Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Providing a sponsor notice to import or supply therapeutic vaping goods in Australia

From 1 March 2024, a sponsor notice must be given by a sponsor of a vaping good to the TGA before the good is imported into, or supplied in, Australia following domestic manufacture.

Published: 1 January 2024

On this page

Purpose

This guidance relates to the Sponsor notice – Vaping goods (Notice to import or supply in Australia therapeutic vaping goods) form that is made under the Therapeutic Goods Regulations 1990 (the TG Regulations) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations) and published on TGA Business Services.

Legislation

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

Introduction

What is a sponsor notice?

From 1 March 2024, a sponsor notice is a notice that must be given by a sponsor of a vaping good to the TGA before the good is imported into, or supplied in, Australia following domestic manufacture. Giving a sponsor notice to the TGA is a requirement that must be satisfied before a vaping good that is intended for smoking cessation or the management of nicotine dependence can be supplied in Australia.

Significant penalties may be imposed in relation to the importation or supply of vaping goods where a sponsor notice has not been given to the TGA relating to the goods.

This guidance details the requirements of a sponsor notice.

A sponsor notice requires a sponsor to declare that a vaping good complies with applicable standards and that the only indications of the vaping good are for smoking cessation or the management of nicotine dependence. If a sponsor notice is required, but cannot be given because the goods do not comply with applicable standards or the indications are broader than smoking cessation or the management of nicotine dependence, importation and supply of the goods will be unlawful.

The TGA will publish a list of vaping goods in relation to which sponsor notices have been given and that can be made available for lawful supply in accordance with the relevant exemption, approval or authority. Vaping goods containing nicotine may only be supplied in accordance with a prescription by a registered pharmacist or other person authorised to supply prescription medicines in the relevant state or territory. Similarly, vaping goods not containing nicotine may only be supplied in accordance with the new exemptions by a registered pharmacist or other person authorised to supply prescription medicines in the relevant jurisdiction.

This guidance document outlines what types of vaping goods require a sponsor notice, how to fill in a sponsor notice form, and how to submit it.

Please note, although a sponsor notice only requires you to notify the TGA of compliance with applicable standards and the indications of vaping goods, other requirements also apply in relation to vaping goods, including record keeping and requirements relating to the persons to whom the goods may be supplied. Please see items 15 and 16 of Schedule 5A to the Therapeutic Goods Regulations 1990 or items 2.17 and 2.18 of Part 2 of Schedule 4 to the Therapeutic Goods (Medical Devices) Regulations 2002 as appropriate.

Vaping goods that require a sponsor notice

A sponsor notice must be given for vaping goods that are finished goods, and also for ingredients or components that are imported or supplied for use in the further manufacture of therapeutic vaping goods in Australia. This includes a vaping good that is:

- a therapeutic vaping substance
- a therapeutic vaping substance accessory (e.g. a filled pod, cartridge or capsule)
- an ingredient or component of a therapeutic vaping substance or a therapeutic vaping substance accessory
- liquid nicotine for use in the manufacture of any therapeutic good (including a good that is not a vaping good)
- a therapeutic vaping device
- a therapeutic vaping device accessory (e.g. an empty pod, cartridge or capsule)
- a component or article of a therapeutic vaping device or therapeutic vaping device accessory
- a therapeutic vaping kit (a combination of therapeutic vaping substances and therapeutic vaping substance accessories that does not include any therapeutic vaping devices)
- a good in a therapeutic vaping pack (a therapeutic vaping pack being combination of vaping goods including therapeutic vaping devices or therapeutic vaping device accessories).

Vaping goods that do not require a sponsor notice

A sponsor notice is not required for a therapeutic vaping goods that is included in the Australian Register of Therapeutic Goods.

A sponsor notice is not required for a vaping good in relation to which a licence and permit under regulation 5 of the Customs (Prohibited Imports) Regulations 1958 has been granted, for example, a disposable vape or a pod or cartridge containing medicinal cannabis that has been imported in accordance with a permit given under regulation 5 of those regulations.

A reusable vaping device that is intended for use with a medicine containing cannabis, or an unfilled cartridge, capsule, pod or other vessel that is only for use with such a reusable vaping device, does not require a sponsor notice, but requires a 'Notice to import cannabis vaping devices' before it can be imported. See the Medicinal cannabis hub for further information.

When must I provide a sponsor notice?

For goods imported into Australia, a sponsor notice must be given before importation.

For goods manufactured in Australia, a sponsor notice must be given before the goods are first supplied in Australia.

You only need to give a sponsor notice to the TGA once in relation to each type of vaping good. You are not required to give a notice before each importation or release for supply of the same type of good.

Sponsors who intend to import or supply vaping goods on or after 1 March 2024 may need to give a sponsor notice to the TGA prior to 1 March 2024 so that import permits can be granted and conditions of exemptions, approvals or authorities, which require a sponsor notice to be given before importation or supply, can be satisfied.

What information must be included in a sponsor notice?

You will need to complete one form for each separate and distinct vaping substance or vaping device type. This means that when you have a range of products, a separate notice will need to be submitted for each separate good. Goods with different flavours, concentrations of nicotine, container type or vaping device characteristics require separate notifications unless, in relation to therapeutic vaping substances

and therapeutic vaping substance accessories, those goods are for supply together in a therapeutic vaping kit. Only one flavour, one concentration of nicotine, one type of container and one type of vaping device is permitted for each notification.

All therapeutic vaping substances and therapeutic vaping substance accessories that are intended to be supplied in a therapeutic vaping kit may be included in a single sponsor form. However, information for each individual good included in a therapeutic vaping kit must be separately provided in the form. Where necessary, sponsors may include additional tables or sections in the form to include information for multiple therapeutic goods in therapeutic vaping kits.

For therapeutic vaping packs, individual forms must be submitted to the TGA for each individual good contained the pack. Unlike therapeutic vaping kits, a separate form must be completed for each good.

As above, you will need to submit a new sponsor notice each time there are changes to the characteristic of your vaping goods, such as flavour, nicotine concentration, other ingredients, container type, device type or the name of your product.

If you have notified that you are importing unfinished or starting materials for further manufacture of vaping goods in Australia, you will need to give a separate sponsor notice to the TGA in relation to the finished vaping goods before it is first supplied in Australia. Finished vaping goods (as opposed to starting materials, components or articles) are goods that are in a form that may be supplied and used as a vaping good by a patient. Starting materials, components or articles in this regard include bulk ingredients for further mixing, manufacture, assembly, labelling or packaging, in Australia.

How do I access the notice form?

The form is located within the TGA Business Services (TBS) portal on our website.

You will need to have a Client ID to login and access the notification form.

If you do not have a Client ID apply for one and access to TBS, see TGA Business Services: getting started with the TGA. You will also find more Information regarding the various 'roles' within TBS at TGA Business Services: how to use the site.

Login to TBS

Once you have received your login details, go to the TGA Business Services (TBS) portal. You will then be prompted to enter your login details on the right-hand side of the screen.

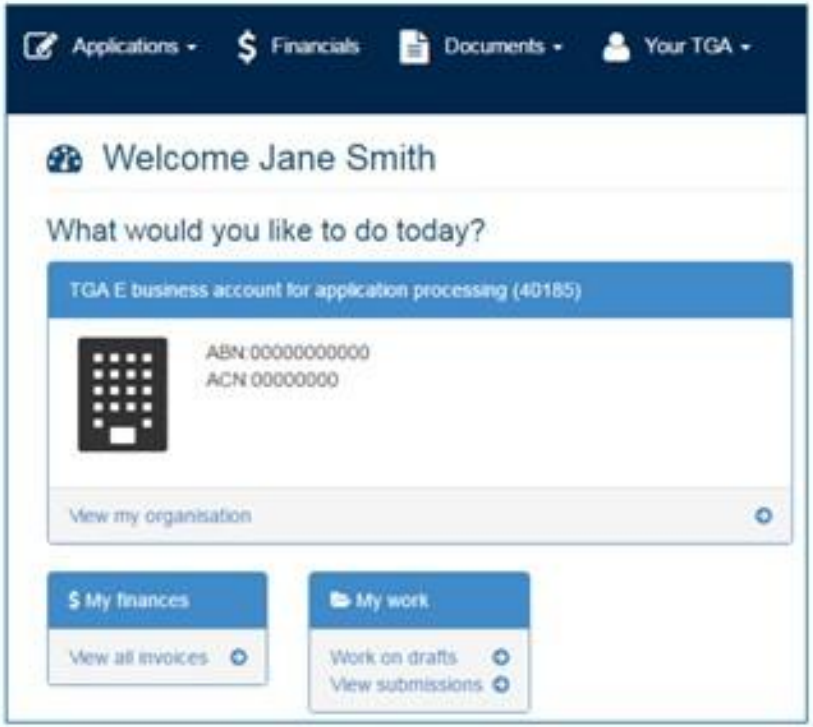
Screenshot of login to TGA Business Services

Show description of image

A screenshot of the login page for the TGA Business Services portal.

Once logged in, you will see a personalised work page or 'dashboard'. What you can see and do on the dashboard will depend on what user role (access level) you have been given.

Screenshot of TGA Business Services dashboard



Show description of image

A screenshot of the TGA Business Services dashboard.

Across the top of the TGA Business Portal dashboard, there are three main menus: Applications; Documents; and Your TGA. If you also have financial access, there will be an additional Financials menu displayed.

You will also find a My work menu on the dashboard with the options Work on drafts or View Submissions. You can select either Work on drafts or View Submissions, which will take you to the online Portal menu.

> **Note**
>
> Only sponsors with a Client ID in the TGA database can submit sponsor notices for vaping goods.
>
> If you are not the sponsor of the vaping good to which the notice relates, you will not be able to complete the notification form.

Navigating to the notice form

Click on the applications button in the dark blue navigator bar and choose 'Notification' under

Screenshot of TGA Business Services dashboard menu

Show description of image

A screenshot of the menu detail on the TGA Business Services dashboard with an arrow pointing to the menu option 'Create Applications & Submissions'.

Filling out the notice form

Only a sponsor, manufacturer or an authorised representative of the sponsor can complete the sponsor notice form at TGA Business Services forms.

Download and save the form on your computer or local network.

Fill out the sections of the form that apply to your vaping good in accordance with this guidance.

There are eight (8) sections that make up the notice form:

1. Sponsor information
2. Vaping good category
3. Vaping good details
4. Manufacturer details
5. Vaping goods containing a vaping substance compliance
6. Vaping devices (not containing a vaping substance) compliance.
7. Vaping goods for further manufacture in Australia
8. Declaration.

More detail on each of these sections is provided below.

Section 1 – Sponsor information

In this section, you need to fill out basic details of your company, replicating the information held in your TGA Client ID, including the contact email address that the TGA can use to communicate with you regarding your vaping good. All correspondence and enquiries will be sent to this address.

Section 2 – Vaping good category

This section requires you to identify the type of vaping good that you are intending to import or supply in Australia. It is important that you carefully consider the options as your selection determines which further sections of the form you will need to fill out. If the correct sections are not completed, the form may be considered invalid, and you will not be able to lawfully import or supply your vaping good.

There are seven (7) vaping good categories. Please select the category that best describes the good for which you are making this notice.

The first three categories relate to finished vaping goods that are ready for use by patients, namely:

- A finished product containing a vaping substance (that is, either a therapeutic vaping substance, a therapeutic vaping substance accessory) or a therapeutic vaping kit as defined item 15 of Schedule 5A to the TG Regulations. For example, a ready-to-use therapeutic vaping substance in a bottle, a cartridge, capsule or pod pre-filled with a therapeutic vaping substance, or a kit containing a combination of these types of goods.
- A finished product that is a therapeutic vaping device or a therapeutic vaping device accessory in a therapeutic vaping pack – see item 15 of Schedule 5A to the TG Regulations. For example, a reusable vaping device, or an unfilled cartridge, capsule or pod for use in or with a reusable vaping device, that is intended to be sold as part of a vaping pack.

- A finished product that is a therapeutic vaping device or a therapeutic vaping device accessory – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations. For example, a reusable vaping device, or an unfilled cartridge, capsule, pod, or other vessel for use in or with a reusable vaping device.

The remaining four categories are to cover the importation of ingredients or components that are for further manufacture in Australia prior to supply, namely:

- An ingredient or component (other than liquid nicotine) for further manufacture of vaping goods in Australia. For example, mint or tobacco flavour in solution to be used in the manufacture of a therapeutic vaping substance.
- Liquid nicotine for further manufacture of vaping goods in Australia.
- Liquid nicotine for further manufacture of other therapeutic goods in Australia. For example, a nicotine liquid for manufacture of nicotine replacement therapies such as gum or lozenges.
- A component or article intended for use in the manufacture of a therapeutic vaping device or a therapeutic vaping device accessory, and not intended for supply to a patient in its current form. For example, a mouthpiece that is for use in the manufacture of a therapeutic vaping device or a heating coil for use in the manufacture of an unfilled cartridge (rather than for direct supply to a patient).

Remaining sections to complete

For all vaping goods, information must be provided to enable the vaping good to be identified with specificity (Section 3), to outline the manufacturing sites (Section 4), and to make necessary declarations (Section 8). These sections are mandatory.

The categories you nominate in Section 2 will determine the *additional sections* of the sponsor notice that you will need to complete (in addition to Sections 3, 4 and 8) as follows:

- Categories 1 and 2: you must complete Section 5: Compliance – vaping substances, vaping substance accessories, vaping kits, and goods in a vaping pack.
- Category 3: you must complete Section 6: Compliance – vaping devices and vaping device accessories (not containing vaping substances)./
- Categories 4 to 7: you must complete Section 7: Ingredients or components for further manufacture in Australia.

Section 3 – Vaping good details

This section requires you to appropriately identify your vaping good.

You only need to fill out the fields in the right-hand column in the tables provided if the field applies to your vaping good. The guidance below outlines in more detail the type of information being sought and what format the information should be submitted.

Please note that, in the case of a therapeutic vaping kit, you may include additional copies of Tables 2 and 3 in this section for each individual therapeutic vaping substance or therapeutic vaping substance accessory, without the need to submit separate forms for each individual good to the TGA.

Australian approved terms have been created to describe the way in which therapeutic goods are presented. These terms include ingredient names, container types and units of measurements. Where possible, TGA approved terminology must be used as defined in the code tables available at TGA approved terminology for therapeutic goods.

Table 1: Vaping goods not containing vaping substances

Complete Table 1 if your vaping good is:

- a therapeutic vaping device or a therapeutic vaping device accessory, and
- does not contain any vaping substance.

This includes a therapeutic vaping device or therapeutic vaping device accessory that is supplied individually or included in a therapeutic vaping pack. Notices for therapeutic vaping substances or therapeutic vaping substance accessories included in therapeutic vaping packs are to be included in separate notices from vaping devices and vaping device accessories.

Fill out all the details that apply to your vaping good. The text in italics in the table below provides guidance on the type of information to be included for each row.

The TGA requires details about your product to be able to distinguish it from other vaping goods (for which a separate notice is required).

Table 1: Vaping goods that do not contain vaping substances. Please fill out all details that are relevant to your good. Guidance and examples have been provided in the right-hand column below.

Vaping good name	Provide the trade name of the therapeutic vaping device or therapeutic vaping device accessory.
Device model	Specify version of the model or article number.
Vaping good description	Provide a brief description of therapeutic vaping device or therapeutic vaping device accessory.
Container type and liquid capacity in mL	Specify the container type e.g. is it a cartridge, tank, pod or capsule, etc, and provide liquid capacity in mL.
Device product identifier GMDN or UDI	Specify the Unique Device Identifier (UDI) or Global Medical Device Nomenclature (GMDN). If no GMDN or UDI is available, please indicate that here.
Rechargeable battery	Indicate ‘yes’ if the battery is rechargeable otherwise indicate ‘no’.

Battery capacity	Specify battery capacity in mAh e.g. 1000 mAh.
Battery composition	Specify the material composition of the battery e.g. nickel-cadmium, nickel-metal hydride, lithium ion.
Battery voltage	Specify whether the battery voltage is fixed or adjustable. If fixed, specify nominal fixed voltage. If adjustable, specify recommended adjustable voltage including the range.
Battery wattage	Specify whether the battery wattage is fixed or adjustable. If fixed, specify nominal fixed wattage. If adjustable, specify recommended adjustable wattage including the range.
Type of heating element	Indicate whether the heating element consists of 'coil', 'wick' or other materials. If 'other' is selected, please describe the heating element material.
Charging unit	Indicate whether the charging unit uses 'USB' or 'other' charger.
Is the airflow adjustable?	Indicate 'yes' if the airflow is adjustable, otherwise indicate 'no'.
Type of control unit(s)	Specify the type of controllers in each unit e.g. printed circuit board (PCB), microcontroller, software, etc.

Table 2: Vaping goods containing vaping substances

Information requested in this table relates to:

- the type of container that holds the therapeutic vaping substance, for example, a bottle, a pod, or a cartridge,
- the container type and liquid volume (in mL) and
- the form of nicotine if included, for example, nicotine betadex complex (ID 101454), nicotine bitartrate dihydrate (ID 105326) or nicotine polacrilex (ID 81807).

If nicotine is included in your vaping good, the quantity of nicotine in (mg/mL) needs to be stated also.

Table 3: Ingredients of vaping substances

This table requires you to provide a list of all the ingredients and the quantity of those ingredients included in your therapeutic vaping substance (except for nicotine, details of which should be included in Table 2 above), including flavours.

An approved ingredient name is required for all ingredients in a therapeutic good. Ingredients can be single molecular entities or complex natural mixtures (e.g., herbal extracts). The TBS website includes publicly available information relating to ingredient names and approved terminology, which does not require a login.

Examples of ingredients including flavours, together with respective ID numbers (found in TGA's Code tables Where to find approved terminology), have been included in the table below.

For more information, please see Where to find approved terminology.

Ingredient name examples	**Quantity**
Propylene glycol ID 55549	e.g., mg/mL
Glycerol ID 53800	
Water ID 93389	
Water - distilled ID 104938	
Sample flavours:	
Artificial Mint Flavour ID 109375 ID 109067	
Mentha arvensis oil ID 103139	
Menthol ID 54475	
Menthol (of Mentha arvensis) ID 104708	

Section 4 – Manufacturer details

In this section, you will need to provide details of all manufacturers and the steps those manufacturers are responsible for undertaking in the manufacture of your vaping goods (including any steps that you carry out in Australia as the relevant sponsor). Some examples of steps in manufacture are storage, testing chemical and physical, finished product manufacturer, packaging, labelling and release for supply.

The manufacturing details required depend on the nature of the vaping good to which the notice relates:

- For all manufacturing steps carried out in relation to the manufacture of therapeutic vaping substances and therapeutic vaping substance accessories, you will need to supply the manufacturer's name, TGA TBS Client ID if you cannot provide a Client ID then please contact TBS Helpdesk by email at ebs@health.gov.au
- For all manufacturing steps carried out in relation to therapeutic vaping devices or therapeutic vaping device accessories, you will need to supply the manufacturer's name, address, country and a contact email address.

Section 5 – Compliance: vaping substances, vaping substance accessories, vaping kits, and goods in a vaping pack

You will need to choose the compliance option that applies to your vaping good:

- your vaping good conforms with any applicable standards, including the Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021, or
- you have consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act 1989 for non-compliance with a standard.

Please tick the box that applies to your good. You must choose one.

If you are unsure of what of the standards your vaping good needs to comply with, our Guidance for Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 and related matters contains detailed information.

> **Note**
>
> Any application for consent to supply must be approved by the TGA before you submit this notice. An application for consent does not mean consent to supply will be granted.
>
> Consent is only granted in exceptional circumstances. More information is provided at Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry.

Compliance with TGO 110 means your vaping good meets the minimum ingredient, child-resistant packaging, and labelling requirements in the TGO 110 and, as a minimum, your vaping device has been manufactured in an ISO 9001 certified facility.

The form provides a checklist of criteria all of which must be satisfied (if applicable) and checked off by you as evidence that your vaping good conforms to TGO 110. This includes:

- details of any testing you have conducted on your good to assess nicotine content (or its absence) and the absence of prohibited ingredients;
- that your vaping good contains only the permitted flavours mint, menthol, or tobacco flavour;
- your product labels include a list of all ingredients including nicotine if applicable, the respective quantities of those ingredients and any warning statements;

- your product packaging has been tested and is child-resistant; and
- the proposed use of your vaping good is only for smoking cessation or the management of nicotine dependence.

Please note, that the TGA may request that you submit your labels to the TGA for inspection.

Section 6 – Compliance: vaping devices or vaping device accessories (not containing a vaping substance)

Complete this section for a vaping good that:

- is a vaping device or vaping device accessory, and
- does not contain a vaping substance, and
- is not to be imported or supplied in a pack.

In this section, you need to declare if the vaping device or vaping device accessory conforms with one or more of the following:

- the Essential Principles (these apply by default to vaping devices and vaping device accessories not containing a vaping substance)
- the Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (the MDSO) (only if the MDSO relevantly applies to your vaping device or vaping device accessory)
- the terms of any consent to supply from the Secretary under section 41MA or 41MAA of the Act for non-compliance with Essential Principles (please note that consent requests are

considered by the TGA on a case-by-case basis and granted in exceptional circumstances for limited periods of time).

Compliance with the Essential Principles

The Essential Principles are default standards that apply in relation to vaping devices and vaping device accessories. The sponsor of a vaping device or vaping device accessory, to which the MDSO applies, may still elect to comply with the Essential Principles.

If you declare compliance with the essential principles (and not the MDSO), you will need to complete the Essential Principles checklist available on our website.

Please note that you are not required to submit the completed checklist to the TGA. However, you are required to hold evidence to demonstrate compliance with the essential principles and provide that evidence to the TGA, if requested.

Compliance with the MDSO

Types of evidence

If the MDSO applies to your vaping device or vaping device accessory, you may elect to declare compliance with the MDSO, as opposed to the Essential Principles. If declaring compliance with the MDSO, you need to complete the 'Evidence of compliance – vaping device or vaping device accessory' subsection for the vaping device or vaping device accessory to which the MDSO applies. To demonstrate compliance, you must hold one or more of the following relevant types of evidence in relation to your vaping device or vaping device accessory:

- valid ISO 9001 certification for the manufacture of the vaping device or vaping device accessory, issued by an IAF accredited organisation and/or

- valid ISO 13485 certification for the manufacture of the vaping device or vaping device accessory, issued by an IAF accredited organisation or a notified body or an auditing organisation recognised by Health Canada or an Australian conformity assessment body
- one of the following valid forms of evidence establishing compliance with requirements for supply of consumer grade e-cigarettes:
    - a marketing authorisation order granted by the United States Food and Drug Administration under the Premarket Tobacco Products Applications and Recordkeeping Requirements Rule, as in force or existing from time to time
    - an authorisation from a member state of the European Union under EU Directive 2014/40/EU, or
    - publication in the United Kingdom Medicines & Healthcare products Regulatory Agency ECIG database, as in force from time to time, listing e-cigarette products notified under the Tobacco and related Products Regulations and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020, as in force or existing from time to time
- certification, licence, notification, or other approval, establishing compliance with requirements for supply of therapeutic goods, issued by one of the following:
    - the United States Food and Drug Administration
    - a notified body designated by an EU country
    - a body designated by the United Kingdom Medicines & Healthcare products Regulatory Agency.

Further information on the above types of evidence requirements for compliance with the MDSO can be found in the Guidance for the TGO 110 and related matters.

Details of evidence

For each type of evidence that is indicated to be held for the vaping device or vaping device accessory, fill out the following details in the table:

- specify the authorising authority, certification, or notification body
- describe the scope of the authorisation, certification, or notification as detailed in the evidence
- specify the authorisation, certificate, notification number or identifier as detailed in the evidence.

If more than one type of evidence is held for the vaping device or vaping device accessory, duplicate the table to include the above details for each type of evidence.

The TGA may ask you to supply the documentation you have identified in this section.

Consent to supply application (non-compliance with the Essential Principles)

> If you are seeking to import or supply a vaping device or vaping device accessory with a consent to supply, the application for consent to supply must be approved by the Secretary before a sponsor notice is made. An application for consent to supply does not guarantee consent to supply will be granted by the Secretary. Decisions of the Secretary will be based on an assessment of the evidence provided, the risk to the public or end user during the period of non-compliance.

If your vaping device or vaping device accessory does not comply with any specific essential principle(s), you may submit a Consent to Supply Application for consideration by the Secretary. The application must be submitted and approved by the Secretary before the sponsor notice is given.

All medical devices, including those that are supplied in accordance with an exemption, approval or authority under the Act are required to meet the Australian regulatory requirements, including the essential principles. Consent is only granted in exceptional circumstances where there are no significant safety or performance concerns. Consent is granted for a limited time in accordance with an appropriate risk mitigation strategy.

A Consent to Supply form can be requested from the Secretary by emailing the TGA at mdconsent@health.gov.au. Fees are associated with an application for consent to supply. The Secretary will review your application and decide whether to grant or deny the request for Consent to Supply, only after all relevant information is received and payment of the fees. More details on the fees can be found on the Fees and charges webpage. Payment of the application fee can be made online; the payment options are provided on the Payment options page.

If you are successful in obtaining a Consent to Supply from the Secretary under section 41MA or 41MAA of the Act, you may proceed to make a declaration in the sponsor notice that the relevant importation or supply will comply with the terms of that consent.

Section 7 – Ingredients or components for further manufacture in Australia

Complete this section only if your vaping good is a starting material, component or article being imported for the purpose of further manufacture of vaping goods, or in the case of liquid nicotine any other therapeutic good, in Australia. For further conditions that apply to your ingredient or component, please refer to item 16 of Schedule 5A to the TG Regulations or item 2.18 of Part 2 of Schedule 4 to the MD Regulations.

In this section you are required to indicate whether:

- your starting material is for use in the manufacture of a vaping good, or other therapeutic good, by a manufacturer that holds all relevant licences or approvals; or
- your article or component is for use in the manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals.

Section 8 – Declaration

A declaration is required that the information provided in the sponsor notice, is, to the best of your knowledge, current and correct and that the statements made in the notice are supported by information and evidence which can and will be provided to the TGA upon request.

The contact person will also need to sign and date the sponsor notice form declaration.

> **Important Note**
>
> Proving 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.

How do I submit my completed notice?

Once you have filled out all sections of the form according to this guidance, you will need to email your completed form as an email attachment to vapenotifications@health.gov.au and mention 'sponsor notice' in the subject of the email.

For more assistance in completing this form, email the TGA at vapenotifications@health.gov.au.

When will I hear back from the TGA?

After you submit the sponsor notice, an automated email acknowledging receipt of your email will be sent back to you.

Once the form has been screened by the TGA, you will receive an email with the outcome.

If your notice has been successfully submitted, you will receive a Notification ID number. You must keep a record of the Notification ID number for your sponsor notice for each vaping good.

If the TGA has determined that your notice has not met the requirements of the form (for example by being incomplete), you will be informed of this outcome and given the opportunity to correct the notice.

Next steps

Once you have received your Notification ID number, you can use this number to apply for an Office of Drug Control licence and permit to import vape goods.

Australia has import clearance requirements for all goods. Sponsors seeking to import vapes, and other persons acting on their behalf, should refer to the Australian Border Force (ABF) website for information on the required declarations to clear imported goods from customs control.

Publication of sponsor notices

We will publish a list of complete sponsor notices on our website in due course.

Variations to vaping goods and new vaping goods

If you vary your vaping good, for example by changing the flavour, label or nicotine content, you will need to submit a new sponsor notice to the TGA.

New goods that are not identical to those included in a previous notice, even if manufactured at the same site as other goods in your range, will also require a new sponsor notice to be submitted to the TGA.

Topics: Vaping hub

Page history

This page was published on **1 一月 2024**.