Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021

I, [name], as delegate of the Minister for Health, make the following Order.

Dated [day] [month] [year]

[Name of delegate] **DRAFT ONLY—NOT FOR SIGNATURE**
Department of Health

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Vaporiser Nicotine) (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Note: This table relates only to the provisions of this instrument as originally made.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) export only medicine;
(b) label;
(c) manufacture;
(d) medicine;
(e) Register;
(f) registered goods.

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 vaporiser nicotine 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, formulated for the purpose of providing flavour to a vaporiser nicotine product.

nicotine means nicotine in salt or base form.

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

(a) nicotine; or

(b) a flavour.

Regulations means the *Therapeutic Goods Regulations 1990*.

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.

vaporiser nicotine products means medicines that contain nicotine and that are:

(a) finished products; and

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

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

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

5 Standard

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

6 Application

This instrument applies to vaporiser nicotine products other than those products that are:

(a) registered goods; or

(b) export only medicines; or

(c) mentioned in item 1 of Schedule 5 to the Regulations and carried by the importer as a passenger on a ship or aeroplane; or

Note: 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.

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

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

(e) 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 vaporiser nicotine product must contain nicotine as the only active ingredient.

Prohibited ingredients

(2) A vaporiser nicotine product must not contain an ingredient that is specified in Schedule 1.

8 Labels

(1) A vaporiser nicotine product must be labelled in accordance with this section.

Ingredients list

(2) The label of a vaporiser nicotine product must include a list of ingredients contained in the product as follows:
   (a) the name of the active ingredient;
   (b) the name of each other ingredient; and
   (c) where the vaporiser nicotine product contains a flavour—the word "flavour".

Nicotine concentration

(3) The label for a vaporiser nicotine product must expressly state the concentration or content of nicotine contained in the product.

Form of information

(4) All information that is displayed on the label must be:
   (a) in English; and
   (b) legible; and
   (c) visible and not obscured; and
   (d) durable.

9 Child-resistant packaging

(1) A vaporiser nicotine 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) section 9 (reclosable packages), other than subsection 9(6); and
(c) section 10 (non-reclosable packages).

(2) A vaporiser nicotine 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 Alternative conformity

(1) Despite the requirements in sections 7, 8 and 9, a vaporiser nicotine product is taken to conform to this standard, if the product is:
(a) a new tobacco product within the meaning of section 910(a) of the Federal Food, Drug, and Cosmetic Act; and
(b) the subject of an order issued under section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

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).

Column 1 Item	Column 2 Ingredient
1	2,3-pentanedione
2	diacetyl
3	diethylene glycol
4	dl-alpha-tocopheryl acetate
5	ethylene glycol