Update on vape regulations

Information for sponsors, importers, manufacturers and wholesalers

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Australian Government Department of Health and Aged Care

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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.

What are vapes?

- The term ‘vapes’ refers to vaping substances, accessories or devices designed or intended for the purpose of vaporising and administering a liquid component by inhalation, using electronic means, in a manner that replicates, or produces an experience similar to smoking.
- Vapes generally comprise a **vaping substance** (e.g. e-liquid) and a **device** (including device components):

Vaping substance

- May or may not contain nicotine
- May be present in pods, cartridges or refillable liquids

Vaping device (inc. device components)

- A device designed to generate or release, by electronic means, an aerosol or vapour (i.e. mist or emission) for inhalation
- Can be a disposable or refillable system
- Refillable systems include, pods, cartridges and refillable chambers

Reforms to the regulation of vapes

The Australian Government has announced reforms to progressively **ban all vapes** within Australia, unless they are therapeutic vapes that comply with the *Therapeutic Goods Act 1989*.

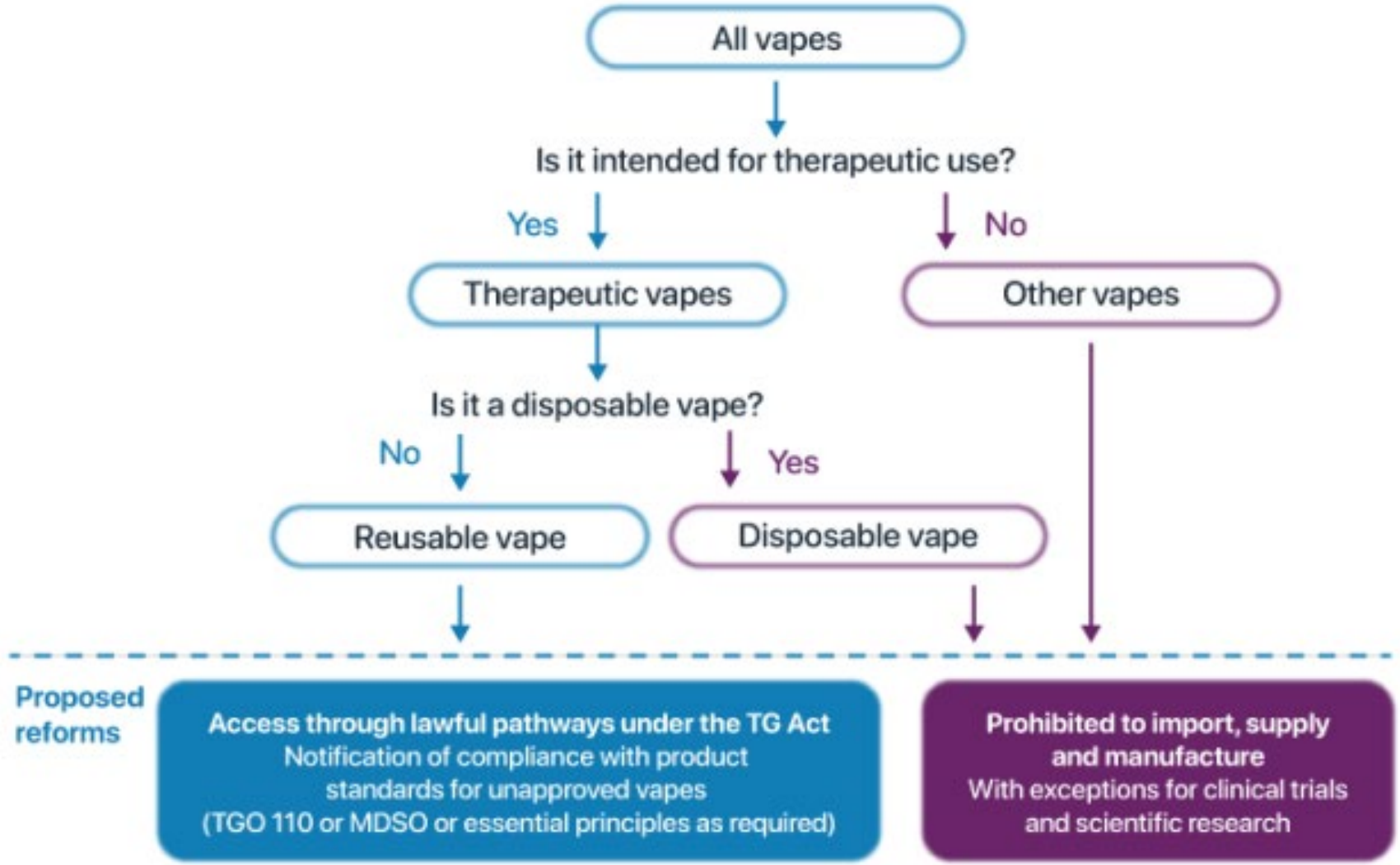
Therapeutic vapes will only be available from people authorised to supply prescription medicines under state and territory laws, such as in pharmacies, and must meet new product standards, among other requirements.

Once the changes are complete, tobacconists, vape shops and convenience stores will no longer be able to lawfully sell any type of vape.

"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate."

The Hon Mark Butler MP, Minister for Health and Aged Care

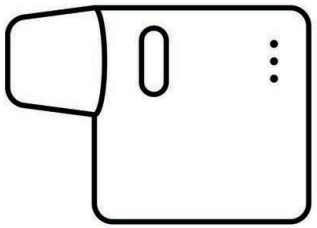
Lawful access to vapes under the reforms



Rationale for vaping reform

- On 1 October 2021, Regulatory changes required a prescription to access nicotine vapes and compliance with *Therapeutic Goods Act 1989*
- No registered therapeutic vaping goods, so vaping goods entered Australian market as unapproved goods with a requirement to comply with a new product standard TGO 110.
- The intention of the 2021 reforms was to prevent children and adolescents from accessing vapes that contain nicotine, while allowing legitimate users to access vapes for smoking cessation under medical supervision with a prescription.
- However, increasing evidence suggested that the 2021 reforms did not meet these objectives.
- Recent data shows that among people aged 14 years and over, current use of vaping goods nearly tripled between 2019 (2.5%) and 2022–2023 (7.0%).
- The increase was even more marked among young people, with current use of vaping goods increasing from 5.3% to 21% among people aged 18 - 24, and from 1.8% to 9.7% among people aged 14 -17.
- This growth in vaping and the unknown quality and safety of vapes represent an unacceptable population health risk, particularly in light of the unfortunate lessons we have learnt from tobacco use.
- Vape use is associated with a number of health risks, including nicotine addiction and the long-term risks are still emerging.
- But there is also evidence that vaping can support some people to quit smoking and may have a role in quitting vaping eg recent Cochrane review.

Stage 1: What changed on 1 January 2024?

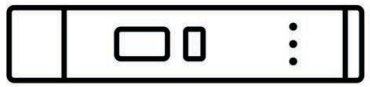


- The importation of ALL disposable vapes is banned (with limited exceptions)

  Note: the sale of previously imported disposable vapes can continue under current laws.

- End of Personal Importation Scheme for disposable vapes.

- New Special Access Scheme (SAS C) pathway to enable medical and nurse practitioners to prescribe therapeutic vapes without requiring pre-authority or approval from the TGA.



- Cessation of advertising permission.

Stage 1: What changed on 1 March 2024?

- The importation of non-therapeutic vapes was banned.
  Note: The supply of previously imported non-therapeutic vapes can continue until domestic controls are implemented in Stage 2 of the reforms

- The Personal Importation Scheme ended for all therapeutic vapes, including vaping devices and vape accessories (pod etc).

- Manufacturers and sponsors required to provide a notification that therapeutic vapes comply with relevant product standards (application form available on the TGA website).

- Importers required to obtain customs licence and permits from the Office of Drug Control (ODC) to import therapeutic vapes.

- Updates to the Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 commenced, limiting flavours to menthol, mint or tobacco for therapeutic vapes.

- New requirements for therapeutic vaping devices.

- List of vapes that are notified to comply with relevant product standards published on TGA website.

Stage 2

- The next stage of reforms is subject to passage of the **Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024**
- Under this Bill:
  - therapeutic vapes that meet TGA requirements would remain available – a prescription will continue to be required for nicotine vapes
  - the domestic manufacture, supply, and commercial possession of all non-therapeutic vapes and disposable single use vapes would be banned
  - most advertising of vapes will be prohibited – the intention is that restricted advertising to health practitioners would be permitted
  - vapes will only be available through pharmacies.

Stage 2 - Parliamentary consideration of the Bill

- Introduced into the House of Representatives on 21 March 2024.
- Referred to the Senate Community Affairs Legislation Committee for inquiry with public hearings on 1 and 2 May 2024.
- Report published on 8 May 2024, with one recommendation: **that the Bill be passed**.
- Dissenting Report from National Party Senators, recommending that the Bill not be passed.
- Additional comments from:
    - **The Australian Greens:** Seeking amendments to ensure personal possession is not criminalised, changes to the reversal of the evidential burden of proof, restricting advertisement of vaping products to medical practitioners, and ensuring appropriate Quit supports as well as investment in waste and recycling.
    - **Coalition (Nationals and Liberal Party):** reiterated concerns that the current prescription only model and will not deliver the Governments intent to address vaping.
- The Bill passed through the House of Representatives (15 May 2024) and introduced into the Senate (16 May 2024) - expected to be considered by the Senate shortly.
- The Bill is due to commence on 1 July 2024 or, if it is passed after this date, it will commence on the day after the bill receives the Royal Assent.

Stage 3: Heightened regulatory standards

June–December 2024 (subject to legislative amendments)

- Enhanced requirements for e-liquid components and increased requirements for the device components of therapeutic vapes.
- Minimum quality and safety standard to include new requirements for:
  - plain packaging
  - pharmaceutical labelling
  - permitted ingredients
  - lower maximum nicotine concentrations
- Standards are proposed to commence December 2024 to allow time for industry to develop compliant products.

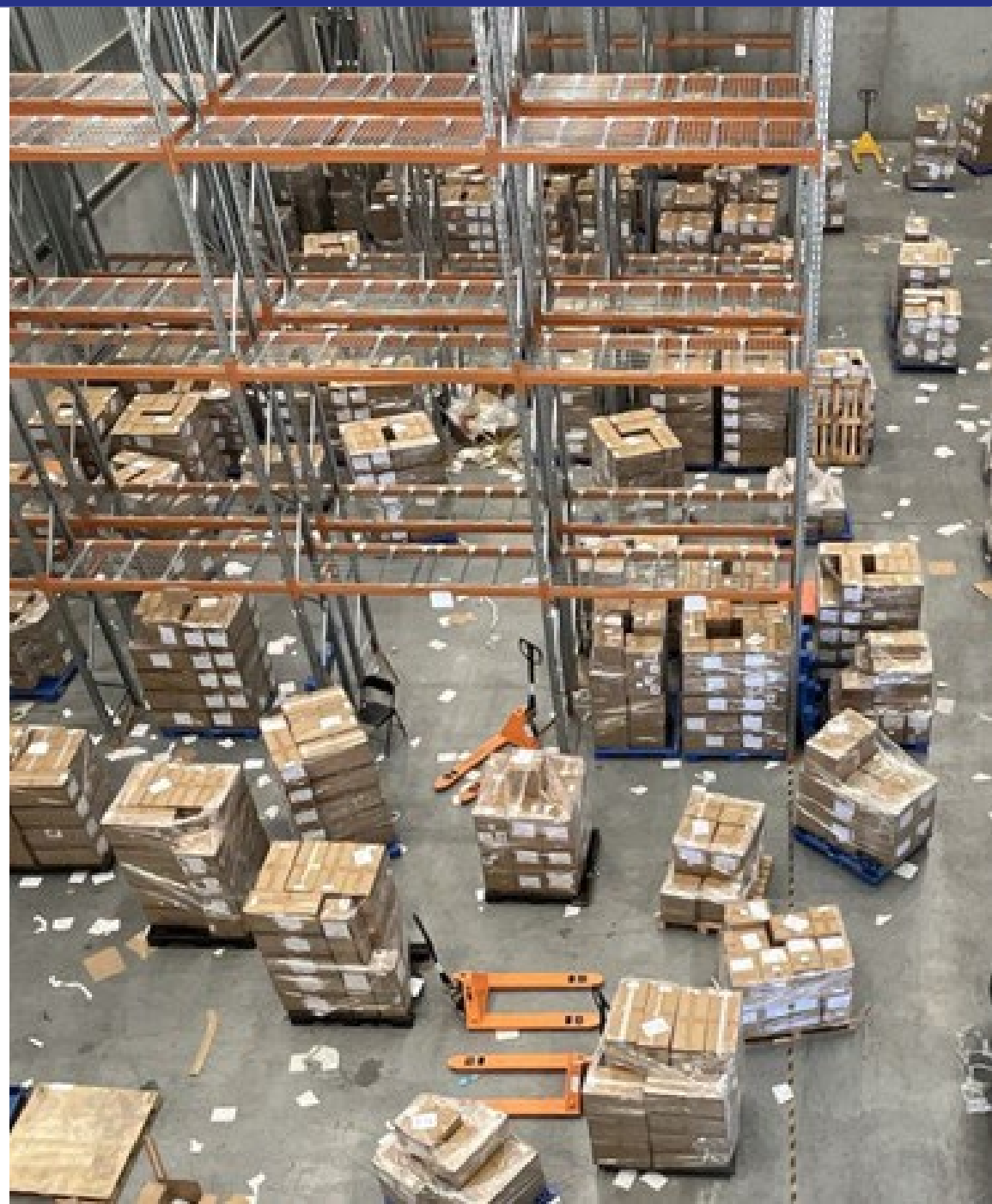
Inclusion on the ARTG – vaping substances

- Any application to register a vaping substance on the ARTG must meet the TGA's high standards for quality, safety and efficacy that are consistent for the registration of all prescription medicines.
- Nicotine, as an active ingredient, is not a new substance. However, nicotine has not yet been evaluated by the TGA for use for smoking cessation in vapes.
- Sponsors must demonstrate, amongst other things, that the formulation, dosage, dosage form and route of administration are safe and effective for their intended purpose.
- Details on how to register prescription medicines are available on the TGA's website. *(How we regulate > Supply a therapeutic good)*
- Potential sponsors are also advised to refer to the *Guideline on the development of medicinal products for the treatment of smoking* available on the European Medicines Agency website.

Inclusion on the ARTG – vaping devices

- For a therapeutic vaping device on the ARTG it must comply with the Essential Principles for medical devices and the relevant conformity assessment procedures must be applied.
- When applying for ARTG inclusion you must either have appropriate comparable overseas regulatory certification for the device (as a class IIb medical device) or seek TGA conformity assessment certification.
- We encourage you to seek a pre-submission meeting with the TGA if you are preparing to seek conformity assessment certification.
- Guidance on the regulatory requirements and industry standards for therapeutic vaping devices is available on the TGA website *(Resources > Checklists > Standards for therapeutic vaping devices)*
- You might also consider engaging a regulatory affairs consultant that can provide services in relation to medical device regulation.

Compliance and enforcement

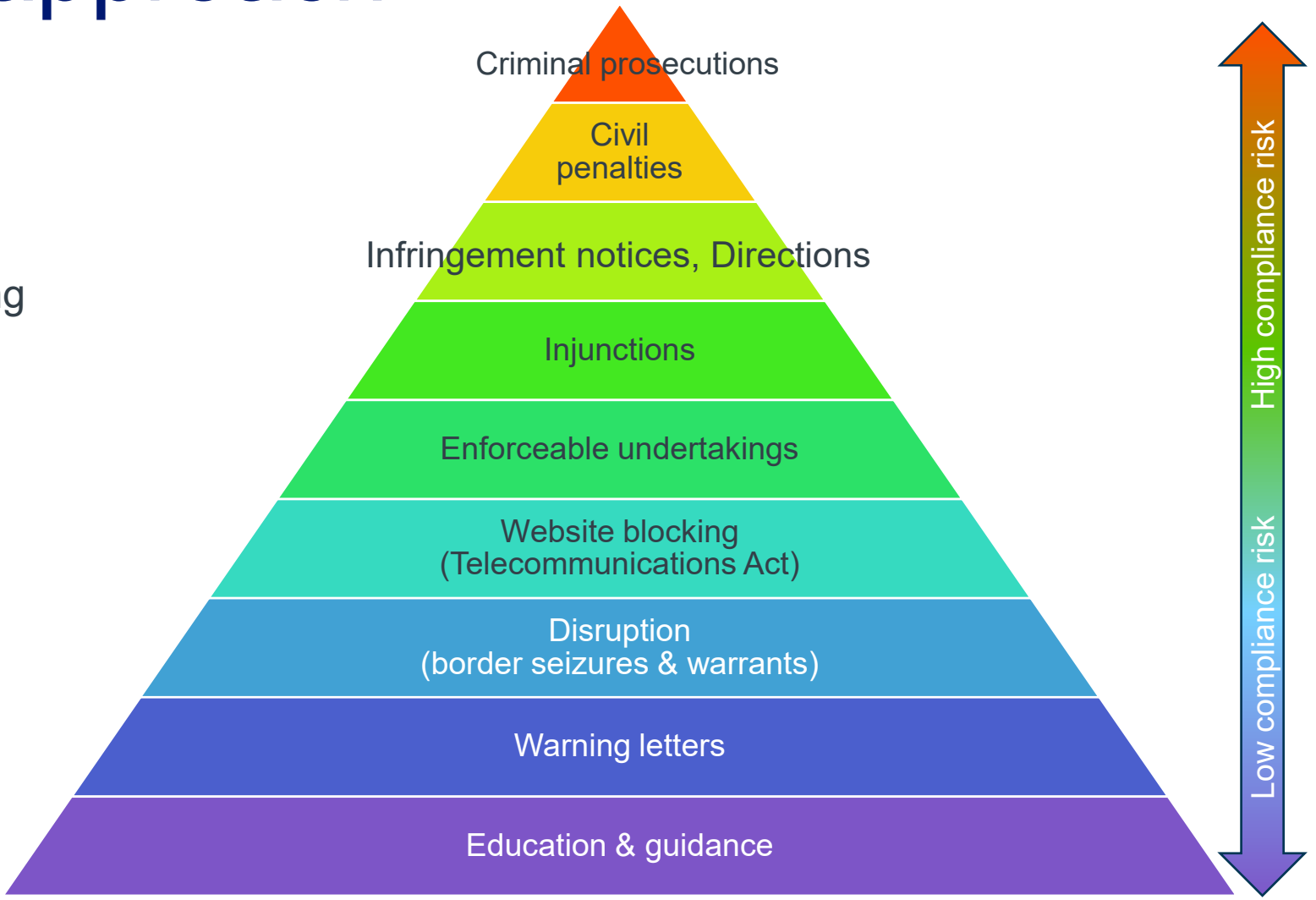


Collaboration with partner agencies

- A national cooperative approach is critical to success in stamping out unlawful vape supply
- National Vaping Working Group
  - National Vaping Enforcement Framework
- Vape Compliance and Enforcement Forum

Enforcement approach

- Communication, education and deterrence
- National cooperative approach
- Intelligence creation and sharing
- Joint operations
- Monitoring of online content
- Complaints and tip-offs
- Compliance testing



Key takeaways for sponsors, importers, manufacturers and suppliers

- It is, and will remain, unlawful for vapes containing nicotine to be supplied outside of a pharmacy setting.
- Disposable and non-therapeutic vapes are being phased out in Australia, with import restrictions already in place.
- Soon, only vapes included on the TGA's List of Notified Vapes can be lawfully manufactured or supplied through existing pathways for supplying unapproved therapeutic goods to market. This requirement already applies to imported goods.
- Sponsors may apply for vapes to be included on the Australian Register of Therapeutic Goods (ARTG).
- Severe penalties will apply for non-compliance.

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Questions?

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