Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding product standards for unapproved therapeutic vapes in Australia

Guidance to quality and labelling requirements of Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024

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Purpose

The purpose of this guidance is to assist sponsors, manufacturers, patients and health care providers to understand the minimum safety and quality requirements for unapproved therapeutic vapes. This guidance includes:

- information on the requirements that apply to unapproved therapeutic vapes under *Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024* – **termed TGO 110 (2024)**
- information about other standards and requirements applicable to unapproved therapeutic vapes

This information is provided for guidance only.

It should not be relied on to address every aspect of the relevant legislation (state, territory and federal). You should seek independent legal advice to ensure that all legal requirements are met.

What this guidance does not cover

This guidance does not include information on how to comply with *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (**TGO 110 (2021)**), which can be found on our website.

In addition, this guidance does not contain clinical or dispensing guidelines for health care providers or make recommendations about prescribing of therapeutic vapes (for example, dosage regimes). Doctors, pharmacists or nurse practitioners considering prescribing or dispensing therapeutic vapes should have regard to clinical guidelines relevant to their practice, such as the Royal Australian College of General Practitioner's guide for health professionals on supporting smoking cessation and any relevant guidelines published by the Pharmaceutical Society of Australia and the Royal Australian and New Zealand College of Psychiatrists.

Practical guidance materials for health care providers is also available on the Vaping hub | Therapeutic Goods Administration (TGA) page of our website.

This guidance does not include information on the requirements that apply to unapproved therapeutic vaping devices and therapeutic vaping device accessories.

Legislation

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

Introduction to updated TGO 110 (2024):

TGO 110 (2024) is a product standard made under section 10 of the *Therapeutic Goods Act 1989* (Act). It sets out minimum safety and quality requirements for unapproved therapeutic vapes that are imported into, supplied in, or exported from Australia. TGO 110 (2024) applies to:

(a) therapeutic vaping substances;

(b) therapeutic vaping substance accessories;

(c) therapeutic vaping kits;

(d) therapeutic vaping substances contained in a vaping kit or a vaping pack;

(e) therapeutic vaping substance accessories contained in a vaping kit or a vaping pack;

(f) therapeutic vaping packs

that are finished products and the only indications for the goods are use for smoking cessation or the management of nicotine dependence. Unless otherwise specified, the vaping goods mentioned above are referred to as **'relevant goods**' for the purpose of this guidance.

TGO 110 (2024) **does not** apply to:

- therapeutic vapes included in the ARTG – the quality, safety and efficacy of registered products are evaluated as part of the TGA's general marketing approval process (noting that currently no unapproved therapeutic vapes appear on the ARTG)
- therapeutic vapes carried by travellers entering Australia for use in the treatment of the traveller or someone the traveller is caring for, who is entering Australia on the same ship or aircraft (subject to quantity limits)
- therapeutic vapes manufactured in, or imported into, Australia for export only
- nicotine replacement therapies (NRTs), such as patches, gum, lozenges and inhalators
- other unapproved products containing nicotine, such as chewing tobacco and snuff
- starting materials, components or articles that are intended to be used in the further manufacture of therapeutic vapes. If the starting material, component or article is being imported into Australia, the sponsor must give a written notice to the TGA prior to importation, for more information on the notification process please visit: Guidance for Sponsor notice – Vaping goods (Notice to import or supply in Australia therapeutic vaping goods) form.
- therapeutic vaping devices or therapeutic vaping device accessories even if they are supplied in a therapeutic vaping pack. For more information on the requirements applying to these products, please refer to MDSO Guidance.

Commencement and transitional provisions for TGO 110 (2024)

The TGO 110 (2024) commenced on 1 October 2024. However, implementation is subject to the following transitional provisions:

- Vapes imported and manufactured in Australia can continue to comply with the previous TGO 110 (2021) requirements until 1 March 2025.

- Vapes supplied in Australia can continue to comply with previous TGO 110 (2021) requirements until 1 July 2025.
- The version of TGO 110 (2021) that commenced in January 2024 will remain applicable for products supplied in Australia until 1 July 2025.
- Products complying either with the standards that commenced in January 2024 or standard commenced in October 2024, can be lawfully supplied in Australia.

Overview of changes

From 1 October 2024, TGO 110 (2024) includes new and enhanced requirements for appearance, ingredients, containers, labelling and packaging of relevant goods, such as:

- increased restrictions on how vapes appear and the information that must be included on labels
- restrictions on the ingredients that can be used for formulating vaping substances, tightening of the definitions for flavours, restriction on menthol concentration and limits on other unavoidable substances
- maximum permitted nicotine content is reduced to 50 mg/mL (base equivalent)
- restrictions are placed on maximum volume for vaping substance container including pods and cartridges
- labelling and packaging requirements are aligned with other therapeutic goods.

Generally, all unapproved relevant goods imported, manufactured, or supplied in Australia must meet the relevant requirements of TGO 110 (2024). However, Australian sponsors may lawfully import goods for supply in Australia with non-compliant packaging and labelling provided the product is repackaged and/or re-labelled to meet the TGO 110 (2024) requirements before the vape is supplied to the market, or if another exemption applies.

Note: An unapproved therapeutic vape that is subject to, and in compliance with, a Premarket Tobacco Product (PMTA) marketing order issued by the United States (US) Food and Drug Administration (FDA) is no longer taken to automatically comply with the TGO 110 (2024) requirements.

Requirements for unapproved therapeutic vapes under TGO 110 (2024):

TGO 110 (2024) specifies requirements for unapproved therapeutic vapes (or ‘vapes’ for the purpose of this guidance) under 4 broad groups:

- General provisions
- Ingredient requirements
- Container requirements
- Labelling and packaging requirements

General provisions

All relevant goods are **finished product** and are subjected to the requirements of TGO 110 (2024). They must only be used for a therapeutic purpose that is, smoking cessation or management of nicotine dependence. There is no other therapeutic indication allowed for vapes in Australia.

Finished products and final dosage form vapes.

TGA defines finished product as a therapeutic good that has completed all stages of production, including packaging in its final container and labelling. This is the product that is ready for supply to the consumers. For vapes, a finished product may not be the final dosage form as some vape liquid may need extemporaneous compounding before supply to the patients and the compounded form then becomes the finished product and requires complying with provisions of TGO 110 (2024).

Therapeutic vaping packs are subjected to the provisions of TGO 110 (2024). However, vaping devices and vaping device accessories that are included in the vaping packs are subjected to the provisions of the MDSO or essential principles.

Name (of the relevant good)

The name of the relevant good is the name assigned to the relevant good by the sponsor and is the name with which that good is identified. This name is mentioned on the label or pack of the product, and it can be:

- a registered trademark for the good; or
- unique, invented, common or scientific name assigned to the good.

To reduce the appeal of vapes for youth and recreational users, the TGO 110 (2024) includes restrictions to ensure appropriate naming of the relevant goods.

What are the restrictions on the 'names' under TGO 110 (2024)?

Section 7 of the TGO 110 (2024) describes the requirements for appropriate naming of the relevant goods. The following restrictions are applicable to all relevant goods, including names of vaping packs and vaping kits.

The name **must not**:

- suggest or associate the vapes with any food, beverage, confectionery or cosmetic product.
- suggest the vape has any health benefit, including but not limited to having healing effect, vitalising or is from natural or organic source or suggesting it to have rejuvenating properties. This does not include for the purpose of smoking cessation or management of nicotine dependence.
- suggest the product or vaping itself is safe, free from harm or does not have side effects.
- in any way or form, be targeted to youth or be attractive to youth. This is a broad and widespread condition that may include names that by expression or by implication targets youth. For example, using names that are trendy and stylised, names associated with cartoon characters or characters from popular culture, names associated with superheros, mythical characters or toys etc.

– be promotional in nature, it should not encourage the use of the product or exaggerate its efficacy or performance.

Ingredients in therapeutic vaping substances

Part 3 of the TGO 110 (2024) sets out requirements for the ingredients in therapeutic vaping substances. These requirements are relevant for vaping substances supplied in a container or a pod/cartridge (therapeutic vaping substance accessories).

All ingredients used in the formulation, except for flavours that are not menthol, must meet the quality standards outlined in at least one of the following:

- the British Pharmacopoeia
- the European Pharmacopoeia
- the United States Pharmacopeia-National Formulary.

This ensures that the ingredients meet a recognised quality standard suitable for therapeutic use in humans.

Evidence of ingredient quality standard must be held by the sponsor and must be produced on request.

Active ingredients

In a therapeutic good, the active ingredients are the therapeutically active components, that are responsible for its physiological or pharmacological action.

Nicotine is the only permitted active ingredient

Nicotine (whether in base or salt form(s)) is the only active ingredient allowed in unapproved therapeutic vaping substances. It is not appropriate to add any other active ingredients to unapproved therapeutic vaping substances.

Limits on nicotine concentration

Therapeutic vaping substances, including substance in a therapeutic vaping substance accessory, must have no more than **50 mg/mL** of nicotine or equivalent base form (see subsection 10(2)). You cannot import, manufacture or supply a therapeutic vaping substance that exceed this concentration.

Health practitioners need to consider whether the nicotine concentration and type of product is appropriate for a particular person's smoking cessation needs.

This limit does not imply that 50 mg/mL products are safe or necessarily appropriate for use.

Ingestion of, or exposure to, vaping substance containing nicotine (including through the skin or eyes) can have toxic, and sometimes severe, effects. Child fatalities, including at least one in Australia, have occurred following ingestion of vaping substance containing nicotine. Vaping substances containing higher concentration of nicotine carry greater risks of poisoning having severe effects.

Actual vs labelled nicotine concentration and content

The actual nicotine base form, nicotine salt and/or equivalent base form concentration or content in a therapeutic vaping substance must be within 90-110% of the stated content. These limits are consistent with standard pharmaceutical quality practices for nicotine products.

The concentration or content of the actual nicotine base form, nicotine salt and/or equivalent base form (depending on what is stated) should be tested using appropriately validated test methods. Due to the wide variety of products available, guidance is not provided on the specific test methods that should be used for a particular product. The laboratory conducting the testing would be expected to research or develop an appropriate method for the product(s) and ensure that method had been validated for its intended purpose.

Permitted Ingredients

The TGO 110 (2024) amendment restricts the formulation of vaping substance to a specified list of ingredients. These ingredients are defined as 'Permitted Ingredients' in the TGO 110 (2024) and are included in Schedule 1 as:

- nicotine
- propylene glycol
- glycerol
- water
- mint, menthol or tobacco flavour.

No other ingredient must be added to the formulation.

Further restrictions to flavours

Since 1 March 2024, unapproved therapeutic vaping substances and vaping substance accessories were only allowed to have menthol, mint, tobacco flavours. The TGO 110 (2024) includes further restrictions on flavouring agents as follows:

- Flavouring agents must not contain any ingredient that is not necessary to produce the relevant flavour or maintain stability of that flavour
- There are a number of **prohibited ingredients** (flavouring agents) that must not be used, as detailed in Schedule 1 Column 3
- If menthol is used as a flavour or an ingredient as a flavouring agent its concentration must not exceed 20 mg/ml (2%) in the vaping substance.

The sponsor must hold evidence to justify the role of individual flavouring agents.

How are flavours and flavouring agents defined:

For the purpose of vaping goods, a flavouring agent can be defined as an ingredient or component, or mixture of ingredients or components, added to a therapeutic vaping substance to provide flavour to the vaping good or stability to the flavour.

Only 3 flavours are permitted in unauthorised vaping substance, these are mint, tobacco and menthol, and must meet the following definitions:

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

Products must not have flavours that are a mix of different tastes. For example, flavour combinations such as cherry mint, chocolate mint or tobacco mint are not permitted.

Any therapeutic vaping substance or vaping substance accessory containing flavour other than the abovementioned flavours cannot be imported, manufactured or supplied in Australia.

Restricted substances

The vaping substance formulation is limited to permitted ingredients. However, it is acknowledged that some chemical entities might still be present unintentionally. These entities may be contaminants, degradation products, residual solvents, or reaction products etc. TGO 110 (2024) provides a list of such ingredients under the title of 'Restricted Substances' in Schedule 2.

This list includes chemical compounds with known health risks when inhaled, heavy metals and tobacco-specific nitrosamines, and states the maximum permitted limit for each compound.

Sponsors must hold the evidence to prove that none of these restricted substances exceed the maximum permitted limit and must provide the evidence to TGA, if requested.

Container requirements

Containers for the purpose of relevant goods is the vessel or article that directly contains the vaping substance. The containers can be bottles, vials, pods or cartridges.

Vaping substance container:

Generally, these are bottles or vessels that contain the vaping substance and used for refilling open system vapes. An individual vaping substance container must not contain more than 60 mL of vaping substance, but multiple containers may be supplied as part of a kit or a pack.

The container and the closure system can only be a combination of black, white, grey or clear and feature not more than 4 other colours or shades, including the colour or shade of any text.

Vaping substance accessory:

A vaping substance accessory is an enclosed container for a closed system vapes, usually in the form of pods or cartridges. The liquid inside the container is not accessible to the consumer.

An individual vaping substance accessory must not have more than 5 mL of vaping substance but multiple vaping substance accessories can be sold as part of a kit or a pack.

The following requirements apply to the container of a therapeutic vaping substance accessory:

- it 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
- 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

- 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.

Please note: if a pod or cartridge is sold without the vaping substance then it is not considered a vaping substance accessory and the requirements of the TGO 110 (2024) are not applicable to it. However, it is considered a vaping device accessory and should comply with the requirements included in the MDSO or Essential Principles.

Labelling and packaging requirements

All labelling and packaging of unapproved therapeutic vapes must meet the specific requirements set out in Part 5 of TGO 110 (2024).

What needs to be labelled

A label for unapproved therapeutic vape is any written, printed or graphic information that is printed on, attached to or supplied with (e.g., information sheet) the container or primary pack of the vape.

Clear and accurate product labels and information sheets are essential to conveying information about a product's quality and safety, allowing health practitioners and individuals to make informed choices about treatment and use.

All containers, primary packs (including vaping kits and packs) and intermediate packaging must contain a label.

- **Primary pack**: a primary pack for a vape is the complete pack that contains vaping goods supplied to the consumers. These are saleable units of vaping goods and can be a box, or a carton or a container (if sold as is). The primary pack can have one or more labels attached to it, or it may have information printed directly on the pack itself. The labelling requirements for primary pack labels are specified in sections 22 and 23 (refer to Appendix 1 for more details on Primary pack label).
- **Intermediate packaging:** may contain one or more vaping good and must be enclosed within a primary pack. Intermediate packaging that obscures the labels of the vaping goods, such as foil or wrapper enclosing a container, must also be labelled (see section 24). If the information on the label of the vaping good(s) can still be seen and read easily, for example, if intermediate packaging is transparent, additional labels are not required (refer to Appendix 2 for details on Intermediate packaging label).
- **Container**: a container for vaping substance may have single or multiple labels and based on the size of container the labelling requirements may slightly vary. Requirements for containers, that are not small or very small containers, are specified in section 25 and 26 (refer to Appendix 3 for details on Container label). , requirements for a 'small container' (from 5 mL to 25 mL capacity) are specified in section 27 and 28, (refer to Appendix 4 for details on small container label). and requirements for a 'very small container' (up to 5 mL capacity) is specified in section 29 and 30 (refer to Appendix 5 for details of very small container label)
- **Therapeutic vaping kits and therapeutic vaping packs:** are considered primary packs but have slightly different labelling requirements. The labelling requirements for therapeutic

vaping kits and therapeutic vaping packs are specified in Division 3 and Division 4 of Part 5, respectively (refer to Appendix 6 for more details on vaping kit and vaping pack label).

Please note: Sample labels included in the appendices are intended for illustrative purposes only and may not meet all the requirements specified by the TGO 110 (2024). For a comprehensive list of relevant requirements for your product, please refer to the appropriate sections in the TGO.

Vaping goods with more than one label

Many containers, primary packs and intermediate packaging have more than one label or different panels on one container. To reduce unnecessary replication of information in these instances, TGO 110 (2024):

- defines the 'main label' for the relevant good
- states the most important information you must display on the main label. The remaining required information can be displayed on other labels or panels.

Main label

The 'main label' is the portion of the label where the name of the relevant good is more or most conspicuously shown. A relevant good can have more than one main label if there are two or more portions of the label where the product name is presented in equal size or prominence. In general, each layer of packaging also has a main label. Some specific container types do not require all main label information and formatting e.g., very small container. The mandatory main label information must all be oriented in the same direction.

How information must be displayed

The information on the labels must have following characteristics:

- **Language**: must be in English
- **Visibility**: must be easy to read, clear and unobscured
- **Durability**: must be able to withstand handling for the shelf-life of the vape
- **Colour**: must stand out against the background, making it easy to see. Dark text on a light background is easier to read whereas highly reflective packaging can be difficult to read. The only exception to this requirement is the expiry date and its prefix and batch number, and its prefix, if they are embossed or debossed instead of printed. Product packaging other than a primary pack that is a container must be mostly white with up to 4 other colours including black. Manufacturers and sponsors may choose to provide additional product or safety information provided that is not promotional information and does not breach the applicable advertising restrictions.

Text size

You must use a text size of not less than 1.5 millimetres for information that is required to be on labels of therapeutic vaping substances or therapeutic vaping substance accessories under the provisions of TGO 110 (2024), except for very small containers.

The following table provides text size requirements for different types of labels.

Table 1. Text size requirement for different label types

Label type	Minimum text size
Primary pack	3.0 millimetres for name and nicotine content 1.5 millimetres for other information
Intermediate packaging	1.5 millimetres for all information
Container	3.0 millimetres for name and nicotine content 1.5 millimetres for other information
Small container (<25 mL)	2.0 millimetres for name and nicotine content 1.5 millimetres for other information
Very small container (<5 mL)	1.0 millimetres for all information
Therapeutic vaping kit	3.0 millimetres for name and nicotine content 1.5 millimetres for other information
Therapeutic vaping pack	3.0 millimetres for name and nicotine content 1.5 millimetres for other information

Appearance of label and packaging

Part 5 of the TGO describes requirements for the appearance of labelling and packaging of unapproved therapeutic vapes.

The vapes must be packaged and labelled in a way that they are not appealing to youth or recreational users, while providing all necessary information required by TGO 110 (2024) for its safe and effective use.

All labels on vapes must be predominantly white and printed material on the label must not feature more than 4 colours or shades. This includes any printed text, logo, pictorial or graphic.

The primary pack, if not the container, must be predominantly white and all printed material on the primary pack must not feature more than 4 colours or shades.

Please note that colour in printed material should only be used for identification of the product and differentiating flavour and strength in a product range. Colour of printed material must not increase attractiveness or appeal of the product.

Black colour used for warning text on the warning panel constitutes one of the 4 permitted colours for printed material.

Prohibited features

Certain features are prohibited from use on any packaging of your product, and include:

- any features that suggest that the product is a food, drink, cosmetic or has health benefits
- any words, symbols or images that do not comply with other provisions in TGO 110 (2024)
- any promotional statement, pictures or design
- heat activated inks, inks designed to appear gradually over time or inks that appear fluorescent in certain light
- panels designed to be scratched or rubbed to reveal text or image.

Space for dispensing labels

The primary pack of your product must include a minimum space of 70 x 30 millimetres for the dispensing label, unless the size of the pack is too small to allow this.

The size exemption does not apply if:

- the label can be redesigned to incorporate the space; or
- the label includes non-mandatory information that can be omitted to allow inclusion of the space.

If the full dispensing label space cannot fit on the label, it is expected that a smaller space will be included where possible.

Warning statement panel

All containers, and primary packs (including vaping kits and packs) unless restricted by size, must be labelled with a warning statement panel that is at least 30% of the total main label size. The warning should state:

"THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE.".

The warning statement text must be:

- in bold, sans serif and capital letters of same thickness and size.
- in black text on a white background.
- orientated the same direction as the product name.
- of a size that fills the panel space, as much as possible.

The warning statement panel is not required for products that do not contain nicotine. However, you should check relevant sections in Part 5 to ensure labels for your products contain other required warning statements.

Child-resistant packaging (CRP)

Accidental ingestion of, or exposure to, vaping substances (including through the skin or eyes) can have toxic, and sometimes severe, effects (SCHEER 2021). Child fatalities, including at least one in Australia, have occurred following ingestion of vaping substances (SCHEER 2021). CRP is

important to minimise the risk of accidental exposure to and/or ingestion of vaping substances, particularly by children.

Patients should also be advised to seek urgent medical attention if they believe that they have, or anyone else has, been exposed to and/or ingested a vaping substance.

Section 21 of TGO 110 relevantly provides that therapeutic vaping substances and therapeutic vaping substances must meet CRP requirements set out in sections 8, 9 and 10 of *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines* (TGO 95), unless the product has been packaged for supply in Canada, the EU, NZ, the UK and the US and meets all CRP requirements imposed in that country.

For further information on the requirements in TGO 95, please refer to Guidance on TGO 95.

What information must be displayed

Certain information must be included on labels of unapproved therapeutic vapes. These are clearly outlined in Tables in sections 22 to 36 of TGO 110 (2024) so will not be replicated in this guidance, instead focusing on specific aspects.

Ingredient list

Where applicable, the relevant goods must be labelled with an ingredient list setting out:

- the name of the active ingredient in the product (which must only be nicotine in base and/or salt form(s)).
- for flavoured products—the word 'flavour' preceded by 'menthol, mint or tobacco/classic', and
- the names of all other ingredients in the product.

The use of an Australian Approved Names for ingredient names is encouraged. The Australian Approved Names List can be searched on the TGA Business Services website under the 'Ingredients' tab.

Other warning statements and 'Signal Heading'

Where applicable, the relevant goods must be labelled with below warning statements regardless of their nicotine content:

- 'Avoid contact with eyes and skin'
- 'Do not swallow'
- 'Poison Information Centre' followed immediately by their contact information

These statements must be on or attached to the container, intermediate packaging (if any) and primary pack of the product.

Vapes are ordinarily to be sold as Schedule 4 medicine and be subjected to signal heading as per 'The Poison Standard (the SUSMP)' .

If the size of the container precludes adding a signal heading, then an additional warning 'KEEP OUT OF REACH OF CHILDREN' must be added to the main label of the container except for a 'very small container'.

Please note that state and territory poisons legislation ordinarily require unapproved products containing nicotine supplied in Australia to include warning statements on the primary pack and

immediate container of the product, unless an exemption applies. Products supplied in Australia are required to meet the requirements of both TGO 110 (2024) and state and territory poison legislation. A product will ordinarily comply with the warning statement requirements in both TGO 110 (2024) and state and territory poisons legislation by including the statements outlined above on the container, intermediate packaging (if any) and primary pack of the product.

Prominence of nicotine content and product name

Clear unambiguous identification of unapproved therapeutic vapes is critical in assisting with their safe use. The nicotine content and the name of the product must be easily identifiable and legible on the labels.

To achieve this:

- The product name must be continuous and uninterrupted by any words or images (the product name does not have to be on a single line if the label design or pack dimensions prevent this). This will assist in differentiating products within a range.
- The word 'nicotine' and its concentration (even if it's 0 mg/mL) must be put together in a single line of text immediately below the name of the product.
- The name of the product and the nicotine content on the label must not be interrupted by other information, words or images.

Nicotine concentration

You must include nicotine content on the main labels of unapproved therapeutic vape.

- for nicotine base products—the nicotine base form concentration in mg/mL
- for nicotine salt products—the equivalent nicotine base form concentration in mg/mL (specifying the concentrations of the nicotine salt(s) in the product will **not** satisfy this requirement)
- for nicotine-free products—the statement, 'nicotine 0 mg/mL'

Example

For product containing 15 mg/mL of nicotine lactate, equivalent to 10 mg/mL nicotine free base:

Nicotine (as lactate) 10 mg/mL

For product containing 5 mg/mL nicotine as benzoate salt, and 15 mg/mL nicotine lactate, equivalent to 12 mg/mL nicotine free base:

Nicotine (as benzoate and lactate) 12 mg/mL

The equivalent base form concentration of a nicotine salt product will depend on the salt form(s) of nicotine used in the product and can vary depending on how the product is prepared. A standard table for converting nicotine salt concentration to equivalent base form concentration has not therefore been provided.

Information required for different type of labels

Labelling requirements for therapeutic vapes vary depends on the type of label (main label or other label) and layer of packaging (primary pack, intermediate packaging, or container). An overview of labelling requirements for different labels is provided in the tables below, and mock-up labels are provided in Appendix 1 to 6.

- **Table 2** contains information requirements for the main label. Where your vaping good has multiple labels then the main label must contain the information identified in Table 2.
- **Table 3** contains information for the other label/s. Where your vaping good has more than one label then the information mentioned in Table 3 can be accommodated on the label that is not the main label.

Please note: if your relevant good has a single label, then information for both main and other label must be included on the same label.

Table 2. Information to be included on the 'Main Label' of different layers of packaging.

	Relevant section of TGO 110 (2024)	Signal headings	Product name	Nicotine content	Flavour	Volume	Warning Panel
Main label of primary pack	22	Yes	Yes	Yes	Yes	Yes	Yes
Intermediate packaging	24	Yes					Yes
Main label of container	25	Yes	Yes	Yes	Yes	Yes	Yes
Main label of small container	27	Yes	Yes	Yes	Yes	Yes	Yes

Main label of very small container	29			Yes	Yes	Yes	
Main label of therapeutic vaping kit	32	Yes	Yes	Yes	Yes	Yes	Yes
Main label of therapeutic vaping pack	35	Yes	Yes	Yes	Yes	Yes	Yes

Table 3. Information that can be included on the <u>other label/s that is/are not the 'Main label'</u>.

	Relevant section of TGO 110 (2024)	**Name of ingredients**	**Batch number preceded by prefix**	**Expiry date preceded by prefix**	**Name and contact of sponsor**	**Storage conditions**	**Warning statements**
Primary pack	23	Yes	Yes	Yes	Yes	Yes	Yes
Intermediate packaging[1]	24	Yes	Yes	Yes			Yes

[1] Intermediate packaging generally has single label therefore in the TGO both main label and other label requirements are combined under 'main label' in section 24

Label of container	26	Yes	Yes	Yes	Yes	Yes	Yes
Label of small container	28		Yes	Yes	Yes[2]	Yes	Yes
Label of very small container	30		Yes	Yes			
Therapeutic vaping kit	33		Yes	Yes	Yes	Yes	Yes
Therapeutic vaping pack	36		Yes	Yes	Yes[3]	Yes	Yes[4]

[2] Only requires name of the sponsor, not the contact detail.
[3] Also requires name and contact details of the manufacturer.
[4] Also requires warning statements, "Risk of fire explosion. Replace only with same size and type battery" and "Warning: Contains button or coin battery. Hazardous if swallowed – see instructions" (if applicable).

Information leaflet

The information leaflet contains critical information on the safe and effective use of an unapproved therapeutic vaping substance or therapeutic vaping substance accessory, especially when dispensed as a Schedule 3 medicine.

The information in the leaflet must be written in English, clearly legible and written in language that will easily be understood by patients. They can be enclosed within the packaging, printed on the packaging, attached to the packaging or available in an electronic form (in a PDF or HTML file).

Information leaflets include:

- Name of the product
- What the product is for and how it works
- Warnings and precautions
- What to do if taking other medicines
- How to use the product properly
- What to be aware of while using it
- Side effects
- Product details

For further detail on requirements for the leaflet refer to Schedule 3 of the TGO. Some useful information on how 'Consumer Medicine Information (CMI)' requirements are implemented for other therapeutic goods can be found on our website.

Microbiological standards

Unapproved therapeutic vapes are also automatically subject to the requirements under subsection 11(1) of the *Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018*, also known as TGO 100. These requirements also apply to vaping substances or vaping substance accessories that are listed in the ARTG as Export Only products.

Non-mandatory container requirements

Tamper-evident packaging

The purpose of tamper-evident packaging is to alert patients to possible safety concerns before the supply or use of those goods. TGO 110 (2024) does not include any tamper-evident requirements for unapproved vapes.

The TGA instead publishes a non-mandatory Code of practice for tamper evident packaging of therapeutic goods. Compliance with the code improves the security of the therapeutic goods supplied in Australia and increases the likelihood that patients can identify when a product has been tampered with.

Suppliers of therapeutic vapes in Australia may wish to consider whether their products should comply with this code, but it is not mandatory.

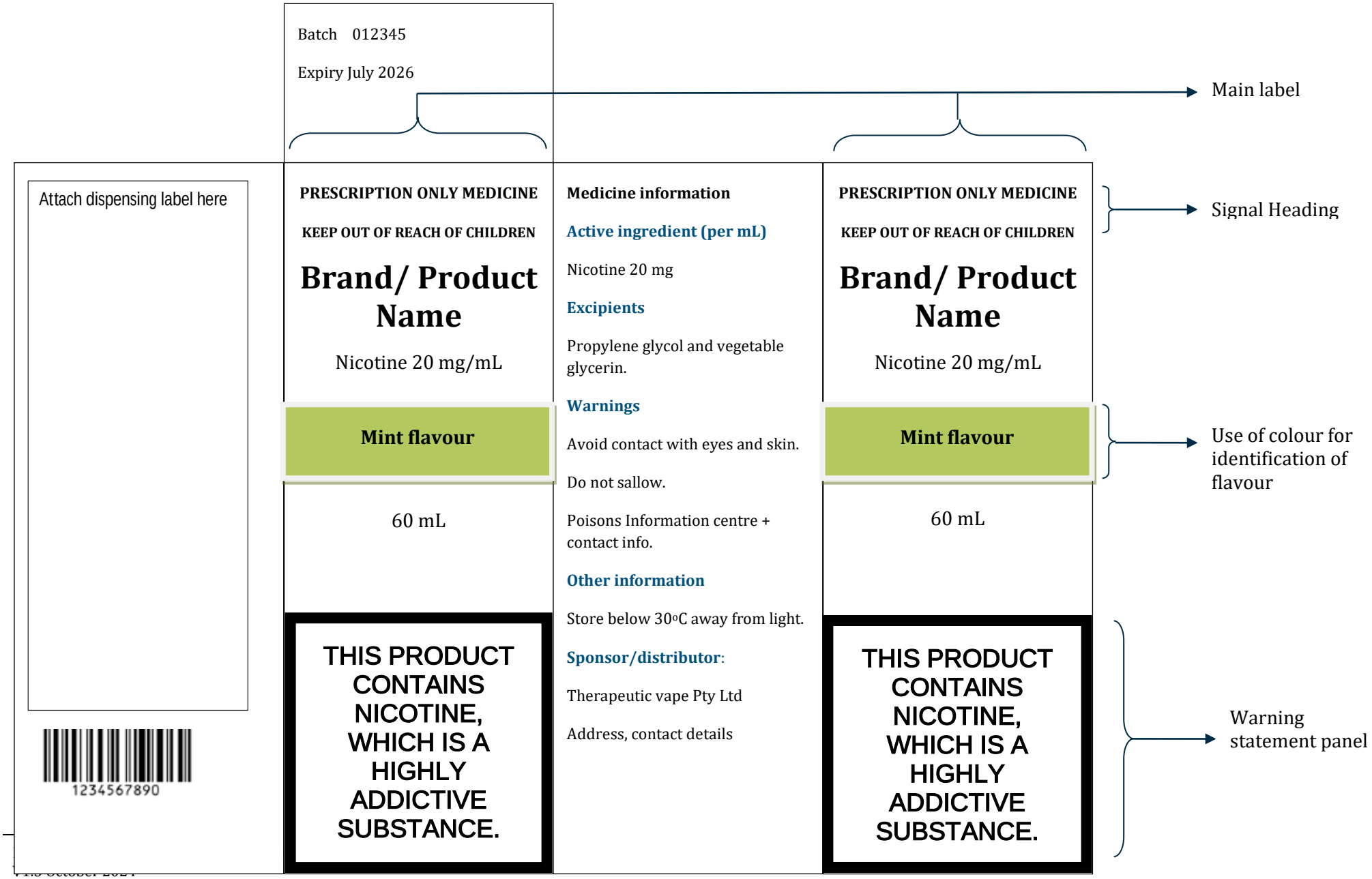
Appendix 1:

Label for Primary Pack

A primary pack is the complete pack in which the vaping goods, or vaping goods and their containers are to be supplied to the customers. Primary pack is the pack that is visible on the shelf and sold through retail.

Requirements for the primary pack label:

- Name of the product prominently displayed in a continuous and uninterrupted manner with nicotine and its content in a single line immediately below the name. They require a text size of at least 3.0 mm.
- Nicotine-free product should include the statement, “nicotine 0 mg/mL”.
- Flavour included as ‘mint’, ‘menthol’ or ‘tobacco/classic’ flavour.
- Volume of fill in mL.
- Information on main labels is oriented in the same direction.
- For products containing nicotine, main label requires nicotine warning statement panel that is at least 30% of the total main label size. The warning statement needs to be in bold, sans serif, capital letters in black text on a white background.
- Batch number and expiry date preceded by prefixes.
- Name of each ingredient
- Name and contact details of sponsor
- Storage conditions
- The words, “Poisons Information Centre” followed immediately by their contact information.
- Warning statements, “Avoid contact with eyes and skin” and “Do not swallow”.
- All information (other than the name and nicotine content) in a text size of at least 1.5 mm.
- Signal heading for prescription medicines and keep out of reach of children.
- Space for dispensing label 70 x 30 millimetres.


Batch 012345
Expiry July 2026
Main label
Attach dispensing label here
PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN
Brand/ Product Name
Nicotine 20 mg/mL
Mint flavour
60 mL
THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE.
1234567890
Medicine information
Active ingredient (per mL)
Nicotine 20 mg
Excipients
Propylene glycol and vegetable glycerin.
Warnings
Avoid contact with eyes and skin.
Do not sallow.
Poisons Information centre + contact info.
Other information
Store below 30ºC away from light.
Sponsor/distributor:
Therapeutic vape Pty Ltd
Address, contact details
PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN
Brand/ Product Name
Nicotine 20 mg/mL
Mint flavour
60 mL
THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE.
Signal Heading
Use of colour for identification of flavour
Warning statement panel

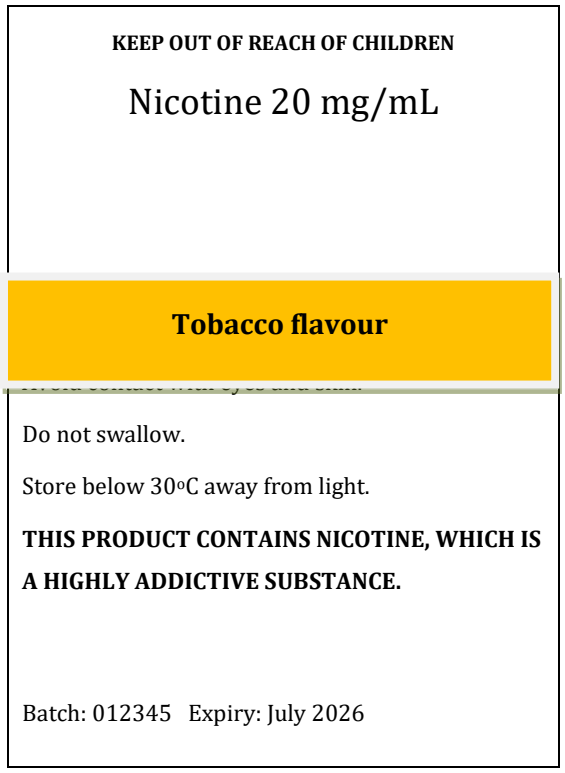
Appendix 2:

Label for Intermediate packaging

Intermediate packaging is the packaging that encloses one or more containers and obscures the labels of a container. Intermediate packaging can be in form of blister pack or card pack or similar and it is enclosed inside a primary pack.

Requirements for intermediate packaging label

- Nicotine and its content. Nicotine-free product should include the statement, "nicotine 0 mg/mL"
- Batch number and expiry date preceded by prefixes
- Name and contact details of sponsor
- Storage condition
- For products containing nicotine, main label requires nicotine warning statement that is at least 30% of the total main label size. The warning statement needs to be in bold, sans serif, capital letters in black text on a white background
- Warning statements, "Keep out of reach of children", "Avoid contact with eyes and skin" and "Do not swallow".
- All information in a text size of at least 1.5 mm



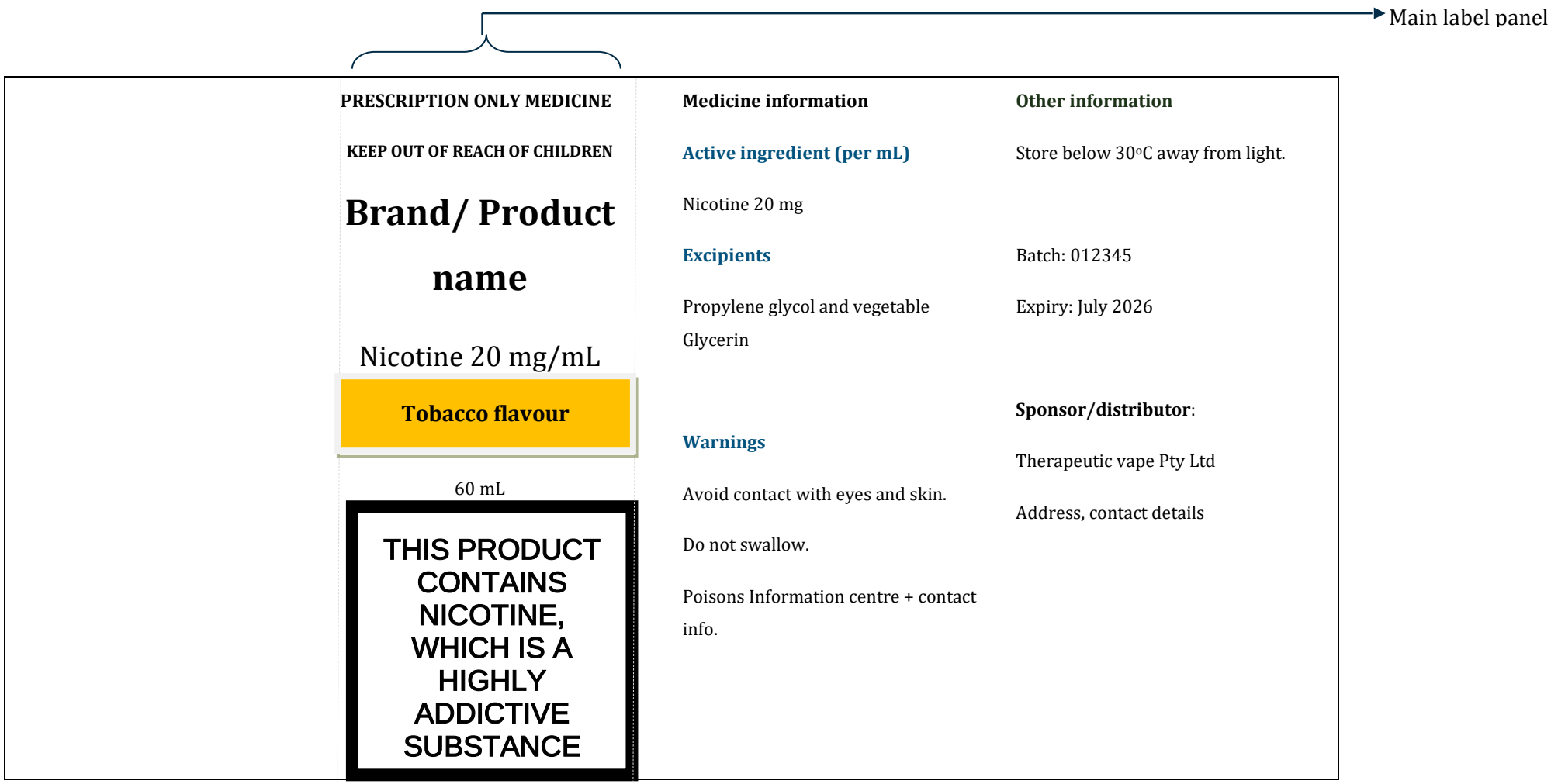
Appendix 3:

Label for container

Container is the packaging of the vaping substance in direct contact with the product. A vaping substance container can be in form of bottle, vial, pod or cartridge. Containers with capacity between 25 mL and 5 mL are classed as small containers and containers with less than 5 mL capacity are classed as very small containers.

Requirements for container label

- Name of the product prominently displayed in a continuous and uninterrupted manner with nicotine and its content in a single line immediately below the name. They require a text size of at least 3.0 mm.
- Nicotine-free product should include the statement, “nicotine 0 mg/mL”.
- Flavour included as ‘mint’, ‘menthol’ or ‘tobacco/classic’ flavour.
- Volume of fill in mL.
- Information on main labels (sides with the product name) is oriented in the same direction.
- For products containing nicotine, main label requires nicotine warning statement that is at least 30% of the total main label size. The warning statement needs to be in bold, San serif, capital letters in black text on a white background.
- Batch number and expiry date preceded by prefixes.
- Name of each ingredient
- Name and contact details of sponsor
- Storage conditions
- the words, “Poisons Information Centre” followed immediately by their contact information.
- Warning statements, “avoid contact with eyes and skin” and “Do not swallow”.
- All information (other than the name and nicotine content) in a text size of at least 1.5 mm.
- Signal heading for prescription medicines and keep out of reach of children.


Main label panel
PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN
Brand/ Product name
Nicotine 20 mg/mL
Tobacco flavour
60 mL
THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE
Medicine information
Active ingredient (per mL)
Nicotine 20 mg
Excipients
Propylene glycol and vegetable Glycerin
Warnings
Avoid contact with eyes and skin.
Do not swallow.
Poisons Information centre + contact info.
Other information
Store below 30°C away from light.
Batch: 012345
Expiry: July 2026
Sponsor/distributor:
Therapeutic vape Pty Ltd
Address, contact details

Appendix 4:

Label for small container

- Name of the product prominently displayed in a continuous and uninterrupted manner.
- Nicotine and its content. Nicotine-free product should include the statement, “nicotine 0 mg/mL”.
- Text size at least 2.0 mm for product name and nicotine content, 1.5 mm for all other information
- Flavour included as ‘mint’, ‘menthol’ or ‘tobacco/classic’ flavour.
- Volume of fill in mL.
- Information on main labels (side with the product name) is oriented in the same direction.
- For products containing nicotine, the nicotine warning statement must be included in bold.
- Batch number and expiry date preceded by prefixes.
- Name of the sponsor
- Storage conditions
- Warning statements, “avoid contact with eyes and skin” and “Do not swallow”.
- For a container that is less than 10 mL – “Keep out of reach of children”.

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

Brand/ Product name

Nicotine 20 mg/mL

Tobacco flavour

20 mL

THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE

Medicine information

Warnings

Avoid contact with eyes and skin.

Not to be taken orally.

Other information

Store below 30°C away from light.

Batch: 012345

Expiry: July 2026

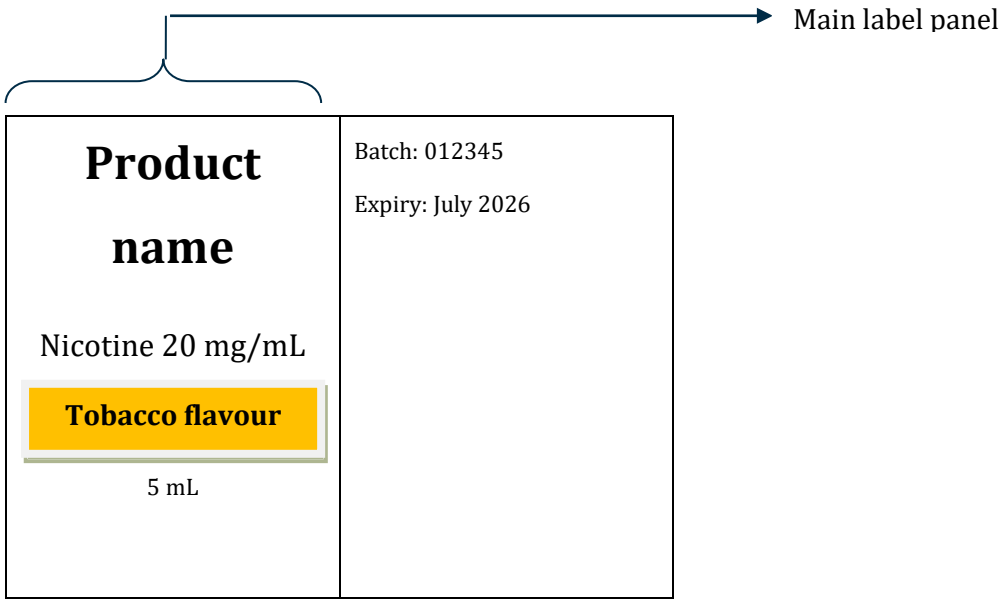
Sponsor/distributor:

Therapeutic vape Pty Ltd

Appendix 5:

Label for Very Small Container

- Following information to be in a text size of at least 1 mm and oriented in same direction:
  - Nicotine and its content. Nicotine-free product should include the statement, “nicotine 0 mg/mL”.
  - Flavour included as ‘mint’, ‘menthol’ or ‘tobacco/classic’ flavour.
  - Volume of fill
- Batch number and expiry date preceded by prefixes.



Appendix 6:

Label for vaping kit or vaping pack

A therapeutic vaping kit and therapeutic vaping pack typically includes vaping devices, substances, and accessories that are used for medical purposes, such as smoking cessation or managing nicotine dependence.

Requirements for vaping kit or pack labels

- Following information to be in text size of at least 3.0 mm and in same orientation:
  - Name of the product prominently displayed in a continuous and uninterrupted manner.
  - For each therapeutic vaping substance or accessory in the kit or pack, quantity of nicotine, volume of fill and flavour (as 'mint', 'menthol' or 'tobacco/classic' flavour).
- For products containing nicotine, main label requires nicotine warning statement that is at least 30% of the total main label size. The warning statement needs to be in bold, sans serif, capital letters in black text on a white background.
- Batch number and expiry date preceded by prefixes.
- Name and contact details of sponsor
- Storage conditions
- the words, "Poisons Information Centre" followed immediately by their contact information.
- Warning statements, "Avoid contact with eyes and skin" and "Do not swallow".
- All information (other than the name and nicotine content) in a text size of at least 1.5 mm.
- Signal heading for prescription medicines and keep out of reach of children.
- Space for dispensing label 70 x 30 millimetres.
- For therapeutic vaping pack, all of the above and plus following requirements:
- Name and address of the manufacturer
- Where the therapeutic vaping pack contain therapeutic vaping device, or a therapeutic device accessory, the warnings statements in a text size of at least 5.0 mm:
  - "KEEP OUT OF REACH OF CHILDREN"; and
  - "RISK OF FIRE EXPLOSION. REPLACE ONLY WITH SAME SIZE AND TYPE BATTERY"; and
  - "WARNING: CONTAINS BUTTON OR COIN BATTERY. HAZARDOUS IF SWALLOWED – SEE INSTRUCTIONS" (if applicable).

Batch 012345

Expiry July 2026

Attach dispensing label here

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

Brand/ product name

Packing list
1 x Name of vaping good
Nicotine 20 mg/mL, 60 mL

Mint Flavour

1 x Name of the vaping good
Nicotine 20 mg/mL, 60 mL

This product contains nicotine, which is a highly addictive substance

Medicine information

Active ingredient (per mL)

Nicotine 20 mg

Excipients

Glycerol and propylene glycol.

Warnings

Avoid contact with eyes and skin.

Do not sallow.

Contains coin battery. Hazardous if swallowed.

Risk of fire explosion. Replace with only same size and type battery.

Poisons Information centre and contact information.

Other information

Store below 30°C away from light.

Sponsor/distributor:

Therapeutic vape Pty Ltd

Address, contact details

Manufacturer:

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

Brand/ product name

Packing list
1 x Name of vaping good
Nicotine 20 mg/mL, 60 mL

Mint Flavour

1 x Name of the vaping good
Nicotine 20 mg/mL, 60 mL

This product contains nicotine, which is a highly addictive substance

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication – Draft guidance	Scientific Evaluation Branch/Regulatory Legal Services Branch	May 2021
V1.1	Original publication – Final guidance Minor updates to improve clarity, accuracy and consistency of language, fix hyperlinks, include an overview of TGO 110 requirements and information on how to report side effects and other problems	Regulatory Legal Services Branch	June 2021
V1.2	Update to the information on the Advertising Guidance	Scientific Evaluation Branch/Regulatory Legal Services Branch	July 2021
V1.3	Updates to 'Health practitioners and consumers using the Personal Importation Scheme' section to include information about labelling and packaging requirements for consumer goods in other jurisdictions. Updates to reflect the introduction of the *Smokefree Environments and Regulated Products Regulations 2021 (New Zealand)* Updates to 'Vaping devices' section to reflect amendments to Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* and include new pictures	Regulatory Legal Services Branch	September 2021
V1.4	Update to include guidance on new reforms, restrictions on flavours, extension to zero therapeutic vapes, etc.	Vaping Implementation and Enforcement Branch/ Vaping Legislative Reform Branch	January 2024

Version	Description of change	Author	Effective date
V1.5	Strengthened product standards applicable to unapproved vaping substance and substance accessories. Key changes include: • restrictions to the formulation of vaping substances to permitted ingredients only and changed restrictions on the level of allowed nicotine (50 mg/mL limit) • enhancement of the packaging and labelling of vapes, including requirements for plain packaging, information leaflets, traceability and restrictions on product names • restrictions to the maximum permitted container volume.	Vaping Implementation and Enforcement Branch/ Vaping Legislative Reform Branch	October 2024

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