

Therapeutic Goods (Manufacturing Principles) Amendment (PIC/S Guide) Determination 2025

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

Dated 26 August 2025

Tracey Duffy

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

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 (PIC/S Guide) 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 | 1 September 2025. | 1 September 2025 |

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

***PIC/S Guide to GMP***means the document titled *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-17, 25 August 2023) published by PIC/S, as in force or existing at 1 September 2025, 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).

Note: The PIC/S Guide to GMP could in 2025 be viewed on the PIC/S’s website (https://picscheme.org).

2 Part 3

Repeal the Part, substitute:

Part 3—Application

8 Application

(1) In this section:

***amending determination***means the *Therapeutic Goods (Manufacturing Principles) Amendment (PIC/S Guide) Determination 2025.*

***sterile therapeutic goods*** means therapeutic goods that are:

(a) sterile medicines; or

(b) sterile active pharmaceutical ingredients.

(2) The amendment of this instrument made by item 1 in Schedule 1 to the amending determination applies to the manufacture of therapeutic goods that occurs on or after 1 September 2025.

(3) Despite subsection (2), the amendment of this instrument made by item 1 in Schedule 1 to the amending determination, only to the extent that the amendment has the effect of incorporating clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 to the PIC/S Guide to GMP, applies to the manufacture of sterile therapeutic goods that occurs on or after 1 March 2026.