

Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 2022

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

Dated 7 March 2022

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 (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 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 the instrument | The day after the instrument is registered. |  |

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 10(3A) 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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021

1 Schedule 1 (cell at table item 7, column 2)

Repeal the cell, substitute:

|  |  |  |
| --- | --- | --- |
|  | a person who, in connection with treatment for a disease, ailment, defect or injury, has been a recipient of viable animal cells or tissuesNote: Viable animal cells or tissues are animal cells or tissues that are live and capable of functioning as intended to provide or support a therapeutic use. |  |

2 Schedule 1 (table item 12)

Repeal the item, substitute:

|  |  |  |
| --- | --- | --- |
| 12 | a person who has engaged in any activity of a sexual nature that puts the person at an increased risk of acquiring infectious diseases that could be transmitted through blood, cells or tissues | ineligible for a period of at least 3 months from the date the person last engaged in the activity |

3 Schedule 1 (table item 15)

Repeal the item, substitute:

|  |  |  |
| --- | --- | --- |
| 15 | a person who resides in, or has travelled to:(a) a region within Australia; or(b) another country;in which a particular epidemiological situation, such as an outbreak of a disease, existed at the time the person resided in, or travelled to, the region or country | ineligible for a period of time based on a risk assessment using the most up-to-date epidemiological data in relation to the particular epidemiological situation in that region or countryNote: A risk assessment using the most up-to-date epidemiological data means an assessment of possible hazards associated with an epidemiological situation such as a disease outbreak, using the most current information available about that situation. |