



**Comment on the Therapeutic Goods Administration's Consultation
Paper on *TGO 110 – Standard for Vaporiser Nicotine***

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About the submitter

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Declaration

Dr Jongenelis does not have any direct or indirect links to, or receive funding from, the tobacco and/or e-cigarette industry.

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About this submission

Responses to each of the questions posed in *TGO 110 – Standard for Vaporiser Nicotine* are presented within the paper, which has been appended to this cover material. Responses are provided in *red italics*.



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Department of Health
Therapeutic Goods Administration

TGO 110 – Standard for Vaporiser Nicotine

Consultation paper

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TGA Health Safety
Regulation



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Overview

The Therapeutic Goods Administration (TGA) is seeking comments on a proposed standard for vaporiser nicotine products.

Vaporiser nicotine products are nicotine-containing products intended to be used in vaping devices such as e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs). This includes vape liquids, e-liquids and e-juices that contain nicotine and/or nicotine salts. This does not include other nicotine replacement therapies (NRTs) containing nicotine, such as patches, gum, lozenges, mouth spray and inhalators nor nicotine-containing products that are not intended for use in ENDs, such as chewing tobacco and snuff.

This standard relates only to unapproved goods – that is, medicines that have not been approved by the TGA and are not registered in the Australian Register of Therapeutic Goods (ARTG). While it is anticipated that a number of vaporiser nicotine products may seek approval by the TGA as medicines in the coming years, it is also anticipated that there will be a significant number of prescriptions written for unapproved goods for smoking cessation.

The proposed standard is in the form of a Therapeutic Goods Order (a TGO) and would be TGO 110. TGOs are legal standards made under section 10 of the *Therapeutic Goods Act 1989* (Act) which specify safety and quality rules for medicines imported into, exported from or supplied in Australia. TGOs can apply to approved or unapproved products, or both, and may be limited to a certain type of medicine. TGOs cannot specify requirements for vaping devices. TGOs are made by the Minister or their delegate.

Feedback is sought on a range of potential requirements that could be included in TGO 110.

The TGA's proposed options – which are subject to feedback in the current public consultation - are set out in the draft Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021 (draft TGO 110). The draft TGO is provided to show you how potential requirements would be documented in a legal instrument.

Scope

This consultation covers the following topics:

- Part 1: Proposed scope of TGO 110.
- Part 2: Potential requirements for unapproved vaporiser nicotine products. This covers labelling, ingredients, packaging, nicotine concentration and container volume.
- Part 3: Related matters. This covers topics related to vaporiser nicotine products, but covered by TGO 110; specifically, default standards (pharmacopoeia) and nicotine purity, and compounding.

The following topics are **not within the scope** of this consultation:

- Vaporiser products that do **not** contain nicotine, which will **not** be covered by TGO 110.
- Clinical guidelines and recommended dosage regimes for nicotine-containing products for smoking cessation.
- Laws about access to vaporiser nicotine products.

Providing feedback

We invite you to provide your feedback by completing our online survey on the [Department of Health's Consultation Hub](#).

All responses will be published on the TGA website, unless you specifically request that your response be kept confidential.

What happens next

We will review all feedback received and, if appropriate, revise the requirements in draft TGO 110 before providing it to the Minister or his delegate for approval. We propose to finalise and publish TGO 110 in April or May 2021 to allow enough time for stakeholders to become familiar with the requirements, and to organise procurement of compliant products, before the requirements come into effect on 1 October 2021.

Background

Regulation of vaporiser nicotine

The TGA recently announced a [decision](#) that, from 1 October 2021, consumers will require a doctor's prescription to import vaporiser nicotine into Australia, regardless of whether the product is for therapeutic or other use (Scheduling decision). This aligns with current State and Territory laws, which prohibit the supply of nicotine-containing e-cigarettes without a valid doctor's prescription.

The Scheduling decision balances the importance of needing to prevent youth and non-nicotine users from taking up use of vaporiser nicotine while allowing current smokers to access these products for smoking cessation on their doctor's advice.

In contrast, some countries, including the United Kingdom (UK), Member States of the European Union (EU), Canada, the United States (US) and New Zealand (NZ), allow vaporiser nicotine products to be sold as consumer goods without a doctor's prescription. Some of these countries have implemented regulatory measures, such as nicotine concentration limits in the UK, the EU and Canada, aimed at reducing youth and non-nicotine user uptake of vaporiser nicotine.

Accessing unapproved vaporiser nicotine products in Australia

There are currently no TGA-approved vaporiser nicotine products registered in the ARTG. Subject to State and Territory laws, unapproved vaporiser nicotine products can be accessed on prescription via the following established access pathways for unapproved medicines:

- [Authorised Prescriber Scheme](#) (APS).
- [Special Access Scheme](#) (SAS).
- [Personal Importation Scheme](#).
- [Clinical Trial Notification and Approval Schemes](#).

More information about accessing unapproved products through these pathways is available on the TGA website at [Accessing unapproved products](#).

TGO for unapproved vaporiser nicotine products

Because there are currently no TGA-approved vaporiser nicotine products, the TGA delegate who made the Scheduling decision also recommended the development of a standard setting out minimum quality and safety requirements for unapproved vaporiser nicotine products. We propose that the Minister or his delegate make a TGO for unapproved vaporiser nicotine products under section 10 of the Act to give effect to this recommendation.

In the consultation relating to the recent Scheduling decision, a range of stakeholders expressed support for the development of a standard for unapproved vaporiser nicotine products and/or the introduction of consistent requirements for things such as labelling and packaging. This included individual consumers, certain e-cigarette industry and vaping representatives as well as both government and non-government organisations such as the Alcohol and Drug Foundation, Victorian and NSW Poisons Information centres, the National Health and Medical Research Council, the Victorian Agency for Health Information's independent Consultative Council on Obstetric and Paediatric Mortality and Morbidity and Queensland Health.

What TGO 110 can and cannot do

As a TGO made under section 10 of the Act, TGO 110 can provide minimum safety and quality requirements for unapproved vaporiser nicotine products, such as requirements relating to labelling, ingredients and packaging.

TGO 110 **cannot** legally specify requirements relating to any of the following matters:

- ✘ Dosage regimes.
- ✘ Vaporiser products that do not contain nicotine and are not otherwise represented as being, or likely to be taken to be, for therapeutic use (e.g. non-nicotine flavoured vaporiser products).
- ✘ The vaping devices themselves (e.g. e-cigarettes, e-cigars and other ENDS).

The TGA does not assess the quality, safety and efficacy of individual unapproved medicines accessed via the established access pathways described above. The responsibility to ensure quality and safety remains with those sourcing and supplying the products.

Vaping devices

The Act only applies to vaping devices that are intended to be used exclusively to vaporise and administer a medicine, such as vaporiser nicotine (see Item 16 of Schedule 1 of the *Therapeutic Goods (Excluded Goods) Determination 2018*). We do **not** regulate any other vaping devices.

In summary, vaping devices that are regulated by the TGA must be approved by the TGA and included in the ARTG **unless** they fall into one of the following categories:

- Devices intended, by the person under whose name the device is or is to be supplied, to be used **exclusively** with a vaporiser nicotine product that contains no other active ingredients and is registered in the ARTG for smoking cessation.
- Devices imported or supplied via one of the established pathways for accessing unapproved medical devices, such as the APS, SAS, Personal Importation Scheme or through the Clinical Trial Approval or Notification Scheme.

As there are no vaping devices or vaporiser nicotine products currently included in the ARTG, all vaping devices that are subject to the Act must currently be imported or supplied via one of the access pathways for unapproved medical devices described above.

These vaping devices must comply with the Essential Principles set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*, unless the TGA has consented to the non-compliance. However, the TGA does **not** assess unapproved devices.



TGO 110 cannot specify quality or safety requirements for vaping devices.

Vaporiser nicotine products from other countries

Products imported under the Personal Importation Scheme and TGO110

We strongly encourage individuals who import unapproved vaporiser nicotine products under the Personal Importation Scheme to check whether the products they are considering meet the requirements in TGO 110 before purchasing. This includes where the product has been prescribed under SAS or APS but is imported via the Personal Importation Scheme rather than supplied in Australia (e.g. dispensed by a pharmacist).

The TGA cannot take action to enforce TGO 110 against overseas manufacturers and suppliers of unapproved vaporiser nicotine products imported via the Personal Importation Scheme. However, non-compliant products can be impounded at the point of import into Australia and may be destroyed.

Manufacturing practices

To manufacture vaporiser nicotine products in Australia (including those supplied as unapproved medicines), a manufacturer must obtain a Good Manufacturing Practice (GMP) licence under Part 3-3 of the Act, unless a relevant exemption applies (see Schedules 7 and 8 of the *Therapeutic Goods Regulations 1990*). The manufacturer may also need a State or Territory poisons licence or approval.

A GMP licence is not required in relation to the manufacture of unapproved vaporiser nicotine products at manufacturing sites outside Australia. GMP clearance is also not required where vaporiser nicotine products are manufactured overseas and supplied as unapproved goods in Australia via the SAS, APS or as part of a clinical trial.

We recommend that sponsors of unapproved vaporiser nicotine products make enquiries into the processes adopted by overseas manufacturers. We also recommend that sponsors and others considering commercially supplying unapproved vaporiser nicotine products in Australia seek a Certificate of Analysis for the product, including for active and excipient ingredients used in the product.

To obtain ARTG registration of a vaporiser nicotine product manufactured wholly or partly outside of Australia, the sponsor must obtain GMP clearance for the overseas manufacturing site(s).

Consumer products from the UK, EU, US, Canada and NZ

Vaporiser nicotine products captured by TGO 110 may be available as consumer goods in other countries. The level of regulation of vaporiser nicotine products available as consumer goods differs between jurisdictions.

US

A marketing order from the US Food and Drug Administration (FDA) is required to lawfully market vaporiser nicotine products as consumer goods in the US, other than products commercially marketed in the US as of 15 February 2007 and not modified since that date.

The premarket tobacco product application (PMTA) pathway is one way to obtain an FDA marketing order. Under the PMTA pathway, applicants must provide scientific evidence demonstrating the product is appropriate for the protection of public health. In deciding whether to authorise marketing through the PMTA pathway, the FDA reviews the product's components, ingredients, additives and considers, among other things:

- Risks and benefits to the US population as a whole (including users and non-users).
- Whether users of any tobacco product(s) would be more or less likely to stop using such products if the proposed new product was available.
- Whether non-users of any tobacco product(s) would be more or less likely to begin using tobacco products if the new product were available.
- Methods, facilities, and controls used to manufacture, process, and pack the product.

It is proposed that unapproved vaporiser nicotine products that are the subject of an [FDA PMTA marketing order](#) are taken to comply with TGO 110 because they have been assessed by the FDA as being appropriate for public health. No vaporiser nicotine products are currently the subject of an FDA PMTA marketing order.

UK, EU and Canada

The UK, Member States of the EU, and Canada do not have pre-market approval requirements but do have quality and safety requirements for vaporiser nicotine products that are sold as consumer goods within those countries. Provided the requirements within the relevant country are complied with:

- Vaporiser nicotine products sold as consumer goods within the **UK and Canada** would meet the proposed requirements in draft TGO 110.
- Vaporiser nicotine products sold as consumer goods within the **EU** would meet the proposed requirements in draft TGO 110, subject to the following:
 - Relabelling (e.g. overstickering), repackaging or provision of an information sheet would be required if the label was not in English and/or did not include an English translation.
 - These products may, but are not expected to, contain excipient ingredients proposed to be prohibited in draft TGO 110. If these prohibitions are adopted, sponsors and others considering commercially supplying these products in Australia would need to check the ingredients against the requirements of TGO 110.

NZ

NZ is currently phasing in tighter restrictions on vaporiser nicotine products contained in the *Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020* (NZ Act). Public consultation is [currently](#) taking place on proposed regulations that are needed to implement some parts of the NZ Act.

Products meeting the proposed regulations would comply with draft TGO 110. The TGA will provide guidance on vaporiser nicotine products sold as consumer goods in the NZ and, if necessary, update TGO 110 once those regulations have been finalised.

Part 1: Proposed scope of TGO 110

TGO 110 is intended to apply to ‘vaporiser nicotine products’ that are imported into or supplied in Australia and are not registered in the ARTG (i.e. that are unapproved goods).

‘Vaporiser nicotine products’ are those which contain nicotine – whether in base or salt form – and are intended to be vaporised and administered by inhalation using a vaping device. Vaporiser nicotine products include nicotine-containing vape liquids, e-liquids and e-juices.

Vaporiser nicotine products may be listed on the ARTG as ‘export only’ medicines and/or imported into, or supplied in, Australia as unapproved medicines for the purpose of a clinical trial (under the Clinical Trial Notification or Clinical Trial Approval Scheme).

Options

1. TGA PROPOSAL:

- **TGO 110 to cover the following types of vaporiser nicotine products:**
 - ✓ **Products accessed via the APS or SAS B, noting that SAS A is not relevant to products for smoking cessation and there are limits on the TGA’s ability to enforce TGO 110 against overseas manufacturers and suppliers of products imported via the Personal Importation Scheme (see Background section).**
 - ✓ **Extemporaneously compounded products.**
 - ✓ **Products supplied as part of a clinical trial.**
- **TGO 110 NOT to cover the following products:**
 - ✗ **Any vaporiser nicotine products which may become registered in the ARTG (the TGA will evaluate the quality, safety and efficacy of these products prior to approval).**
 - ✗ **Any vaporiser nicotine products that may become listed on the ARTG as export only products.**
 - ✗ **Vaporiser nicotine products carried by travellers to Australia in accordance with the [Traveller’s Exemption](#) or by visiting international sports teams, military forces, medical teams, ships and Governments in accordance with Therapeutic Goods Regulations 1990.**
 - ✗ **Other NRTs containing nicotine, such as patches, gum, lozenges, mouth spray and inhalators.**
 - ✗ **Other products containing nicotine that are not intended for use in vaping devices, such as combustible tobacco products, chewing tobacco and snuff.**
 - ✗ **Vaporiser products that do not contain nicotine (e.g. non-nicotine vaporiser products, flavour refills that can be mixed with nicotine refills).**
 - ✗ **Vaporiser nicotine that is not in the form of a finished product (e.g. ingredients used in commercial manufacture or compounding and/or products imported in bulk for dispensing by a pharmacist).**

- **Vaporiser nicotine products subject to an FDA PMTA marketing order deemed to comply with the requirements in TGO 110.**

(Sections 4, 6 and 10 of draft TGO 110)

2. As per Option 1, but TGO 110 NOT to cover clinical trial products.
3. As per Option 1, but TGO 110 to cover vaporiser nicotine products listed on the ARTG as export only.
4. As per Option 1, but products manufactured, packaged and labelled for supply in the UK, EU, Canada, NZ **AND/OR** other countries in accordance with the laws of those countries are deemed to comply with the requirements in TGO 110.
5. Other.

Issues

Requiring export only products to comply with TGO 110 would assist in ensuring that vaporiser nicotine products that are of poor quality or known to be unsafe are not eligible to be listed on the ARTG and could not therefore be lawfully exported from Australia. However, some other countries allow vaporiser nicotine products to be sold as consumer goods. These countries may have different safety and quality requirements to TGO 110. Imposing TGO 110 on export only vaporiser nicotine products may exclude or restrict lawful export to those countries.

Depending on the requirements included in TGO 110, there may be a desire to conduct a clinical trial on a non-compliant product (e.g. one contains an ingredient that may be prohibited under TGO 110). Some clinical trial products may be unable to comply with TGO 110 (e.g. adhering to labelling requirements for ingredient lists and nicotine concentration statements would not be possible for a blinded clinical trial). These products could be excluded from TGO 110 entirely or, alternatively, the TGA could give consent to non-compliance on a case-by-case basis.

TGO 110 will set minimum safety and quality requirements for unapproved vaporiser nicotine products. Products marketed in the US under an FDA PMTA marketing order have been assessed by the FDA as being appropriate for the protection of public health, based on scientific evidence. These products may not be labelled with ingredients lists or nicotine content or concentration. Products from the UK, EU, Canada and, if the proposed regulations are adopted, NZ are subject to regulatory requirements, including in relation to labelling, but are not subject to pre-market assessment by a regulator.

Justification

We propose to exclude vaporiser nicotine products listed on the ARTG as export only products from the scope of TGO 110, to ensure that TGO 110 does not exclude the possibility of the lawful export of vaporiser nicotine products to countries where they are regulated as consumer goods.

We propose that unapproved vaporiser nicotine products that are imported or supplied for the purpose of clinical trials must comply with TGO 110. This will ensure some minimum safety and quality requirements are met for these products. However, we will consider giving consent to non-compliance on a case-by-case basis where appropriate to do so.

We propose deeming that consumer products that are the subject of an FDA PMTA marketing order comply with TGO 110. These products would not need to separately comply with the specific requirements in TGO 110. This is because these products have been assessed by the FDA as being appropriate for public health. Alternatively, we could provide consents to non-

compliance with TGO 110 for these products under sections 14 and 14A of the Act or require them to comply with some or all requirements in TGO 110 (e.g. the proposed labelling requirements).

We do not propose deeming products marketed in the UK, EU, Canada or NZ to be compliant with TGO 110 as these products are not subject to pre-market assessment.

Questions

1. Do you think that export only vaporiser nicotine should be required to comply with TGO 110? Why or why not?

No response.

2. Do you think clinical trial products should be required to comply with TGO 110? Why or why not?

Yes. It is unethical to provide participants of a clinical trial with a product that does not meet Australia's minimum safety and quality requirements for that product.

3. Do you think products that are the subject of an FDA PMTA marketing order, or that are supplied in the UK, EU, Canada, NZ and/or another country in accordance with the relevant requirements of that country, should be deemed to comply with TGO 110 (in whole or in part)? Why or why not?

No, these products should not be deemed to automatically comply with TGO 110. To ensure rigorous safety and quality standards, these products should be subject to independent assessment against the criteria set out in the TGO 110.

4. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

5. Do you have any other comments about the products covered by or excluded from draft TGO 110?

No.

Part 2: Potential requirements for unapproved vaporiser nicotine products

Introduction

Primary objectives of TGO 110

Objective 1: Assist in meeting the need for health practitioners and individuals to know what is in the product the person is inhaling for smoking cessation.

Health practitioners and individuals need product information to assess and compare products and make informed decisions about treatment and use (including allowing appropriate and effective dosage for smoking cessation).

Objective 2: Minimise the risk of accidental exposure to and/or ingestion of vaporiser nicotine products, particularly by young children.

Nicotine is a highly toxic substance. Any ingestion of nicotine may cause mild toxicity and even low amounts of nicotine may be lethal to children.

Other relevant considerations

It is important to keep the nature and purpose of the recent Scheduling decision in mind when assessing how best to meet these objectives. In particular:

- The Scheduling decision is intended to provide important protection for youth and non-nicotine users from risk of uptake of vaporiser nicotine products, by ensuring these products will only be able to be accessed with a doctor's prescription. Imposing additional requirements in TGO 110 to reduce attractiveness to youth may result in overregulation, given that the prescribing doctor will have the key decision-making role around access.
- The Scheduling decision also aimed to ensure that current smokers could access vaporiser nicotine products for smoking cessation on their doctor's advice. Including overly restrictive requirements in TGO 110 may inadvertently prevent a doctor from prescribing, or a current smoker from accessing, an appropriate vaporiser nicotine product to meet the individual's smoking cessation needs.

Labelling – ingredient lists

Potential requirement for the names of active and/or excipient ingredients to be listed (declared) on the labels of unapproved vaporiser nicotine products (e.g. the label of the product, the container or its primary pack) **OR** to be listed **either** on the label of the product or in a document (information sheet) provided with the product.

Other jurisdictions

Vaporiser nicotine products sold as consumer goods within the UK, the EU and Canada must have active and excipient ingredient lists on their labels, except the ingredients of flavours. NZ is consulting on a proposal to require all ingredient names and quantities to be included on the label of vaporiser nicotine products sold as consumer goods.

Options

1. List active ingredient plus all excipient ingredients (including all component ingredients of any flavours).
2. **TGA PROPOSAL: List active ingredient plus all excipient ingredients *except* components of flavours (listed as 'flavour') (subsection 8(2) of draft TGO 110).**
3. List active ingredient only.
4. Option 1, 2 or 3, but information to be stated on label only (no option to provide the list on an information sheet).
5. No ingredient labelling requirements.

Issues

It is important that health practitioners and individuals know what the person is inhaling for smoking cessation so they can fully assess and compare products and make informed decisions about treatment and use. This is true of both active and excipient ingredients, as the risk profiles of excipient ingredients may vary.

Information declared on a label will only be available to doctors and individuals once the product has been purchased, but this may still be useful in assessing ongoing use. However:

- Products which do not currently have this information on the label would either need to be repackaged/relabelled or, if permitted, supplied with an information sheet.
- Ingredient lists for some products may be too long to fit on a standard label (particularly if ingredients of flavours are listed).

Consumer goods sold in the UK, the EU and Canada must already be labelled with active and excipient ingredients (except the ingredients of flavours), although EU labels may be in a language other than English.

We understand that some products in these jurisdictions have 'peel-off' or double-sided labels to fit all of the information. Allowing the information to be provided on the label **or** in an information sheet may avoid the need for such labels, although there may be an increased risk of the information sheet being lost or destroyed.

Justification

We propose requiring all active and excipient ingredients to be listed on labels or information sheets, except ingredients of flavours (listed as 'flavour'). This will assist in meeting the need for health practitioners and individuals to know what the person is inhaling for smoking cessation. Vaporiser nicotine products labelled for supply in the UK, Canada and (where the label includes information in English) the EU in accordance with the laws of the relevant country will already meet this requirement. We propose deeming products that are the subject of an FDA PMTA marketing order to comply with this requirement, regardless of how they are labelled.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

A combination of Option 1 and Option 4 is preferred. Evidence indicates that flavours and additives are harmful, with some (e.g., cherry) more harmful than others owing to their component ingredients (Bahl et al., 2012; Kosmider et al., 2016; Sassano et al., 2018). It is therefore important

that the component ingredients of any flavours are also listed on vaporiser nicotine products and that these are listed on the label, not just the information sheet (which can too easily be separated from the product).

References:

Bahl, V., Lin, S., Xu, N., Davis, B., Wang, Y., & Talbot, P. (2012). Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. Reproductive Toxicology, 34(4), 529-537. <https://doi.org/10.1016/j.reprotox.2012.08.001>

Kosmider, L., Sobczak, A., Prokopowicz, A., Kurek, J., Zaciera, M., Knysak, J., Smith, D., & Goniewicz, M. L. (2016). Cherry-flavoured electronic cigarettes expose users to the inhalation irritant, benzaldehyde. Thorax, 71(4), 376-377. <https://doi.org/10.1136/thoraxjnl-2015-207895>

Sassano, M. F., Davis, E. S., Keating, J. E., Zorn, B. T., Kochar, T. K., Wolfgang, M. C., Glish, G. L., & Tarran, R. (2018). Evaluation of e-liquid toxicity using an open-source high-throughput screening assay. PLoS Biology, 16(3). <https://doi.org/10.1371/journal.pbio.2003904>

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Labelling – nicotine concentration

Potential requirement for nicotine concentration or content to be included on the label of the product (e.g. the label of the product, the container or its primary pack) **OR** for it to be included **either** on the label of the product or in an information sheet provided with the product.

Other jurisdictions

- Vaporiser nicotine products sold as consumer goods within the UK and the EU must be labelled with nicotine content.
- Vaporiser nicotine products sold as consumer goods within Canada must be labelled with nicotine concentration in mg/mL. NZ is currently consulting on a proposal to also require labelling of nicotine concentration as mg/mL.

Options

1. State nicotine concentration or, for nicotine salt products, nicotine base form equivalent concentration (i.e. of nicotine only, not nicotine salt concentration) in mg/mL.
2. State nicotine concentration or nicotine salt concentration in mg/mL.
3. **TGA PROPOSAL: State nicotine concentration or content (subsection 8(3) of draft TGO 110).**
4. Option 1, 2 or 3, but information must be included on the label (no option to instead provide the concentration on an information sheet supplied with the product).
5. No nicotine concentration or content labelling requirements.

Issues

It is important that health practitioners and individuals know the nicotine concentration or content of a vaporiser nicotine product to enable them to make informed decisions around treatment and use, including to assist in titration of an appropriate dose for smoking cessation.

For a nicotine salt product, the concentration/content of nicotine salt will be different to the concentration/content of nicotine only (i.e. the base form equivalent). Lack of clarity as to which concentration/content is specified could affect treatment with the product.

Differences in how concentration/content is expressed (e.g. mg/mL, percentage, total content) also make it more difficult – although still possible - to compare and switch between products.

However, nicotine delivery using vaporiser nicotine is not only dependent on the nicotine concentration or content of the product. Factors such as the vaping device and user behaviour also play a role. Due to these other factors, even if the precise nicotine concentration or content of a product is known, people are likely to need to adjust their use to titrate an appropriate dose for their smoking cessation needs.

Consumer goods sold in the UK and the EU must be labelled with nicotine content, whereas consumer goods sold in Canada must be labelled with nicotine concentration in mg/mL. Products from other jurisdictions may specify percentage concentration and/or total nicotine content or make no nicotine concentration/ content declaration.

Justification

We propose requiring the concentration or content of nicotine to be specified on the label of vaporiser nicotine products or provided in an information sheet. This would assist in meeting the need for health practitioners and individuals to know what the person is inhaling without requiring relabelling of, or information sheets to be provided with, products sold as consumer goods in other countries with nicotine concentration/content labelling requirements (particularly the UK, EU and Canada). The relative strengths of products could still be compared.

We propose deeming products that are the subject of an FDA PMTA marketing order to comply with this requirement, regardless of how they are labelled.

Consistent with standard pharmaceutical quality practice, we would expect actual content or concentration to be within 90 – 110% of that specified on the label or information sheet.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

Option 3 is preferred but it does not go far enough. It is recommended that the option be changed to explicitly require that vaporiser nicotine products state nicotine concentrations or content in mg/ml to avoid the vaping industry taking advantage of the currently vague directive. Requiring that a single unit of measurement be used across all products will reduce confusion among consumers and health practitioners.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Labelling – warning statements

Potential requirement for warning statements to be included on the label of the product (e.g. the label of the product, the container or its primary pack) **OR either** on the label of the product or in an information sheet provided with the product. These warning statements may be:

- Warning statements and safety directions (e.g. to ‘Keep out of reach of children’ or ‘avoid contact with skin/eyes’).
- Pregnancy warnings.
- Nicotine addictiveness warnings (e.g. ‘Nicotine is addictive’).

Other jurisdictions

Warning label requirements for vaporiser nicotine products sold as consumer goods in other countries include nicotine addictiveness warnings (UK, EU, Canada and the US, and currently proposed in NZ), ‘keep out of reach of children’ (UK and currently proposed in NZ) and toxicity and first aid treatment statement (Canada and currently proposed in NZ).

Options

1. Require the provision of warning statements and safety directions **AND/OR** pregnancy warning **AND/OR** addictiveness warning.
2. Option 1, but warning be included on label only (no option to provide it on an information sheet).
3. **TGA PROPOSAL: Rely on State/Territory requirements for warnings statements and safety directions in the Poisons Standard (i.e. no other requirements in TGO 110).**

Issues

There are toxicity risks associated with accidental exposure to and/or ingestion of vaporiser nicotine products. Under and subject to State and Territory poisons legislation, the Poisons Standard requires vaporiser nicotine products to have the following:

- Safety directions on the label (‘Avoid contact with eyes’ and ‘Avoid contact with skin’) (Appendix F of the Poisons Standard).
- Warning statement on the dispensing label (e.g. the label applied by the pharmacist) (to ‘KEEP OUT OF REACH OF CHILDREN’) (Appendix L of the Poisons Standard).

Vaporiser nicotine products may present risks when used in pregnancy and carry a risk of addiction. We expect doctors would consider these risks, particularly in comparison to the risks associated with other smoking cessation treatments or continued use of combustible nicotine products (e.g. cigarettes), before prescribing a vaporiser nicotine product for smoking cessation.

Justification

We propose relying on existing State and Territory requirements for labels/ dispensing labels to include warning statements and safety directions set out in the Poisons Standard. This will avoid regulatory overlap and avoid products needing to be repackaged/relabelled, without

compromising the safety of users or children. Pharmacists may also consider applying cautionary advisory labels under professional standards.¹

We do not propose requiring pregnancy or nicotine addictiveness warnings on vaporiser nicotine products. We expect doctors to consider these risks before prescribing a vaporiser nicotine product. Warning statements may undermine an individual's smoking cessation treatment by discouraging continuation with the treatment recommended by their doctor.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

Option 1 is preferred, with the added requirements that (1) the warning statement be present on both the label and information sheet and (2) pregnancy AND nicotine addictiveness warnings be mandated. The TGA proposal defaulting to the requirements of individual States/Territories will cause a tremendous amount of confusion for consumers and health practitioners. The Federated nature of Australia's Government has been very problematic for the regulation of e-cigarettes to date. Federal legislation regarding the sale of nicotine-containing e-cigarettes has provided clarity. By contrast, the lack of Federal legislation regarding the use of nicotine e-cigarettes (for example, in public places) and the sale of non-nicotine e-cigarettes has led to different laws in each State and Territory, creating considerable confusion. The TGA has an opportunity to mandate the provision of warning statements and safety directions (Option 1) and it should adopt this approach, especially given the sale of vaporised nicotine products has come under Federal, not State/Territory, legislation to date.

It is also critical that warning statements be placed on vaporised nicotine products. Although doctors should be considering these risks before prescribing the products and adequately informing their patients of these, patients are likely to forget these risks prior to purchase, making a reminder critical. On-label warnings are unlikely to discourage continuation of treatment if the patient has been adequately informed of these risks by their doctor and the warning is simply acting as a reminder.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Ingredients – prohibiting certain ingredients

Potential prohibition on certain ingredients in unapproved vaporiser nicotine products.

¹ Pharmaceutical Society of Australia, [Professional Practice Standards](#), Pharmaceutical Society of Australia, 2017, accessed 8 February 2021, standard 8.8.7

Other jurisdictions

- Several ingredients are prohibited from vaporiser nicotine products sold as consumer goods in the [UK](#),² the [EU](#),³ and [Canada](#)⁴ (full lists available at links provided). The lists of prohibited ingredients do **not** apply to therapeutic goods or export-only products.
- Canadian consumer law also prohibits any the manufacture, import, advertisement or sale of any consumer product that is a danger to human health or safety. [Canadian guidance](#) identifies known toxic ingredients that should not be used in vaporiser nicotine products to ensure compliance with this prohibition.⁵
- The US FDA can only make a PMTA marketing order if there is evidence that allowing the product to be marketed in the US would be appropriate for the protection of public health.
- From 11 May 2021, colourings will be [banned](#) in vaporiser nicotine products sold in NZ.⁶ NZ is currently consulting on a proposal to allow several substances to be present only in trace levels technically unavoidable during manufacture. The full lists are available [here](#).

Options

1. **TGA PROPOSAL: Prohibit active ingredients other than nicotine (which may include caffeine and any vitamins) and the following ingredients which carry known health risks (section 7 and Schedule 1 of draft TGO 110):**
 - Ethylene glycol.
 - Diethylene glycol.
 - Diacetyl.
 - 2,3-pentanedione.
 - Vitamin E acetate.
2. Prohibit active ingredients other than nicotine only.
3. Prohibit additional individual ingredients that are associated with health concerns and could be present in flavours.
4. Do not prohibit any ingredients.

Issues

Other active ingredients

² Medicines and Healthcare Products Regulatory Agency (MHRA), [Ingredient guidance Great Britain](#), MHRA, Government of the United Kingdom, accessed 5 February 2021.

³ [Directive 2014/40/EU](#), the European Parliament and of the Council, 3 April 2014 - on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, accessed 5 February 2021.

⁴ [Tobacco and Vaping Products Act](#) (S.C. 1997, c. 13), Canada, Schedule 2, accessed 5 February 2021.

⁵ Health Canada, [Industry Guide to Vaping Products Subject to the Canada Consumer Product Safety Act](#), Government of Canada, 2020, accessed 5 February 2021.

⁶ Ministry of Health, [Vaping information for all industry](#), Government of New Zealand, 2021, accessed 5 February 2021.

Active ingredients are therapeutically active ingredients responsible for the physiological or pharmacological actions. This may include vitamins and minerals, amino acids, caffeine or other stimulants or cannabinoids.

Nicotine (whether in base or salt form) is the only active ingredient expected to be required for vaporiser nicotine products to be used for smoking cessation.

Other ingredients that may pose a risk to human health

Typically, vaporiser nicotine products sold as consumer goods contain nicotine (as the active ingredient), vegetable glycerine, propylene glycol and flavours (comprised of a number of component ingredients).

We understand that limited information exists on the inhalation safety of many ingredients in vaporiser nicotine products. Particular concerns have been identified with certain ingredients:

- The National Industrial Chemicals Notification and Assessment Scheme (now the Australian Industrial Chemicals Introduction Scheme) has [reported](#) potential health concerns with a number of ingredients in flavours.⁷

For many of these ingredients, there was evidence of a chemical hazard but insufficient evidence to determine if inhaling the ingredient was actually likely to be a risk to human health. However, the report particularly raised concerns about diketone flavourings (such as diacetyl and 2,3-pentanedione) commonly used to produce a buttery or creamy flavour, which have been linked to irreversible lung damage known as bronchiolitis obliterans, or 'popcorn lung'. Diacetyl and 2,3-pentanedione (also known as acetylpropionyl) cannot be used as ingredients in vaporiser nicotine products sold as consumer goods in Canada and the UK.

- Additional health concerns associated with certain flavouring ingredients have been raised by a recent review of nicotine-containing electronic cigarettes.⁸ This includes concerns regarding chemicals used to create buttery or creamy flavours (acetoin), cinnamon flavours (cinnamaldehyde and eugenol), fruit flavours (linalool, limonene and benzaldehyde), anise flavours (estragole) and vanilla (vanillin). Although some of these substances are able to be used as flavours in foods and oral medicines, there is limited inhalation safety data.

In 2020, the FDA and Centers for Disease Control and Prevention (CDC) [investigated](#) a national outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI) which resulted in over 2,000 hospitalisations or deaths. Vitamin E acetate (also known as dl-alpha-tocopheryl acetate), an additive in some tetrahydrocannabinol-containing vaping products, was strongly linked to the outbreak.⁹

- Ethylene glycol and diethylene glycol cannot be used as diluents in vaporiser nicotine products in Canada and the UK. The presence of ethylene glycol in vaporiser nicotine

⁷ National Industrial Chemicals Notification and Assessment Scheme (NICNAS), [Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns](#), Department of Health, Australian Government, 2019, accessed 5 February 2021.

⁸ A Taylor, K Dunn and S Turfus, [A review of nicotine-containing electronic cigarettes-Trends in use, effects, contents, labelling accuracy and detection methods](#), *Drug Testing and Analysis*, 2021, Online ahead of print, accessed 5 February 2021.

⁹ CDC, [Outbreak of Lung Injury Associated with the Use of E-cigarette, or Vaping, Products](#), Department of Health and Human Services, Federal Government of the United States, 2020, accessed 5 February 2021.

products is particularly associated with markedly enhanced toxicological hazards compared to conventionally used glycerol and propylene glycol.¹⁰

The UK, EU and Canada also prohibit colouring agents (e.g. food grade colouring additives that create coloured emissions) in vaporiser nicotine products sold as consumer goods. Colouring agents will be banned in NZ from 11 May 2021. We understand there are concerns that colouring agents may encourage youth uptake and that there is limited evidence regarding the inhalational safety of these types of ingredients.

Contaminants

We are also aware of concerns about the quality of ingredients (particularly excipient ingredients) used in unapproved vaporiser nicotine products. In particular, the potential for these ingredients to have high levels of contaminants.

Under the Act, an ingredient for which there is a monograph in the British Pharmacopoeia (BP), European Pharmacopoeia (Eur. Ph.) and/or United States Pharmacopoeia – National Formulary (USP) must comply with that monograph unless an exemption is issued. Further information about nicotine purity is provided in Part 3.

We recommend that sponsors and others considering commercially supplying unapproved vaporiser nicotine products in Australia seek a Certificate of Analysis for the product, including the active and excipient ingredients.

Justification

We propose prohibiting, as a general class, active ingredients other than nicotine or nicotine salts in vaporiser nicotine products. This may include vitamins and minerals, amino acids, caffeine or other stimulants or cannabinoids that have a pharmacological or physiological effect.

We also propose prohibiting a list of specific ingredients which carry known safety risks with inhalation. This list of prohibited ingredients currently proposed is: ethylene glycol, diethylene glycol, diacetyl, 2,3-pentanedione, vitamin E acetate (see Schedule 1 of draft TGO 110).

Vaporiser nicotine products sold as consumer goods in the UK and Canada in accordance with the relevant laws in those countries will comply with the proposed requirements in section 7 and Schedule 1 of draft TGO 110. Vaporiser nicotine products sold as consumer goods in the EU *may* – but are not expected to – contain one or more of the excipient ingredients in Schedule 1 of draft TGO 110. NZ is currently consulting on a proposal to allow certain substances only in trace levels technically unavoidable during manufacture, including pharmacologically active components and the substances listed in Schedule 1 of draft TGO 110.

We propose deeming products that are the subject of an FDA PMTA marketing order to comply with the proposed requirements in section 7 and Schedule 1 of the draft TGO 110, as these products are assessed by the FDA as being appropriate for the protection of public health.

This does not mean that all other excipient ingredients are safe for use in individual vaporiser nicotine products. We do not assess the quality or safety of ingredients in unapproved products.

We would continue to review the list of prohibited ingredients and amend the list in Schedule 1 if and when additional evidence became available about the ingredients used in vaporiser

¹⁰ C Hutzler, M Paschke, S Kruschinski, F Henkler, J Hahn, A Luch, '[Chemical hazards present in liquids and vapours or electronic cigarettes](#)', *Arch. Toxicol*, 2014 Jul;88(7):1295-308.

nicotine products. The guidance supporting TGO 110 may also refer to other ingredients which are suspected, but not confirmed, to pose a health risk.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

A combination of Option 1 and Option 3 is preferred as all ingredients that are associated with health concerns should be prohibited.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Ingredients - flavours

Potential requirement to prohibit the flavours of unapproved vaporiser nicotine products.

Other jurisdictions

- Confectionary, dessert, cannabis, soft drink and energy drink flavours are prohibited from vaporiser nicotine products sold as consumer goods in Canada. Canada is considering further limiting the flavours available to tobacco, mint and menthol. The prohibition does **not** apply to therapeutic goods or vaporiser nicotine products exported from Canada.
- The UK and the EU do not restrict the flavours available in vaporiser nicotine products sold as consumer or therapeutic goods.
- From 11 August 2021, NZ will allow general retailers to sell [only](#) tobacco, mint and menthol flavoured vaporiser nicotine. Specialist retailers will be able to sell other flavours.¹¹

Options

1. Allow certain flavours only (e.g. tobacco, mint, menthol).
2. Prohibit certain flavours (e.g. cannabis, soft drink, dessert, bubblegum, candy).
3. **TGA PROPOSAL: No limits on flavours.**

Issues

Flavoured vaporiser products may or may not contain nicotine. Some flavoured non-nicotine vaporiser products may be inhaled on their own; others may be mixed with vaporiser nicotine prior to use.

¹¹ Ministry of Health, [Vaping information for all industry](#), Government of New Zealand, 2021, accessed 5 February 2021.

The [Report of the Senate Select Committee on Tobacco Harm Reduction](#)¹² (Senate Report) refers to stakeholder submissions suggesting that, for some people, the flavour of a vaporiser nicotine product may impact whether it is an effective smoking cessation treatment.¹³

However, the Senate Report also refers to stakeholder concerns about the following:

- Potential safety risks associated with the ingredients of flavours (both in nicotine and non-nicotine vaporiser products).¹⁴
- Potential attractiveness to youth of certain flavours such as fruit, candy and flavours with unusual names (e.g. 'Oba Oba' and 'Beast').¹⁵

Flavoured vaporiser products that do not contain nicotine are outside the scope of TGO 110. Subject to Commonwealth industrial chemical legislation, and State and Territory laws, these products may be able to be lawfully purchased from vape shops or online without a prescription. In Australia, the requirement to have a doctor's prescription to be supplied or, from 1 October 2021, to import vaporiser nicotine products will restrict access to these products by youth and non-nicotine users.

Justification

We do not propose limiting flavours in vaporiser nicotine products, except where there is evidence that a component ingredient of the flavour poses a risk to human health (see Ingredients - prohibiting certain ingredients section).

Prohibiting certain flavours may limit a doctor's ability to prescribe, or a person's ability to access, a pre-mixed vaporiser nicotine product in the flavour the person finds most effective for smoking cessation (e.g. flavoured pod). It would not prevent people from purchasing flavoured non-nicotine vaporiser products to mix with vaporiser nicotine products.

The risk of uptake of vaporiser nicotine products by youth and non-nicotine users will be addressed by these products being available only on prescription.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

Option 1 is preferred. As noted above, there is evidence indicating that certain flavours in vaporiser nicotine products are harmful, with some (e.g., cherry) more harmful than others owing to their component ingredients (Bahl et al., 2012; Kosmider et al., 2016; Sassano et al., 2018). It is critical that these flavours be prohibited. However, Option 2 is open to industry manipulation: prohibiting certain flavours will simply result in the vaping industry creating new ones (which they are very good at, with over 4000 flavours created to date). To stymie industry tactics, it is critical that the TGA mandates which flavours are allowable instead (Option 1). The list of allowable flavours should be minimal, with those that deliberately appeal to youth (e.g., Unicorn Milk, Skittles, Red

¹² Senate Select Committee on Tobacco Harm Reduction, Parliament of Australia, [Report](#), 2020, accessed 5 February 2021.

¹³ [Senate Report](#), Chair's Report paragraphs [4.37], [4.49], [4.85], [6.80] – [6.81].

¹⁴ [Senate Report](#), Committee Report by the Majority paragraphs [4.23] - [4.25], [5.70] - [5.72], [6.13]; Senator Griff's additional comments paragraph [1.13]; Chair's Report paragraphs [5.11] – [5.12], [6.75], [6.80], [6.82].

¹⁵ [Senate Report](#), Committee Report by the Majority paragraphs [4.23], [4.72] [4.118], [5.72] - [5.73]; Senator Griff's additional comments paragraph [1.21]; Chair's Report paragraphs [5.50], [5.87], [6.82] – [6.85].

Bull) excluded. The law to be adopted in New Zealand, which only allows tobacco, mint, and menthol flavoured vaporiser nicotine, should be considered.

While it is noted by the TGA that “The risk of uptake of vaporiser nicotine products by youth and non-nicotine users will be addressed by these products being available only on prescription”, the availability of these flavours will still contribute to the appeal of vaporiser nicotine products among youth and their desire to access these products by any means necessary, including flouting the prescription-only model. The very limited evidence indicating that use of flavoured vaporiser nicotine products leads to more effective smoking cessation does not warrant the public health risk associated with keeping these products on the market and simply hoping that the prescription-only model minimises youth uptake.

2. Would any of these options, particularly the TGA’s proposed option, have an impact on you? How?

No.

Packaging – child-resistant packaging

Potential requirement for unapproved vaporiser nicotine products to be supplied in child-resistant packaging.

Child-resistant closure requirements in the Poisons Standard

From 1 October 2021, subject to State and Territory legislation, **all** liquid vaporiser nicotine products must have child-resistant closures (CRCs) meeting the requirements of the Poisons Standard. These requirements are:

- The product must have at least **one** of the following:
 - A CRC compliant with Australian Standard AS 1928-2007.
 - Packaging compliant with a Ministerial standard made under section 10 of the Act, such as [Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines \(TGO 95\)](#) or TGO 110 (once made).
 - If it is in a can fitted with a press-on lid, a ‘double tight’ or ‘triple tight’ lid.
- Packages must retain child-resistant properties for the expected life of the medicine and the CRC must be appropriate for the container (Part 2, Section 2.4(2) of the Poisons Standard).

Child-resistant packaging requirements in TGO 95

TGO 95 sets out child-resistant packaging (CRP) requirements that apply to certain medicines registered in the ARTG (amongst others). TGO 95 will apply to any vaporiser nicotine liquids approved by the TGA. TGO 95 requires the following:

- For **reclosable packages** (see section 9 of TGO 95):
 - The package must comply with at least one of the specific standards listed in TGO 95 (which includes Australian Standard AS 1928-2007).
 - The sponsor must hold evidence of compliance with the standard and other matters and information on certain matters relating to the container.

- Adequate directions for opening and effectively closing the package must be included on the package or its label.
- For **non-reclosable packages** (see section 10 of TGO 95):
 - The package must be blister or other sealed unit formed from paper, film, plastic material, metal foil or other sheet or strip material (or combination) in which a single dosage unit is enclosed (multiple dosage units can be in a strip or sheet of the same material).
 - The package must not be formed from cellulose film or un-laminated paper.
- All packages must remain fit until the expiry date of the medicine, retain the child-resistant properties for the expected number of opening or closings, not be adversely affected by the contents of the package and not require sight, or unusual strength or dexterity, to re-engage the child-resistant feature (see section 8 of TGO 95).

Other jurisdictions

The UK, the EU, Canada and the US require CRP for vaporiser nicotine products sold within those jurisdictions as consumers goods. NZ is currently consulting on a proposal to require CRP for vaporiser nicotine products sold as consumer goods.

Options

1. Impose requirements equivalent to TGO 95 (as described above).
2. **TGA PROPOSAL:**
 - **Products packaged for supply within the UK, the EU, Canada, the US and NZ must either comply with CRP requirements imposed in that country OR the requirements applicable to all other products.**
 - **All other products must meet requirements equivalent to TGO 95 (as described above) (excluding requirement to provide directions for opening/closing).**
(section 9 of draft TGO 110).
3. Impose alternative child-resistant packaging requirements.
4. Rely on State/Territory requirements for vaporiser nicotine products to have CRC compliant with the Poisons Standard (no additional CRC or CRP requirements in TGO 110).

Issues

Any ingestion of nicotine may cause mild toxicity and even low amounts of nicotine may be lethal to children. CRP is important for minimising the risk of accidental exposure to and/or ingestion of vaporiser nicotine products by children.

Unless TGO 110 specifies alternative requirements, the Poisons Standard will require unapproved vaporiser nicotine products supplied in Australia to have a CRC compliant with Australian Standard AS 1928-2007 from 1 October 2021 (subject to State and Territory legislation).¹⁶

In contrast, TGO 95 allows products to be packaged in accordance with *either* Australian Standard AS 1928-2007 *or* one of the other four standards specified in TGO 95 (being international, British, Canadian and US standards). TGO 95 also requires sponsors to hold certain evidence and information (as described above) and for directions for opening/closing the container to be provided on the container or its label.

The UK, EU, Canada and the US all require vaporiser nicotine products sold as consumer goods to have some form of CRP, but the exact requirements differ between jurisdictions. NZ is currently consulting on a proposal to introduce requirements similar to those in the UK. The requirements in these countries do not mandate compliance with Australian Standard AS 1928-2007 or requirements equivalent to TGO 95.

Justification

We propose allowing products packaged for supply within the UK, the EU, Canada, the US and (once CRP requirements are introduced) NZ to be supplied in Australia in that packaging, provided they meet the CRP requirements under the law of the relevant country. This will avoid the need for UK, EU, Canadian, US and (once CRP requirement are introduced) NZ products to be repackaged prior to supply in Australia without compromising child safety.

We propose requiring all other products to have CRP meeting requirements equivalent to TGO 95, except for the requirement to include directions for opening/closing on the product

¹⁶ Vaporiser nicotine products are not provided in a can, meaning the 'double-tight' or 'triple-tight' lid requirements are not relevant to these products.

label. This will allow products to comply with a broader range of standards than relying on the Poisons Standard alone, while ensuring that appropriate standards apply.

Excluding the requirement to include directions for opening/closing the container on the product label is proposed as many samples reviewed by the TGA which have a child-resistant mechanism do not include such directions.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

No response.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Packaging – tamper-proof/evident packaging

Potential requirement for unapproved vaporiser nicotine products to be supplied in tamper-proof/-evident packaging.

Options

1. Require tamper-proof/-evident packaging.
2. **TGA PROPOSAL: Do not impose tamper-proof/-evident packaging requirements.**

Other jurisdictions

The UK and the EU require tamper-proof/-evident closures for vaporiser nicotine products sold as consumer goods. NZ is currently consulting on a proposal to require tamper-evident packaging for vaporiser nicotine products sold as consumer goods within NZ.

Discussion

Tamper-proof/-evident packaging may assist in giving people confidence that their vaporiser nicotine product has not been tampered with following manufacture.

However, products which do not currently have tamper-proof/-evident packaging would need to be repackaged to meet such a requirement before they could be supplied in Australia.

Unlike the requirement for CRP, requiring tamper-proof/-evident packaging may not be proportionate to the risk of tampering. As prescription-only medicines, vaporiser nicotine products supplied within Australia (e.g. through pharmacies) should not be accessible by the general public prior to purchase.

Further, we would not be able to enforce these requirements against overseas suppliers of products imported via the Personal Importation Scheme.

TGA proposal

We do not propose any mandatory requirements for unapproved vaporiser nicotine products to be in tamper-/evident-proof packaging. Sponsors may want to consider using tamper-evident packaging compliant with our [Code of practice for tamper-evident packaging of therapeutic goods](#).

Questions

1. Which option (whether listed above or not) do you prefer? Why?

No response.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Nicotine concentration

Potential requirement to restrict the nicotine concentration of vaporiser nicotine products. This might be a maximum limit on nicotine concentration and/or a requirement for actual nicotine concentration to be within a specified range of the concentration stated on the label.

Other jurisdictions

The nicotine concentration of vaporiser nicotine products sold as consumer goods is limited to 20 mg/mL in the UK and the EU and 66 mg/mL in Canada. Canada is currently consulting on a proposal to lower its limit to 20 mg/mL. These limits do **not** apply to therapeutic goods. NZ is currently consulting on a proposal to limit base form nicotine concentration to 20 mg/mL and nicotine salt concentration to 50 mg/mL in vaporiser nicotine products sold as consumer goods.

Options

1. Maximum nicotine concentration of 20 mg/mL **OR** 66 mg/mL **OR** another level.
2. **TGA PROPOSAL: No limit on nicotine concentration or active ingredient content.**

Issues

The Senate Report states that commercial vaporiser nicotine products come in a concentration of up to 50 mg/mL,¹⁷ although we understand that some products may be available at nicotine concentrations > 50 mg/mL.

The Senate Report also notes many individuals in Australia mix their own vaporiser nicotine products.¹⁸ We understand that vaporiser nicotine products are presently available for purchase online with nicotine concentrations >100 mg/mL for at-home mixing (e.g. with flavoured non-nicotine vaporiser products).

Nicotine concentration limited by doctor's prescription

¹⁷ [Senate Report](#), Committee Report by the Majority paragraph [1.18]; Chair's Report paragraph [1.15].

¹⁸ [Senate Report](#), Committee Report by the Majority paragraph [4.72]; Chair's Report paragraph [1.15].

The Scheduling decision means that, from 1 October 2021, people will only be able to access products with the nicotine concentration prescribed by their doctor. The appropriate nicotine concentration is a matter for doctors to determine in consultation with the person concerned, having regard to any clinical guidelines. The concentration will need to be high enough for the person to titrate an effective dose of nicotine to meet their smoking cessation needs.

Concerns about youth uptake

Canada is currently consulting on a proposal to limit nicotine concentration in vaporiser nicotine products sold as consumer goods to 20 mg/mL (reduced from 66 mg/mL). The policy rationale behind this proposal is to minimise uptake of vaporiser nicotine products by youth. In Australia, youth access is restricted by the requirement to have a doctor's prescription to be supplied or, from 1 October 2021, import vaporiser nicotine products.

Toxicity and fatality concerns

Nicotine is a highly toxic substance. There are serious risks associated with accidental ingestion of, or exposure to, most (if not all) vaporiser nicotine products. This is why we are proposing CRP for all vaporiser nicotine products. Subject to State and Territory legislation, dispensing labels for vaporiser nicotine products will also need to include a warning statement to 'KEEP OUT OF REACH OF CHILDREN'.

At-home mixing

Even with CRP and warning labels, at-home mixing carries a particular risk of accidental ingestion of, or exposure to, vaporiser nicotine. The consequences of this may also be more serious if higher concentration products (e.g. 100 mg/mL or higher) are used for mixing.

When at-home mixing, people may also accidentally prepare a vaporiser nicotine product above or below the concentration the doctor has advised them to use. This could impact the effectiveness of treatment and may have safety implications.

On the other hand, some people may be presently using vaporiser nicotine products mixed at-home and found them to be an effective smoking cessation treatment. Users may be unwilling to switch to another vaporiser nicotine product or smoking cessation treatment, or may have already tried those alternatives without success.

Justification

We do **not** propose to set a limit on maximum nicotine concentration for unapproved vaporiser nicotine products. The maximum nicotine concentration a person can access will depend on what their doctor has prescribed. Setting a maximum nicotine concentration could limit the ability for a doctor to prescribe, or a patient to access, a suitable product to meet the individual's clinical needs. In particular:

- It is possible that some people, particularly heavy smokers, may require a nicotine concentration at the higher-end of the pre-mixed products currently available (e.g. 50 mg/mL or higher) to titrate an effective dose for smoking cessation.
- Setting a limit at or just above the higher-end of the currently available pre-mixed products may limit access to products developed in the future, particularly given the rapid evolution of these products.
- Setting a limit of 100 mg/mL may preclude some people from at-home mixing. Whether at-home mixing is suitable is a decision for doctors in consultation with patients. There may be cases where it is the most appropriate treatment for an individual (e.g. if they are already

using at-home mixed vapouriser nicotine products and are unwilling to consider alternative products or smoking cessation treatments, or have not had success with those alternatives).

Questions

1. Which option (whether listed above or not) do you prefer? Why?

Option 1. It is critical that limits be placed on the nicotine concentration of vapouriser nicotine products to minimise the consequences associated with accidental poisoning. CRP may assist with reducing risk of poisoning in children, but it does not assist with reducing risk in adults. The nicotine concentration limit placed on vapouriser nicotine products should be based on available evidence regarding 'effective' doses for smoking cessation. This evidence can then be communicated to patients via their doctor, reducing at-home mixing. Not placing a limit communicates a message to consumers and health practitioners that higher doses may be more effective when this may not be the case. If the TGA is concerned about at-home mixing, then limits should be placed on the amount of nicotine that can be imported for personal use or dispensed by pharmacists at any one time, as is the case for other controlled substances such as benzodiazepines.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Volume

Potential requirement to set a maximum volume of vapouriser nicotine in a single container. The limit may be the same for all concentrations of vapouriser nicotine or differ based on nicotine concentration.

Other jurisdictions

Vapouriser nicotine products sold as consumer goods in the UK and the EU are limited to 2 mL for a tank/pod and 10 mL for a refill container. These limits do **not** apply to vapouriser nicotine products sold as therapeutic goods in the UK or the EU. NZ is currently proposing to limit container volume for vapouriser nicotine products sold at retail as consumer goods to 100 mL and to limit total nicotine content per container to 500 mg.

Options

1. Maximum volume of 10 mL **OR** 1000 mL **OR** another level (all concentrations).
2. Range of maximum volumes applicable to different nicotine concentrations.
3. **TGA PROPOSAL: No limit on volume.**

Issues

Setting a maximum volume may assist to minimise the risks arising from accidental exposure to and/or ingestion of vapouriser nicotine products.

The amount of vapouriser nicotine a person can access will be limited to what they have been prescribed. People using the Personal Importation Scheme can only import a maximum of three

months' worth of unapproved vaporiser nicotine and domestic prescriptions/peats are generally limited to one months' supply.

The volume of vaporiser nicotine that a person may be prescribed could be vastly different depending on whether it is for one or three months' supply, the nicotine concentration of the product and the person's clinical needs. Further, some products may only be available in a particular container size and/or relative costs may differ between container sizes.

Justification

We do **not** propose setting a maximum container volume for unapproved vaporiser nicotine products. People will only be able to access what they have been prescribed and this is likely to differ significantly between people and products. One option would be to specify different volume limits for products with different nicotine concentrations, but this could be very complicated to navigate.

We propose addressing the risks of accidental exposure to and/or ingestion of vaporiser nicotine through CRP requirements. The volume limit that would be required to mitigate the risks of toxicity in children would be a significant restriction on the vaporiser nicotine products available for smoking cessation in Australia.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

Option 3 is preferred as it allows a person to access the amount of vaporiser nicotine they have been prescribed, and only that amount. I urge the TGA to consider placing limits on the supply of vaporiser nicotine products under the Personal Importation Scheme and reduce the current allowable supply from three months to one month.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Other questions/ comments

1. Are there any other potential minimum requirements for unapproved vaporiser nicotine products the TGA should consider including in TGO 110?

No.

2. Would you like to be consulted on any draft guidance prepared for TGO 110?

Yes.

Part 3: Related matters

Default standards and nicotine purity

Under the Act, monographs in the BP, Eur. Ph. and/or USP are considered 'default standards'. Medicines must comply with relevant default standards unless an exemption is issued. For vapouriser nicotine products, the TGA has identified the following default standards:

- Monographs which may apply to the nicotine active pharmaceutical ingredient (API default standards): Ph. Eur. monograph 1452 and USP monograph – Nicotine.
- Monographs which may apply to the finished product (product default standards): Ph. Eur. monograph 0671, USP monograph - Inhalation and nasal drug products: General information and product quality tests and USP monograph - Inhalation and nasal drug products: aerosols, sprays and powders - performance quality tests.

Other jurisdictions

Vapouriser nicotine products sold as consumer goods are **not required** to comply with monographs in the UK, the EU or Canada, although Health Canada does recommend compliance. The UK and the EU require ingredients to be of 'high purity'. The [UK](#) guidance states that vapouriser nicotine products seeking approval as therapeutic goods must comply with the API and product default standards from the Ph. Eur.

Options

1. Do not exempt unapproved vapouriser nicotine from complying with the default standards.
2. **TGA PROPOSAL: Exempt unapproved vapouriser nicotine products covered by TGO 110 from complying with product default standards (see draft *Therapeutic Goods (Exempt Monographs) Determination 2021*).**
3. Exempt unapproved vapouriser nicotine from complying with API default standards.
4. Exempt unapproved vapouriser nicotine from complying with all default standards.

Issues

Unless an exemption is made, the product default standards would require unapproved vapouriser nicotine products to meet certain pharmacopoeial quality standards, including microbial quality and labelling requirements. These standards may not be considered in the development of consumer goods. Many products available as consumer goods in other countries may not meet the product default standards. Requiring unapproved vapouriser nicotine to comply with the product default standards may therefore limit a doctor's ability to prescribe, or a person's ability to access, a suitable product to meet the individual's clinical needs.

The API default standards specify requirements for nicotine purity and limits on impurities. Again, it is possible that these standards may not be considered in the development of consumer goods. However, pharmacopoeial-grade nicotine is expected to be commercially available, and retaining the requirement to comply with the API default standards is therefore not expected to have a significant impact on product availability. The API default standards are also important in ensuring that health practitioners and users know that the active ingredient in vapouriser nicotine product is pharmacopoeial-grade.

Justification

We propose exempting unapproved vaporiser nicotine products covered by TGO 110 from the operation of the product default standards. Requiring compliance with the product default standards could significantly restrict the unapproved vaporiser nicotine products available in Australia. The product default standards **would** still apply to products seeking TGA approval.

We propose retaining the operation of the API default standards for unapproved vaporiser nicotine products. The nicotine purity requirements and impurity limits are important minimum safety requirements and not expected to significantly impact the availability of unapproved vaporiser nicotine products available in Australia.

We recommend that sponsors and others considering commercially supplying unapproved vaporiser nicotine products in Australia seek a Certificate of Analysis for the product, including for active and excipient ingredients.

Questions

1. Which option (whether listed above or not) do you prefer? Why?

No response.

2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

No.

Compounding

TGO 110 will apply to compounded unapproved vaporiser nicotine products.

Unapproved vaporiser nicotine products may only be compounded in accordance with the Act and the *Therapeutic Goods Regulations 1990*. Pharmacists considering compounding unapproved vaporiser nicotine products should also have regard to the Pharmacy Board of Australia's [Guidelines on compounding medicines](#) and related guidance documents.¹⁹

Questions

1. Do you have any comments on the application of TGO 110 to compounded vaporiser nicotine products?

No.

¹⁹ Pharmacy Board of Australia, [Guidelines on compounding of medicines](#), Pharmacy Board of Australia, 2015 (updated 2017), accessed 5 February 2021.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	February 2021

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