Therapeutic Goods (Therapeutic Vaping Goods—Sponsor Notice Form) Approval 2023

I, Chris Bedford, as delegate of the Secretary of the Department of Health and Aged Care, make the following approval.

Dated 21 December 2023

Chris Bedford
Acting First Assistant Secretary
Regulatory Practice and Support Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Therapeutic Vaping Goods—Sponsor Notice Form) Approval 2023*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 January 2024.	1 January 2024

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under:

(a) items 15 and 16 in the table in Schedule 5A to the *Therapeutic Goods Regulations 1990*; and

(b) items 2.17 and 2.18 in the table in Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) medical device;

(b) Secretary;

(c) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Regulations means the *Therapeutic Goods Regulations 1990*.

TGA Business Services means the TGA Business Services portal, accessed via the Therapeutic Goods Administration website.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.

TGA, or ***Therapeutic Goods Administration***, means the part of the Department known as the Therapeutic Goods Administration.

5 Approved form

For the purposes of items 15 and 16 in the table in Schedule 5A to the Regulations and items 2.17 and 2.18 in the table in Part 2 of Schedule 4 to the MD Regulations, the approved form for a sponsor notice referred to in those items is the form appended to this instrument, accessible from 1 January 2024 at:

(a) the *Vaping Substance Notice* link, under the *Prescription Medicines* heading, in the *Create Applications & Submissions* menu, in TGA Business Services; or

(b) the *Vaping Device Notice* link, under the *Medical Device* heading, in the *Create Applications & Submissions* menu, in TGA Business Services.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as '**For official use only**'.
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>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

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

If information in the form relating to your therapeutic vaping good 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 your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see here guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, 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: Vaping good category

Select one vaping good category for this notice:

☐ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Please complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (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).[1]

Please complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Please complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Please complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Please complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Please complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Please complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

If your vaping good is a vaping device, or a component of, or accessory to, a vaping device, fill out all of the details that apply to your vaping good in Table 1.

For finished goods that are, or contain, vaping substances (including kits), also complete Table 2 and 3 below, using the approved terminology in TGA Code Tables, e.g. the Australian approved names of ingredients, and as specified in the published guidance.

Where the details in the tables differ between your vaping goods, a separate notice is required for each good (unless the good is a therapeutic vaping kit). For example, goods with different flavours, concentrations of nicotine, container type or vaping device characteristics, require separate notifications.

For therapeutic vaping kits, one notice can be provided. The notice must include the details of all vaping goods in the kit.

Table 1: Vaping goods that do not contain vaping substances (please fill out all details that are relevant to your good)

Vaping good name:	
Device model:	
Vaping good description:	
Liquid capacity in mL:	
Device product identifier GMDN or UDI:	
Rechargeable battery:	☐ Yes ☐ No
Battery capacity:	
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	
Battery voltage:	
Battery wattage:	
Type of heating element:	☐ Coil ☐ Wick ☐ Other please describe
Charging unit:|	☐ USB ☐ Other
Is the airflow adjustable?	☐ Yes ☐ No
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	

Table 2: Vaping goods that contain vaping substances

Vaping good description:	
Container type:	
Liquid volume in mL:	
Nicotine form (if applicable):	
Nicotine quantity:	

Table 3: Ingredients of vaping substances

For vaping substances, list all ingredients (except for nicotine, details of which should be included in Table 2), including flavour, using the Australian Approved Ingredient name where possible.

Ingredient name	Quantity

Section 4: Manufacturer details

Please provide details of all manufacturers of your vaping goods. Please provide details, as appropriate, of the manufacturers of the finished goods you are importing or supplying, or further manufacturers who will use the ingredients or components you are importing.

Additional tables can be copied and inserted below if more manufacturing sites are used. Examples of steps in manufacture include storage, testing chemical and physical, finished good manufacture, packaging, labelling and release for supply.

For vaping goods containing a vaping substance, please provide the following details:

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

For vaping devices or components, please provide the following details:

Manufacturer name:	
Site address:	
Country:	
Contact email:	

Manufacturer name:	
Site address:	
Country:	
Contact email:	

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

Complete this section if the vaping good is ready to be supplied in Australia and is, or contains, a vaping substance, vaping substance accessory, vaping kit or a good in a vaping pack.[2] Please see item 15 of Schedule 5A to the TG Regulations for further conditions that apply to your good.

The vaping good:

☐ conforms with applicable standards, including *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023*. **Complete the TGO 110 compliance evidence below.**

Or

☐ I have consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act, for non-compliance with a standard. (Note: consent is only granted in exceptional circumstances)

TGO 110 compliance evidence

☐ Testing is performed on each batch of vaping goods.

☐ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility	
Address of the facility	
Date tested (dd/mm/yyyy)	

☐ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).

☐ Testing will confirm the absence of prohibited ingredients.

☐ Batch-specific test results can be made available upon request.

☐ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☐ The labels comply with the requirements of TGO 110.

☐ The product label includes a list of all ingredients required by TGO 110.

☐ The product label includes quantity of nicotine as an active ingredient (if applicable).

☐ The product label includes applicable warning statements.

☐ Copies of labels can be provided upon request.

☐ The good has child-resistant packaging.

---

[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

☐ The only indications for the good are 'for smoking cessation' or 'the management of nicotine dependence'.

☐ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

Section 6: Compliance – vaping devices or vaping device accessories

Complete this section for a good that is a vaping device or vaping device accessory that does not contain a vaping substance and is not to be imported or supplied in a pack. See the footnotes at the bottom of this page as to which standards apply to your vaping device. Please see item 2.17 of Part 2 of Schedule 4 to the MD Regulations for further conditions that apply to your good.

The vaping device or device accessory:

☐ conforms with the essential principles[3]. **Complete the *Essential Principles* checklist available on the TGA website (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices).** You do not need to submit the completed checklist.

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies, and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

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

Evidence of compliance – vaping device or vaping device accessory

For vaping devices and vaping device accessories to which the MDSO applies, select one or more of the following relevant types of valid evidence held that demonstrates that your device complies with applicable requirements if your good does not comply with the essential principles:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

---

[3] Essential principles: for goods that prior to 1 March 2024 were represented to be solely for use with a medicine.
[4] MDSO: for goods that prior to 1 March 2024 were never represented to be solely for use with a medicine (these goods may comply with the MDSO as an alternative to the essential principles).

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the vaping good is a starting material, component or article being imported for the purpose of further manufacture in Australia. Please see, as appropriate, item 16 of Schedule 5A to the TG Regulations or item 2.18 of Part 2 of Schedule 4 to the MD Regulations for further conditions that apply to these goods.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals.

☐ The article or component is for use in the lawful 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

Section 8.1: 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.

Section 8.2: 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

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.

Name			
Signature		Date	

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