Therapeutic Goods (Therapeutic Vaping Goods—Transitional Manufacturer Notification 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—Transitional Manufacturer Notification 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Note: This table relates only to the provisions of this instrument as originally made.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 regulation 97 of the *Therapeutic Goods Regulations 1990*.

4 Definitions

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

(a) Secretary;

(b) therapeutic goods.

In this instrument:

Regulations means the *Therapeutic Goods Regulations 1990*.

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

5 Approved form

For the purposes of notifying the Secretary of a step in the manufacture of therapeutic goods under subregulation 97(1) of the Regulations, the approved form is the form appended to this instrument, accessible from 1 January 2024 via the *Transitional manufacturers* link under the *Manufacturing unapproved vapes for smoking cessation or the management of nicotine dependence* heading within

the *Vapes: information for importers, manufacturers and wholesalers* page of the *Vaping hub* on the Therapeutic Goods Administration website.

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

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>.

Notification to carry out steps in the manufacture of therapeutic vaping goods from 1 January 2024 – 1 December 2024 without GMP

About this form

You must submit this notification to the TGA to qualify as a transitional manufacturer under regulation 97 of the *Therapeutic Goods Regulations 1990* and be exempt, between 1 January 2024 and 1 December 2024, from the requirement to hold a manufacturing licence under Part 3-3 of the *Therapeutic Goods Act 1989* in relation to the manufacture of therapeutic vaping goods. You may only submit this notification if, as at 2 May 2023, you were carrying out a step in the manufacture of non-therapeutic vaping goods that is equivalent to the step of manufacture that you intend to undertake in relation to therapeutic vaping goods.

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

If the information in the form is incomplete or does not satisfy the legal requirements for an effective notification, you may not qualify for the exemption.

A list of transitional vaping manufacturers of therapeutic vaping goods who have notified the TGA under regulation 97 of the *Therapeutic Goods Regulations 1990* will be published on the TGA website.

What you'll need to complete this form

- Manufacturer information
- Information about the vaping goods that you previously manufactured, and the therapeutic vaping goods intended to be manufactured such as the following:
  (a) a therapeutic vaping substance;
  (b) a therapeutic vaping substance accessory;
  (c) a therapeutic vaping kit
- Details about the step/s of manufacture that you propose to carry out in relation to particular kinds of therapeutic vaping goods from 1 January 2024, and the equivalent step of manufacture of other vaping goods that were the same kind of goods as the therapeutic vaping goods as at 2 May 2023.

Legislation

The notification is made under regulation 97 of Division 23 of Part 9 of the *Therapeutic Goods Regulations 1990*.

Section 1: Manufacturer details

Manufacturer name:	
ABN/ACN:	
TGA client ID (if any):	
Contact person name:	
Contact person position:	
Contact person email:	
Contact person telephone:	

Section 2: Therapeutic vaping good proposed to be manufactured

Select the kind of therapeutic vaping good this notification is for:

☐ therapeutic vaping substance

☐ therapeutic vaping substance accessory

☐ therapeutic vaping kit

Section 3: Manufacturing site details

Please provide your details and the proposed site of manufacture.

Additional tables can be copied and inserted below if more manufacturing sites are used.

Manufacturing site name:	
ABN/ACN:	
TGA Site ID (if any):	
Contact person name:	
Contact person email address and telephone:	
Main manufacturing site address (street number, street, suburb, state, postcode):	
Steps in the manufacture at the main manufacturing site:	

Secondary manufacturing site address (street number, street, suburb, state, postcode):	
Steps in the manufacture at the secondary site:	

Section 4: Manufacture of non-therapeutic vaping goods as at 2 May 2023

Additional tables can be copied and inserted below if more manufacturing sites are used.

Details of non-therapeutic vaping goods:	
Manufacturing site address (street number, street, suburb, state, postcode):	
Step(s) in the manufacture carried out as at 2 May 2023	

Section 5: Manufacture of therapeutic vaping goods to be carried out from 1 January 2024

Additional tables can be copied and inserted below if more manufacturing sites are used.

Details of therapeutic vaping goods:	
Manufacturing site address (street number, street, suburb, state, postcode):	
Step(s) in the manufacture to be carried out from 1 January 2024:	

Examples of a manufacturing step are the following:

(a) manufacture of the dosage form (i.e. manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory)
(b) manufacture of the finished product (i.e. manufacture of a therapeutic vaping substance, a therapeutic vaping substance accessory, or a therapeutic vaping kit)
(c) packaging and labelling of a therapeutic vaping good
(d) storage

Section 6: Declaration

Section 6.1: 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 manufacturer to discuss the notification where necessary.

Section 6.2: 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 notification 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 gmp@health.gov.au