Australian Government
Department of Health
Therapeutic Goods Administration

Nicotine vaping products and vaping devices

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

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TGA Health Safety Regulation

Contents

About this guidance

Nicotine vaping products are finished products that contain nicotine (in base and/or salt form(s)) in solution that are intended to be vaporised and inhaled using a vaping device (e.g. an e-cigarette or other electronic nicotine delivery system). These products include nicotine vape liquids, e-liquids and e-juices and nicotine in disposable e-cigarettes. 'Heat-not-burn' and other tobacco products are **not** nicotine vaping products and are not covered by this guidance.

There are currently no nicotine vaping products registered in the Australian Register of Therapeutic Goods (ARTG). Consumers can legally access 'unapproved' nicotine vaping products (i.e. products that are not registered in the ARTG) with a valid prescription via established access pathways; namely, the Authorised Prescriber Scheme (APS), the Special Access Scheme – Category B (SAS), the Personal Importation Scheme or as part of a clinical trial. Domestic access may be subject to state and territory requirements.

The TGA does not assess the safety, quality and efficacy of 'unapproved' nicotine vaping products nor of Export Only products listed on the ARTG (together, unregistered nicotine vaping products). The long-term health risks of nicotine vaping products are still unclear and evidence of their potential effectiveness for smoking cessation is currently mixed, with more reliable, large-scale studies required (Hartmann-Boyce et al. 2021, Patnode et al. 2021, Pound et al. 2021, SCHEER 2021, Wang et al. 2021, Zhang et al. 2021).[1]

There are many nicotine replacement therapies (e.g. nicotine patches, gum, lozenges, mouth sprays and inhalators) in the ARTG that have been assessed by the TGA for safety, quality and efficacy.

The purpose of this guidance is to help health practitioners, consumers, importers and other sponsors, wholesalers and manufacturers to understand the minimum safety and quality requirements for unregistered nicotine vaping products and our role in regulating vaping devices. This guidance includes:

- general information about *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* (TGO 110)
- information on the requirements for unregistered nicotine vaping products under TGO 110
- information about other standards and requirements applicable to nicotine vaping products
- an overview on the TGA's role in regulating vaping devices.

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 of the legal requirements are met.

If you require clarification of a particular requirement, you can email info@tga.gov.au.

[1] Full references are provided in Appendix A to this guidance.

What this guidance does not cover

This guidance does not contain clinical guidelines for health practitioners or make recommendations about prescribing or usage of nicotine vaping products or vaping devices (for example, dosage regimes). Health practitioners considering prescribing or dispensing nicotine vaping products should also have regard to any clinical guidelines relevant to their practice, such as the RACGP smoking cessation guidelines and any relevant guidelines published by the Pharmaceutical Society of Australia and the Royal Australian and New Zealand College of Psychiatrists.

Advertising nicotine vaping products

To assist industry and health practitioners to understand their obligations in relation to the advertising of nicotine vaping products, we have published guidance on Advertising nicotine e-cigarettes and liquid nicotine to the Australian public .

The TGO 110 product standard

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (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 nicotine vaping products that are not registered in the ARTG and that are imported into, supplied in, or exported from Australia. All nicotine vaping products currently available in Australia are unregistered nicotine vaping products.

Commencement

TGO 110 comes into effect on 1 October 2021.

Objectives of TGO 110

TGO 110 aims to:

- help health practitioners and consumers access accurate information about what is in the unregistered nicotine vaping product the person is inhaling
- stop substances with known, demonstrable health risks associated with inhalation, and active ingredients not required for smoking cessation, from being added as ingredients in these products, and
- minimise the risks of and associated with accidental exposure to and/or ingestion of nicotine vaping products, particularly by children, which can be fatal.

There are risks associated with the use of any unregistered nicotine vaping products, particularly as these products have not been assessed by the TGA for quality, safety and efficacy. TGO 110 requirements cannot address all questions and concerns about these products. In particular, the long-term health risks of nicotine vaping products are still unclear and evidence of their potential effectiveness for smoking cessation is currently mixed, with more reliable, large-scale studies required (Hartmann-Boyce et al. 2021, Patnode et al. 2021, Pound et al. 2021, SCHEER 2021, Wang et al. 2021, Zhang et al. 2021).

Nicotine vaping products captured by TGO 110

The requirements in TGO 110 only apply to unregistered nicotine vaping products imported into, supplied in, or exported from, Australia. Nicotine vaping products are finished products (i.e. those that do not require further manufacture prior to supply to the consumer) containing nicotine in solution that are intended to be vaporised and inhaled using a vaping device. They include:

- both nicotine base products (i.e. products where the nicotine in solution is in base form) and nicotine salt products (i.e. products where the nicotine in solution is in salt form), and
- both products that are ready for immediate use by consumers (i.e. where the nicotine is 'pre-mixed' with the flavouring) **and** products that are designed for consumers to mix with flavourings/other diluents at home prior to use.

TGO 110 applies to the following types of nicotine vaping products:

- ✓ products purchased in Australia via the Authorised Prescriber Scheme (APS) or Special Access Scheme (SAS)
- ✓ extemporaneously compounded products
- ✓ products supplied as part of a clinical trial
- ✓ products listed in the ARTG as Export Only products (these are not registered products and have not been assessed by the TGA).

TGO 110 applies **in part** to nicotine vaping products imported via the Personal Importation Scheme (including where the prescription for the product was issued under the APS or SAS). See the Personal Importation Scheme section of this guidance for further information.

TGO 110 **does not** apply to:

- ✘ any nicotine vaping products that may be registered in the ARTG in the future. The safety, quality and efficacy of registered products are evaluated as part of the TGA's general marketing approval process
- ✘ nicotine vaping products carried by travellers to Australia in accordance with the Traveller's Exemption or carried by visiting medical team accompanying someone with a critical illness, visiting international sports teams, by visiting military forces, in the medical supplies of a visiting ship and by visiting Government officials in accordance with *Therapeutic Goods Regulations 1990*
- ✘ nicotine replacement therapies containing nicotine that are not classified as Schedule 4 prescription only products, such as patches, gum, lozenges, mouth spray and inhalators
- ✘ other unapproved products containing nicotine, such as chewing tobacco, snuff and 'heat-not-burn' tobacco products
- ✘ vaping products that do not contain nicotine, e.g. non-nicotine flavour refills that can be mixed with nicotine
- ✘ starting materials that are intended to be used in the further manufacture of nicotine vaping products, such as ingredients for use in the commercial manufacture or extemporaneous compounding of nicotine vaping products.

Section 6 of TGO 110 defines what products are captured by the standard.

Overview of TGO 110 requirements

TGO 110 sets out requirements for the information that must be stated on the "label" of unregistered nicotine vaping products (either on the container, primary pack or in an information sheet provided with the product), the packaging of the products, the ingredients in the products and the records that must be maintained by Australian sponsors of the products.

There is no offence or civil penalty in the Act for importing a product without TGO 110 compliant packaging or labelling. This means that:

- Australian sponsors can import products for supply in Australia (e.g. via Australian retail or online pharmacies) 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 sponsor supplies it to a wholesaler, pharmacy or any other person,
- Products imported directly by consumers from overseas suppliers via the Personal Importation Scheme are not subject to the packaging and labelling requirements in TGO 110, although people using the Personal Importation Scheme are still encouraged to check if their product has compliant labelling and packaging. These products are also exempt from the record-keeping requirements in TGO 110. The TGO 110 ingredient requirements will continue to apply to these products.

The Personal Importation Scheme section of this guidance provides further information about the application of TGO 110 to the scheme and includes a list of questions health practitioners and consumers might want to ask overseas suppliers prior to prescribing or purchasing a product via the scheme.

An unregistered nicotine vaping product that is subject to, and compliant with, a Premarket Tobacco Product (PMTA) marketing order issued by the US Food and Drug Administration (FDA) it 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.

Application of TGO 110 requirements

The table below summarises the application of the TGO 110 requirements to products that are supplied, or are imported for the purpose of supply, in Australia and those imported via the Personal Importation Scheme. Further information about each requirement is available in this guidance via the hyperlinks below.

TGO 110 requirement	Products supplied in Australia (including products imported for supply in Australia) *	Products imported via Personal Importation Scheme
Labelling requirements (information to be provided on container, primary pack or in information sheet)		
Ingredient list	✓	✘
Nicotine concentration (mg/mL)	✓	✘
Warning statements	✓	✘

TGO 110 requirement	Products supplied in Australia (including products imported for supply in Australia) *	Products imported via Personal Importation Scheme
Packaging requirements		
Child-resistant packaging	✓ (except FDA PMTA marketing order compliant products)	✘
Ingredient requirements		
Nicotine (base and/or salt form(s)) the only active ingredient	✓ (except FDA PMTA marketing order compliant products)	✓ (except FDA PMTA marketing order compliant products)
Nicotine concentration/ content within 90 – 110% of what (if anything) is stated on the label	✓ (except FDA PMTA marketing order compliant products)	✓ (except FDA PMTA marketing order compliant products)
Nicotine (or equivalent base form) concentration ≤ 100 mg/mL	✓ (except FDA PMTA marketing order compliant products)	✓ (except FDA PMTA marketing order compliant products)
No prohibited ingredients added to product	✓ (except FDA PMTA marketing order compliant products)	✓ (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.

Personal Importation Scheme

The Personal Importation Scheme provided for by Item 1 of Schedule 5 to the *Therapeutic Goods Regulations 1990* allows a person to import up to 3 months' worth of an unregistered nicotine vaping product for themselves or an immediate family member with a valid prescription (which may include a prescription issued under the APS or SAS). This includes where a person fills their prescription online using an overseas supplier.

Requirements that apply

Nicotine vaping products that are imported via the Personal Importation Scheme **must meet** the Ingredients requirements in TGO 110, namely:

- the prohibitions on products containing active ingredients other than nicotine and specified substances with known health risks associated with inhalation being added as ingredients to these products
- the 100 mg/mL limit on the nicotine base form concentration (for nicotine base products) or equivalent base form concentration (for nicotine salt products), and
- the requirement for nicotine (base form, salt form and/or equivalent base form) concentration or content to be within +/- 10% of that stated on the label or in any information sheet provided with the product. As outlined below, the TGO 110 labelling requirements (including the nicotine concentration labelling requirements) do not apply to products imported via the Personal Importation Scheme. However, because this is an ingredient requirement (not a labelling requirement), it will still apply to products imported via the Personal Importation Scheme if they are labelled with, or come with an information sheet that includes, a statement of nicotine (base form, salt form and/or equivalent base form) concentration or content.

If we have reasonable grounds for suspecting that a product does not comply with these requirements, the product may be intercepted and not released from Customs.

Requirements that do not apply

The labelling, packaging and record-keeping requirements in TGO 110 do **not** apply to unregistered nicotine vaping products imported via the Personal Importation Scheme. This is because there is no offence or civil penalty in the Act for importing a product without TGO-compliant packaging or labelling. If you use the Personal Importation Scheme you are still encouraged to source products that have the ingredient and nicotine concentration information, warning statements and child-resistant packaging (CRP) required under TGO 110.

The packaging and labelling (and all other) requirements in TGO 110 **do apply** to products supplied domestically (e.g. through a community pharmacy), including those accessed via the APS or SAS.

Health practitioners and consumers using the Personal Importation Scheme

Before prescribing for, or purchasing a product via, the Personal Importation Scheme, you are encouraged to confirm if the product you are considering complies with TGO 110 and otherwise comes with appropriate information and packaging and limited levels of contaminants.

Some questions you might like to ask the overseas supplier of the product are:

- Has the FDA (in the US) issued a PMTA (or 'Premarket Tobacco Product') marketing order for the product and does the product comply with all the requirements in that order? You can also check the list of PMTA marketing orders on the FDA's website.
- If the FDA has **not** issued a PMTA marketing order for the product, or the product does not comply with all the requirements in that order:
  - Is nicotine (in base and/or salt form(s)) the only active ingredient in the product?
  - Are any of the ingredients added to the product on the prohibited ingredients list (see the table in the Prohibited ingredients section of this guidance)? You could also check this yourself if the supplier provides you with a full ingredient list for the product (including the ingredients used in any flavours).

  - Are there manufacturing controls to make sure that the nicotine content/concentration of the product is within +/- 10% of what is stated on the label or in the information provided with the product?
  - Is the nicotine concentration in the product no more than 100 mg/mL (for nicotine salt products, this refers to the equivalent base form concentration)?
  - Are any of the contaminants in the table in the Contaminants section of this guidance present in the product at a concentration above 10 parts per million (ppm)? Have tests been done on the level of these contaminants in the product's aerosol (i.e. its mist/ emission)?
  - Is the product in child-resistant packaging?
- Will information be provided about the ingredients and nicotine concentration of the product and are there warnings statements on the product (particularly about keeping the product away from children and avoiding contact with the eyes/skin)?

Record-keeping obligations for Australian sponsors

Australian sponsors of nicotine vaping products must maintain records with sufficient information to demonstrate that those products conform to TGO 110 (section 10 of TGO 110).

Who is an Australian sponsor

The sponsor of a nicotine vaping product is the person who:

- imports, exports, or manufactures (for supply in Australia), the product, or
- arranges for another person to do any of those things in relation to the product.

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

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

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

Types of records that must be kept

The types of records sponsors are expected to maintain for the purpose of 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, and
  - no prohibited ingredients have been 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:

- products that are imported via the Personal Importation Scheme
- products for which the FDA has issued a PMTA marketing order that comply with all of the requirements specified in that order.

Labelling of nicotine vaping products

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

Unregistered nicotine vaping products must be 'labelled' with the information set out in Schedule 2 to TGO 110 and described below (subsection 8(1) of TGO 110), being an ingredient list, statement of nicotine concentration and three specific warning statements.

To comply with the labelling requirement, each piece of information must be either:

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

(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 of the information **must** be in English, legible, visible (and not obscured) and durable (subsection 8(3) of TGO 110).

Manufacturers and sponsors may choose to provide additional product or safety information provided that it is **not** promotional information and does not breach the advertising restrictions applicable to nicotine vaping products. Further information is included in the Advertising nicotine vaping products guidance.

Any such additional information may also be 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

Unregistered nicotine vaping products 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. "cherry flavour"), or the name of each ingredient in the flavour, and
- the names of all of other excipient ingredients

(Item 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

Unregistered nicotine vaping products 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,

  (Item 2 of Schedule 2 to TGO 110).

The equivalent base form concentration of a nicotine salt product will depend on which salt form(s) of nicotine are 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

Unregistered nicotine vaping products must be labelled with the following warning statements:

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

  (Item 3 of Schedule 2 to TGO 110).

TGO 110 requirements can be complied with including these statements on or attached to the container or primary pack of, or in information supplied with, the product.

However, state and territory poisons legislation requires unregistered nicotine products supplied within Australia to include these statements on the primary pack and immediate container of the product, unless an exemption applies. Domestically supplied products are required to meet the requirements of both TGO 110 and state and territory poisons legislation.

Including these statements on the primary pack and immediate container will mean that the requirements of both TGO 110 and state and territory poisons legislation are complied with.

Product packaging and closures

Child-resistant packaging (CRP)

Accidental ingestion of, or exposure (such as through the skin or eyes) to, nicotine vaping products can have toxic, and sometimes severe, effects (SCHEER 2021). Child fatalities, including at least one in Australia, have occurred following ingestion of nicotine vaping products (SCHEER 2021). CRP is important for minimising the risk of accidental exposure to and/or ingestion of nicotine vaping products, particularly by children, although risks still remain.

When prescribing or dispensing nicotine vaping products, 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 nicotine vaping products (where relevant) and/or if nicotine vaping products are used in vaping devices without child-resistant safety features (including where a child is able to suck on the vaping device). Consumers 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 or ingested a nicotine vaping product.

Section 9 of TGO 110 provides that nicotine vaping products must have CRP meeting the requirements set out in sections 8, 9 and 10 of *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines* (**TGO 95**) (excluding the requirement in subsection 9(6) of TGO 95 to provide directions for opening/closing), unless they are:

- products packaged for supply within the UK, the EU, Canada and the US which are packaged in accordance with CRP requirements imposed in that country
- if and when the recently proposed CRP requirements are introduced in NZ, products packaged for supply within NZ which are packaged in accordance with those CRP requirements, or
- products in relation to which the FDA has issued a PMTA marketing order that comply with all of the requirements specified in that order. It is expected that these requirements will include some form of CRP.

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 nicotine vaping products that may be registered in the ARTG in the future following TGA evaluation.

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

No other mandatory container requirements

Tamper-evident packaging

The purpose of tamper-evident packaging is to alert consumers of possible safety concerns before they purchase or use goods. TGO 110 does not include any tamper-evident requirements for unregistered nicotine vaping products.

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 therapeutic goods supplied in Australia and increases the likelihood that consumers can identify when a product has been tampered with.

Suppliers of nicotine vaping products 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 so health practitioners can prescribe the right product for their patient.

People will only be able to purchase the amount of the product they have been prescribed. People using the Personal Importation Scheme can only import up to 3 months' supply per importation (and no more than 15 months' supply in a 12 month period).

Ingredients in nicotine vaping products

TGO 110 sets out a number of requirements relating to the active and excipient ingredients used in unregistered nicotine vaping products. These requirements **do** apply to products imported via the Personal Importation Scheme, but cannot be enforced against the overseas suppliers of those products.

Products for which the FDA has issued a PMTA marketing order, and that comply with all of the requirements in that order, do **not** need to comply with the ingredient requirements in TGO 110. 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 unregistered nicotine vaping products - these products **must not** contain any other active ingredients (subsection 7(1) of TGO 110).

It is not appropriate to add other active ingredients to nicotine vaping products as they would not be needed to assist in the cessation of smoking or nicotine addiction.

Actual vs labelled nicotine concentration/content

The actual nicotine base form, nicotine salt and/or equivalent base form concentration or content in the nicotine vaping product must be within 90-110% of that stated:

- on or attached to the container or primary pack of the product (including on an over-sticker), or
- in information provided with the product label or packaging

(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 via 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

Unregistered vaping products 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).

No one will be able to import, export or supply in Australia a nicotine vaping product that is ready for supply to consumers (including products that are designed for consumers to mix with flavourings/other diluents at home prior to use) exceeding this concentration limit.

Consumers 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 what 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

Accidental ingestion of, or exposure (such as through the skin or eyes) to, nicotine vaping products can have toxic, and sometimes severe, effects (SCHEER 2021). Child fatalities, including at least one in Australia, have occurred following ingestion of nicotine vaping products (SCHEER 2021). Higher concentration nicotine vaping products carry greater risks of poisoning having severe effects (SCHEER 2021).

In addition, higher concentration products (including 100 mg/mL products) must be mixed by consumers with flavourings/other diluents (which are not covered by TGO 110) at home prior to use. 'At-home' mixing carries additional risks of mixing the wrong concentration and/or of accidental contamination. Accidental exposure may also occur during 'at-home' mixing.

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 nicotine vaping products are propylene glycol, glycerine/glycerol and (possibly) flavouring chemicals.

Prohibited ingredients

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

This does not mean that all other ingredients in unregistered nicotine vaping products are safe

There is limited evidence available about the safety of inhaling the ingredients (including flavourings) used in nicotine products (SCHEER 2021). Just because an ingredient is safe to consume 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 unregistered nicotine vaping products.

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 nicotine vaping products carry demonstrable health risks associated with inhalation.

Ingredient	Comments
acetoin	• used in foods to create buttery or creamy flavour • associated with irreversible lung damage (NICNAS 2019) • can be a source of diacetyl in nicotine vaping products (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 flavour • 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 nicotine vaping products 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 nicotine vaping products in Canada and the UK
ethylene glycol	• respiratory irritation observed in humans and exposure linked to renal toxicity (Fowles et al. 2017; ATSDR 2010), presence in vaping products associated with toxicological hazards (Hutzler et al. 2014) • cannot be used as a diluent in consumer nicotine vaping products in Canada and the UK

Ingredient	Comments
Pentane-2,3-dione (2,3-pentanedione or acetylpropionyl)	• used in foods to create buttery or creamy flavour • 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 nicotine vaping products 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 unregistered nicotine vaping products. Provided they have not been added to the product as an ingredient, these 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 reasonable steps to minimise levels of these substances in their products as contaminants or as a result of the manufacturing process to the maximum extent possible. If one or more of these substances is present in the product at a concentration above 10 ppm (parts per million), we will assume the substance has been added to the product as an ingredient, which is prohibited under TGO 110, rather than it being present as a contaminant or by-product of the manufacturing process.

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

Flavoured nicotine vaping products

If one or more of the prohibited ingredients listed above is added as an ingredient in a flavour, TGO 110 prohibits the use of that flavour in unregistered nicotine vaping products. TGO 110 does not otherwise prohibit or restrict the flavours that may be added to these products.

This does not mean that all other flavours are safe. Please see the warning in the Prohibited ingredients section of this guidance about the limited inhalation safety evidence available for ingredients (including flavourings) in unregistered nicotine vaping products.

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

Contaminants and product quality

Default standards

The *Therapeutic Goods (Exempt Monographs) Determination 2021* exempts unregistered nicotine vaping products 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. Nicotine vaping products that seek to be registered on the ARTG will still be expected to comply with all applicable default standards.

Microbiological standards

Unregistered nicotine vaping products 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 do not apply to unregistered nicotine vaping products that are listed in the ARTG as Export Only products or to products imported via the Personal importation Scheme.

Contaminants

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

Some potential contaminants identified as having inhalation risks that may be present in nicotine vaping products and/or their 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 nicotine vaping products or their aerosols. Australian sponsors are encouraged to take reasonable steps to minimise the levels of these contaminants in their products and their 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 consumers prescribing for and using 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).

There is currently insufficient information to specify a 'safe' level of these contaminants and we would therefore suggest adopting a cut-off for each contaminant in the nicotine vaping product itself of no more than 10 ppm. This is consistent with the threshold for scheduling of Schedule 1 – 6 in substances in the current Poisons Standard (see paragraph 1(2)(j) of Part 1 of the current Poisons Standard). The level of the contaminant in the nicotine vaping product 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 consumers and health practitioners to report any suspected side effects related to unregistered nicotine vaping products.

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 unregistered nicotine vaping products 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 unregistered nicotine vaping products is available on our website.

Vaping devices

This section is intended to clarify the TGA's role in regulating different types of vaping devices.

Vaping devices are electronic devices used to heat vaping products to produce an aerosol (i.e. mist or emission) that can be inhaled. Vaping devices include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes, vape pens and other electronic nicotine delivery systems ('ENDs').

There are a broad variety of vaping devices. These include:

- devices that users can refill multiple times, often with various vaping products sold separately to the device, including what may be thought of as "traditional" vaping devices
- entirely disposable devices (e.g. disposable e-cigarettes) that are pre-filled with a vaping product, cannot be refilled and are disposed of once the battery or vaping product runs out,
- non-refillable pods that contain heating elements (typically a coil) and a vaping product (which may be soaked in a material wick wrapped around the coil) and are used with a rechargeable/reusable battery.

Disposable, non-refillable devices (including both entirely disposable devices, such as disposable e-cigarettes, and non-refillable, disposable pods that contain heating elements) are **not** medical devices for the purpose of the Act and are therefore not regulated by the TGA.[2]

[2] Device either does not meet the definition of 'therapeutic good' in the Act, is an excluded good under the *Therapeutic Goods (Excluded Goods) Determination 2018* and/or declared not to be a medical device under the Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010.

Refillable devices:

- **are** medical devices for the purpose of the Act if they are intended to be used **exclusively with 'medicinal vaping products'** (i.e. vaping products that contain nicotine (in salt and/or base form(s)) and/or another active ingredient, such as cannabis),
- are **not** medical devices for the purpose of the Act if they are intended to be used only with 'non-medicinal vaping products' (i.e. vaping products that contain no active ingredients, such as flavour only products), ***or*** are intended to be used with both non-medicinal and medicinal vaping products.[3]

In each case, the relevant intention is that of the person in whose name the device is, or is to be, supplied.

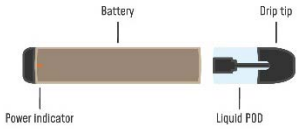
Devices not regulated by the TGA

The following devices are **not** medical devices for the purpose of the Act – and are therefore not regulated by the TGA - when used with, or intended to be used with, the vaping products specified in the table. These devices are considered to be consumer goods. The Australian Competition and Consumer Commission (ACCC) and state and territory consumer agencies regulate product safety issues with these devices.

Medicinal vaping products used in these devices will still be regulated by the TGA under the medicines framework. In particular, **unregistered nicotine vaping products used or contained in these devices are still subject to TGO 110.**

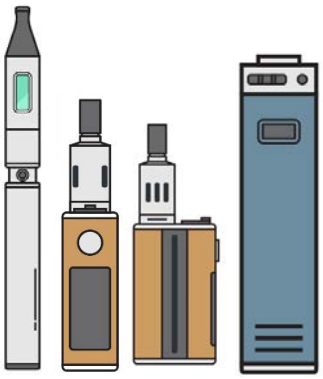
Type of device	Vaping product(s) used with device
"Traditional" vaping devices (COMMON) *Refillable, reusable device for use. Vaping product often sold separately to the device.* Examples: 	• Device intended to be used only with non-medicinal (e.g. flavour only) vaping products.[4] • Device intended to be used with non-medicinal vaping products and one or more medicinal vaping products.[5]

[3] Device does not meet the definition of 'therapeutic good' in the Act or is an excluded good under the *Therapeutic Goods (Excluded Goods) Determination 2018.*
[4] Device does not meet the definition of 'therapeutic good' in the Act or is an excluded good under the *Therapeutic Goods (Excluded Goods) Determination 2018.*
[5] Device does not meet the definition of 'therapeutic good' in the Act or is an excluded good under the *Therapeutic Goods (Excluded Goods) Determination 2018.*

Type of device	Vaping product(s) used with device
Disposable, non-refillable devices (INCREASINGLY AVAILABLE) *Includes (1) devices that are entirely disposable (e.g. disposable e-cigarettes that are becoming increasingly popular with high school students)* ***and*** *(2) disposable pods that contain the heating elements and are used with a reusable battery.*[6] Example:  * Provided pod is non-refillable and has heating elements.	• Device contains non-medicinal vaping product.[7] • Device contains medicinal vaping product.[8] The medicinal vaping product will be regulated by the TGA and, if an application was made to register the medicinal vaping product on the ARTG, the TGA would take the device elements into consideration in assessing whether to register the vaping product.

Devices regulated by the TGA

The following devices **are** medical devices – and therefore regulated by the TGA - when intended to be used with the vaping products specified. The vaping products used in these devices are separately regulated by the TGA as medicines.

Type of device	Vaping product(s) used with device	How device regulated by the TGA
Refillable device for use only with medicinal vaping products (UNCOMMON) Example: 	Device intended to be used only with: • a nicotine vaping product that is not registered in the ARTG (or registered in the ARTG other than for smoking cessation); and/or • another medicinal vaping product (e.g. cannabis) (whether in the ARTG or not).	**Standard medical device**[9] Device must be included in the ARTG as a medical device or accessed via one of the pathways for unapproved medical devices. The 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.

[6] Where the heating elements are contained in the pod, the pod *is* the device and the device is therefore disposable and non-refillable (even if it clips into a reusable battery).
[7] Device does not meet the definition of 'therapeutic good' in the Act or is an excluded good under the *Therapeutic Goods (Excluded Goods) Determination 2018.*
[8] Device declared not to be a medical device under the Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010.
[9] See definition of 'medical device' in section 41BD of the Act.

Type of device	Vaping product(s) used with device	How device regulated by the TGA
 * Provided device is intended, by the person in whose name it is or is to be supplied, to be used exclusively with a medicinal vaping product.	Device intended to be used only with a nicotine vaping product that is registered in the ARTG for smoking cessation.	**Exempt medical device**[10] Device is a medical device but does **not** need to be included in ARTG or accessed via one of the pathways for unapproved medical devices. The EPs, conformity assessment procedures and adverse reporting requirements **do** apply. Further information on these requirements can be found in the Australian regulatory guidelines for medical devices.

[10] Item 2.11A of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002.*

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Version history

Version	Description of change	Author	Effective date
V1.0	Original publication – Draft guidance	Scientific Evaluation Branch/Regulatory and 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 and Legal Services Branch	June 2021
V1.2	Update to the information on the Advertising Guidance	Scientific Evaluation Branch/Regulatory and Legal Services Branch	July 2021

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