



Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021

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

Dated 13 May 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

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Part 1—Preliminary

1 Name

- (1) This instrument is the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*.
- (2) This instrument may also be cited as TGO 110.

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 2021.	1 October 2021

Note: This table relates only to the provisions of this instrument as originally made.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 section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

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

- (a) container;
- (b) export only medicine;
- (c) label;
- (d) manufacture;
- (e) medicine;
- (f) primary pack;
- (g) Register;
- (h) registered goods;
- (i) sponsor.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

finished product means a product in relation to which all steps of manufacture have been carried out, prior to supply to an ultimate consumer.

Note 1: A step of manufacture does not include any process undertaken by an ultimate consumer in accordance with directions for use in relation to a product.

Note 2: A finished product does not include a nicotine vaping product imported in bulk for compounding by a pharmacist, prior to being supplied to an ultimate consumer.

flavour means an ingredient, or mixture of ingredients, added to a nicotine vaping product for the purpose of providing flavour to the product.

nicotine means nicotine in salt or base form.

nicotine vaping product means a medicine that contains nicotine in solution and that is:

- (a) a finished product; and
- (b) intended to be vaporised and administered by inhalation using a vaping device.

Note 1: Nicotine vaping products may also be described as nicotine vape liquids, or nicotine e-liquids.

Note 2: Examples of vaping devices include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

other ingredient means an ingredient contained in a nicotine vaping product other than:

- (a) nicotine; or
- (b) a flavour.

Regulations means the *Therapeutic Goods Regulations 1990*.

stated content means any amount or concentration of nicotine that is stated to be present in a nicotine vaping product on the label of that product, including where the amount or concentration is stated as the equivalent base form amount or concentration of nicotine.

TGO 95 means the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95).

Note: TGO 95 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

5 Standard

The matters specified in this instrument constitute a standard for nicotine vaping products.

6 Application

This instrument applies to nicotine vaping products other than:

- (a) registered goods; or
- (b) therapeutic goods mentioned in item 1 of Schedule 5 to the Regulations where those goods are carried by the importer as a passenger on a ship or aeroplane; or

Note 1: Item 1 of Schedule 5 to the Regulations applies to therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family in certain circumstances.

Note 2: This instrument applies to nicotine vaping products that are therapeutic goods mentioned in item 1 of Schedule 5 to the Regulations where those goods are imported into Australia other than by a passenger on a ship or aeroplane for the treatment of the importer or the importer's immediate family.

(c) mentioned in item 9 of Schedule 5 to the Regulations; or

Note: Item 9 of Schedule 5 to the Regulations applies to starting materials for use in the manufacture of therapeutic goods, except when prepackaged for supply for other therapeutic purposes or formulated as a dosage form.

(d) 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 apply in relation to therapeutic goods that are imported by particular persons or are part of the medical supplies of a visiting ship or aircraft.

Part 2—Requirements

7 Ingredients

Active ingredients

- (1) A nicotine vaping product must contain nicotine as the only active ingredient and:
 - (a) where the nicotine is in base form—the base form concentration of nicotine must be not more than 100 mg/mL; or
 - (b) where the nicotine is in salt form—the equivalent base form concentration of nicotine must be not more than 100 mg/mL.
- (2) The amount or concentration of nicotine in a nicotine vaping product must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content.

Prohibited ingredients

- (3) A substance specified in Schedule 1 must not be added as an ingredient to a nicotine vaping product.

8 Labels

- (1) A nicotine vaping product must be labelled in accordance with this section.
- (2) The information specified in an item of the table in Schedule 2 must be:
 - (a) on or attached to the container or the primary pack of a nicotine vaping product; or
 - (b) supplied with the container or the primary pack of a nicotine vaping product.

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 nicotine vaping product complies with this subsection if the information specified in items 1 and 2 of Schedule 2 is printed on a sticker placed over the container of the product, and the information specified in item 3 of 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 nicotine vaping product must be:
- (a) in English; and
 - (b) legible; and
 - (c) visible and not obscured; and
 - (d) durable.

9 Child-resistant packaging

- (1) A nicotine vaping product 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 nicotine vaping product 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.

10 Record-keeping

- (1) Records in relation to a nicotine vaping product must be maintained by the sponsor of the product.
- (2) The records must contain sufficient information to demonstrate that the nicotine vaping product conforms with this standard.
- (3) This section does not apply in relation to a nicotine vaping product that is imported into Australia in accordance with item 1 of Schedule 5 to the Regulations.

11 Alternative conformity

- (1) A nicotine vaping product is taken to comply with the requirements specified in sections 7, 9, and 10, if the product:
 - (a) is a new tobacco product within the meaning of section 910(a) of the Federal Food, Drug, and Cosmetic Act; and
 - (b) is the subject of an order issued under section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act; and
 - (c) complies with all requirements specified in the order mentioned in paragraph (b).

Note 1: An order issued under section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act is commonly referred to as a premarket tobacco product marketing order.

Note 2: A premarket tobacco product marketing order may only be issued in relation to a new tobacco product that is the subject of a premarket tobacco product application for which a premarket review has been conducted by the United States Food and Drug Administration, determining that the marketing of the product is appropriate for the protection of public health in accordance with section 910(c)(4) of the Federal Food, Drug, and Cosmetic Act.

Note 3: The United States Food and Drug Administration publishes a list of premarket tobacco product marketing orders on its website at www.fda.gov.

- (2) For the purposes of this section, a reference to the Federal Food, Drug, and Cosmetic Act is a reference to that Act of the United States, as in force or existing from time to time.

Schedule 1—Prohibited ingredients

Note: See subsection 7(3).

Prohibited ingredients	
Column 1	Column 2
Item	Ingredient
1	2,3-pentanedione
2	acetoin
3	benzaldehyde
4	cinnamaldehyde
5	diacetyl
6	diethylene glycol
7	dl-alpha-tocopheryl acetate
8	ethylene glycol

Schedule 2—Labelling information

Note: See section 8.

Labelling information	
Column 1	Column 2
Item	Information
1	a list of ingredients contained in the nicotine vaping product as follows: <ul style="list-style-type: none">(a) the name of each active ingredient; and(b) the name of each other ingredient; and(c) where the product contains a flavour—either:<ul style="list-style-type: none">(i) the word “flavour” or a description that includes the word “flavour” (such as “cherry flavour”); or(ii) the name of each ingredient contained in the flavour
2	the concentration of nicotine contained in the nicotine vaping product 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”
