Update on improvements in TGA standards for quality and safety of unapproved vapes

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

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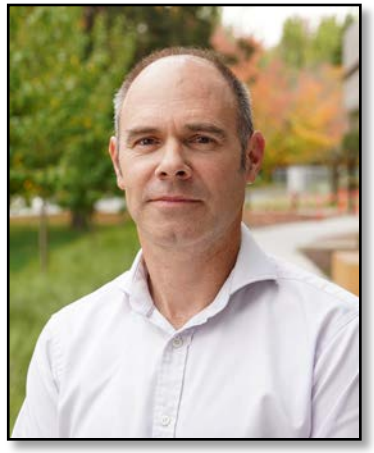

Dr Tony Manderson

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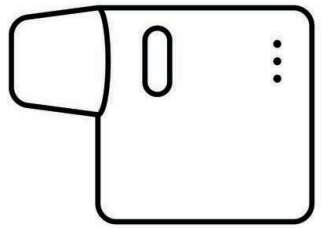
29 April 2024

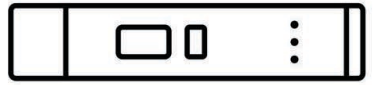
Overview

- Background on the reforms
- Vaping substance standards (TGO 110)
    - First stage
    - Packaging and labelling
    - Container volume
    - Ingredients
- Future considerations – GMP
- Vaping devices and accessory standards
    - Essential Principles
    - Medical Devices Standards Order (MDSO)
        - Electrical and battery safety
        - Toxicological risk assessment
        - Plain design
- Questions

Background

- Oct 2021: Introduction of TGA standards for nicotine vaping products - *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*
- Nov 2022 - Jan 2023: Consultation on potential regulatory reforms
- May 2023: Minister for Health and Aged Care announced action on vaping
- Sep 2023: Targeted consultation on proposed reforms
- 28 Nov 2023: Minister for Health and Aged Care announced enhanced controls on importation, manufacture, supply, commercial possession and advertisement of vapes to be implemented throughout 2024
- Jan - March 2024: First stage of enhancements to TGA standards were implemented.





Stage 2: Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

- The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) was introduced to Parliament on 21 March 2024.
- If passed, the Bill would amend the *Therapeutic Goods Act 1989* (the TG Act) to prohibit the:
    - **importation,**
    - **domestic manufacture,**
    - **supply,**
    - **commercial possession and**
    - **advertisement**

  of disposable single use and non-therapeutic vapes.
- The Bill **maintains legitimate patient access to therapeutic vapes** for smoking cessation and the management of nicotine dependence, where clinically appropriate.
- Provides a single consistent framework that will apply nationally, irrespective of nicotine content or therapeutic claims.

Product standards for unapproved vapes

From 1 March 2024, importers of vapes are required to provide notifications to the TGA declaring compliance with relevant product standards. These include:

Therapeutic Goods (Standard for Therapeutic Vaping Goods) (**TGO 110**) Order 2021	• Applies to e-liquids including vaping substances, vaping substance accessories, vaping kits, and goods in a vaping pack
Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (**MDSO**)	• Applies to vaping devices or vaping device accessories (not containing a vaping substance)

First Stage of reforms to improve TGO110

- Effective from March 2024 (published January 2024)

- **Changes implemented:**
    - Extending the requirements to unapproved non–nicotine vapes
    - Extending the regulatory controls for the device component of a vape
    - Restricting flavour choice to mint, menthol and tobacco.

Second Stage reforms to improve TGO 110

- Likely publication May 2024
- Anticipated to be effective in December 2024

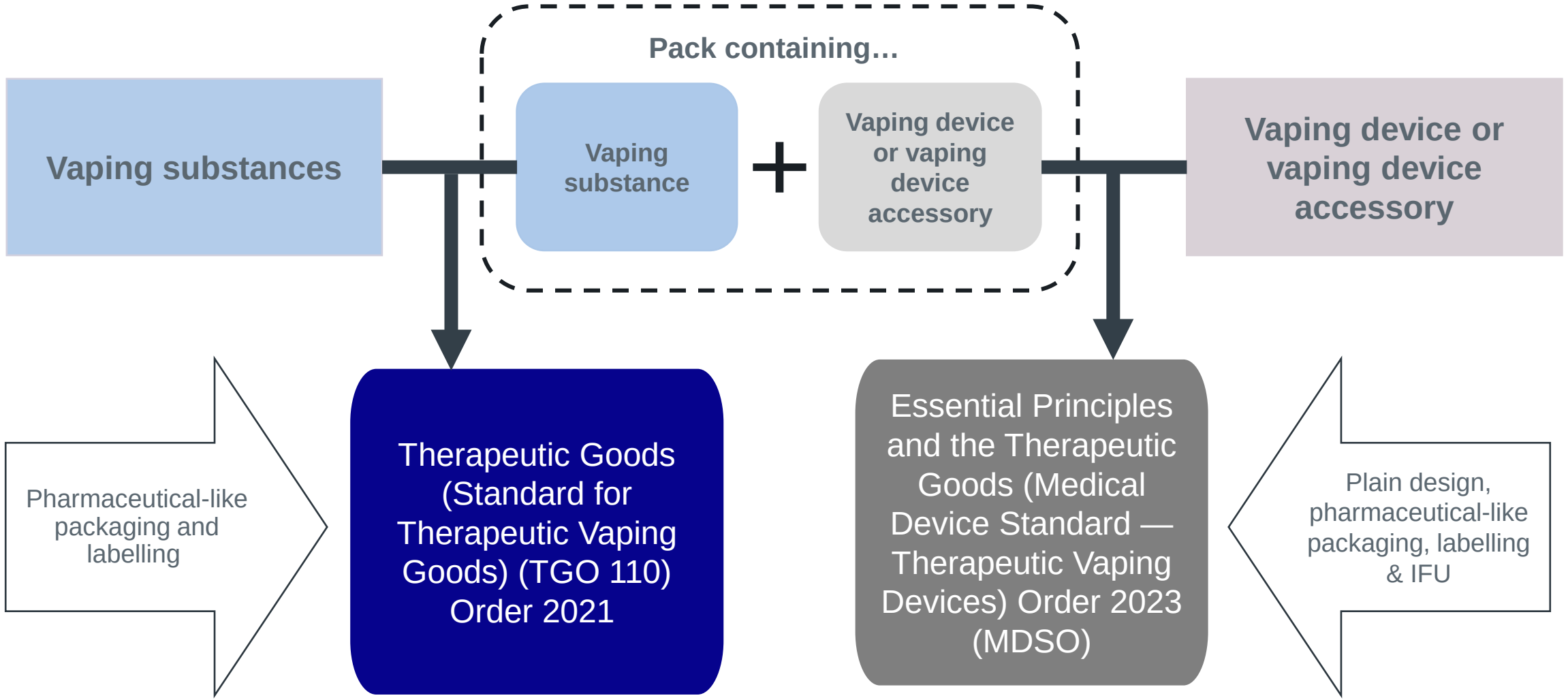
Proposed changes to be implemented:

- **Changes to packaging and labelling**
  - Pharmaceutical like packaging and labelling
  - Restrictions on appearance of vapes
  - New warning statements
- **Restrictions on container volume**
- **Restrictions on ingredients**
  - Limits on permitted ingredients
  - Reducing the maximum allowed contents of nicotine
  - Introducing maximum limit for menthol contents
- **Changes to alternative conformity requirements**

Changes to

PACKAGING AND LABELLING REQUIREMENTS

Proposed changes to packaging & labelling for unapproved vapes



Proposed pharmaceutical-like packaging and labelling

- Packaging and labelling requirements for primary pack, intermediate pack and primary container to align with other therapeutic goods (specified under TGO91)
    - Vapes are prescription only medicines. Complying with TGO91 requirements will ensure that the information for safe use of vapes is available on labels and packs
    - This will also reinforce the message that vapes are not recreational products
- Name of the good and flavour descriptor must not in any way be promotional or designed to attract young people or new users. It should not suggest any health benefit or resemble a food or beverage
- Devices and device accessories sold as part of a vaping kit or pack must comply with requirements specified in MDSO or EPs
- Each component of a vaping kit must be labelled independently as a standalone item

Restrictions on appearance of vapes

- Packaging and labelling must be predominantly white
- Packaging and labelling must not feature more than 3 other colours.
    - All printing (on label and packaging) must be in single colour except for expiry date and batch number.
    - A coloured strip can be used to identify flavour and strength
- Certain features on packaging and labelling are prohibited, such as:
    - Features suggesting the product either is, or resembles, a different type of good such as a food item, beverage, cosmetic product or health product
    - Promotional text, symbols, logos, emblems, or any other pictorial
    - Features that can amend packaging or labels post retail sale, such as removable tabs, fold panels or colour changing inks
- These requirements must cascade through all packaging and labelling components

New warning statements

- We propose two new warning statements be included on labels and packaging **in addition to** the currently enforced warning statements

Proposed new warning statements

- THIS PRODUCT CONTAINS NICOTINE, WHICH IS HIGHLY ADDICTIVE SUBSTANCE
- NOT TO BE INGESTED.

Are you ready for the changes to packaging and labelling?

Are the colour restrictions proposed for vape packaging and labelling sufficient to assist pharmacy dispensing, and consistent with other prescription medicines?

Restrictions on

INGREDIENTS

Maximum allowed contents of nicotine

Proposed nicotine limits

- An upper limit of 50 mg/mL (base equivalent) to apply for any prescriptions for the first 12 months
  - Prescribing 50 mg/mL through all or some access pathways (SAS-C, AP and SAS-B)
  - Prescribing nicotine concentrations above 20 mg/mL (to 50 mg/mL) only through SAS-B and classical Authorised Prescription (HREC approval) after 12 months

- In previous consultations we proposed to restrict maximum nicotine concentration to 20 mg/mL
- A lot of feedback was received on this aspect, including from prescribers. There are a lot of aspects to balance in any final decision, including:
  - Limited evidence for the need for vapes above 20 mg/L (mainly for smoking cessation)
  - High level of nicotine addiction within the community at present
  - Front-line prescribers relaying the needs of people trying to stop smoking or manage nicotine addiction dependence
  - Ease of access to high concentration vapes and the impact on population health

Maximum allowed contents of menthol

Proposed menthol limits

- Restrict menthol contents in a vaping substance to a maximum of 1% w/v

- In the November 2023 consultation, we proposed a maximum limit of 0.1% w/v for menthol in vapes
- Stakeholders suggested 0.1% menthol might be too weak and would impact efficacy of product. It would also make them less appealing, which may lead to treatment failure
- Toxicological data indicates menthol contents above 2% are clearly hazardous in vaping substances, but limited data still

Does this concentration balance risk with user need for flavours other than tobacco?

Restrictions on ingredients: **Permitted ingredients**

To enhance the quality of products available in the Australian market, we propose the following:

Recommended ingredients allowed to formulate vaping substance

- Only ingredients listed in this table (right) may be added to the formulation
- All raw materials other than flavours must comply with one or more applicable pharmacopoeia requirements (BP, EP or USP-NF)
- Ingredients in the flavour must all relate to the flavour or its stability.

Ingredient	
Nicotine free base or salt form	
Flavours, either: (a) mint or menthol flavour; or (b) tobacco flavour	
glycerol	
propylene glycol	
water	

Restrictions on ingredients: **Unavoidable ingredients**

- Unintentional chemical entities may be present in a vaping substance formulation
- Where these ingredients are unavoidable, TGO110 will include a list of maximum permitted limit each one of them
- The list is not intended to be exhaustive but will be progressively updated as and when new information on such chemical entities becomes available

Part 1 – Compounds

Column 1	Column 2	Column 3	
Item	**Ingredient**	**Limit mg/L**	**Limit ppm**
1	acetaldehyde	200 mg/L	22 ppm
2	diethylene glycol	1000 mg/L	1,000 ppm
3	ethylene glycol	1000 mg/L	1,000 ppm
4	formaldehyde	22 mg/L	22 ppm
5	Menthol	5000 mg/L	5000 ppm

Part 2 – Metals

Column 1	Column 2	Column 3	
Item	**Ingredient**	**Limit mg/L**	**Limit ppm**
1	aluminium	12 mg/L	12 ppm
2	antimony	4 mg/L	4 ppm
3	arsenic	0.4 mg/L	0.4 ppm
4	cadmium	0.6 mg/L	0.6 ppm
5	chromium	0.6 mg/L	0.6 ppm
6	iron	12 mg/L	12 ppm
7	lead	1 mg/L	1 ppm
8	mercury	0.2 mg/L	0.2 ppm
9	nickel	1 mg/L	1 ppm
10	tin	12 mg/L	12 ppm

Part 3 – tobacco specific nitrosamines

Column 1	Column 2	Column 3	
Item	**Ingredient**	**Limit mg/L**	**Limit ppm**
1	4-methyl-N-nitrosamino-1-(3-pyridyl)-1-butanone	50 µg/L	0.05 ppm
2	N-nitrosonornicotine	50 µg/L	0.05 ppm
3	N-nitrosonatabine	50 µg/L	0.05 ppm

Restrictions on

CONTAINER VOLUME

Recommended volume limits

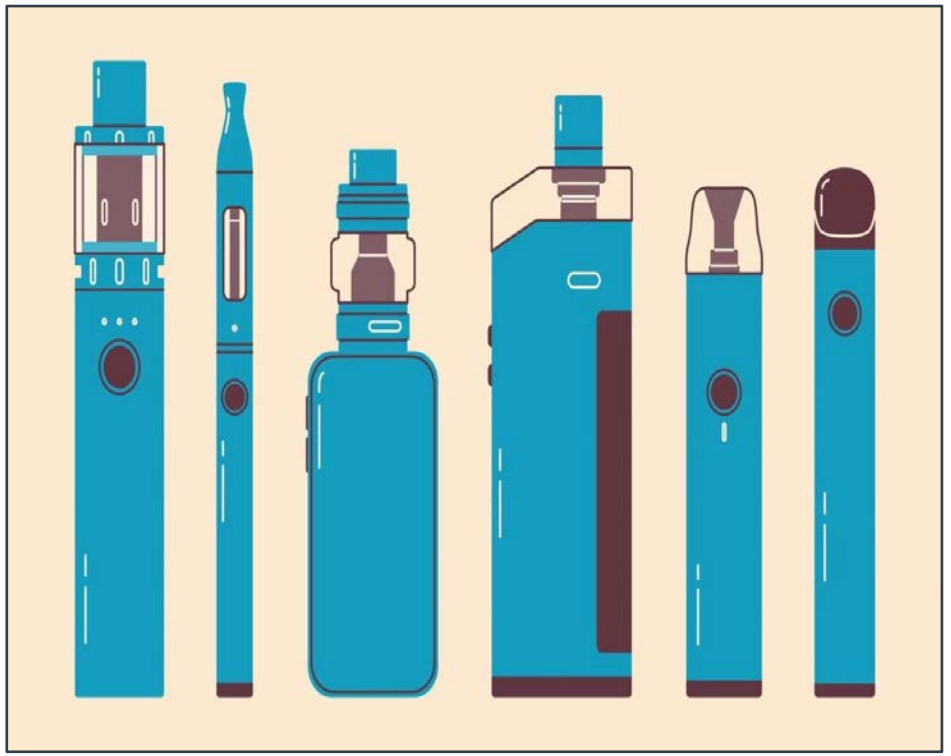
- Volume of vaping substance accessory (pods / cartridge) must not exceed 5 mL
- Volume for a retail container of a vaping substance must not exceed 30-60 mL.

- In previous consultations, we proposed a maximum of 2 mL volume limit for pod/cartridges and 120 mL volume limit for vaping substance container.
- Propose to lift the limit on pod volume to 5 mL – closed system vapes are generally safer than open system and allowing higher volume will make product more economical for consumers.
- Propose to limit the volume of open systems to 30-60 mL – with the proposal to lift the maximum nicotine concentration to 50 mg/mL (rather than 20 mg/mL) the safety concerns are higher and there should be greater restriction to the volume in the re-fill bottles.

Do you agree with these proposed volume limits? If not, why not.

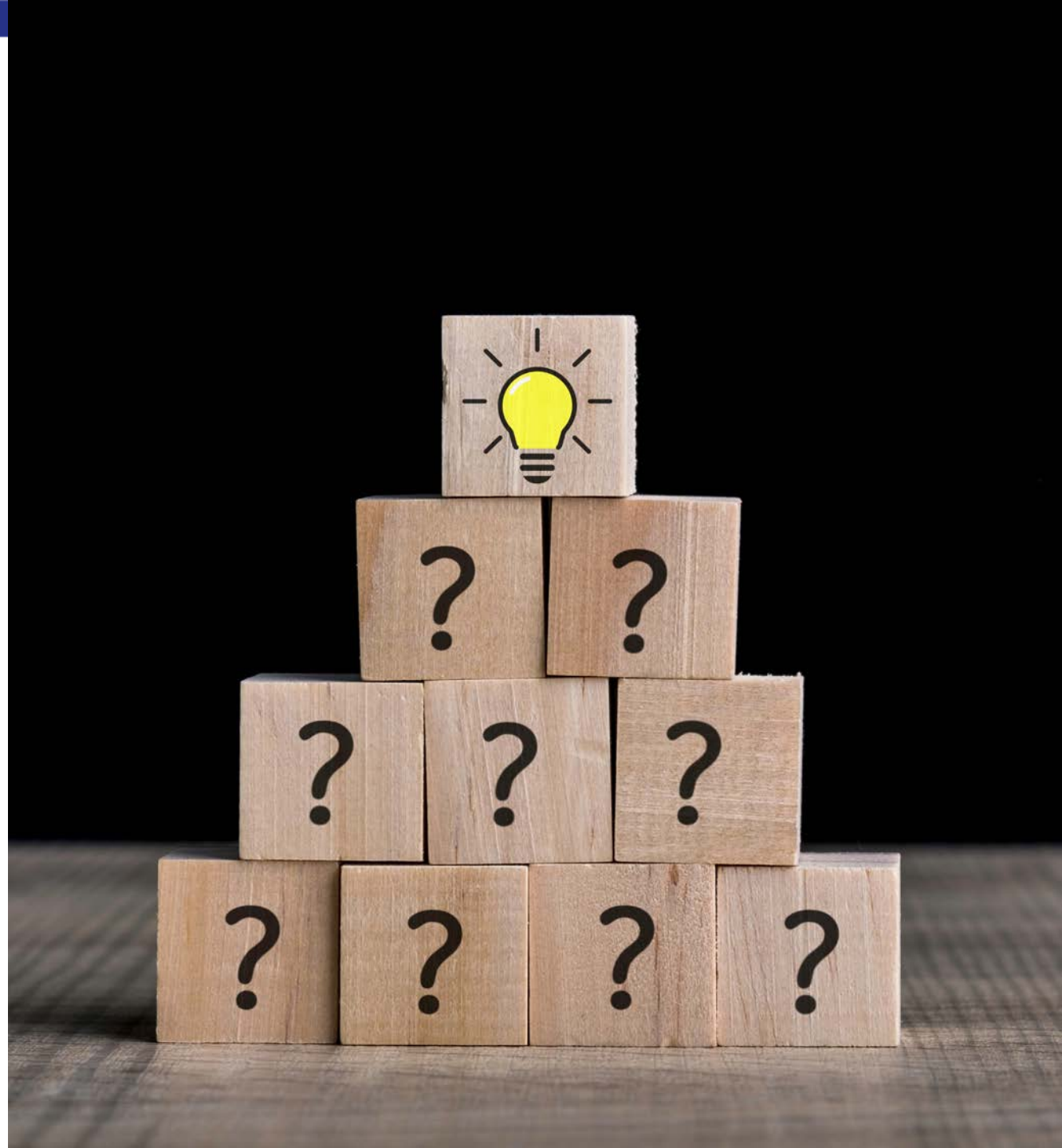
Alternative conformity requirements

- Under current regulations, a vaping substance or vaping substance accessory allowed to be marketed under the *Food Drug and Cosmetic Act* of the United States of America is taken to comply with TGO110 requirements relating to ingredients, child resistant packaging and record keeping



- Upon implementation of recommended changes in TGO110, there will no longer be sufficient similarity of approach – some requirements could still be equivalent, and guidance will outline where these exist

Further considerations to improve product standards



GMP requirements for the nicotine substance for vapes

- All manufacturing sites in Australia must hold a GMP licence issued by the TGA for the manufacture of therapeutic goods. This applies to sites that undertake **all** or **part** of the manufacture of a vape containing nicotine.

- To create a fair playing field for domestic manufacturers, TGA is considering introducing GMP requirements for nicotine in vapes manufactured overseas.

Recommended tiered approach to introducing GMP requirements

- Stage 1: The active pharmaceutical ingredient (nicotine) in vape formulation, must be manufactured at GMP-certified facilities, e.g. manufacturers holding a Certification of Suitability to the Monographs of the European Pharmacopoeia (CEP)
- Stage 2: GMP requirements apply to all aspects of vape manufacture

Do you support imposing GMP requirements to all vapes and the proposed tiered approach?

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Leon Weekes
Director
Specialist Evaluation Section

29 April 2024

Updating Medical Device Standards Order for Therapeutic vaping devices and accessories

Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021

- Applies to e-liquids including vaping substances, vaping substance accessories, vaping kits, and goods in a vaping pack

Essential Principles and Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (MDSO)

- **Applies to vaping devices** or vaping device accessories (not containing a vaping substance)

Regulatory pathways: Therapeutic vaping devices and accessories

Therapeutic vaping devices and accessories *previously excluded* from the therapeutic goods framework, or *exempt* from inclusion in the ARTG

Supply via the unapproved pathway

Essential Principles (EPs)

- Safety and performance requirements for all medical devices
- Set out in the Therapeutic Goods (Medical Devices) Regulations 2002
- Apply to therapeutic vaping devices that were previously exempt from inclusion in the ARTG

Medical Device Standards Order (MDSO)

- Alternative option for demonstrating compliance with the essential principles
- Order sets out the minimum requirements therapeutic vaping devices or therapeutic vaping device accessories must meet
- Applies to therapeutic vaping devices that were previously excluded from the therapeutic goods framework

Therapeutic vaping devices and accessories

Supply via the approved pathway

Included in the ARTG

- Must meet the Essential Principles
- Must have appropriate Conformity Assessment evidence, either from TGA or a recognised comparable overseas regulator.

Proposed changes to the Medical Device Standards Order

Current MDSO

- Quality management certification, or
- Evidence to demonstrate that consumer e-cigarette requirements of certain international regulators are met, or
- Comparable international regulatory approval from the US, EU or UK

Increased product standards for therapeutic vaping devices

Proposed MDSO (December 2024)

- Requirements for instructions, labelling, pharmaceutical-like packaging, and plain design for vaping devices
- Technical requirements - **vaping devices must meet international regulations for medical devices, OR the following product standards:**
  - Quality management system certification specific to medical devices
  - Risk management for medical devices
  - Battery standards and Australian electrical safety and marking
  - Product safety requirements: dosage control, prevention of accidental activation, and battery venting
  - Toxicological risk assessment for the vaping device
  - Removing international e-cigarette pathways – vaping devices must meet the new technical requirements

Heightened regulatory standards

We are proposing the following minimum quality and safety standards for therapeutic vaping devices and therapeutic vaping device accessories be implemented in December 2024:

- **pharmaceutical-like packaging and plain design**
- **labelling and instructions for use** to ensure use of these goods as intended and allow their traceability in case of an adverse event
- **quality management system specific for medical devices** to ensure therapeutic vaping devices produced are fit for their intended purpose
- **removing e-cigarette regulatory compliance evidence** as acceptable evidence and replacing this with more targeted product requirements that align more closely with medical device regulatory requirements

Note: A targeted consultation occurred in February/March 2024 to inform these requirements

- **medical device risk management and toxicological risk assessment** to ensure that risks related to the use of the device are identified and appropriately managed
- **compliance with Australian electrical safety standards and international battery standards** to reduce the risks associated with electrical systems and batteries
- product design including having evidence to demonstrate:
  - the **device can deliver a specified dose** that is verified by the manufacturer
  - the **device has a venting mechanism that channels pressure away from the user** in the event of a fire or explosion
  - the **device is designed and verified to minimise the risk of accidental activation of the device**

Proposed changes: Electrical safety and battery standards

We propose that therapeutic vaping devices and therapeutic vaping device accessories must meet certain standards including:

- **International standards for batteries** (IEC standards & UN test methods as applicable)
- **Australia and New Zealand requirements for electrical safety and button battery safety** (where applicable)

Do you support the proposed battery and electrical requirements?

Proposed changes: Toxicological Risk Assessment

- To mitigate toxicological risks associated with inhaled vapour, specifically where those risks relate to the vaping device, we are proposing a requirement for manufacturers of therapeutic vaping devices and therapeutic vaping device accessories to have conducted a toxicological risk assessment.
- This is consistent with some industry standards for vaping devices.
- The manufacturer must also reduce any unacceptable risks identified in the toxicological risk assessment

Do you support this proposal?

Proposed changes: Plain design of the device

To be implemented in December 2024

- We propose that therapeutic vaping devices and therapeutic vaping device accessories must have a plain design through restriction of colours that are displayed on all exterior visible surfaces to reduce the risk of diversion of these devices to youth or the black market.

Do you support the proposal to require a plain design through restriction of colours for therapeutic vaping devices and accessories?

Do you have any other suggestions in relation to this proposal on plain design and how it can be achieved?

Transitional arrangements for TGO and MDSO

Considering the impact of the reforms on the supply chain, we propose the following transitional arrangements:

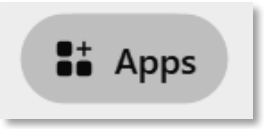
Two-tiered approach with a 3–6-month supply transition

- From December 2024 all imported and domestically manufactured vapes would need to comply with the new standards. This is tier one, the transition for manufacturers.
- A further 3-6 month transition will enable importers, wholesalers and pharmacists to manage their stock levels before the new requirements are fully implemented at the point of supply. This is tier two, the transition for those in the supply chain.
- After this 3-6 month transition all vapes that are supplied either in a wholesale setting or to a patient must meet the new standards.

Do you support this proposal?

How did we go?

Take a moment to complete our survey



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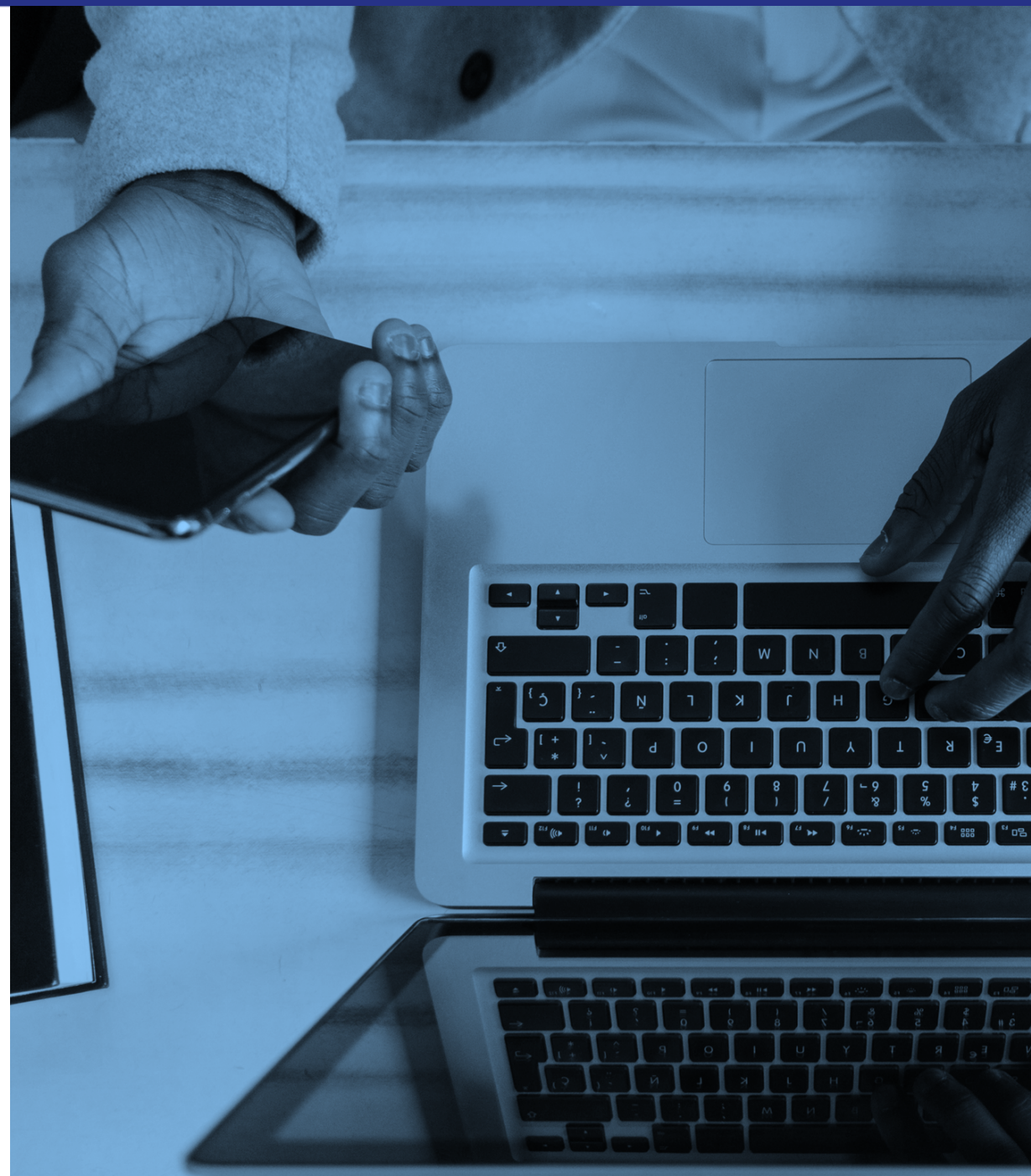

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