Australian Government
Department of Health
Therapeutic Goods Administration

Requirements for unapproved therapeutic vapes for smoking cessation and the management of nicotine dependence

Guidance on the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* and related matters

Version 1.4, January 2024

TGA Health Safety Regulation

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Contents

Glossary

Australian Register of Therapeutic Goods (ARTG): the public database of therapeutic goods that may be lawfully supplied in Australia. The ARTG is the main pathway for consumers to access medicines, biologicals and medical devices in Australia.

Authorised Prescriber (AP) Scheme allows authorised medical practitioners to prescribe therapeutic goods that are not included in the ARTG to certain patients with a particular medical condition.

contaminant: a chemical in a therapeutic vaping substance (and sometimes a therapeutic vaping device) that is not intended as an ingredient or component.

disposable vape: defined in the TG Regulations, namely, a fully assembled vaping device with all constituent parts fixed permanently in place that is not designed or intended to be disassembled but that is pre-filled with a vaping substance and not designed or intended to be refilled and therefore is ordinarily disposed of once the vaping substance runs out. Disposable vapes refer only to closed system (sealed unit) vaping devices.

ingredient: a chemical that is intended to be in an e-liquid (e.g. a flavour).

MD Regulations: *Therapeutic Goods (Medical Devices) Regulations 2002.*

nicotine replacement therapy (NRT) products: a range of products included in the ARTG that are used to support smoking cessation, such as gum, lozenges, inhalators, and patches.

therapeutic vaping device: defined in the MD Regulations, namely, a therapeutic good that is a device that generates or releases, or is designed to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user, but does not include a therapeutic cannabis vaping device or a disposable vape (a therapeutic vaping device is designed or intended to be reused or refilled).

therapeutic vaping device accessory: defined in the MD Regulations, namely, an unfilled and refillable cartridge, capsule, pod or other vessel that is designed to contain a therapeutic vaping substance and is for use in or with a therapeutic vaping device but does not include a therapeutic cannabis vaping device accessory.

therapeutic vaping kit: defined in the TG Regulations, namely, a package containing one or more therapeutic vaping substances or therapeutic vaping substance accessories and no other goods.

therapeutic vaping pack: defined in the TG Regulations, namely, a primary pack including at least one therapeutic vaping device or therapeutic vaping device accessory, and may contain one or more therapeutic vaping substances or therapeutic vaping substance accessories.

therapeutic vaping substance: defined in the TG Regulations, namely, a liquid or other substance designed or intended for use in or with a vaping device. Therapeutic vaping substances usually contain propylene glycol, glycerol, and flavourings, and may or may not contain nicotine.

therapeutic vaping substance accessory: defined in the TG Regulations, namely, a cartridge, capsule, pod or other vessel that contains a therapeutic vaping substance and is designed or intended for use in or with a therapeutic vaping device.

therapeutic vape: expression used in this guidance for convenience to refer to one or more of the following:

(a) a therapeutic vaping device that is supplied in a therapeutic vaping pack;
(b) a therapeutic vaping device accessory that is supplied in a therapeutic vaping pack;

(c) a therapeutic vaping substance; or
(d) a therapeutic vaping substance accessory.

TGA: Therapeutic Goods Administration.

TG Act: *Therapeutic Goods Act 1989* (Cth).

TG Regulations: *Therapeutic Goods Regulations 1990* (Cth).

unapproved therapeutic goods: therapeutic goods that are not included in the ARTG and have not been evaluated by the TGA for quality, safety and efficacy. There are established pathways under the TG Act that allow access to unapproved therapeutic goods in certain circumstances, including the Special Access Scheme and the AP Scheme.

About this guidance

The purpose of this guidance is to help health practitioners, patients, as well as importers, and manufacturers and wholesalers to understand the minimum safety and quality requirements for 'unapproved' therapeutic vapes that are indicated for smoking cessation or the management of nicotine dependence. This guidance includes:

- information on the requirements that apply to 'unapproved' therapeutic vapes under *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 (*TGO 110)
- information about other standards and requirements applicable to therapeutic vapes, and
- an overview on the TGA's role in regulating therapeutic vaping devices and therapeutic vaping device accessories.

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 your own independent legal advice to ensure that all legal requirements are met.

If you require clarification of a particular requirement, you can email nvp@health.gov.au.

What this guidance does not cover

This guidance does not contain clinical guidelines for health practitioners or make recommendations about prescribing or usage of therapeutic vapes (for example, dosage regimes). Health 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.

The guide published by the Royal Australian College of General Practitioners is currently being updated to include guidance on prescribing therapeutic vapes, including for persons under 18, and supporting vaping cessation.

Practical guidance materials for prescribers is also available on the Vapes: information for prescribers | Therapeutic Goods Administration (TGA) page of our website.

Advertising and promotion of therapeutic vapes

The advertising of therapeutic vapes is generally prohibited in Australia. Some states and territories also restrict the promotion of therapeutic vapes.

Information shared between a doctor, pharmacist or nurse practitioner and their patient during consultation or treatment is not subject to the advertising rules for therapeutic goods, including the prohibition on advertising prescription medicines or unapproved goods. Presenting factual and balanced information about therapeutic vapes is also unlikely to be considered advertising, depending on the context in which the information is presented.

The Government has announced that it will introduce amendments to the TG Act in 2024 to restrict the advertising of all vapes, subject to very limited exceptions.

To further understand your obligations in relation to the advertising of vapes you may refer to Advertising | Therapeutic Goods Administration (TGA).

Product standard TGO 110

The *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110) is a product standard made under section 10 of the *Therapeutic Goods Act 1989* (Act).

TGO 110 sets out minimum safety and quality requirements for unapproved therapeutic vapes that are imported into, supplied in, or exported from Australia. All therapeutic vapes currently available in Australia are unapproved. TGO 110 applies to:

(a) therapeutic vaping substances;
(b) therapeutic vaping substance accessories;
(c) therapeutic vaping kits;
(d) goods in a therapeutic vaping pack (including therapeutic vaping devices and therapeutic vaping device accessories)

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

Commencement

Amendments to TGO 110 commenced on 1 January 2024 to support the implementation of the vaping reforms and extend the operation of TGO 110 to therapeutic vapes not containing nicotine. Further substantive amendments to TGO 110 are anticipated over the course of 2024.

Objectives

TGO 110 specifies the minimum requirements for the quality and safety of therapeutic vapes. It is intended to provide an assurance to medical practitioners and patients that therapeutic vapes for smoking cessation and the management of nicotine dependence meet minimum safety and quality requirements with a view to:

- ensuring that health care providers and patients have access to accurate information about the content of these products;
- ensuring that substances with known, demonstrable inhalation risks are not used as ingredients in these products;
- minimising the risk of, and risks associated with, accidental exposure to or ingestion of these products, particularly by children, given the toxicity of nicotine;
- ensuring that the unapproved device components and accessories used for vaping comply with minimum quality standards.

Principally, the new TGO 110 applies to therapeutic vapes not containing nicotine and introduces restrictions on flavours for therapeutic vapes imported or manufactured on or after 1 March 2024. Specifically, TGO 110:

- establishes minimum standards relating to the ingredients, labelling and packaging of zero-nicotine vaping substances, to align with current standards applying to therapeutic vapes containing nicotine; and
- restricts the flavour of all therapeutic vaping substances to menthol, mint or tobacco flavour.

Application

TGO 110 applies to unapproved therapeutic vapes imported into, manufactured in, or supplied in Australia that are finished products (i.e. those that may be supplied to a patient). Specifically, TGO 110 applies to:

- therapeutic vaping substance and therapeutic vaping substance accessories, irrespective of nicotine content; and
- therapeutic vaping kits, and goods in a therapeutic vaping pack, including therapeutic vaping devices and therapeutic vaping device accessories.

Such goods may be:

✓ supplied under the Authorised Prescriber (AP) Scheme or the Special Access Scheme (SAS);

✓ supplied as part of a clinical trial; or

✓ extemporaneously compounded.

TGO 110 **does not** apply to:

✘ therapeutic vapes that may be included in the ARTG in the future – the quality, safety and efficacy of registered products are evaluated as part of the TGA's general marketing approval process;

✘ 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;

✘ therapeutic vapes manufactured in, or imported into, Australia for export only;

✘ nicotine replacement therapies (NRTs), such as patches, gum, lozenges and inhalators, and 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 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.

Please refer to section 6 of TGO 110 for the application of the standard.

Overview

TGO 110 sets out requirements for the information that must be stated on the label of unapproved therapeutic vapes (either on the container, primary pack or in an information sheet provided with the product), the packaging of the goods, the ingredients in the vaping substance, quality requirements for vaping devices and vaping device accessories and the records that must be maintained by the sponsors of these goods.

There is no offence or civil penalty in the TG Act for importing a therapeutic vape without TGO 110 compliant packaging or labelling. This means that 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 (e.g. by over-stickering or providing an information sheet) to meet the TGO 110 requirements **before** the vape is supplied to a wholesaler, pharmacy or any other person authorised to supply prescription medicines.

Products imported directly by patients from overseas suppliers in accordance the Personal Importation Scheme will not be subject to the requirements in TGO 110. However, the Personal Importation Scheme stopped for disposable vapes on 1 January 2024, and will cease to apply to the importation of all other vapes on 1 March 2024.

An unapproved therapeutic vape that is subject to, and compliant with, a Premarket Tobacco Product (PMTA) marketing order issued by the United States (US) Food and Drug Administration (FDA) is taken to automatically comply with the packaging and ingredient requirements in TGO 110 and is exempt from the record-keeping requirements in TGO 110. These products must still have TGO 110-compliant labelling before being supplied in Australia. For therapeutic vaping devices and vaping device accessories, the alternative conformity requirements are outlined in Schedule 1 to the MDSO (Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023).

Summary of TGO 110 requirements

The table below summarises the application of the TGO 110 requirements to therapeutic vapes that are supplied, or are imported for the purpose of supply, in Australia. Further information about each requirement is available in this guidance via the hyperlinks below. Further information about the 'TGO 110 equivalent or similar' packaging and labelling requirements imposed by the European Union (EU), United Kingdom (UK), Canada and New Zealand, being jurisdictions from which Australians import therapeutic vapes, is set out in the Packaging and labelling of consumer products supplied within the UK, EU, Canada and New Zealand section.

TGO 110 requirement	Applies to products supplied in Australia (including products imported for supply in Australia) *
Labelling requirements (information to be provided on container, primary pack or in information sheet)	
Ingredient list	✓
Nicotine concentration (mg/mL)	✓
Warning statements	✓
Packaging requirements	
Child-resistant packaging	✓ (except FDA PMTA marketing order compliant products)
Ingredient requirements	
Nicotine (base and/or salt form(s)) being the only active ingredient	✓ (except FDA PMTA marketing order compliant products)

TGO 110 requirement	Applies to products supplied in Australia (including products imported for supply in Australia) *
Nicotine concentration/ content within 90 – 110% of that which is stated on the label	✓ (except FDA PMTA marketing order compliant products)
Nicotine (or equivalent base form) concentration ≤ 100 mg/mL	✓ (except FDA PMTA marketing order compliant products)
Only mint, menthol or tobacco flavoured therapeutic vaping substances are allowed	✓ (except FDA PMTA marketing order compliant products)
No prohibited ingredients added to product	✓ (except FDA PMTA marketing order compliant products)
Record-keeping obligations for Australian sponsors	
Maintain records demonstrating conformance with TGO 110	✓ (except FDA PMTA marketing order compliant products)

* Packaging and labelling requirements can be met *after* importation into Australia (e.g. a sponsor may import a product with non-compliant labelling and then over-sticker the product in Australia prior to supply to a wholesaler or directly to pharmacy or other health practitioner). Ingredient and record-keeping requirements must be complied with at the time of importation.

Record-keeping obligations for sponsors

Australian sponsors of therapeutic vapes must maintain records with sufficient information to demonstrate that those products conform to TGO 110, as required by section 10 of TGO 110.

Who is an Australian sponsor?

The sponsor of therapeutic vapes is the person who:

- imports, exports, or manufactures the goods, or
- arranges for another person to do any of those things in relation to the good.

This is usually a company who has imported the product for supply through Australian pharmacies. Health practitioners who supply products directly to patients (including dispensing pharmacists), and wholesalers, will **not** be the sponsor of goods that have sourced from Australian suppliers.

However, pharmacists, other health practitioners, and/or wholesalers **will be the sponsor** of a therapeutic vape if they:

- import, or arrange to import, the good themselves directly from an overseas supplier, for supply to Australian patients (e.g. order a product online rather than sourcing it from an Australian supplier)
- export or arrange to export the good from Australia (e.g. send it to a patient overseas), or
- extemporaneously compound or manufacture the good themselves.

Types of records that must be kept

The types of records sponsors are expected to maintain in accordance with section 10 of TGO 110 include:

- copies of the labels of the product showing the information required under TGO 110
- records showing the design of the packaging used for the product and how it meets the child-resistant packaging requirements in TGO 110
- evidence that the product conforms to each of the Ingredient requirements in TGO 110, such as a declaration from the manufacturer and/or a certificate of analysis (or similar document(s)) for the finished product showing that:
  - there are no active ingredients in the product other than nicotine (in base and/or salt form(s))
  - the nicotine base form, nicotine salt and/or equivalent base form concentration or content of the product is within +/- 10% of any such concentration or content stated on the label of the product (including in any information sheet provided with the product)
  - the nicotine base form, or equivalent base form, concentration of the product does not exceed 100 mg/mL,
  - no prohibited ingredients have been added to the product, and
  - only permitted flavours are added to the product.

A certificate of analysis or similar document should set out the test(s) performed, the test method used (e.g. lab reference code or details of the technique), the result of the test and the requirements for the test. Due to the wide variety of products available, we cannot provide guidance on the specific test methods that should be used. 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.

Ideally, a certificate of analysis (or similar document) would also show the composition of all ingredients added to the product and the results of testing the product, and its aerosol, for potentially harmful contaminants (particularly those referred to in the Contaminants section of this guidance). This information is not, however, required to demonstrate conformance with TGO 110.

Different flavoured products have different ingredients and you cannot necessarily rely on records relating to one flavour of a product to show that another flavour also complies with the ingredient requirements in TGO 110.

Updates and record retention

The records you hold will need to be updated where changes are made to the product (e.g. to the ingredients, including the suppliers of those ingredients) or the manufacturing process for the product. This is because the records must be relevant to each product imported, exported or supplied in Australia.

This does not mean you should immediately dispose of your old records if you stop being the sponsor of a product or update a product. We expect you to maintain records relevant for each product for the following periods:

- if the product is labelled with an expiry date, at least 12 months after the expiry date for the last product imported, exported or manufactured for supply in Australia, or
- in any other case, 5 years after the product is last imported, exported or manufactured for supply in Australia, or supplied by you or on your behalf, whichever comes later.

These record-keeping requirements do **not** apply to:

- therapeutic vapes that are imported via the Personal Importation Scheme (which ceases to operate in its entirety on 1 March 2024)
- therapeutic vapes for which the FDA has issued a PMTA marketing order that comply with all of the requirements specified in that order.

Labelling of therapeutic vapes

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.

Unapproved therapeutic vapes must be labelled with the information set out in Schedule 2 to TGO 110.

To comply with the labelling requirements, the information specified in Schedule 2 to TGO 110 must be either:

- on or attached to the container or primary pack of the product (including by way of over-stickering), or
- supplied with the container or primary pack of the product (e.g. in an information sheet)

  (see subsection 8(2) of TGO 110).

It is not necessary for each type of information to be provided in the same way. For example, a product may have the nicotine concentration and warning statements specified in an over-sticker on the primary pack and the ingredient list set out in an information sheet provided with the product. However, all information required under TGO 110 **must** be in English, legible, visible (and not obscured) and durable (see subsection 8(3) of TGO 110).

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.

Any such additional information may also be included on, or attached to, the container or primary pack of the product or in information supplied with the product with the information required under TGO 110.

Ingredient list

Unapproved therapeutic vaping substances or therapeutic vaping substance accessories 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 nicotine salt products—the particular type of each nicotine salt in the product must be listed.
- for flavoured products—either the word "flavour", or a description including the word "flavour" (e.g. "mint flavour"), or the name of each ingredient in the flavour, and
- the names of all of other excipient ingredients

  (see item 1 of Part 1 of Schedule 2 to TGO 110).

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

Nicotine concentration

Unapproved therapeutic vaping substances or therapeutic vaping substance accessories containing nicotine must be labelled with:

- 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 concentration of the nicotine salt(s) in the product will **not** satisfy this requirement)

  (see item 2 of Part 1 of Schedule 2 to TGO 110).

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.

Warnings statements

Unapproved therapeutic vaping substances containing nicotine must be labelled with all three warning statements mentioned below whereas therapeutic zero nicotine substances only require the first warning statement:

- 'KEEP OUT OF REACH OF CHILDREN'
- 'Avoid contact with eyes'
- 'Avoid contact with skin'

  (see item 3 of Part 1 of Schedule 2 to TGO 110).

As above, these statements must be on or attached to the container or primary pack of the product, or in information supplied with the container or primary pack of the product.

Please note that state and territory poisons legislation ordinarily requires 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 and state and territory poison legislation.

A product will ordinarily comply with the warning statement requirements in both TGO 110 and state and territory poisons legislation by including the statements specified in item 3 of Part 1 of Schedule 2 to TGO 110 on the primary pack and immediate container of the product.

Product packaging and closures

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.

When prescribing or dispensing therapeutic vapes, prescribing health practitioners and dispensing pharmacists are expected to advise of the risk of accidental child poisoning if the container is left open in the process of refilling/mixing of vaping substances (where relevant) and/or if vaping substances are used in vaping devices or vaping device accessories without child-resistant safety features (including where a child is able to suck on the vaping device or vaping device accessory). Patients should also be provided with the Poisons Information Centre phone number (13 11 26) and 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 9 of TGO 110 relevantly provides that therapeutic vaping substances and therapeutic vaping substance accessories 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 the UK, the EU, Canada, the US and NZ and meets all CRP requirements imposed in that country. Alternative conformity requirements are also specified in section 11 of TGO 110.

Child-resistant packaging requirements in TGO 95

TGO 95 sets out CRP requirements that apply to certain medicines registered in the ARTG amongst others. TGO 95 will apply to any therapeutic vape that is registered in the ARTG in the future following TGA evaluation. For unapproved vapes, CRP requirements are specified in, and are therefore applied to those goods pursuant to, TGO 110 as mentioned above.

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

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 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.

Container volumes

TGO 110 does not include any restrictions on the volume of the container. However, we anticipate that the volume of containers will reflect amounts considered appropriate by suitable practitioners in the course of prescribing therapeutic vapes.

Ingredients in therapeutic vaping substances

TGO 110 includes requirements relating to the active and excipient ingredients used in unapproved therapeutic vapes.

Vaping substances or vaping substance accessories for which the FDA has issued a PMTA marketing order do **not** need to comply with the ingredient requirements in TGO 110 provided the product complies with all requirements specified in the marketing order. This is because the FDA assesses the ingredients used in those products to determine whether issuing the PMTA marketing order for the product is appropriate for the protection of public health based on an evaluation of scientific data.

Active ingredients

Active ingredients are those therapeutically active components in a product responsible for its physiological or pharmacological action. This includes ingredients such as cannabinoids, vitamins, amino acids, caffeine, and other stimulants that have a physiological or pharmacological effect in the final formulation.

Nicotine is the only permitted active ingredient

Nicotine (whether in base and/or salt form(s)) is the only active ingredient allowed in unapproved therapeutic vaping substances or therapeutic vaping substance accessories to which TGO 110 applies. These products **must not** contain any other active ingredients (see subsection 7(1) of TGO 110).

It is not appropriate to add other active ingredients to therapeutic vaping substances or therapeutic vaping substance accessories as they would not be needed to assist in the cessation of smoking or the management of nicotine dependence.

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 that stated:

- on or attached to the container or primary pack of the therapeutic vaping substance or therapeutic vaping substance accessory (including an over-sticker), or
- in information supplied with the container or primary pack of a therapeutic vaping substance or therapeutic vaping substance accessory.

  (see subsection 7(2) of TGO 110).

These limits are consistent with standard pharmaceutical quality practices for nicotine products.

The actual nicotine base form, nicotine salt and/or equivalent base form concentration or content (depending on what is stated) should be tested using appropriately validated test methods. Due to the wide variety of products available, we cannot provide guidance 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.

This is an ingredient requirement, not a labelling requirement, and therefore also applies to products imported under the Personal Importation Scheme (if they carry a statement of the nicotine base form, nicotine salt and/or equivalent base form concentration or content).

Limits on nicotine concentration

Unapproved therapeutic vaping substances and therapeutic vaping substance accessories containing nicotine must have:

- for nicotine base products, a base form concentration,
- for nicotine salt products, an equivalent base form concentration,

  of no more than **100 mg/mL** (subsection 7(1) of TGO 110).

You cannot import, manufacture or supply a therapeutic vaping substance that is ready for supply which exceeds this concentration limit.

Patients will only be able access a product with a concentration matching that specified in their prescription (either by personal importation or purchasing from an Australian pharmacy). Health practitioners need to consider whether the amount of nicotine concentration and type of product is appropriate for a particular person's smoking cessation needs.

This limit does not mean that 100 mg/mL products are safe or necessarily appropriate for use.

Ingestion of, or exposure to, vapes containing nicotine (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 vapes containing nicotine (SCHEER 2021). Higher concentration vapes containing nicotine carry greater risks of poisoning having severe effects (SCHEER 2021).

Excipient ingredients and flavours

Excipients are the ingredients added to the product that are not the active ingredient(s). The excipient ingredients typically used in therapeutic vaping substances and therapeutic vaping substance accessories are propylene glycol, glycerine/glycerol and (possibly) flavours.

Prohibited ingredients

The substances in the table below must **not** be added as ingredients in unapproved therapeutic vaping substances or therapeutic vaping substance accessories (see subsection 7(3) and Schedule 1 to TGO 110). **There are known health risks associated with inhaling these ingredients.** References to relevant scientific articles about these prohibited ingredients are included in Appendix A to this guidance.

This does not mean that all other ingredients in unapproved vapes are safe

There is limited evidence available about the safety of inhaling the ingredients (including flavourings) used in vapes (SCHEER 2021). Just because an ingredient is safe to consume or ingest as a food or in a tablet or capsule does not necessarily mean it is safe to inhale (SCHEER 2021).

We do not assess the safety of ingredients used in unapproved therapeutic vapes.

However, we will revise the list of prohibited ingredients in Schedule 1 to TGO 110 if and when more evidence becomes available showing that other ingredients used in vapes carry demonstrable health risks associated with inhalation.

Ingredient	Comments
acetoin	• used in foods to create buttery or creamy flavours • associated with irreversible lung damage (NICNAS 2019) • can be a source of diacetyl in therapeutic vapes (Vas et al. 2019)
benzaldehyde	• used in foods and drinks to create cherry and almond flavours • classified by the Globally Harmonized System of Classification and Labelling of Chemicals as 'Harmful in inhaled' - Cat. 4 (H332) (ECHA Infocard) • reported to possibly cause respiratory failure, depression of the central nervous system and convulsions at high concentrations (IMAP Report - Benzaldehyde)
cinnamaldehyde	• used in foods to create a cinnamon flavour • capable of cytotoxicity, impaired immune cell function and sensitisation (IMAP Report – Cinnameldehyde; Muthumalage et al. 2018)
diacetyl	• used in foods to create buttery or creamy flavours • linked to irreversible lung damage known as bronchiolitis obliterans, or 'popcorn lung' (NICNAS 2019; Allen et al. 2016; Clapp & Jaspers 2017, NIOSH 2016) • prohibited ingredient in consumer vapes containing nicotine in Canada and the UK
diethylene glycol	• central nervous system, renal and cardiac toxicity have been demonstrated following exposure to diethylene glycol (Fowles et al. 2017; SCCP 2008), inhalation-specific toxicity data is limited • cannot be used as a diluent in consumer vapes containing nicotine in Canada and the UK

Ingredient	Comments
ethylene glycol	• respiratory irritation observed in humans and exposure linked to renal toxicity (Fowles et al. 2017; ATSDR 2010), presence in vapes associated with toxicological hazards (Hutzler et al. 2014) • cannot be used as a diluent in consumer vapes containing nicotine in Canada and the UK
pentane-2,3-dione (2,3-pentanedione or acetylpropionyl)	• used in foods to create buttery or creamy flavours • structurally related replacement for diacetyl (Allen et al. 2016) and associated with respiratory impairment (decreased lung function), fibrosis of the intrapulmonary airways in rats (similar to bronchiolitis obliterans in humans) (NIOSH 2016) • prohibited ingredient in consumer vapes containing nicotine in Canada and the UK
vitamin E acetate (dl-alpha-tocopheryl acetate)	• associated with outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI) which resulted in over 2,000 hospitalisations or deaths (Blount et al. 2020; Boudi et al. 2019).

TGO 110 only prohibits these substances being added as ingredients to a therapeutic vape. Provided these substances have not been added to therapeutic vapes as ingredients, the substances may be present in the product without breaching TGO 110 (e.g. in low levels as a contaminant of an ingredient or the result of manufacturing process).

However, Australian sponsors are encouraged to take all reasonable steps to minimise levels of these substances in their vapes as contaminants or as a result of the manufacturing process to the maximum extent possible. If one or more of these substances are present in the vape, they should be at concentration less than or equal to 10 ppm (parts per million). It is unlikely that these substances can be present at higher than 10 ppm concentration if present as a contaminant or a by-product, and the TGA may ask you to justify why the substances, if identified, are above this concentration.

See Contaminants and product quality section of this guidance for information about other substances that may be present in therapeutic vapes.

Permitted flavours in therapeutic vaping substances

From 1 March 2024, vaping substances and vaping substance accessories will only be allowed to have mint, menthol or tobacco flavours. Any vaping substance or vaping substance accessory containing a flavour other than the abovementioned flavours alone or in combination will not be allowed to be imported, manufactured or supplied in Australia.

- For the purposes of TGO 110 compliance—***mint or menthol flavour*** means the taste or smell that a reasonable person would associate with mint or menthol.
- For the purpose of TGO 110 compliance—tobacco ***flavour*** means the taste or smell that a reasonable person would associate with tobacco.

Health practitioners should be aware that different flavoured vapes of the same brand, or different brands of vapes with the 'same' flavour, may have different safety profiles and should not necessarily be considered substitutable. For example, the mint flavour used in one product may be made up of different ingredients to the mint flavour used in another product. Similarly, a

mint flavoured product of a brand will have different ingredients to a tobacco flavoured product of the same brand.

Contaminants and product quality

Default standards

The *Therapeutic Goods (Exempt Monographs) Determination 2021* exempts unapproved therapeutic vaping substances to which TGO 110 applies from complying with any default standards (i.e. any monograph or monographs in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia-National Formulary) that would otherwise apply to those products or the ingredients used in those products. Therapeutic vaping substances or therapeutic vaping substance accessories that are included in the ARTG will still be expected to comply with all applicable default standards.

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 will not apply to unapproved therapeutic vaping substances or therapeutic vaping substance accessories that are listed in the ARTG as Export Only products or to products imported under the Personal Importation Scheme until its cessation on 1 March 2024.

Contaminants

Concerns have been raised by health practitioners and others about the quality of unapproved therapeutic vaping substances and resulting aerosols. In particular, the potential for these products and/or resulting aerosols to have high levels of contaminants.

Some potential contaminants identified as having inhalation risks that may be present in vapes and/or resulting aerosols are set out in the table below. Full references are included in Appendix A to this guidance.

Potential contaminant	Comments
acetaldehyde (also known as ethanal)	• respiratory irritation, respiratory tract carcinogenicity in rats following long term exposure (FDA 2012; SCHEER 2021)
acrolein (also known as acraldehyde)	• severe respiratory irritation (FDA 2012; SCHEER 2021)
formaldehyde	• respiratory irritation, respiratory tract carcinogenicity in rats following long term exposure. In humans, changes in lung function have been reported (FDA 2012; SCHEER 2021)

TGO 110 does not prohibit or set limits on the presence of these contaminants in therapeutic vaping substances or resulting aerosols. Australian sponsors are encouraged to take reasonable steps to minimise the levels of these contaminants in their products and resulting aerosols to the

maximum extent possible (noting that the presence of contaminants in the aerosol may be affected by the type of device used and the temperature to which the product is heated).

Health practitioners and patients prescribing for use under the Personal Importation Scheme are also encouraged to make enquiries of product suppliers about the levels of these contaminants in their products and whether they test the aerosol for these contaminants and under what conditions (e.g. the type of device used for testing, the temperature to which the product was heated) noting, of course, that the Personal Importation Scheme for therapeutic vapes ceases in its entirety on 1 March 2024.

There is currently insufficient information to specify a 'safe' level of the contaminants identified above, and we would therefore suggest adopting a cut-off for each contaminant in the therapeutic vaping substance itself of no more than 10 ppm. This is consistent with the threshold for substances included in Schedule 1 to 6 of the current Poisons Standard (see paragraph 1(2)(j) of Part 1 of the current Poisons Standard). The level of the contaminant in the therapeutic vaping substance does not necessarily reflect the level of the contaminant that may be present in the product's aerosol.

Report side effects and problems

We strongly encourage patients and health practitioners to report any suspected side effects related to unapproved therapeutic vapes.

The TGA has an important role in monitoring the safety of 'unapproved' products. Reporting side effects and problems helps us to understand the safety of a product. We investigate significant safety concerns as part of ensuring product safety in the Australian community.

Deficiencies or defects with unapproved therapeutic vapes thought to have arisen during manufacture, storage or handling can also be reported to the TGA.

Further information about reporting problems or adverse events (including side effects) involving unapproved therapeutic vapes is available on our website.

Therapeutic vaping devices and therapeutic vaping device accessories

Vaping devices such as vape-pens, e-cigarettes and e-cigars, are electronic devices used to heat vaping substances in the form of an aerosol, vapour or mist for direct inhalation. Some vaping substances are supplied in vaping substance accessories (e.g. prefilled) while other vaping devices and vaping device accessories (such as pods, capsules and cartridges) are supplied separately to vaping substances. Devices such as humidifiers, diffusers and nebulisers are not considered vaping devices and this section does not apply to them.

From **1 March 2024**, all vaping devices and vaping device accessories (including an unfilled cartridge, capsule, pod or other vessel) for use with a therapeutic vaping substance or therapeutic vaping substance accessory will be covered by the therapeutic goods framework.

Vaping devices and vaping device accessories supplied separately to vaping substances or vaping substance accessories, and otherwise not supplied in a therapeutic vaping pack, will be required to comply with any one or more of the following requirements:

- the Essential Principles, or
- where applicable, the Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (the MDSO).

Where a therapeutic vape is supplied in a therapeutic vaping pack (irrespective of whether the pack contains a therapeutic vaping substance or a therapeutic vaping substance accessory), all goods in the pack must comply with TGO 110, including a therapeutic vaping device or therapeutic vaping device accessory, such as an empty pod or cartridge. TGO 110 requires all vaping devices and vaping device accessories supplied in a therapeutic vaping pack to meet the Essential Principles or, where applicable, the requirements under MDSO (Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023).

The MDSO has limited operation. It applies to therapeutic vaping devices or therapeutic vaping device accessories that:

- ✓ were previously excluded from the operation of the TG Act under item 16 of Schedule 1 to the Therapeutic Goods (Excluded Goods) Determination 2018, prior to the repeal of that item on 1 January 2024
- ✓ are intended by the person under whose name those devices are or are to be supplied, only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence; and
- ✓ are imported or manufactured on or after 1 March 2024.

Therapeutic vaping devices or therapeutic vaping device accessories that comply with the MDSO are taken to comply with the Essential Principles. All other therapeutic vaping devices and therapeutic vaping device accessories must comply with the Essential Principles even if those goods are not included in the ARTG. Therapeutic vaping devices and therapeutic vaping device accessories may be included in the ARTG under the medical devices framework (Chapter 4 of the *Therapeutic Goods Act 1989*) if they meet the regulatory requirements for a medical device and have appropriate evidence to support an ARTG inclusion.

Changes to requirements

New exemptions apply to 'unapproved' therapeutic vaping devices and therapeutic vaping device accessories under the therapeutic goods framework.[1]

What do the changes mean for sponsors?

The new exemptions:

- **replace** the former exemptions for vaping devices that were designed or intended exclusively for use with nicotine for smoking cessation
- **extend** to vaping devices that were previously excluded from the operation of the TG Act (ie. those that were not exclusively for the administration of a medicine) – these devices are now required to demonstrate compliance with the Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023
- **introduce** new requirements for sponsors to notify the TGA prior to importation or supply of therapeutic vaping devices, therapeutic vaping device accessories and components or articles used in the manufacture of those goods (as the case may be); **components or articles used in the manufacture of a therapeutic vaping device or therapeutic vaping device accessory** include batteries, atomisers or mouthpieces that are intended for further manufacture and not ready for supply to ultimate consumers:
    - the notice for therapeutic vaping devices and therapeutic vaping device accessories must include a statement that those goods are intended, by the person under whose name the goods are to be supplied, only to administer or contain a therapeutic vaping substance whose only indications are use for

[1] New regulation of vapes starting January 2024 | Therapeutic Goods Administration (TGA)

smoking cessation or the management of nicotine dependence; the notice must also state that the goods conform with the essential principles;

- the notice for **components or articles used in the manufacture of a therapeutic vaping device or therapeutic vaping device accessory** must include a statement stating that such manufacture will be in accordance with the requirements of the Act, by a manufacturer that holds all relevant licences or approvals (however described) required under the law of the State or Territory in which the manufacture is to occur; this notice only applies in relation to imported components or articles to enable appropriate permits to be obtained from the Office of Drug Control by the importer. Please refer to the Guide on Sponsor notice – Vaping Goods.

- **increase** regulatory controls and oversight of the legitimate supply of therapeutic vaping devices and therapeutic vaping device accessories in Australia through pharmacy settings.

Note: The new exemptions are intended to be transitional in nature. The regulatory requirements will increase over time, such that therapeutic vaping devices and therapeutic vaping device accessories are expected to meet all applicable Class IIb medical device requirements in the future, including conformity assessment.

Essential Principles

The essential Principles consist of six general principles relating to the health and safety requirements for medical devices with a focus on making sure the benefits of devices outweigh the risks.

Medical devices supplied in Australia must comply with the Essential Principles to ensure that they are safe and perform as intended. Sponsors are required to monitor the safety and performance of medical device on an ongoing basis to ensure ongoing compliance with the Essential Principles.

It is the sponsor's responsibility to demonstrate compliance with the Essential Principles, hold appropriate evidence of compliance and provide such information to the TGA upon request.

The Essential Principles Checklist template may be accessed using the link: Essential Principles checklist (medical devices) | Therapeutic Goods Administration (TGA).

On occasion, there may be extenuating circumstances preventing compliance to one or more parts of the Essential Principles. In such circumstances, sponsors may request consent to import, supply or export medical devices, which do not meet an aspect of the Essential Principles, for a limited period of time and with an appropriate risk mitigation strategy. This request is considered by the Secretary on a case-by-case basis and the decision to either grant or to deny, is based on an assessment of the evidence provided, the timeframe for non-compliance to be rectified within and the risk to the public or end user during the period of non-compliance.

There are criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989*, for persons who import, supply or export medical devices that do not meet the Essential Principles for safety and performance.

Where consent to supply is granted for a medical device that is non-compliant with the Essential Principles, ongoing regulatory responsibilities of the sponsor remain including, but not limited to, undertaking recall action, and reporting of adverse events.

A Consent to Supply application form can be requested from the TGA by emailing mdconsent@health.gov.au. The Secretary will review your application only after receiving all

relevant information and payment of fees and decide whether to grant or deny the request for consent of the non-compliant devices.

There are fees associated with submitting a Consent to Supply Application to import or supply a vaping device or accessory that is not compliant. Details can be found on the Fees and charges webpage. Payment of the application fee can be made online; the options available are provided on the Payment options page.

MDSO (Medical Devices Standard Order)

The Medical Device Standards Order (*Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023)* provides the following options to demonstrate compliance:

1. quality management certification ISO 9001:2015 or ISO 13485:2016; or
2. comparable regulatory approval from the United States (US), European Union (EU) or United Kingdom (UK); or
3. evidence to demonstrate that consumer e-cigarette requirements of the United States (US), European Union (EU) or United Kingdom (UK) are met.

As mentioned above, the MDSO has limited application. Further, it will be subject to periodic updates to provide more specific regulatory requirements for therapeutic vaping devices and therapeutic vaping device accessories with the aim to create a compliance pathway on the level of Class IIb medical devices.

Quality management certification

A valid ISO 9001:2015 certificate or ISO13485:2016 certificate for the manufacture of a therapeutic vaping device or therapeutic vaping device accessory may be issued by one of the following bodies:

- an organisation that has been accredited by an Accreditation Body that is a member of the International Accreditation Forum (IAF), or
- a notified body designated through the European Union (EU) Medical Device Regulation (EU 2017/745) or EU Medical Device Directive 93/42/EEC, or
- an auditing organization (AO) recognized by Health Canada under section 32.1 of the Medical Devices Regulations (MDR), or
- an Australian Conformity Assessment Body (AU CAB).

Comparable regulatory approval

The minimum evidence to demonstrate compliance with regulatory requirements for vaping devices or vaping device accessories from the US, EU or UK are as follows:

- an approval letter or marketing authorisation order from the US FDA for the device, through any relevant scheme including the Pre-Market Approval (PMA), Humanitarian Device Exemption (HDE) or De Novo Premarket notification 510(k), or
- certification to European Union (EU) Medical Device Regulation (EU 2017/745) or EU Medical Device Directive 93/42/EEC (through a designated notified body of those regulations), or

- United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA) granted marketing authorisation through the UK Medical Device Regulations 2002 (as amended) or license under the Human Medicines Regulations 2012

Consumer e-cigarette authorisation or notification

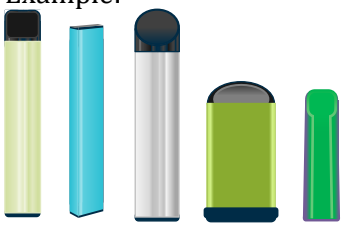
Consumer e-cigarette evidence may be obtained from any of the following countries:

- **United States (US) Food and Drug Administration (FDA)**
    - marketing authorisation order granted under the Premarket Tobacco Product Applications and Recordkeeping Requirements Rule (PMTA), and in accordance with the US FDA Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS), or
    - the product must be published on the FDA's Premarket Tobacco Product Marketing Granted Orders website (www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders), or
    - the company must provide to the TGA a copy of the written marketing order from the US FDA.
- **European Tobacco Products Directive (EUTPD)** – a valid notification under Article 20 of Directive 2014/40/EU and evidence of member state authorisation of the electronic cigarette (Article 20) product (e.g. a valid market authorisation letter or an acknowledgement from a member state of the EU). If required, this evidence must be translated into English.
- **United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA**) – a valid notification through the Tobacco and related Products Regulations (TRPR) and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020. The e-cigarette product must be listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

Regulation of vaping devices and vaping device accessories

Disposable vapes

From 1 January 2024, the importation of disposable vapes will be prohibited, subject to very limited exceptions as outlined in the table below. The ban will apply to disposable vapes irrespective of nicotine content or therapeutic claims.

Type of vaping device	Vaping substance or vaping substance accessory used with device or device accessory	Regulation by the TGA
Disposable, non-refillable vaping device *(e.g. single unit, disposable e-cigarettes)* Example: 	Containing therapeutic or non-therapeutic substances	From 1 January 2024, the importation of disposable vapes will be prohibited, subject to very limited exceptions such as use for scientific research or clinical trials.

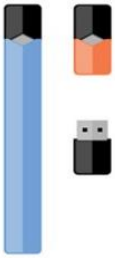
Refillable, reusable vaping devices and vaping device accessories

Refillable, reusable vaping devices and vaping device accessories when designed or intended to be used with vaping substances or vaping substance accessories are now regulated as follows.

Type of vaping device or vaping device accessory	Vaping substance or vaping substance accessory used with vaping device or vaping device accessory	Regulation by the TGA
Refillable, reusable vaping device or vaping device accessory Example: 	Designed or intended for use with a therapeutic vaping substance or therapeutic vaping substance accessory other than for smoking cessation or the management of nicotine dependence (e.g. medicinal cannabis)	**Standard medical device**[2] Device must be included in the ARTG as a medical device or imported and supplied under an approval or authority for medical devices (SAS B or AP). Compliance with Essential Principles (EPs), conformity assessment procedures and adverse event reporting requirements apply. Further information about these requirements can be found in the Australian regulatory guidelines for medical devices.

[2] See definition of ***medical device*** in section 41BD of the *Therapeutic Goods Act 1989*.

Type of vaping device or vaping device accessory	Vaping substance or vaping substance accessory used with vaping device or vaping device accessory	Regulation by the TGA
	Designed or intended for use with a therapeutic vaping substance or a therapeutic vaping substance accessory containing nicotine or zero-nicotine (and no other active ingredient) for smoking cessation or the management of nicotine dependence.	Compliance with Essential Principles (EPs) and adverse event reporting requirements in accordance with the new exemption. Further information about these requirements can be found in the Australian regulatory guidelines for medical devices. Sponsors must submit notification to the TGA prior to importing or supplying the vaping device or vaping device accessory in Australia (the latter following domestic manufacture)
	Designed or intended for use with a therapeutic vaping substance or a therapeutic vaping substance accessory containing nicotine or zero-nicotine (and no other active ingredient) for smoking cessation or the management of nicotine dependence, where the vaping device had previously been excluded from the operation of the *Therapeutic Goods Act 1989* prior to 1 January 2024.	Compliance with the Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (MDSO) Sponsors must submit notification to the TGA prior to importing or supplying the vaping device or vaping device accessory in Australia (the latter following domestic manufacture)

Type of vaping device or vaping device accessory	Vaping substance or vaping substance accessory used with vaping device or vaping device accessory	Regulation by the TGA
Therapeutic vaping pack containing two or more of therapeutic vaping goods including at least one therapeutic vaping device or therapeutic vaping device accessory 	Therapeutic vaping pack may or may not contain a therapeutic vaping substance or a therapeutic vaping substance accessory	All goods within a therapeutic vaping pack must meet requirements under TGO 110 or obtain consent to supply from the Secretary under section 14 or 14A of the *Therapeutic Goods Act 1989* (consent is only granted in exceptional circumstances). TGO 110 requires each therapeutic vaping device or therapeutic vaping device accessory in a therapeutic vaping pack to meet the essential principles or the requirements of the MDSO (where applicable). In practice, this means that the same quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories irrespective of whether those goods are supplied separately or within a therapeutic vaping pack. Sponsors must submit notification to the TGA prior to importing or supplying each vaping device or vaping device accessory in Australia (the latter following domestic manufacture)

Type of vaping device or vaping device accessory	Vaping substance or vaping substance accessory used with vaping device or vaping device accessory	Regulation by the TGA
Therapeutic vaping kits containing therapeutic vaping substance accessories with device components	Therapeutic vaping substance accessories contain both device and substance components	Kits that contain a therapeutic vaping substance or vaping substance accessory must meet requirements under TGO 110 or obtain consent to supply from the Secretary under section 14 or 14A of the *Therapeutic Goods Act 1989* (consent is only granted in exceptional circumstances). Each vaping substance accessory in a therapeutic vaping kit must meet requirements under the essential principles or the MDSO, where applicable, for the device component of the accessory in addition to the requirements in the TGO 110 relating to the substance component. Sponsors must submit notification to the TGA prior to importing or supplying the vaping substance accessory in Australia (the latter following domestic manufacture)

Appendix A: References

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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

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Reference/Publication # D23-4683113