

Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration 2025

I, Tracey Duffy, as delegate of the Secretary of the Department of Health and Aged Care, make the following declaration.

Dated 20 January 2025

Tracey Duffy

First Assistant Secretary  
Medical Devices and Product Quality Division  
Health Products Regulation Group  
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration 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 | The day after this instrument is registered. |  |

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 41BD(3) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023

1 Section 4

Insert:

***therapeutic vaping substance*** has the same meaning as in the Regulations.

***vaping device*** has the meaning given by subsection 41P(1) of the Act.

2 Schedule 1 (table item 3)

Omit “therapeutic good” (wherever occurring), substitute “medicine”.

3 Schedule 1 (at the end of the table)

Add:

|  |  |
| --- | --- |
| 12 | vaping devices that are pre-filled with a therapeutic vaping substance that form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) |