

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

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

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health.

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test, or require that goods be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“the Principal Order”) is made under section 10 of the Act and establishes a ministerial standard for therapeutic goods that comprise, contain or are derived from human cells or human tissues, specifying minimum requirements for the quality and safety of such products in respect of donor screening.

Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act. The *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 2022* (“the Amendment Order”) is made by a delegate of the Minister under that subsection, and amends the Principal Order to provide greater clarity in relation to the meaning of a small number of terms or phrases used in Schedule 1 to the Principal Order.

### **Background**

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by specifying ministerial standards under section 10 of the Act by reference to a range of matters, including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act.

The Principal Order sets out requirements relating to donor screening and minimising the risk of infectious disease transmission via ‘HCT products’ being, products that comprise, contain or are derived from human cells (including haematopoietic progenitor cells), human tissues, blood or blood components (including plasma). The Principal Order does not apply to a number of specified kinds of HCT products, including, for example, faecal microbiota transplant products and certain kinds of samples of human cells or human tissues.

Complying with the Principal Order necessitates the collection of medical and social history of donors of material used in the manufacture of HCT products. The private tissue banks and sponsors that collect this information are regulated by the *Privacy Act 1988* in relation to the collection and handling of such information. Whereas the state and territory public sector tissue banks are regulated by applicable state and territory privacy laws in relation to such information. Obtaining this information is crucial in ensuring the safety of HCT products for recipients, particularly in relation to the risk of microbial contamination and severe disease transmission. As such, the collection of personal and health information is necessary and proportionate in the circumstances for the purposes of ensuring the safety of such high-risk products.

The purpose of the Amendment Order is principally to address concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation in relation to clarity of drafting, and to clarify the intended operation of these ineligibility criteria. The Amendment Order amends the Principal Order, principally to clarify the meaning and operation of the following phrases in Schedule 1 to the Principal Order, which sets out criteria and periods of ineligibility for a person to be a donor of HCT products in specified circumstances:

- ‘recipient of viable animal cells or tissues’ in table item 7 of Schedule 1 – to clarify that viable animal cells and tissues are animal cells or tissues that are live and capable of functioning as intended to provide or support a therapeutic use;
- ‘sexual activity that puts the person at an increased risk of acquiring infectious diseases’ in table item 12 of Schedule 1 – to clarify that this relates to any activity of a sexual nature that puts the person at such an increased risk;
- ‘travelled to another country or region within Australia with exposure to particular epidemiological situations’ in table item 15 of Schedule 1 – to clarify that this is intended to relate to where a person resides in, or has travelled to, a region within Australia, or another country, in which a particular epidemiological situation existed at the time the person resided in, or travelled to, that region or country; and
- ‘ineligible for a period of time based on a risk assessment using the most up-to-date epidemiological data’ in table item 15 of Schedule 1 – to clarify that such a risk assessment 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.

## **Consultation**

Extensive consultation was conducted in relation to the development of the Principal Order. As the amendments made by the Amendment Order simply address the concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation in relation to the clarity of drafting, and do not make substantive changes to the content of the Principal Order, further consultation was not considered necessary.

A regulation impact statement is not required for the amendments made by the Amendment Order (OBPR reference 43510).

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Order is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

## **Attachment A**

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

#### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 2022* (“the Amendment Order”).

#### **Section 2 – Commencement**

This section provides that the Amendment Order commences on the day after it is registered on the Federal Register of Legislation.

#### **Section 3 – Authority**

This section provides that the legislative authority for making the Amendment Order is subsection 10(3A) of the *Therapeutic Goods Act 1989* (“the Act”).

#### **Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to the Amendment Order is amended or repealed, as set out in the applicable items in that Schedule. Any other item in a Schedule to the Amendment Order has effect according to its terms.

#### **Schedule 1—Amendments**

Schedule 1 to the Amendment Order amends the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“the Principal Order”).

Item 1 amends table item 7 of Schedule 1 to the Principal Order, to clarify that ‘recipient of viable animal cells or tissue’ relates to a person who, in connection with treatment for a disease, ailment, defect or injury, receives animal cells or tissues that are live and capable of functioning as intended to provide or support therapeutic use.

Item 2 repeals and substitutes table item 12 of Schedule 1 to the Principal Order, to clarify that a person who has engaged in any activity of a sexual nature that puts that person at an increased risk of acquiring infectious diseases that could be transmitted through blood, cells or tissues, is ineligible to donate human cell or tissue products for a period of 3 months from the date the person last engaged in the activity.

Item 3 repeals and substitutes table item 15 of Schedule 1 to the Principal Order, to clarify that a person who resides in, or has travelled to, a region in Australia, or another country, with an exposure to a particular epidemiological situation (such as an outbreak of a disease) is ineligible to donate human cell or tissue products for a period time to be determined based upon a risk assessment. A risk

assessment is an assessment of possible hazards associated with the epidemiological situation, using the most current information about that situation.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### Overview of the legislative instrument

The *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“the principal instrument”) is made under section 10 of the *Therapeutic Goods Act 1989* (“the Act”) and establishes a ministerial standard for therapeutic goods that comprise, contain or are derived from human cells or human tissues, specifying minimum requirements for the quality and safety of such products in respect of donor screening.

Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act. The *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 2022* (“the amendment instrument”) is made by a delegate of the Minister under that subsection.

The purpose of the amendment instrument is to address concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation in relation to clarity of drafting. The amendment instrument amends the principal instrument, principally to clarify the meaning and operation of the following phrases:

- ‘recipient of viable animal cells or tissues’ in table item 7 of Schedule 1 – to better highlight that 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;
- ‘sexual activity that puts the person at an increased risk of acquiring infectious diseases’ in table item 12 of Schedule 1 - to better highlight that this relates to any activity of a sexual nature that puts a person at an increased risk of acquiring infectious diseases that could be transmitted through blood, cells or tissues;
- ‘travelled to another country or region within Australia with exposure to particular epidemiological situations’ - to better reflect that this relates to where a person resides in, or has travelled to, a region within Australia or another country with exposure to a particular epidemiological situation such as an outbreak of a disease; and
- ‘ineligible for a period of time based on a risk assessment using the most up-to-date epidemiological data’ in table item 15 of Schedule 1 – to better reflect that such a risk assessment means an assessment of possible hazards associated with the epidemiological situation (such as a disease outbreak), using the most current information about that event.

## **Human rights implications**

The amendment instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The amendment instrument takes positive steps to promote the right to health by helping to ensure the safety, quality and efficacy of therapeutic goods that are derived from human cells and tissues. The amendment instrument amends the principal instrument to clarify the meaning and operation of certain terms that appear within the instrument to ensure that the principal instrument effectively identifies the circumstances in which a person is ineligible to donate human cells and tissues. This is particularly critical to ensure the safety of such products from the risk of the transmission of infectious diseases in connection with these high-risk therapeutic goods that are for use in a recipient.

## **Conclusion**

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.