0 mg/mL
4	ethylene glycol	1.0 mg/mL
5	formaldehyde	0.022 mg/mL

Part 2—Metals

Restricted substances		
Column 1	Column 2	Column 3
Item	Ingredient	Limit
1	aluminium	0.012 mg/mL
2	antimony	0.004 mg/mL
3	arsenic	0.0004 mg/mL
4	cadmium	0.0006 mg/L
5	chromium	0.0006 mg/mL
6	iron	0.012 mg/mL
7	lead	0.001 mg/mL
8	mercury	0.0002 mg/mL
9	nickel	0.001 mg/mL

Restricted substances		
Column 1	Column 2	Column 3
Item	Ingredient	Limit
10	tin	0.012 mg/mL

Part 3—Tobacco-specific nitrosamines

Restricted substances		
Column 1	Column 2	Column 3
Item	Ingredient	Limit
1	4-methyl-N-nitrosamino-1-(3-pyridyl)-1-butanone	0.050 µgm/mL
2	N-nitrosornicotine	0.050 µg/mL
3	N-nitrosonatabine	0.050 µg/mL
4	N-nitrosonanabasine	0.050 µg/mL

11 At the end of the instrument

Add:

Schedule 3—Information leaflet

Note: See section 37.

Information leaflet		
Column 1	Column 2	Column 3
Item	Heading	Information
1	name of the good	the name
2	why am I using this	indication of the good
3	what should I know before using this	all of the following: (a) the warning statements, as relevant: (i) this product contains nicotine, which is a highly addictive substance; and (ii) keep out of reach of children; and (iii) do not swallow; and (iv) avoid contact with eyes and skin; (b) any contraindication for the goods
4	what if I am taking other medicines	all of the following: (a) instructions for users to discuss other medicines

Information leaflet

Column 1	Column 2	Column 3
Item	Heading	Information
		taken with the prescriber or pharmacist; (b) instructions on common drug interactions
5	how do I use this	all of the following: (a) advice for users to discuss instructions for use with the prescriber or pharmacist; (b) information relating to: (i) how frequently the goods can be used; (ii) how many puffs to be taken at a time; (iii) maximum daily puffs; (iv) how long the goods can be used for; (c) the statement “do not give to children under 18 years of age without medical supervision”
6	what should I know while I am using this	all of the following: (a) instructions in case of overuse and accidental use; (b) instructions on storage and disposal
7	are there any side effects	all of the following: (a) common side effects of the good; (b) serious side effects of the goods; (c) instructions on how to report side effects
8	product details	all of the following: (a) active (main) ingredients in the form of “Nicotine [<i>insert concentration in mg/mL</i>]; (b) inactive (other) ingredients; (c) potential allergens

Schedule 2—Amendments

Therapeutic Goods (Exempt Monographs) Determination 2021

1 Section 4 (paragraphs (a) and (b) of the note)

Repeal the paragraphs.

2 Section 4

Repeal the following definitions:

- (a) definition of *regulations*;
- (b) definition of *TGO 110* (including the note);
- (c) definition of *therapeutic vaping substance*;
- (d) definition of *therapeutic vaping substance accessory*.

3 Schedule 1 (table item 1)

Repeal the item.