

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

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

Dated 15 December 2023

Professor Anthony Lawler

Deputy Secretary

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 (Vaping) Declaration 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 | At the same time as the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*.However, this instrument does not commence at all if the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* does not commence. |  |

Note: This table relates only to the provisions of this instrument as originally made.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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (paragraph (b) of the note)

Repeal the paragraph, substitute:

(b) therapeutic good.

2 Section 4

Insert:

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

***therapeutic vaping device*** has the same meaning as in the MD Regulations.

***therapeutic vaping device accessory*** has the same meaning as in the MD Regulations.

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

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

3 Schedule 1 (table item 3)

Repeal table item, substitute:

|  |  |
| --- | --- |
| 3 | articles that are intended to administer a therapeutic good in such a way that the therapeutic good and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi‑dose) |

4 Schedule 1 (at the end of the table)

Add:

|  |  |
| --- | --- |
| 10 | therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack |
| 11 | therapeutic vaping substance accessories |