



Australian Government
Department of Health
Therapeutic Goods Administration

TGO 110: Standard for unapproved vaporiser nicotine products

Information session on proposed standard



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4 March 2021

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
 - Messages will only be visible to the moderator and speaker
 - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **‘Chat’** function
- Relevant links will be sent to you via the chat function box
- Live polls will be conducted throughout this event.



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What we will cover today

- Why the TGA is proposing a standard for unapproved vaporiser nicotine products
- What TGO 110 is and what it legally can and cannot do
- What products would be covered
- The proposed safety and quality requirements
- Next steps

Today's webinar focusses on the proposed minimum safety and quality requirements for vaporiser nicotine products in Australia. We will not be reopening the discussion on the recent decision to change the way vaporiser nicotine can be accessed from 1 October 2021.

Why the TGA is proposing a standard

-  A doctor's prescription will be needed to access vaporiser nicotine products for any use
-  There are no TGA-approved vaporiser nicotine products registered on the Australian Register of Therapeutic Goods (ARTG) at this time
-  Consumers can access unapproved medicines through:
 - Authorised Prescriber Scheme (APS)
 - Special Access Scheme (SAS)
 - Personal Importation Scheme
 - Clinical Trial Approval/Notification Schemes
-  Need for health practitioners and consumers to know what is in the product and to minimise chances of accidental exposure or ingestion (particularly by young children)

What the standard (TGO 110) can and cannot do

A Therapeutic Goods Order (or TGO) **CAN** specify minimum safety and quality requirements for:

- ✓ Labelling
- ✓ Packaging
- ✓ Ingredients



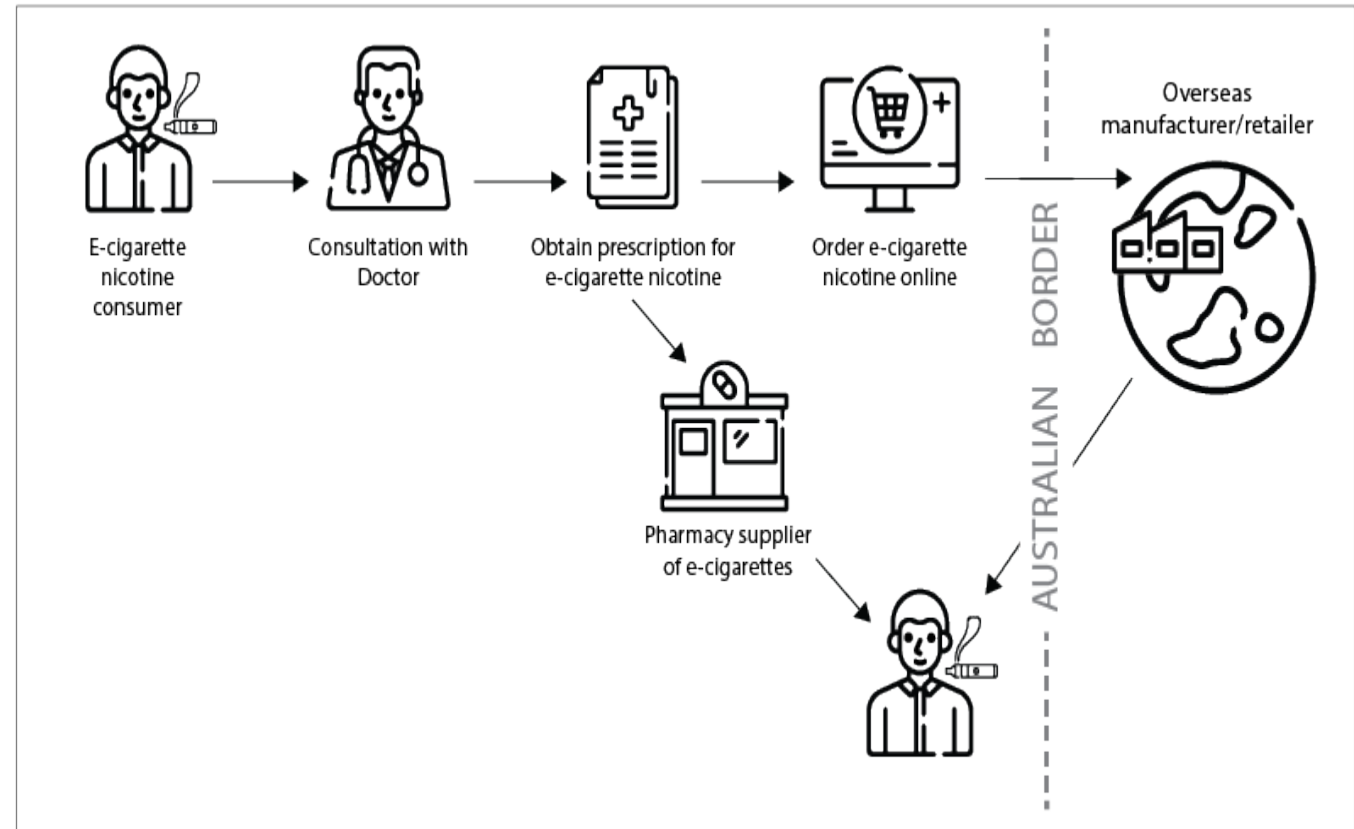
A TGO **CANNOT** specify requirements for:

- ✗ 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
- ✗ Vaping devices themselves, e.g. e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs)

What products would be covered

It is proposed that TGO 110 **WILL** cover:

- ✓ Products accessed via APS and SAS B (subject to comments on Personal Importation Scheme)
- ✓ Clinical trial products
- ✓ Compounded products



What products would not be covered

Proposed that TGO 110 will **NOT** cover:

- ✗ Products evaluated by the TGA and registered in the ARTG
- ✗ Export-only products
- ✗ Other nicotine replacement therapies (NRTs) (e.g. patches, gum, lozenges, mouth spray, inhalators)
- ✗ Other nicotine products not intended for use in vaping devices (e.g. combustible tobacco, chewing tobacco, snuff)
- ✗ Products imported by travellers and groups specified in the *Therapeutic Goods Regulations 1990*
- ✗ Vaporiser nicotine that is not a finished product (e.g. raw ingredients)

Overseas products

- Personal Importation Scheme
- Overseas manufacturing
- Proposed TGO110 requirements vs. products sold as consumer goods in other countries



US	UK*	Canada*	EU*	NZ*
Deemed to comply If subject to a PMTA marketing order from FDA	Would comply	Would comply	Likely to comply If label is in or includes English	Would comply If proposed regulations introduced

*As long as the product meets the requirements of that country

When we talk about US, UK, EU, Canadian and NZ regulatory regimes in this Webinar, we are referring to requirements for consumer goods

Labelling – ingredient lists

TGA PROPOSAL

The label or information sheet must list the name of the active ingredient + presence of flavours + names of other excipients (*aligned with Canada, UK, EU, NZ proposal*)

OTHER OPTIONS:

1. The label or information sheet to list active ingredient(s) + all excipients (including ingredients of flavours)
2. The label or information sheet to list active ingredient(s) only
3. Any of the above, but on the label only (no option to provide information sheet)
4. No ingredient list on the label or information sheet



Labelling - Nicotine concentration

TGA PROPOSAL

The label or information sheet must state the nicotine concentration or content (*aligned with UK, EU*)

OTHER OPTIONS:

1. The label or information sheet to state base form or base form equivalent nicotine concentration in mg/mL
2. The label or information sheet to state nicotine concentration or nicotine salt concentration in mg/mL (*Canada, NZ proposal*)
3. Any of the above, but on the label only (no option to provide information sheet)
4. No nicotine concentration or content labelling requirements



Labelling - Warning statements

TGA PROPOSAL

Rely on State/Territory requirements for warning statements and safety directions in Poisons Standard

- ‘KEEP OUT OF REACH OF CHILDREN’ (on the dispensing label)
- ‘Avoid contact with eyes’ (on the label or information sheet)
- ‘Avoid contact with skin’ (on the label of information sheet)

OTHER OPTIONS:

1. Additional mandatory warning statements and safety directions (*UK, Canada, NZ proposal*) **AND/OR** pregnancy warning **AND/OR** addictiveness warning (*UK, EU, Canada, US, NZ proposal*)
2. Option 1, but on the label only (no option to provide information sheet)

Packaging - Child-resistant packaging (CRP)

TGA PROPOSAL

Products packaged for supply in the US, UK, EU, Canada and (if proposed CRP regulations introduced) NZ may be supplied in Australia in packaging complying with CRP requirements imposed in that jurisdiction.

All other products must meet requirements for TGO 95 (except requirement to provide directions for opening/closing)

OTHER OPTIONS

1. Impose requirements equivalent to TGO 95 for all unapproved vaporiser nicotine products
2. Impose alternative CRP requirements
3. Rely on State/Territory requirements for child-resistant closures compliant with the Poisons Standard



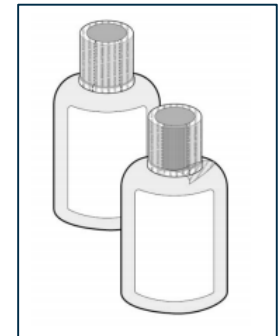
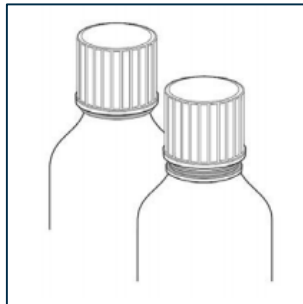
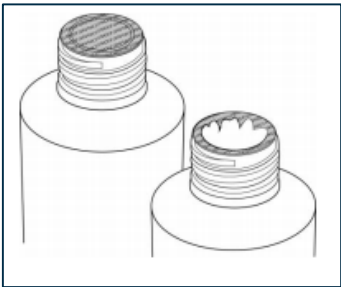
Packaging - Tamper-proof/-evident packaging

TGA PROPOSAL

No mandatory requirements for tamper-proof/-evident packaging for vaporiser nicotine products

OTHER OPTIONS

1. Require tamper-proof/-evident packaging (*UK, EU, NZ proposal*)



Ingredients - Prohibiting certain ingredients

TGA PROPOSAL

Prohibit the following ingredients in vaporiser nicotine products:

- active ingredients other than nicotine
- other ingredients with known health risks - ethylene glycol, diethylene glycol, diacetyl, 2,3- pentanedione, vitamin E acetate

(aligned with UK, Canada, NZ proposal)

OTHER OPTIONS:

1. Prohibit active ingredient other than nicotine only
2. Prohibit other ingredients which have been associated with health concerns
3. Do not prohibit any ingredients



Ingredients - Restrictions on flavours

TGA PROPOSAL

No limits on flavours (except where specific ingredient prohibitions apply) *(aligned with UK, EU)*

OTHER OPTIONS:

1. Allow certain flavours only (e.g. tobacco, mint, menthol) *(From 11 Aug 2021, NZ restriction on general retailers)*
2. Prohibit certain flavours (e.g. cannabis, soft drink, energy drink, dessert, confectionary) *(Canada)*

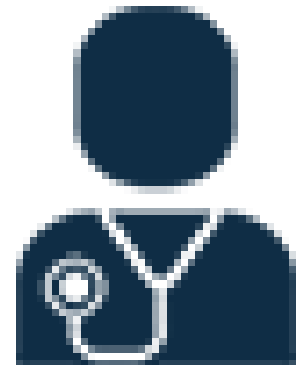
Limits on nicotine concentration

TGA PROPOSAL

No limit on nicotine concentration or content

OTHER OPTIONS

1. Maximum nicotine concentration of:
 - i. 20 mg/mL (*UK, EU, Canadian proposal*) **OR**
 - ii. 66 mg/mL (*Canada*) **OR**
 - iii. another level (*NZ proposal – different levels for nicotine vs nicotine salt products*)



Limits on container volume

TGA PROPOSAL

No limit on container volume (*aligned with Canada*)

OTHER OPTIONS

1. Maximum volume of:
 - i. 10 mL (*UK, EU*) **OR**
 - ii. 1000 mL **OR**
 - iii. another level (applicable to all concentrations) (*NZ proposal*)
2. Range of maximum volumes applicable to different nicotine concentrations



Default standards and nicotine purity

TGA PROPOSAL

Vaporiser nicotine products covered by TGO 110 would be exempt from European Pharmacopoeia (Ph. Eur.) and United States Pharmacopeia (USP) monographs for finished inhalation products

OTHER OPTIONS

1. Do not exempt products from complying with any applicable monographs in the British Pharmacopoeia (BP), Eur. Ph. or USP
2. Exempt products covered by TGO 110 from nicotine monographs in the Eur. Ph. and USP
3. Exempt products covered by TGO 110 from all applicable monographs in the BP, Eur. Ph. and USP



Next steps

- **Slides and outcomes** of this webinar will be published on the TGA's website
- Make your submission on the proposed TGO 110 through the **TGA Consultation Hub by 31 March 2021**
- **Review public submissions**
- Final TGO 110 and draft guidance expected to be published in **April or May 2021**
- **TGO 110 would come into effect on 1 October 2021**

Contact us

Nicotine.Standard@health.gov.au

Our speakers are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

LIVE POLL

More information



TGA website www.tga.gov.au



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TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>



Website and link references

TGO 110 – Standard for Vaporiser Nicotine - Consultation

<https://consultations.health.gov.au/tga/tgo110-standard-for-vaporiser-nicotine/>

Vaporiser nicotine and e-cigarette information hub

<https://www.tga.gov.au/nicotine-e-cigarettes>

Access to nicotine e-cigarettes: questions and answers

<https://www.tga.gov.au/nicotine-e-cigarettes-questions-and-answers>

Accessing unapproved products information hub

<https://www.tga.gov.au/accessing-unapproved-products>

Questions?



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