Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025

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

Dated 10 December 2025

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health, Disability and Ageing

Authorised Version F2025L01530 registered 10/12/2025

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1 Name

This instrument is the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 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 January 2026.	1 January 2026

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

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

1 Section 4 (note)

Repeal the note, substitute:

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

(a) included in the Register;
(b) listed goods;
(c) medical device;
(d) medicine;
(e) Register;
(f) registered goods;
(g) therapeutic goods.

2 After section 5

Insert:

6 Application, saving and transitional provisions

(1) This section applies to articles in items 8 to 11 of the table in Schedule 1 that, immediately before the commencement of the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025*, were included in the Register as a kind of medical device.

(2) Items 8 to 11 of the table in Schedule 1, as inserted by Schedule 1 to the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025*, do not apply to the medical devices mentioned in subsection (1) until the earlier of:

(a) the date on which the goods become registered goods or listed goods; and
(b) 1 January 2031.

(3) Despite subsection (2), the articles mentioned in subsection (1) may be dealt with in accordance with the amendments made by the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025*, including for the purposes of the following:

(a) an application for the registration or listing of the therapeutic goods;
(b) any applicable provisions in Part 3-2 of the Act in relation to applications for the registration or listing of therapeutic goods.

3 Schedule 1 (at the end of the table)

Add:

8	toothpastes and other dentifrices that achieve their principal intended action through having an effect by chemical or pharmacological means
9	head or body lice treatments that achieve their principal intended action through having an effect by chemical or pharmacological means
10	moisturisers and emollients that achieve their principal intended action through having an effect by chemical, metabolic or pharmacological means

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11	weight loss treatments that are ingested into the body and that affect absorption of calories in the gastrointestinal system by metabolic means

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