

Therapeutic Goods (Reportable Medicines) Determination 2018

I, Jane Cook, as delegate of the Minister for Health, make the following determination.

Dated Fifth of December 2018

(*signed by*)

Jane Cook

First Assistant Secretary

Medicines Regulation Division

Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Reportable Medicines) Determination 2018*.

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 2019. | 1 January 2019 |

Note: This table relates only to the provisions of this instrument as originally made.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

4 Definitions

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

(a) medicine;

(b) registered goods;

(c) reportable medicine.

In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

5 Reportable medicine

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.

Schedule 1— Reportable medicines

(section 5)

| **Column 1**  **Item** | **Column 2**  **Medicine** |
| --- | --- |
| 1 | adrenaline autoinjector |
| 2 | glucagon injection |
| 3 | glyceryl trinitrate sublingual |
| 4 | levonorgestrel |
| 5 | monobasic sodium phosphate |
| 6 | naloxone injection |
| 7 | naloxone nasal spray |
| 8 | salbutamol autohaler |
| 9 | salbutamol inhaler |
| 10 | terbutaline inhaler |
| 11 | ulipristal |