



Therapeutic Goods (Therapeutic Vaping Goods—Sponsor Notice and Restatement Form) Approval 2025

I, Ashley McLachlan-Bent, as delegate of the Secretary of the Department of Health and Aged Care, make the following approval.

Dated 28 February 2025

Ashley McLachlan-Bent
Acting Assistant Secretary
Vaping Implementation and Enforcement Branch
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Therapeutic Vaping Goods—Sponsor Notice and Restatement Form) Approval 2025*.

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 March 2025.	1 March 2025

Note: This table relates only to the provisions of this instrument as originally made.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:

- items 15 and 16 in the table in Schedule 5A to the *Therapeutic Goods Regulations 1990*; and
- 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:

- Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

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.

TG Regulations means *Therapeutic Goods Regulations 1990*.

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

5 Approved form—sponsor notice

For the purposes of:

- (a) paragraph (a) of column 3 of items 15 and 16 in the table in Schedule 5A to the TG Regulations; and
- (b) paragraph (a) of the column headed “Conditions” of items 2.17 and 2.18 in the table in Part 2 of Schedule 4 to the MD Regulations;

the approved form for giving a sponsor notice to the Secretary under those provisions is the online form titled *Sponsor notice – Therapeutic vaping goods*, accessed via the *Applications* tab within TGA Business Services, as in force or existing on 1 March 2025.

6 Approved form—restatement

For the purposes of:

- (a) paragraph (e) of column 3 of item 15 of the table in Schedule 5A to the TG Regulations and
- (b) paragraph (e) of the column headed “Conditions” of item 2.17 in the table in Part 2 of Schedule 4 to the MD Regulations;

the approved form for the statements mentioned in those provisions is the online form titled *Sponsor notice – Therapeutic vaping goods*, accessed via the *Applications* tab within TGA Business Services, as in force or existing on 1 March 2025.

7 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Therapeutic Goods (Therapeutic Vaping Goods—Sponsor Notice Form) Approval 2024

1 The whole of the instrument

Repeal the instrument.