



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>.

Notice to import cannabis vaping devices

Notice to import therapeutic cannabis vaping devices and accessories not included in the Australian Register of Therapeutic Goods

About this notice

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 (*therapeutic cannabis vaping device*), or an unfilled cartridge, capsule, pod or other vessel (*therapeutic cannabis vaping device accessory*) that is intended for use with such a device.

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.

You do not need to complete this notice for pre-filled cartridges, capsules, pods or other vessels containing cannabis. Different requirements apply to those goods.

Once complete, send this notification form to cannabismvapenotifications@health.gov.au

If information in the form relating to your device is incomplete, we may not be able to provide you a notification number.

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.

Guidance

Guidance will be available on the TGA website to help you complete this notice.

What you'll need to complete this form

- **Your TGA client ID** – see [guidance](#) on creating a TGA client ID.
- **Details about your device** – you will need to tell us key details about the device you intend to import.
- **Evidence of compliance with essential principles** – you will need this for each device you intend to import.

Legislation

This notice is made for the purposes of paragraph 5A(13)(a) of the [Customs \(Prohibited Imports\) Regulations 1956](#), and paragraph (c) in the column headed “Conditions” of item 2.1 of Part 2 of Schedule 4 to the [Therapeutic Goods \(Medical Devices\) Regulations 2002 \(the MD Regulations\)](#).

Section 1: Sponsor information

Company name:	
TGA client ID:	
Contact email:	

Section 2: Cannabis vaping device category

A separate form is needed for each therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory that you intend to import.

A *therapeutic cannabis vaping device* is a reusable vaping device that is intended for use with a medicine containing cannabis (this includes components of those devices such as batteries, mouthpieces etc).

A *therapeutic cannabis vaping device accessory* is an empty cartridge, capsule, pod or other vessel that is intended to be filled with a medicinal cannabis product or a medicinal synthetic cannabis product and used with a cannabis vaping device.

For further information concerning definitions of these devices, please see the Dictionary of the [MD Regulations](#).

Select the cannabis vaping device category that applies to your product (only select one):

- ☐ Therapeutic cannabis vaping device
- ☐ Therapeutic cannabis vaping device accessory

Section 3: Cannabis vaping device details

Fill out all the details that apply to your therapeutic cannabis vaping device or therapeutic cannabis device accessory in Table 1 below as applicable.

Where the details in Table 1 differ between your therapeutic cannabis vaping device and/or therapeutic cannabis vaping device accessory, a separate notice must be submitted for each good.

Table 1: Details of your good (please fill out all details that are relevant)

Cannabis vaping device/accessory name:	
Device model:	
Cannabis vaping device or device accessory description:	
Liquid capacity in mL:	
Container type (e.g. pod, capsule, cartridge):	
Device product identifier GMDN or UDI:	
Rechargeable battery:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not include a battery

Battery capacity:	
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	
Battery voltage:	
Battery wattage:	
Type of heating element:	<input type="checkbox"/> Coil <input type="checkbox"/> Wick <input type="checkbox"/> Other - please describe
Charging unit: (e.g. USB-C)	<input type="checkbox"/> USB <input type="checkbox"/> Other
Is the airflow adjustable?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	

Section 4: Compliance with the essential principles

The therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory:

- ☐ complies with the essential principles. **Complete the *Essential Principles* checklist available on the TGA website (<https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices>).** (Note: you do not need to submit the completed checklist).

OR

- ☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the *Therapeutic Goods Act 1989* (the Act) for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period).

AND

- ☐ I hold information or evidence to support compliance with the essential principles or consent being given under section 41MA or 41MAA of the Act (as applicable).

Section 5: Declaration

5.1 Privacy Information

General [privacy information](#) is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

5.2 Declaration

- ☐ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.
- ☐ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.



Important Note

Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under section 137.1 of the Commonwealth Criminal Code.

Name

Signature

Date



Send this completed notification form to cannabisvapenotifications@health.gov.au