



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

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## 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 tissues

Note: 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 |
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#### **3 Schedule 1 (table item 15)**

Repeal the item, substitute:

- |    |  |   |
|----|--|---|
| 15 | a person who resides in, or has travelled to:<br>(a) a region within Australia; or<br>(b) another country;<br>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 country<br>Note: 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. |
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