



Vape Reform Discussion

Office of Drug Control and
the Therapeutic Goods Administration



Australian Government
Department of Health and Aged Care
Office of Drug Control

ODC.GOV.AU

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past present and emerging.

I would like to extend that acknowledgement and respect to Aboriginal and Torres Strait Islander peoples here today.

Welcome

Housekeeping



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Vaping reforms and the cannabis industry

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Australian Government Department of Health and Aged Care

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Background and timeline

Date	Milestone
October 2021	Changes to the regulatory requirements for nicotine vaping products including classification as prescription medicines
May 2023	Minister for Health and Aged Care announced action on vaping
November 2023	Minister for Health and Aged Care announced enhanced controls on importation, manufacture, advertising, supply and commercial possession of vapes to be implemented throughout 2024
January 2024	Import restrictions commenced
March 2024	Further import restrictions imposed



Minister's announcement

- On 28 November 2023, the Minister for Health and Aged Care announced the Government's next steps on vaping.
- This included the proposed implementation of the reforms and the relevant measures, comprising three stages:
 - Stage 1: Import controls – January to March 2024
 - Stage 2: Domestic controls – February to July 2024 (subject to legislative amendments)
 - Stage 3: Heightened regulatory standards – February to December 2024 (subject to legislative amendments)

“Vaping was sold to governments and communities around the world as a therapeutic product to help long-term smokers quit. It was not sold as a recreational product - especially not one targeted to our kids but that is what it has become.”

- Mark Butler, Minister for Health and Aged Care (28 November 2023)

The Reforms

January – March 2024

New import controls

Prohibition on the importation of vapes

- Disposable single use vapes, other than cannabis disposable vapes, from 1 January 2024
- All vapes that are not the subject of an import licence and permit from 1 March 2024
 - In practice this means all non-therapeutic vapes

Cannabis vapes

- Existing regulations relating to cannabis-related products remain in place for imports, with an import licence and import permit required from the Office of Drug Control (ODC)
- From 1 March 2024, importers of reusable cannabis vaping devices and cannabis cartridges that do not contain medicinal cannabis will need an import licence and permit from the ODC
- From 1 March 2024, importers of unapproved (unregistered) cannabis vaping devices and cannabis cartridges that do not contain medicinal cannabis must also notify the TGA prior to importation

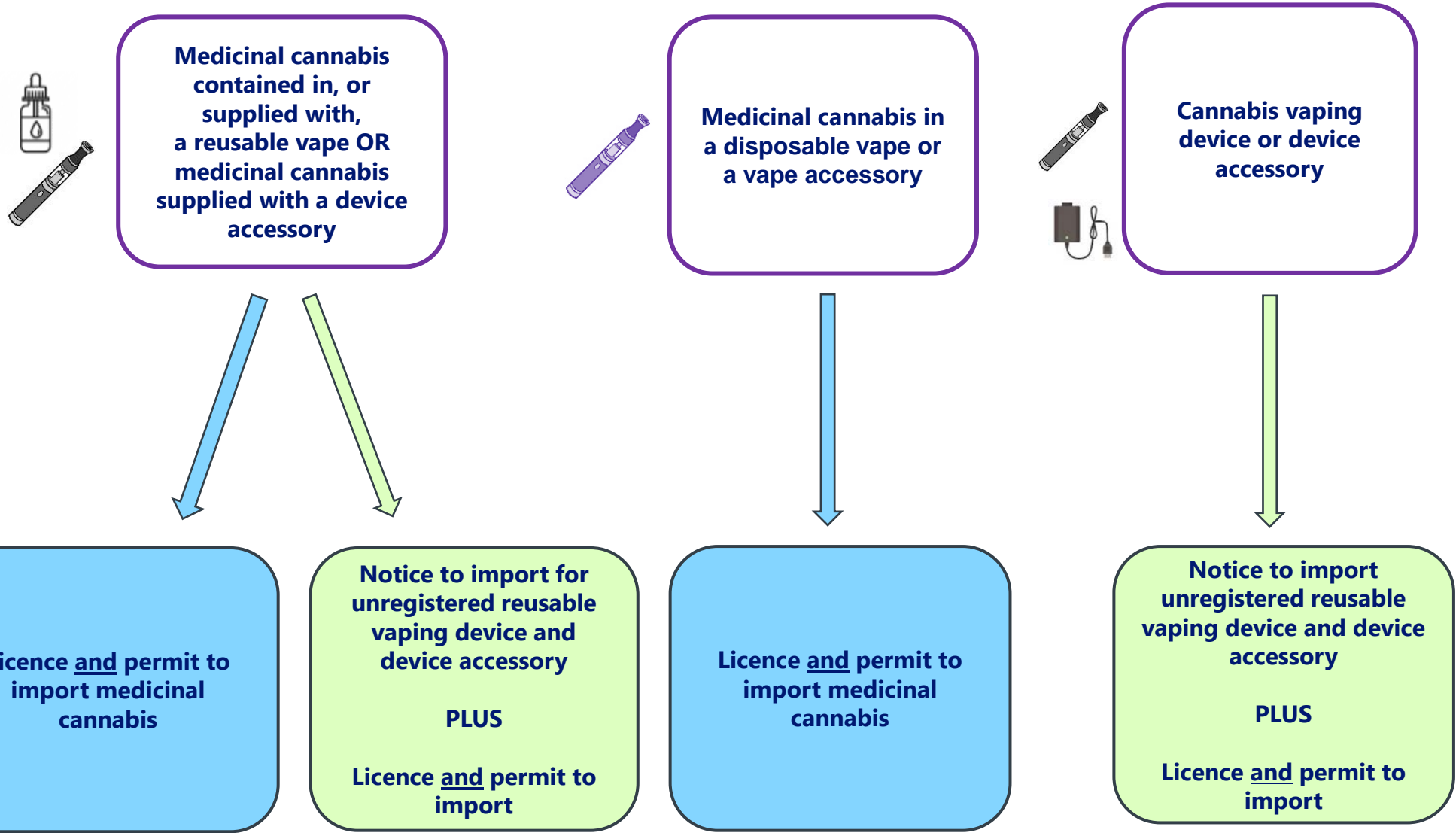


The notice – from 1 March 2024

- A notice is required for unregistered reusable cannabis vaping devices and empty cartridges intended to be used with cannabis vaping devices (*cannabis vaping device accessories*)
- The notice is a precondition to receiving an import licence and permit for a cannabis vaping device or device accessory
- Giving a notice to the TGA does not guarantee the issuing of an import licence and permit
- In the notice, an importer must declare the relevant goods proposed to be imported comply with the essential principles
- The requirement to comply with the essential principles is not new. Reusable cannabis vaping devices and empty cartridges intended to be used with cannabis vaping devices should have already been complying with the essential principles



Changes to the importation of cannabis vapes from 1 March 2024



The notice

The new notice to import form may be accessed at the [Cannabis vapes: Information for importers](#) page on the [Medicinal cannabis hub](#)

Guidance for the notice is being prepared and will be made available shortly.

Further information and resources are available at [Cannabis vapes: Information for importers](#) via the [Medicinal cannabis hub](#)

Content will continue to be updated, so please check back regularly for further updates.

 <p>Australian Government Department of Health and Aged Care Therapeutic Goods Administration</p>	<p>TGA USE ONLY</p>
<p>This form, when completed, will be classified as 'Official'. For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at https://www.tga.gov.au/treatment-information-provided-tga.</p>	
<h2>Notice to import cannabis vaping devices</h2>	
<p>Notice to import therapeutic cannabis vaping devices and accessories not included in the Australian Register of Therapeutic Goods</p>	
<h3>About this notice</h3>	
<p>You must submit this notice to the TGA prior to the importation of a reusable vaping device that is intended for use with a medicine containing cannabis (<i>therapeutic cannabis vaping device</i>), or an unfilled cartridge, capsule, <u>pod</u> or other vessel (<i>therapeutic cannabis vaping device accessory</i>) that is intended for use with such a device.</p>	
<p>You must complete a separate notice for each different type of therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory that you intend to import.</p>	
<p>You do not need to complete this notice for pre-filled cartridges, capsules, <u>pods</u> or other vessels containing cannabis. Different requirements apply to those goods.</p>	
<p>Once complete, send this notification form to cannabisvapenotifications@health.gov.au</p>	
<p>If information in the form relating to your device is incomplete, we may not be able to provide you a notification number.</p>	
<p>You should be aware that the TGA may publish certain information relating to this notice – such as the name of the sponsor and details of the device.</p>	

Further information

The TGA is holding a public webinar next week to provide an overview of the vaping reforms and how these reforms will impact consumers, suppliers and health professionals.

When: Wednesday 17 January 2024

Time: 3:30pm - 4:30pm AEDT

Where: online

If you would like to attend you will need to register at [Vaping reforms webinar - overview of regulatory changes](#), accessed via the TGA website.

This page can be found by searching 'Vaping reforms webinar' on the TGA website.





Vaping Reforms

Applying for a licence and permit to import medicinal cannabis vaping goods

Office of Drug Control



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Office of Drug Control (ODC) and vaping goods

- The Office of Drug control (ODC) regulates the import of certain prohibited substances under the Customs (Prohibited Imports) Regulations 1956 (PI Regulations).
- Amendments to Section 5A of the PI Regulations require importers of vaping goods to obtain a licence and permission (permit) to lawfully import a vaping good into Australia.
- For ODC to issue an import licence and permit for medicinal cannabis vaping goods, the importer must comply with applicable Therapeutic Goods Administration (TGA) and ODC requirements.

Vaping goods

mean:



A **vape** is a device (whether filled with a vape substance) that generates or releases using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user.

A **vape accessory** is a cartridge, capsule, pod, vial, dropper bottle, drip bottle or other vessel that contains, or designed to contain, a vaping substance.

A **vaping substance** is a liquid or other substance intended for use in a vape, or nicotine in solution in any concentration, including in salt or base form.

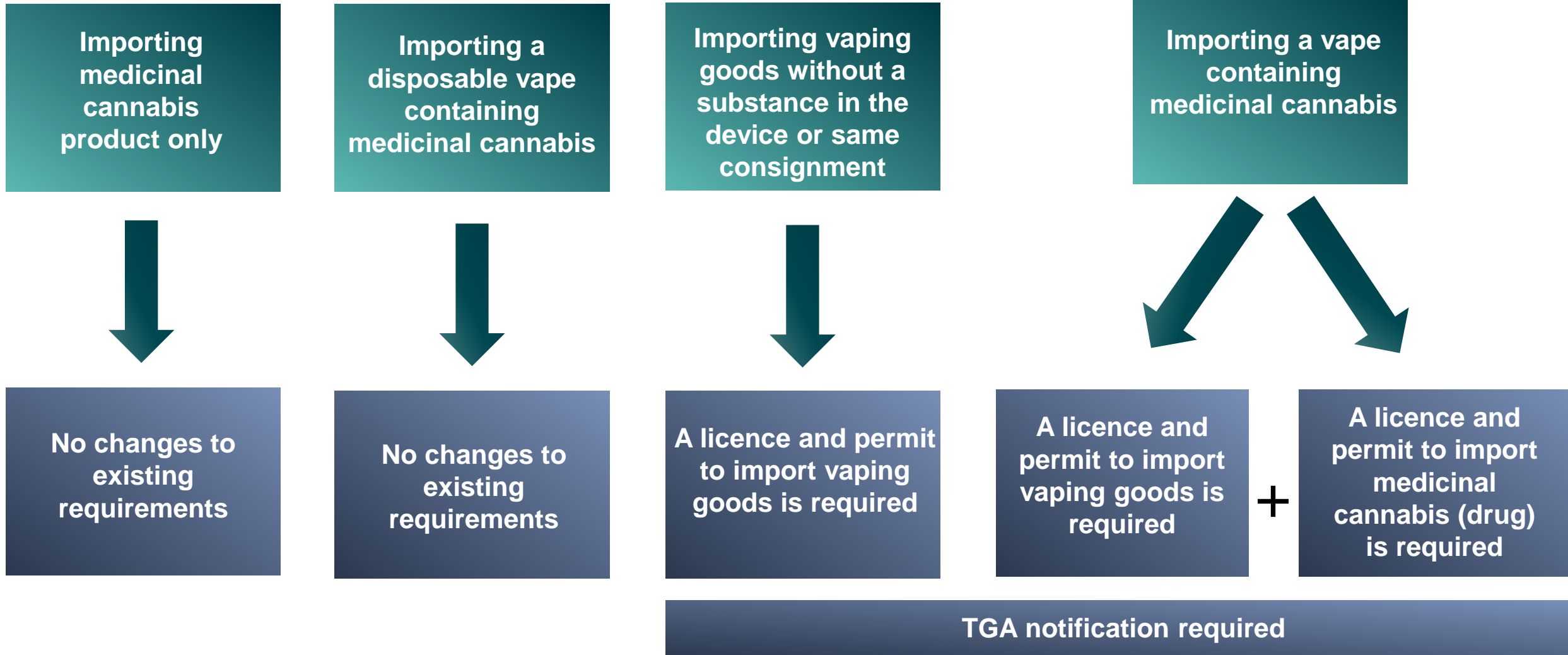
Important dates for vaping good reforms

On 1 January 2024 the import of disposable vapes became prohibited unless the importer holds a licence and permit issued by the ODC under the PI Regulations.

From 1 March 2024 the import of other vaping goods, including vapes, vape accessories and vaping substances will require an import licence and import permit issued by the ODC.



Example scenarios for importers



Vaping good licence and permit applications

1

Ensure you fulfill your obligations with the TGA either by submitting a Notification confirming that the product meets the requirements set out under the *Therapeutic Goods Act 1989* or by registering your product on the Australian Register of Therapeutic Goods (ARTG).

2

Apply for a licence with ODC.

The importer must ensure they hold any licence required by State and Territory Law to import vaping goods or other controlled substances.

The importer must be registered for the Goods and Services Tax (GST).

The importers' business must have a valid Australian Business Number (ABN).

3

If an import licence for vaping goods is granted, the importer is required to apply for an import permit for each specific type of vaping good intended for import under Regulation 5A of the PI Regulations.

4

Once the importer has received their licence and permit, the importer may import their vaping goods for which they have permission.



1

Ensure you have fulfilled any obligations with the TGA

Some vaping goods (such as vape devices) need to meet TGA requirements. Imported medicinal cannabis will also still need to meet existing TGA requirements, such as those related to TGO 93.

Therapeutic cannabis vaping goods must either be included in the ARTG, or the Notification to the TGA must state that the goods comply with applicable requirements under the *Therapeutic Goods Act 1989*. This does not apply to a disposable vape or a vape accessory which contains medicinal cannabis.

2

Apply for a licence to import vaping goods

Applicant pre-requisites

1. Importers must hold any relevant licence or approval under State and Territory Law for supplying vaping goods.
2. The importer's business must be registered for the Goods and Services Tax (GST).
3. The importer must have an Australian Business Number (ABN).

A digital/scanned copy of a National Police Certificate (NPC) must be included for the primary licence holder and all authorised contacts. The NPC must be less than 12 months old.

Note that you should not import vaping goods before obtaining a licence and permit or the Australian Border Force (ABF) may seize the goods.

Regulation 5 (drugs) substances under the Customs (Prohibited Imports) Regulations 1956

- For an import containing a **medicinal cannabis** product alongside or within a **vape**, you will need two licences and two permits. One licence and one permit for the vape, and one licence and one permit for the medicinal cannabis product.
- However, if a medicinal cannabis product is contained within a **disposable vape** or a **vape accessory**, you will only need to apply for one licence and one permit to import the medicinal cannabis product.



3

Apply for a permit to import vaping goods

A permit will be required before importing a vaping good, including a vape, a vape accessory, and vaping substances. A permit is required for each product type intending to be imported.

4

Importation of vaping goods

Once an import licence and the necessary import permits have been issued by the ODC, an importer may import the relevant vaping goods.

The importer must comply with the conditions set out on their import licence, such as providing reports to ODC on imported vaping goods, or the licence may be revoked.

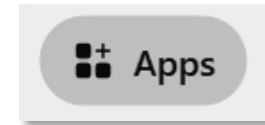
Useful links

- Importing vaping goods into Australia
 - <https://www.odc.gov.au/importers/importing-vaping-goods-australia>
- Guidance for completing an application for a licence to import vaping goods
 - <https://www.odc.gov.au/resources/guidance/guidance-completing-application-licence-import-vaping-goods>
- Application for a licence to import vaping goods
 - <https://www.odc.gov.au/resources/application-forms/application-form-licence-import-vaping-goods>
- Guidance for completing an application for a permit to import vaping goods
 - <https://www.odc.gov.au/resources/guidance/guidance-completing-application-permission-import-vaping-goods>
- Application for a permit to import vaping goods
 - <https://www.odc.gov.au/resources/application-forms/application-form-permission-import-vaping-goods>
- Federal Register of Legislation - Customs (Prohibited Imports) Regulations 1956
 - <https://www.legislation.gov.au/F1996B03651/latest/text>
- Australian Customs Notice No. 2023/51 – New Import Control on Vaping Goods
 - <https://www.abf.gov.au/help-and-support-subsite/CustomsNotices/2023-51.pdf>
- Therapeutic Goods Administration – Vaping Hub
 - <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>



How did we go?

Take a moment to complete our survey



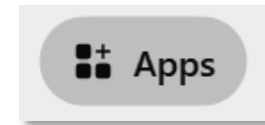
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Questions?

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