



Therapeutic Goods (Manufacturing Principles) Amendment Determination 2024

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

Dated 23 May 2024

Jennifer Burnett
Acting First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2024*.

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	3 June 2024.	3 June 2024

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 009-16, 1 February 2022) published by PIC/S, as in force or existing at 3 June 2024, 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).

2 Part 3

Repeal the Part, substitute:

Part 3 – Application

8 Application

- (1) The amendment of this instrument made by item 1 in Schedule 1 to the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2024* applies in relation to therapeutic goods manufactured on or after 3 June 2024.
- (2) Despite subsection (1), the amendment of this instrument made by item 1 in Schedule 1 to the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2024*, only to the extent that the amendment has the effect of incorporating Annex 16 of the PIC/S Guide to GMP, applies to therapeutic goods manufactured on or after 3 September 2024.