



Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021

I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 24 September 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021*.

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 | 30 September 2021. | 30 September 2021 |

Note: This table relates only to the provisions of this instrument as originally made.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 sections 10 and 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Consequential amendments

Therapeutic Goods (Manufacturing Principles) Determination 2020

1 Section 4 (subparagraph (b)(iii) of the definition of *technical master file*)

Omit “TGO 88”, substitute “TGO 108”.

2 Section 4 (definition of *TGO 88*)

Repeal the definition (including the note).

3 Section 4

Insert:

TGO 108 means the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021*.

Note: TGO 108 is published on the Federal Register of Legislation at www.legislation.gov.au.

Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020

4 Section 4 (definition of *TGO 88*)

Repeal the definition (including the note).

5 Section 4

Insert:

TGO 108 means the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021*.

Note: TGO 108 is published on the Federal Register of Legislation at www.legislation.gov.au.

6 Schedule 1 (table item 25, column 2)

Omit “TGO 88”, substitute “TGO 108”.