Improvements in TGA standards for quality and safety of unapproved vapes

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Acknowledgement of Country

In the spirit of reconciliation, 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

Welcome

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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New product standards for unapproved vapes

Therapeutic Goods Amendment (Standard for Therapeutic Vaping Goods) Instrument 2024 (TGO 110)

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

Essential Principles and the Therapeutic Goods (Medical Device Standard-Therapeutic Vaping Devices) Amendment Order 2024 (MDSO)

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

Guidance now available

Guidance supporting updated TGO110
https://www.tga.gov.au/resources/guidance/guidance-supporting-updated-tgo110

Guidance supporting updated MDSO
https://www.tga.gov.au/resources/guidance/guidance-supporting-updated-mdso-instrument

Transitional arrangements for TGO and MDSO

New Standards commenced on 1 October.

The following transitional arrangements:

Two-tiered approach with two transitions of 5 + 4 months

- **Import and manufacture transition ends 1 March 2025**
    - all imported and domestically manufactured vapes must comply with the new standards. This is tier one, the transition for manufacturers.
- **Supply transition ends 1 July 2025**
    - To 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.
- From 1 July 2025 all vapes that are supplied either in a wholesale setting or to a patient must meet the new standards.

Restrictions on **INGREDIENTS**

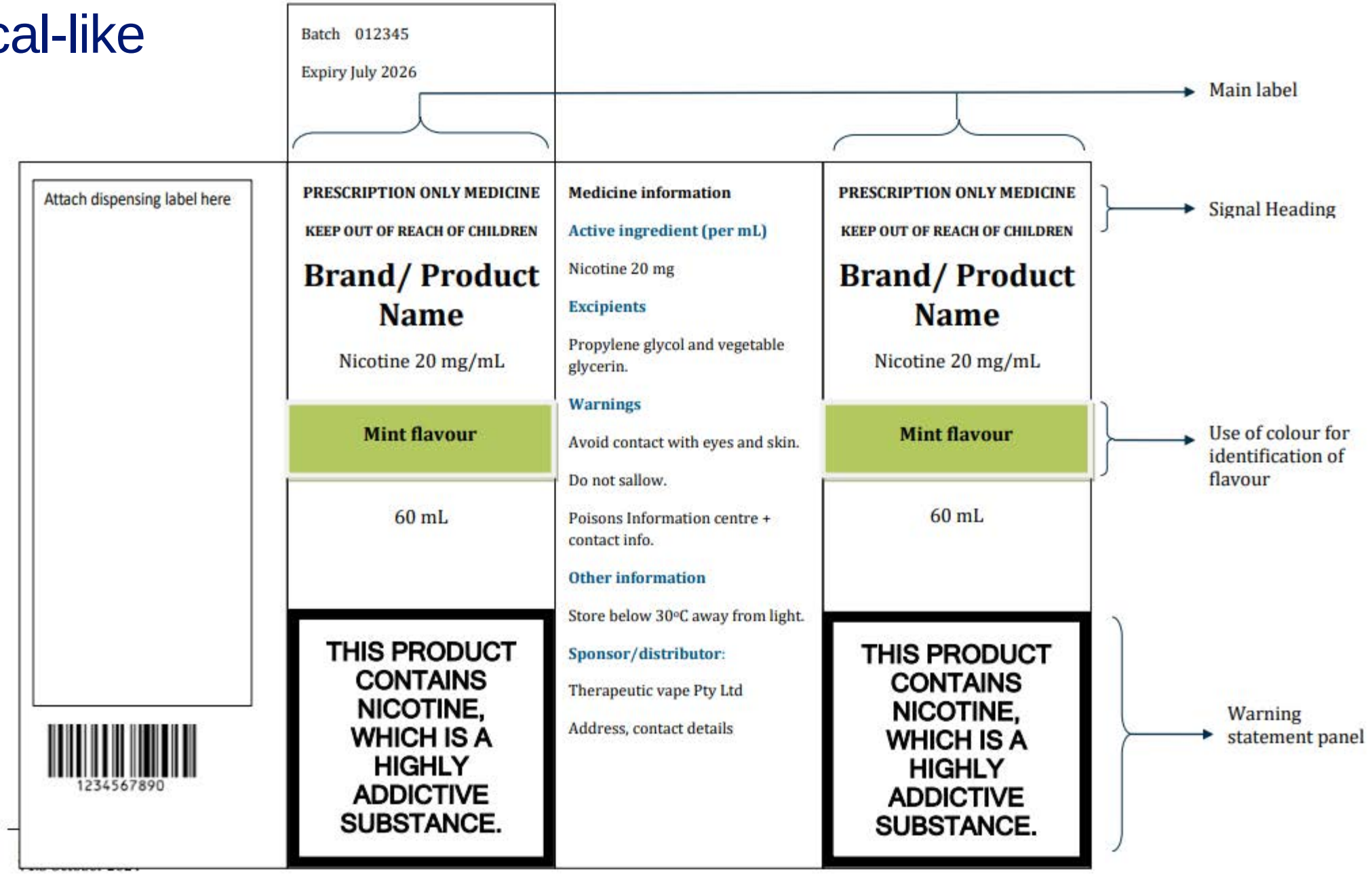
- **Nicotine limit** of 50 mg/mL (base equivalent)
- **Permitted ingredients -** nicotine (free base or salt form), propylene glycol, glycerine, flavour and water
- **Pharmacopeial grade ingredients**
- **Flavours –** further restriction to definition, menthol limit and prohibited ingredients
- **Restricted ingredient list**

PACKAGING AND LABELLING REQUIREMENTS

Aligning with medicines and making packaging less attractive

- **Pharmaceutical-like plain packaging –** predominantly white and very restricted use of colour
- **Labels –** clearly outlined for primary pack, intermediate pack and primary container to align with other therapeutic goods (specified under TGO91) + batch number for traceability
- **Restrictions on the name of the good**
- **Information leaflet –** equivalent to CMI

Pharmaceutical-like packaging



Restrictions on product name

Name of the good

For example, a registered trademark for the good or a unique, invented, common or scientific name assigned to the good

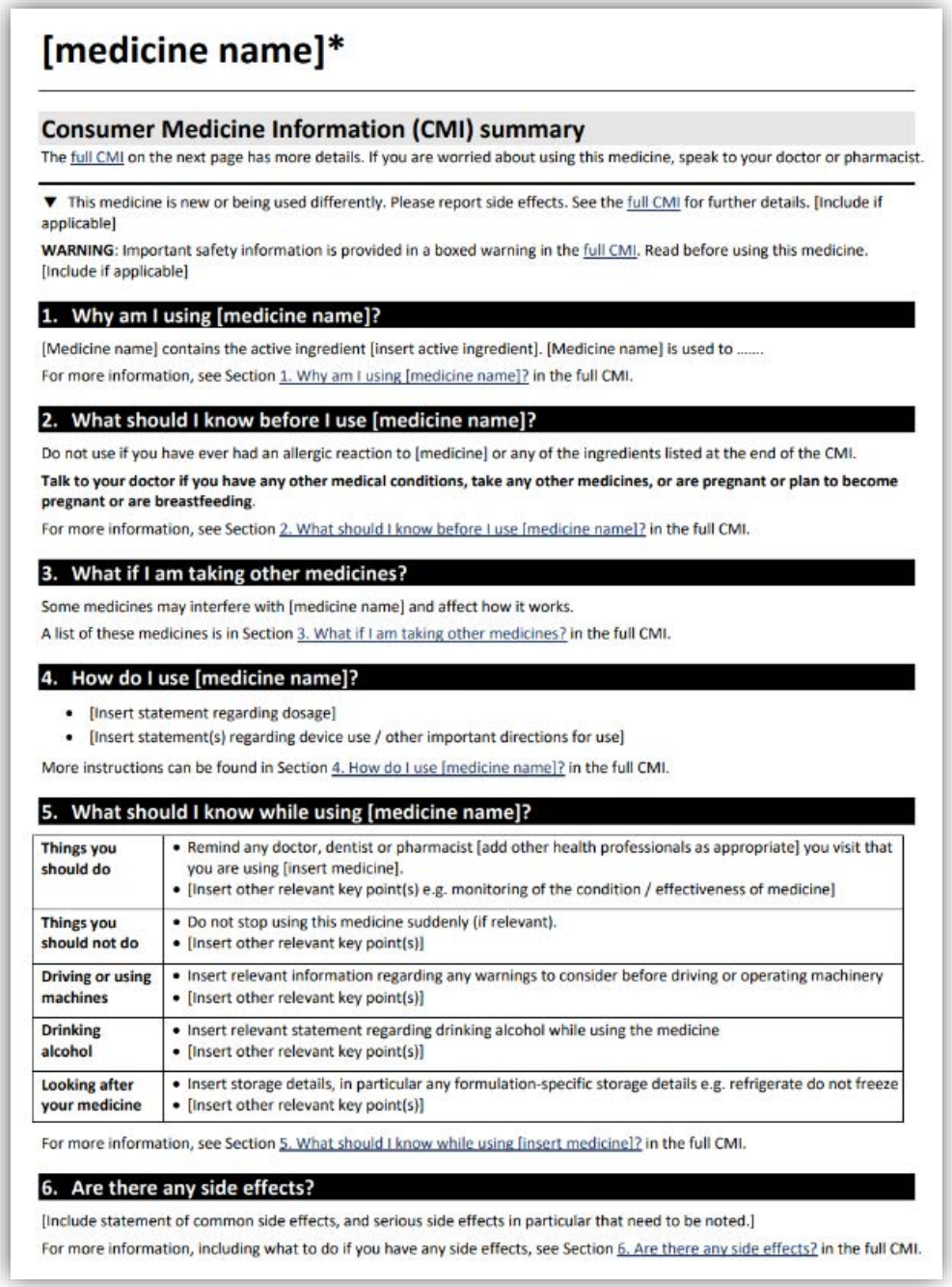
The name must not:

- be in any way attractive to children or adolescents; or
- whether expressly or by implication:
    - suggest that the goods are a food, beverage or cosmetic product
    - suggest that the goods have health benefits, including healing, vitalising, natural, organic or rejuvenating properties
    - suggest that the goods are safe, without harm or without side effects
    - promote the use or supply of the goods
    - exaggerate, or be likely to exaggerate, the efficacy or performance of the goods
    - encourage, or be likely to encourage, inappropriate or excessive use of the goods.

Information Leaflet

Information leaflets include:

- Name of the product
- What the product is for and how it works
- Warnings and precautions
- What to do if taking other medicines
- How to use the product properly
- What to be aware of while using it
- Side effects
- Product detail



[medicine name]*

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details. [Include if applicable]

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine. [Include if applicable]

1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to .....

For more information, see Section 1. Why am I using [medicine name]? in the full CMI.

2. What should I know before I use [medicine name]?

Do not use if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use [medicine name]? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section 4. How do I use [medicine name]? in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	• Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using [insert medicine]. • [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]
Things you should not do	• Do not stop using this medicine suddenly (if relevant). • [Insert other relevant key point(s)]
Driving or using machines	• Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	• Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	• Insert storage details, in particular any formulation-specific storage details e.g. refrigerate do not freeze • [Insert other relevant key point(s)]

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Restrictions on **CONTAINER VOLUME**

Volume restrictions

- 5 mL for vaping substance accessory (pods / cartridge)
- 60 mL for vaping substance (refill)

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Updated Medical Device Standards Order for Therapeutic vaping devices and accessories

Therapeutic Goods Amendment (Standard for Therapeutic Vaping Goods) Instrument 2024 (**TGO 110**)

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

Essential Principles and the Therapeutic Goods (Medical Device Standard-Therapeutic Vaping Devices) Amendment Order 2024

- **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

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

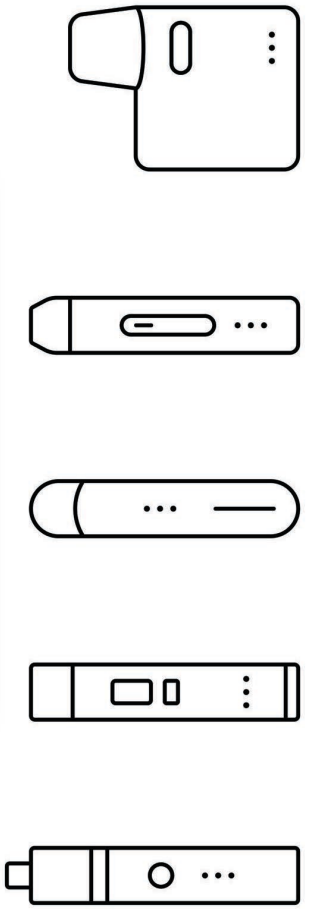
Increased product standards for therapeutic vaping devices

New MDSO (March-July 2025 implementation)

- Requirements for instructions, labelling, naming, pharmaceutical-like packaging, and plain design for vaping devices and their accessories
- Technical requirements - **vaping devices must meet following product standards:**
  - Quality management system certification specific to medical devices for the manufacturer
  - Risk management for medical devices & requirement to manage and mitigate certain risks
  - Battery standards (various ISO standards, ACCC standards)
  - Australian electrical safety standards and markings
  - Product safety requirements including; dosage control, prevention of accidental activation, battery venting, thermal safety, child safety features, basic durability requirements
  - Toxicological risk assessment for the vaping device
  - Removing alternative compliance options: ISO9001, international e-cigarette & medical device regulatory pathways – vaping devices must meet the new technical requirements

Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
  - **plain design, naming restrictions & pharmaceutical-like packaging**
  - **labelling and instructions for use** to ensure use of these goods as intended and enable their traceability in case of an adverse event



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

Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
  - **quality management systems for medical devices (ISO13485)** to ensure therapeutic vaping devices produced are fit for their intended purpose
    - ISO 9001 no longer accepted
  - **removing e-cigarette & medical device pathways** as acceptable evidence and replacing this with more targeted requirements

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

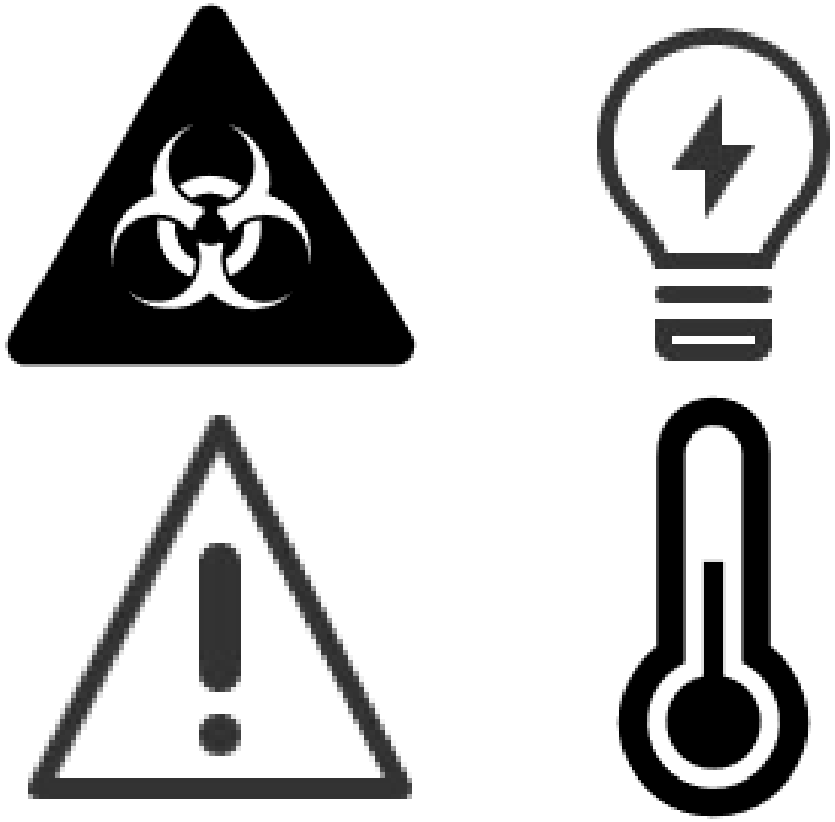
Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
- **medical device risk management and toxicological risk assessment** to ensure that risks related to the use of the device are identified and appropriately managed. Manufacturers must mitigate the following risks:
  - **risks relating to the toxicity of emissions**
  - **risks relating to the toxicity of the materials**
  - **risks relating to batteries (if applicable), including risk of fire or explosion**
  - **electrical hazards or risks**
  - **risks relating to the usability, misuse and leaking of medicinal substances**
  - **risks relating to heating of the device**

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

Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
  - product design including:
    - the **device can deliver the specified emitted mass or dose of medicine**
    - the **device has a venting mechanism that channels pressure away from the user**
    - **prevention of inadvertent actuation**
    - **thermal safety**
    - **basic durability**
    - **child resistant features**
    - **battery safety**
    - **material safety (toxicity)**



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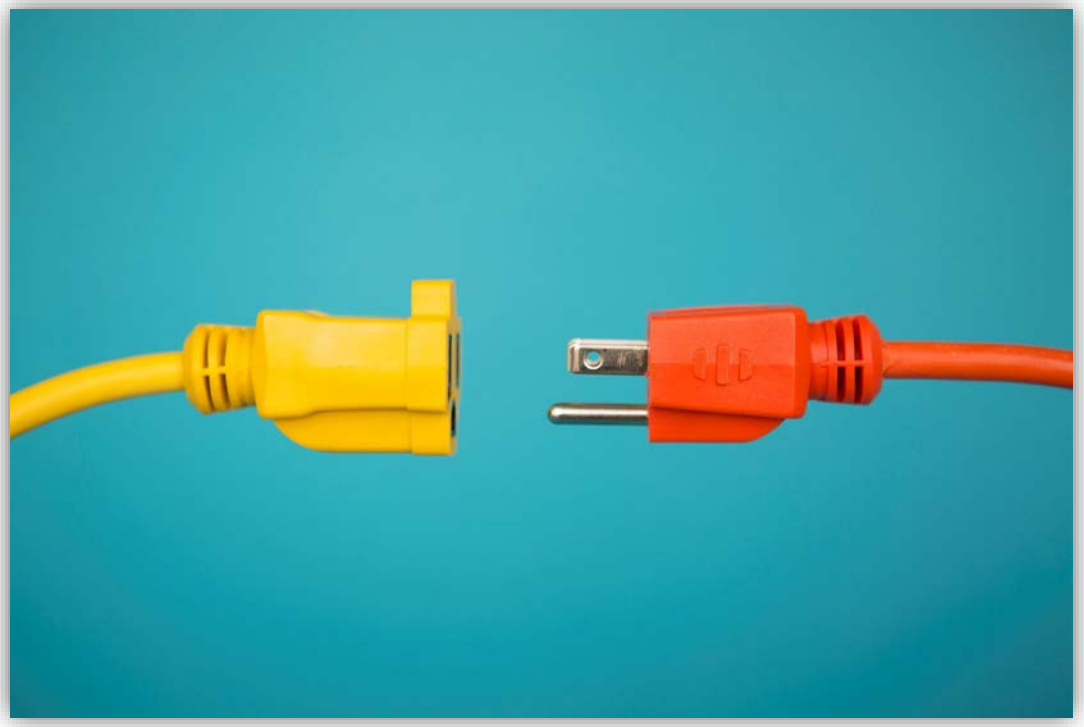
Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
  - **compliance with Australian electrical safety standards**
  - AS/NZS 3820: Essential safety requirements for low voltage electrical equipment
  - AS/NZS 4417.1: Marking of electrical products to indicate compliance with regulations



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

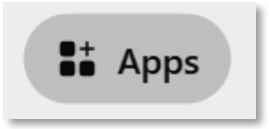
Heightened regulatory standards

- The following minimum quality and safety standards apply to therapeutic vaping devices and therapeutic vaping device accessories:
  - **compliance with international battery standards** to reduce the risks associated with electrical systems and batteries including:
    - **IEC standards for lithium, nickel or single use batteries** (IEC 62133 series, IEC 60086)
    - **Conformity with UN/DOT 38.3** for transport safety of lithium batteries
  - **ACCC button battery standards** (if applicable) for both the device and any batteries supplied separately. *Consumer Goods (Button/Coin Batteries) Safety Standard 2020* and related requirements

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

How did we go?

Take a moment to complete our survey



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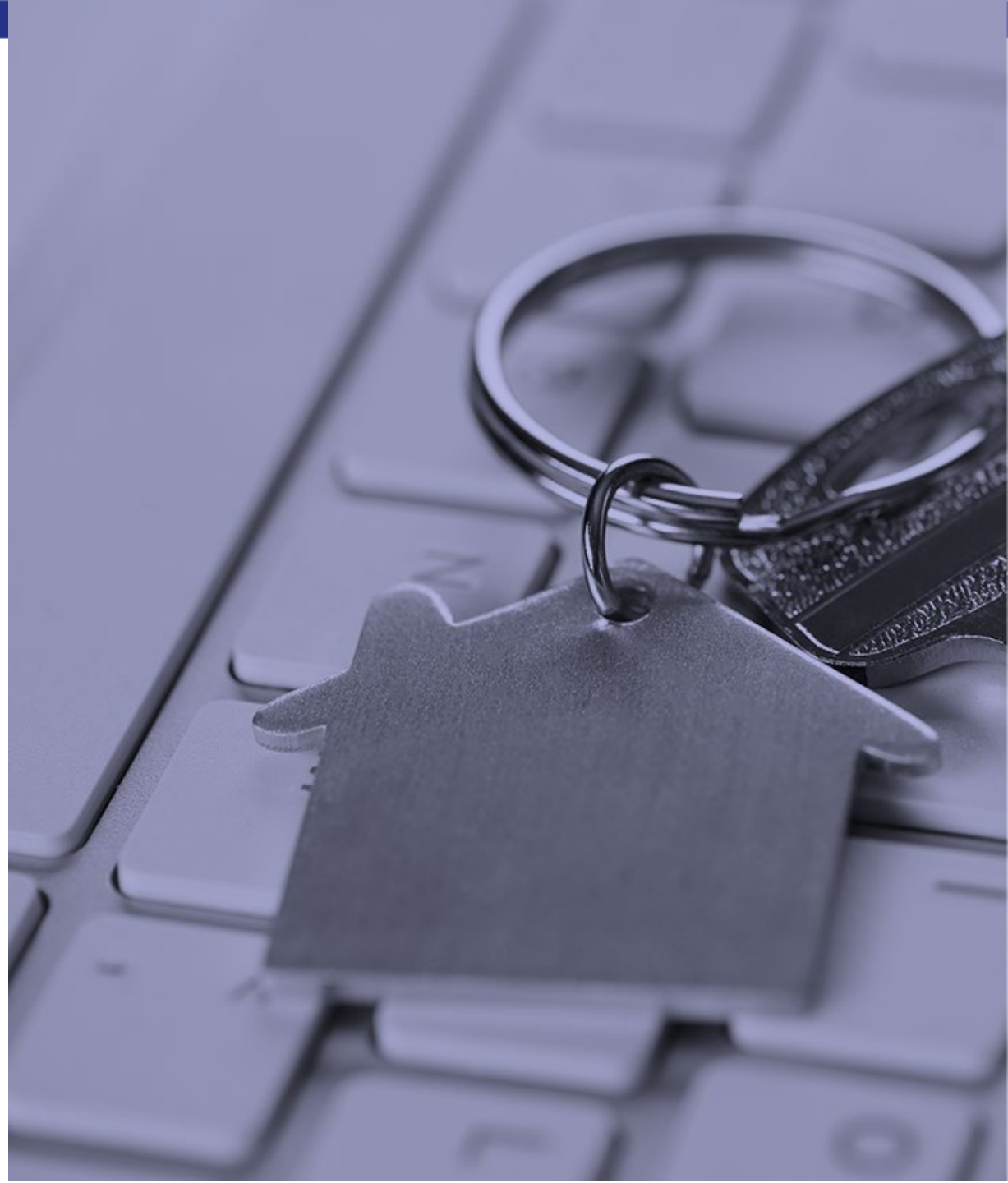
Contact us

Vaping enquiries

vapeengagement@health.gov.au



Questions?

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