

Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022

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

Dated 29 March 2022

Tracey Duffy

First Assistant Secretary

Medical Devices and Product Quality Division

Health Products Regulation Group

Department of Health

Contents

1 Name 1

2 Commencement 1

3 Authority 1

4 Schedules 1

Schedule 1—Amendments 2

Therapeutic Goods (Manufacturing Principles) Determination 2020 2

1 Name

This instrument is the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022*.

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 July 2022. | 1 July 2022 |

Note: This table relates only to the provisions of this instrument as originally made.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 section 36 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Manufacturing Principles) Determination 2020

1 Section 4 (definition of *PIC/S Guide to GMP*)

Repeal the definition (including the note), substitute:

***PIC/S Guide to GMP*** means the document *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021) published by PIC/S, as in force or existing at 1 July 2022, and includes the Annexes to that document other than the following:

(a) Annex 4 (Manufacture of veterinary medicinal products other than immunologicals);

(b) Annex 5 (Manufacture of immunological veterinary medical products);

(c) Annex 14 (Manufacture of medicinal products derived from human blood or plasma).