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

Authorised Version F2022L00428 registered 30/03/2022

Contents

Authorised Version F2022L00428 registered 30/03/2022

Authorised Version F2022L00428 registered 30/03/2022

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Authorised Version F2022L00428 registered 30/03/2022

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).

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