Therapeutic Goods (Reportable Medicines) Determination 2025

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 5 March 2025

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Reportable Medicines) Determination 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Note: This table relates only to the provisions of this instrument as originally made.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 30EH(2) of the *Therapeutic Goods Act 1989*.

4 Definitions

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

(a) active ingredient;
(b) current Poisons Standard;
(c) medicine;
(d) registered goods;
(e) reportable medicine.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

5 Reportable medicines

The medicines set out in Schedule 1, being medicines that are registered goods, are determined to be reportable medicines for the purposes of subparagraph 30EH(1)(b)(ii) of the Act.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Reportable Medicines

Note: See section 5.

Reportable Medicines	
Column 1	**Column 2**
Item	**Medicine**
1	medicines that contain one of the following: (a) cyproheptadine; (b) levonorgestrel; (c) pancreatic extract; (d) theophylline; (e) ulipristal
2	medicines that: (a) contain barium sulfate as an active ingredient; or (b) contain calcium gluconate, and are in the dosage form of an injection or a preparation for topical use; or (c) contain folinic acid (as calcium folinate) when included in Schedule 2 to the current Poisons Standard; or (d) contain glucagon, and are in the dosage form of an injection; or (e) contain glyceryl trinitrate, and are for sublingual use; or (f) contain hydroxocobalamin, and are in the dosage form of an injection; or (g) contain isosorbide dinitrate when included in Schedule 3 to the current Poisons Standard; or (h) contain magnesium sulfate as the only active ingredient, and are in the dosage form of an injection or an intravenous infusion; or (i) contain mannitol as an active ingredient, and are in the dosage form of a powder for inhalation; or (j) contain monobasic sodium phosphate as the only active ingredient; or (k) contain naloxone, and are in the dosage form of an injection or a nasal spray; or (l) contain salbutamol, and are in the dosage form of a preparation for inhalation; or (m) contain terbutaline, and are in the dosage form of a preparation for inhalation
3	medicines for the treatment of anaphylaxis or management of cardiac arrest, that contain adrenaline (epinephrine) as the only active ingredient
4	medicines that are in the dosage form of an injection and that contain one of the following as the only active ingredient: (a) phytomenadione; (b) sodium bicarbonate; (c) thiamine

5	medicines for intravenous phosphate supplementation, that are in the dosage form of an injection or an infusion and that contain one of the following as an active ingredient: (a) dibasic potassium phosphate; (b) dibasic sodium phosphate; (c) monobasic potassium phosphate; (d) monobasic sodium phosphate
6	medicines that contain 0.9% sodium chloride as the only active ingredient, and are in the dosage form of an injection or an intravenous infusion
7	medicines for the treatment of poisonings, that are in the dosage form of an injection and that contain one of the following as an active ingredient: (a) ethanol; (b) sodium calcium edetate; (c) sodium nitrite; (d) sodium thiosulfate
8	medicines for the treatment of poisonings or drug overdosage by oral ingestion, that contain activated charcoal as an active ingredient
9	medicines for the treatment of scabies, that contain one of the following as an active ingredient: (a) benzyl benzoate; (b) permethrin
10	medicines for oral bicarbonate supplementation, that contain sodium bicarbonate as an active ingredient

Schedule 2—Repeals

Note: See section 6.

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1 The whole of the instrument

Repeal the instrument.