



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Note: This table relates only to the provisions of this instrument as originally made.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

- (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) 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 provision 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.