

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

*Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021*

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

*Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021*

*Therapeutic Goods (Biologicals—Specified Things) Instrument 2021*

*Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*

*Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021*

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 Biologicals—Labelling Requirements) (TGO 107) Order 2021* (“TGO 107”), the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“TGO 108”) and the *Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021* (“TGO 109”) are made under section 10 of the Act. The purpose of these orders is to establish ministerial standards 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 labelling (TGO 107), donor screening (TGO 108) and a range of other matters including manufacturing, packaging and storage (TGO 109).

The *Therapeutic Goods (Biologicals—Specified Things) Instrument 2021* (“the Specified Things Instrument”) is made under subsections 32A(2) and (3) of the Act for the purpose of specifying things that are (where those things also satisfy paragraph 32A(1)(b) of the Act), and things that are not, biologicals for the purposes of the Act.

The Specified Things Instrument provides a single snapshot of products for which the Secretary has, by legislative instrument, specified things for the purposes of subsections 32A(2) and (3) of the Act. It also repeals the previous Therapeutic Goods (Things that are not Biologicals) Determination No. 1 of 2011 (“the 2011 Determination”), and the *Therapeutic Goods (Things that are Biologicals) Specification 2019* (“the 2019 Specification”), the former of which would otherwise sunset on 1 October 2021.

The *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021* (“the Repeal Instrument”) is made under section 10 of the Act, for the purpose of repealing the following legislative instruments that would otherwise sunset on 1 October 2021:

- Therapeutic Goods Order No. 83 Standards for human musculoskeletal tissue (“TGO 83”);
- *Therapeutic Goods Order No. 84 Standards for human cardiovascular tissue* (“TGO 84”);
- Therapeutic Goods Order No. 85 Standards for human ocular tissue (“TGO 85”);
- Therapeutic Goods Order No. 86 Standards for human skin (“TGO 86”);
- Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals* (“TGO 87”); and
- *Therapeutic Goods Order No. 88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products* (“TGO 88”).

The *Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021* (“the Consequential Amendment Instrument”) is made under sections 10 and 36 of the Act, for the purpose of making minor, consequential amendments to update two other instruments, the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020* and the *Therapeutic Goods (Manufacturing Principles) Determination 2020*. The amendments replace references in each of those instruments to TGO 88 with references to the new TGO 108.

## **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.

Taken together, TGO 83, TGO 84, TGO 85, TGO 86, TGO 87 and TGO 88 formed minimum safety and quality related requirements to be followed in relation to the collection, manufacture, transport and storage of particular kinds of human cells and tissues, and overarching requirements relating to the labelling of biologicals generally, and, in the case of TGO 88, requirements relating to donor

selection and testing for minimising infectious disease transmission via human tissues, human cellular therapy products and blood and blood components.

These instruments are repealed in the Repeal Instrument. However, the standards constituted by the instruments for the manufacture of therapeutic goods that comprise, contain or are derived from human cells or tissues are reproduced in new TGO 107, TGO 108 and TGO 109.

TGO 107 sets out labelling requirements for biologicals and has the effect of replacing TGO 87, principally without introducing new regulatory requirements. This order does not apply to biologicals mentioned in item 13 of Schedule 5A to the *Therapeutic Goods Regulations 1990*, and only the requirements specified in subsections 9(3) and 10(2) apply in relation to biologicals exported from Australia.

TGO 108 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). TGO 108 has the effect of replacing TGO 88, principally without introducing new regulatory requirements. It 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.

TGO 109 sets out general and specific requirements relating to all biologicals, human musculoskeletal tissue products, human cardiovascular tissue products, human ocular tissue products, human skin products and human amnion products. TGO 109 has the effect of replacing TGO 83, TGO 84, TGO 85 and TGO 86, principally without introducing new regulatory requirements.

The new orders are also designed to update a small number of technical requirements and improve the presentation and readability of requirements for these products, compared to the earlier instruments.

The Specified Things Instrument is made under subsections 32A(2) and (3) of the Act, and similarly has the effect of replacing (without significant modification) the 2011 Determination, while also repealing the 2011 Determination. The Specified Things Instrument also repeals and replaces the 2019 Specification, again without modification.

In replacing both of these instruments, the Specified Things Instrument provides a single snapshot of products for which the Secretary has exercised the power under subsection 32A(2) of the Act to specify things that are biologicals (where those things also satisfy paragraph 32A(1)(b) of the Act), and the power under subsection 32A(3) of the Act to determine things that are not biologicals, for the purposes of the Act.

Finally, the Consequential Amendment Instrument makes a small number of minor, consequential amendments to update references to TGO 88 in the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020* and the *Therapeutic Goods (Manufacturing Principles) Determination 2020* with references to the new TGO 108.

## Consultation

The Office of Best Practice Regulation (“OBPR”) advised that a regulation impact statement was not required in relation to the making of this package of instruments (OBPR ID 43510). A certification process was sufficient on the basis that the legislative instruments are remade without major substantive changes. The changes incorporated into these instruments are only minor in nature and all relevant stakeholders were given notice of the changes.

Extensive consultation was conducted in relation to development of these instruments. Public consultation was open for six weeks between 27 May 2021 and 11 July 2021. The consultation paper proposed to remake the standards and legislative instruments for HCT products, blood and blood components without substantially altering the current substantive requirements of the standards. All proposed substantive changes were included in the consultation paper for stakeholder comment and discussion, including a small number of proposed amendments to reduce regulatory burden. For example, in relation to exemptions for donors for autologous and directed allogenic HCT products, reducing deferral period for donors with high-risk sexual behaviour and allowing alternatives for donors who have had potential exposure to malaria may be accepted without any deferral period if the HCT material is manufactured using specified additional treatments.

The paper also proposed increases in regulation for mandating additional information on labels for Class 3 and 4 biologicals, testing ‘plasma for fractionation only donors’ for HBV by nucleic acid testing (NAT) and mandating processing timeframe of 72 hours for completion of processing for human cardiovascular tissue products.

The TGA received 33 responses, including from sponsors, patients, and industry representative bodies such as the International Society for Cell and Gene Therapy (“ISCT”), Eye Bank Association of Australia and New Zealand (“EBAANZ”), Australian Tissue Donation Network, state and territory tissue banks, the Biotherapeutics Association of Australasia, Gilead Sciences Pty Ltd, Janssen-Cilag Pty Ltd, Novartis, Australian Red Cross Lifeblood and CSL Behring.

There was overall agreement from respondents that the former orders and instruments were fit for purpose and were operating effectively and efficiently. There was also support for the majority of the proposed updates to the former orders, with the exception of a proposal for the introduction of additional donor blood testing requirements for manufacturers who collect only tissue that will be released for the purpose of corneal transplantation (“cornea-only manufacturers”).

Feedback on this issue has been incorporated into TGO 108 through the inclusion of a three year transition period for “cornea only manufacturers”, during which those manufacturers will not be required to comply with the new donor blood testing requirements.

Details of the instruments are set out in attachments **A** to **F**.

The instruments are 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 G**.

The instruments are disallowable legislative instruments. The instruments commence on 30 September 2021.

**Details of the *Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021***

**Part 1 – Preliminary**

This Part provides for the name of the *Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021* (“the Order”), its commencement, authority and application, transitional arrangements and definitions for key terms used in the Order.

**Section 1 – Name**

This section provides that the name of the Order is the *Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021*, and that the Order may also be cited as TGO 107.

**Section 2 – Commencement**

This section provides that the Order commences on 30 September 2021.

**Section 3 – Authority**

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

**Section 4 – Definitions**

This section provides the definitions of key terms used in the Order, including ‘allogeneic use’, ‘expiry date’ and ‘HCT materials’. This section also notes that some expressions used in the Order, such as ‘batch’, ‘biological’, ‘container’, ‘label’, ‘manufacture’, ‘primary pack’ and ‘Register’, have the same meaning as in the Act.

**Section 5 – Standard**

This section provides that the matters specified in the Order constitute a standard for biologicals in relation to labelling.

**Section 6 – Application**

This section provides that the Order applies to biologicals supplied in Australia, other than biologicals that are mentioned in item 13 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (subject to compliance with the condition in that item). It also provides that the Order does not apply in relation to biologicals exported from Australia, other than the requirements specified in subsections 9(3) and 10(2) of the Order.

## **Section 7 – Transitional arrangements**

This section provides that despite the repeal of the Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals* (“TGO 87”) by the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*, TGO 87 can be complied with as an alternative standard to the one constituted by the Order for the duration of the transition period, which is defined as the period beginning on 30 September 2021 and ending on 30 September 2022. This provides a period of a year for sponsors and manufacturers of relevant biologicals to prepare to comply with the Order.

## **Part 2 – Labelling requirements**

This Part specifies the labelling requirements for both HCT materials used in the manufacture of biologicals as well as for biologicals themselves.

## **Section 8 – General requirements**

This section provides general requirements for labelling of both HCT materials and biologicals. This includes specifications for the size of lettering on a label and its legibility. This section also mandates that labels be attached securely to products and that labels are clearly visible. This section also provides that where products are enclosed in transparent coverings and the label is visible through that covering, an extra label does not have to be attached to the covering.

## **Section 9 – Labels of HCT materials**

This section provides specific requirements for the labelling of HCT materials, principally by requiring the information outlined in Schedule 1 to be on or attached to HCT materials, including particular requirements in relation to circumstances where HCT materials are too small to hold a label with all required information.

## **Section 10 – Labels of biologicals**

This section provides specific requirements relating to the labelling of biologicals, principally by requiring the information outlined in Schedule 2 to be on or attached to, or supplied with, biologicals, including particular requirements in relation to circumstances where products are too small to hold a label with all required information.

## **Schedule 1 – Labels in relation to HCT materials**

This schedule outlines the information that must be on or attached to HCT materials for the purposes of section 9, including the type of material and a unique donor identifier.

## **Schedule 2 – Labels in relation to biologicals**

### **Part 1 – Information on or attached to containers and primary packs**

This part of Schedule 2 outlines the information that must be on or attached to the containers and primary packs of biologicals for the purposes of section 10, including the batch number and unique identifier of the donor.

## **Part 2 – Information on, attached to, or supplied with containers or primary packs**

This part of Schedule 2 outlines the information that must be on or attached to, or supplied with, the containers and primary packs of biologicals for the purposes of section 10, including the sponsor's details and a description of the biological.

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

**Part 1 – Preliminary**

This Part provides for the name of the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“the Order”), its commencement, authority and application, transitional arrangements and definitions for key terms used in the Order.

**Section 1 – Name**

This section provides that the name of the Order is the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021*, and that the Order may also be cited as TGO 108.

**Section 2 – Commencement**

This section provides that the Order commences on 30 September 2021.

**Section 3 – Authority**

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

**Section 4 – Definitions**

This section provides the definitions of key terms used in the Order, including ‘autologous use’, ‘asystole’ and ‘HCT products’. This section also notes that some expressions used in the Order, such as ‘export only medicine’, ‘manufacture’, ‘Register’ and ‘standard’, have the same meaning as in the Act.

**Section 5 – Standard**

This section provides that the matters specified in the Order constitute a standard for HCT products in relation to donor screening.

**Section 6 – Application**

This section provides that the Order applies to HCT products other than the HCT products listed in paragraphs 6(a) to (c), including for example faecal microbiota transplant products and certain kinds of samples of human cells or tissues.

**Section 7 – Transitional arrangements**

This section provides that despite the repeal of the *Therapeutic Goods Order No. 88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that*



*are human blood and blood components, human tissues and human cellular therapy products* (“TGO 88”) by the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*, TGO 88 can be complied with as an alternative standard to the one constituted by the Order for the duration of the transition period, which is defined as the period beginning on 30 September 2021 and ending on 30 September 2022. This provides a period of a year for sponsors and manufacturers of relevant HCT products to prepare to comply with the Order.

## **Section 8 - Special transitional arrangements for cornea only manufacturers**

This section provides that, for the period beginning on 30 September 2021 and ending on 30 September 2024, the special transitional arrangements in subsection 8(3) may be complied with by cornea-only manufacturers as an alternative to the blood sample testing requirements specified in paragraph 11(6)(b) and subsection 11(7) of the Order.

The special transitional arrangements in subsection 8(3) of the Order require that blood samples of a deceased donor of human ocular tissue collected in accordance with paragraph 11(6)(a) of the Order must be serology tested for HIV-1, HIV-2, HCV and HBsAg.

## **Part 2 – Requirements**

This Part specifies the screening requirements for HCT products to which the Order applies.

## **Section 9 – General requirements**

This section specifies general requirements for the screening of HCT products, including for example that an HCT product must be manufactured in accordance with procedures that mitigate the risk of infectious disease transmission, and that an HCT product must not be released for supply unless the applicable procedures and requirements specified in the Order have been satisfied.

## **Section 10 – Medical and social history of donors**

This section provides requirements relating to obtaining a medical and social history of living donors and deceased donors of HCT materials, including for example that a medical and social history of a living donor, covering the ineligibility criteria specified in Schedule 1 to the Order and any other relevant matters, must be obtained through an interview.

## **Section 11 – Blood samples—taking and testing**

This section provides requirements relating to the taking and testing of blood samples from both living and deceased donors of HCT materials for the purposes of donor screening, including for example that blood samples must be taken using aseptic procedures.

## **Section 12 – Physical assessment**

This section provides requirements relating to the conducting of a physical assessment of a donor of HCT materials (other than a donor of HCT materials used exclusively for plasma fractionation in the manufacture of export only medicines) including, for example that in the case of a living donor (other than a living donor of human musculoskeletal tissue only) such an assessment must be conducted at

the time of collection. Further, the assessment must include, among other things, a clinical inspection of any physical features or characteristics of a donor that may indicate that the donor poses a risk of infectious disease transmission, such as an abrasion, laceration or tattoo.

### **Schedule 1 – Ineligibility criteria for donor selection**

This schedule lists donor ineligibility criteria for donors of HCT materials for the purposes of section 10, including for example that a person who is infected with HCV, HIV-1 or HIV-2 is to be permanently ineligible.

**Details of the *Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021***

**Part 1 – Preliminary**

This Part provides for the name of the *Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021* (“the Order”), its commencement, authority and application, transitional arrangements and definitions for key terms used in the Order.

**Section 1 – Name**

This section provides that the name of the Order is the *Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021*, and that the Order may also be cited as TGO 109.

**Section 2 – Commencement**

This section provides that the Order commences on 30 September 2021.

**Section 3 – Authority**

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

**Section 4 – Definitions**

This section provides the definitions of key terms used in the Order, including ‘allogeneic use’, ‘critical materials’ and ‘HCT materials’. This section also notes that some expressions used in the Order, namely ‘bioburden’, ‘biological’, ‘container’, ‘manufacture’, ‘standard’ and ‘supply’ have the same meaning as in the Act.

**Section 5 – Standard**

This section provides that the matters specified in Part 2 of the Order constitute a standard for all biologicals, and that the matters specified in Parts 3 to 7 of the Order constitute a standard for the relevant kinds of human tissue to which each of those parts relate.

**Section 6 – Application**

This section provides that the Order applies to biologicals, other than biologicals that are faecal microbiota transplant products, those mentioned in item 13 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (subject to compliance with the condition in that item) or samples of HCT material that are biopsied for in vitro diagnostic examination and not for further manufacture or reintroduction or transplantation to a person.

## **Section 7 – Transitional arrangements**

This section provides that despite the repeal of the Therapeutic Goods Order No. 83 Standards for human musculoskeletal tissue, *Therapeutic Goods Order No. 84 Standards for human cardiovascular tissue*, Therapeutic Goods Order No. 85 Standards for human ocular tissue and Therapeutic Goods Order No. 86 Standards for human skin, as well as subsections 9(13) to (15) and sections 12 and 13, of the *Therapeutic Goods Order No. 88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products*, by the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*, those instruments and provisions can be complied with as an alternative standard to the standards constituted by the Order, for the transition period.

The transition period is defined as the period beginning on 30 September 2021 and ending on 30 September 2022. This provides a period of a year for sponsors and manufacturers of relevant HCT products to prepare to comply with the Order.

## **Part 2 – Standard for all biologicals**

This Part specifies general requirements that must be met in the manufacture of all biologicals, including requirements relating to the HCT materials used in the manufacture of those biologicals. Unless otherwise specified, the requirements in Part 2 apply to all biologicals, including a biological that is also subject to a specific standard in Parts 3 to 7 of the Order.

## **Section 9 – Diseases and conditions that may compromise biologicals**

This section provides that a biological must not be manufactured using HCT materials collected from a donor who is known to have a disease or condition that may compromise the quality, safety or efficacy of the biological, except in specified circumstances.

## **Section 10 – Critical materials**

This section provides that the critical materials used in the manufacture of a biological must meet specified criteria, including for example that the materials must not be contaminated with, or be likely to introduce, microorganisms or other infectious disease agents, and must not adversely affect the quality, safety or efficacy of the biological.

## **Section 11 – Microbial contamination control strategy**

This section provides that a risk-based microbial control strategy, which considers the nature of HCT materials and biologicals, must be implemented to minimise intrinsic and extrinsic microbial contamination of HCT materials and biologicals, and must specify storage, handling and transportation requirements (including in relation to temperature and duration) for the HCT materials and biologicals.

## **Section 12 – Samples for bioburden testing**

This section provides that samples must be taken for bioburden testing, using a validated sampling technique and testing using a validated test method.

### **Section 13 – Bioburden testing requirements**

This section provides for a number of requirements relating to bioburden testing, including for example that written specifications for HCT materials and biologicals must include specified microorganisms determined on the basis of a risk assessment, and that samples must demonstrate that HCT materials are free from contamination with specified microorganisms.

### **Section 14 – Sterilisation**

This section provides that the sterilisation process for a biological that is terminally sterilised must be validated to ensure a maximal sterility assurance level of  $10^{-6}$ .

### **Section 15 – Collection from deceased donors**

Subsection 15(1) provides that HCT materials must be collected from a deceased donor as soon as possible after asystole, and that collection must be completed not later than 24 hours after asystole if the body has been refrigerated below 10°C within 12 hours of asystole or, if not, not later than 15 hours after asystole.

Subsection 15(2) provides that section 15 does not apply in relation to the kinds of human tissue listed in paragraphs 15(2)(a), (b) or (c).

### **Section 16 – Storage and transportation**

This section provides a number of requirements relating to the storage and transportation of HCT materials, including for example that immediately following collection and prior to processing, HCT materials must be stored at less than 10°C for not longer than 72 hours or as otherwise validated by the manufacturer to prevent microbial proliferation and to ensure the quality, safety and efficacy of the biological manufactured using the HCT materials.

### **Section 17 – Containers of biologicals**

This section provides that a biological (other than a human ocular tissue product to which Part 5 of the Order applies) must be sealed within a sterile container and must be at least double packaged so as to prevent ingress or egress of all materials and ensure that any breach of integrity of the container and packaging is evident.

### **Part 3 – Standard for human musculoskeletal tissue**

This Part specifies requirements that must be met in the manufacture of human musculoskeletal tissue products that have been subjected to only minimal manipulation, including requirements relating to human musculoskeletal tissue that is collected for use in the manufacture of those products. Unless otherwise specified, a biological to which this part applies must also meet the general requirements in Part 2 of the Order in addition to the specific requirements in this part.

## **Section 19 – Application of this Part**

This section provides that Part 3 applies in relation to human musculoskeletal tissue products that have been subjected to only minimal manipulation.

## **Sections 20 to 24**

These sections provide a number of technical requirements that must be followed in relation to the collection, testing and manufacture of human musculoskeletal tissue products to which this part applies, in relation to the collection of such tissue from a deceased donor, bioburden testing, the maximum residual calcium of such products, the maximum residual moisture content of such products when freeze-dried and requirements relating to storage and transportation.

## **Part 4 – Standard for human cardiovascular tissue products**

This part specifies requirements that must be met in the manufacture of human cardiovascular tissue products that have been subjected to only minimal manipulation and that are manufactured for allogenic use only, including requirements relating to human cardiovascular tissue that is collected for use in the manufacture of those products. Unless otherwise specified, a biological to which Part 4 applies must also meet the general requirements in Part 2 in addition to the specific requirements in this part.

## **Section 26 – Application of this Part**

This section provides that this part applies in relation to human cardiovascular tissue products that have been subjected to only minimal manipulation and that are manufactured for allogenic use only.

## **Sections 27 to 30**

These sections provide a number of technical requirements that must be followed in relation to the testing, collection and manufacture of human cardiovascular tissue products to which this part applies, in relation to the collection and handling of such tissue that is not subjected to a bioburden reduction process, the collection and handling of such tissue that is subjected to a bioburden reduction process, that human cardiovascular tissue that is a heart valve must be a competent valve prior to cryopreservation, and requirements relating to storage and transportation.

## **Part 5 – Standard for human ocular tissue products**

This part specifies requirements that must be met in the manufacture of human ocular tissue products that have been subjected to only minimal manipulation and that are manufactured for allogenic use only, including requirements relating to human ocular tissue that is collected for use in the manufacture of those products. Unless otherwise specified, a biological to which this part applies must also meet the general requirements in Part 2 in addition to the specific requirements in this part.

## **Section 32 – Application of this Part**

This section provides that this part applies in relation to human ocular tissue products that have been subjected to only minimal manipulation and that are manufactured for allogenic use only.

## **Sections 33 to 37**

These sections provide a number of technical requirements that must be followed in relation to the testing, collection and manufacture of human ocular tissue products to which this part applies, in relation to storage and transportation, the testing and handling of storage medium for excised cornea, containers for human ocular tissue products and the examination and evaluation of human ocular tissue.

## **Part 6 – Standard for human skin products**

This part specifies requirements that must be met in the manufacture of human skin products that have been subjected to only minimal manipulation, including requirements relating to human skin that is collected for use in the manufacture of those products. Unless otherwise specified, a biological to which this part applies must also meet the general requirements in Part 2 in addition to the specific requirements in this part.

### **Section 39 – Application of this Part**

This section provides that this part applies in relation to human skin products that have been subjected to only minimal manipulation.

## **Sections 40 to 43**

These sections provide a number of technical requirements that must be followed in relation to the testing, collection and manufacture of human skin products to which this part applies, in relation to processing, bioburden testing, freeze-dried human skin products, and storage and transportation.

## **Part 7 – Standard for human amnion products**

This part specifies requirements that must be met in the manufacture of human amnion products that have been subjected to only minimal manipulation, including requirements relating to human amnion that is collected for use in the manufacture of those products. Unless otherwise specified, a biological to which this part applies must also meet the general requirements in Part 2 in addition to the specific requirements in this part.

### **Section 45 – Application of this Part**

This section provides that this part applies in relation to human amnion products that have been subjected to only minimal manipulation.

## **Sections 46 to 49**

These sections provide a number of technical requirements that must be followed in relation to the testing, collection and manufacture of human amnion products, including requirements relating to collection, terminal sterilisation, dehydrated or freeze-dried human amnion products, and storage and transportation.

## **Details of the *Therapeutic Goods (Biologicals—Specified Things) Instrument 2021***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Biologicals—Specified Things) Instrument 2021* (“the Instrument”).

### **Section 2 – Commencement**

This section provides that the Instrument commences on 30 September 2021.

### **Section 3 – Authority**

This section provides that the legislative authority for making the Instrument is section 32A of the *Therapeutic Goods Act 1989* (“the Act”).

### **Section 4 – Definitions**

This section provides the definitions of key terms used in the Instrument, including ‘biological medicine’ and ‘faecal microbiota transplant product’. This section also provides that the expression ‘biological’ has the same meaning as in the Act.

### **Section 5 – Specified things—biologicals**

This section provides that, for subsection 32A(2) of the Act, the things mentioned in Schedule 1 are specified for the purposes of subparagraph 32A(1)(a)(ii) of the Act, with the effect that those things are biologicals for the purposes of the Act where paragraph 32A(1)(b) is also satisfied.

### **Section 6 – Specified things—not biologicals**

This section provides that, for subsection 32A(3) of the Act, the things specified in Schedule 2 are determined not to be biologicals for the purposes of the Act.

### **Section 7 – Repeals**

This section provides that each instrument that is specified in Schedule 3 is repealed as set out in the applicable items in that Schedule.

### **Schedule 1 – Specified things: biologicals**

This schedule specifies things for the purposes of section 5, with the effect that the things are biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act (where those things also satisfy paragraph 32A(1)(b)). Specifically, the things specified in Schedule 1 are things that comprise or contain live animal cells, tissues or organs, and things that are faecal microbiota transplant products.



## **Schedule 2 – Specified things: not biologicals**

This schedule specifies things for the purposes of section 6, with the effect that the things are not biologicals for the purposes of subsection 32A(3) of the Act. Specifically, the things specified in Schedule 2 are things that are biological medicines (other than vaccines that contain viable human cells), haematopoietic progenitor cells used for haematopoietic reconstitution, IVD medical devices and in-house IVD medical devices, and samples of human cell or tissue of an individual that are solely for diagnostic purposes in that individual.

## **Schedule 3 – Repeals**

This schedule provides for the repeal of the *Therapeutic Goods (Things that are Biologicals) Specification 2019*, and the Therapeutic Goods (Things that are not Biologicals) Determination No.1 of 2011, for the purposes of section 7.

## **Details of the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021* (“the Instrument”).

### **Section 2 – Commencement**

This section provides that the Instrument commences on 30 September 2021.

### **Section 3 – Authority**

This section provides that the legislative authority for making the Instrument is section 10 of the *Therapeutic Goods Act 1989* (“the Act”). In particular, subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1).

### **Section 4 – Schedules**

This section provides that 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 own terms.

### **Schedule 1 – Repeals**

This schedule provides for the repeal of the following instruments:

- Therapeutic Goods Order No. 83 Standards for human musculoskeletal tissue;
- *Therapeutic Goods Order No. 84 Standards for human cardiovascular tissue;*
- Therapeutic Goods Order No. 85 Standards for human ocular tissue;
- Therapeutic Goods Order No. 86 Standards for human skin;
- Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals;* and
- *Therapeutic Goods Order No. 88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products.*

## **Details of the *Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021* (“the Instrument”).

### **Section 2 – Commencement**

This section provides that the Instrument commences on 30 September 2021.

### **Section 3 – Authority**

This section provides that the legislative authority for making the Instrument is section 10 and section 36 of the *Therapeutic Goods Act 1989* (“the Act”).

### **Section 4 – Schedules**

This section provides that 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 own terms.

#### **Schedule 1 – Consequential amendments**

This schedule amends the *Therapeutic Goods (Manufacturing Principles) Determination 2020*, principally to replace a reference in that instrument to TGO 88 with a reference to TGO 108, and to make related consequential amendments.

This schedule amends the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products (TGO 105) Order 2020*, principally to replace a reference in that instrument to TGO 88 with a reference to TGO 108, and to make related consequential amendments.

## Statement of Compatibility with Human Rights

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

*Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021*

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

*Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021*

*Therapeutic Goods (Biologicals—Specified Things) Instrument 2021*

*Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*

*Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021*

These disallowable legislative instruments are 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 instruments

The *Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021* (“TGO 107”), the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* (“TGO 108”) and the *Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021* (“TGO 109”) are made under section 10 of the Act. The purpose of these orders is to establish ministerial standards 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 labelling (TGO 107), donor screening (TGO 108) and a range of other matters including manufacturing, packaging and storage (TGO 109).

The *Therapeutic Goods (Biologicals—Specified Things) Instrument 2021* (“the Specified Things Instrument”) is made under subsections 32A(2) and (3) of the Act for the purpose of specifying things that are (where those things also satisfy paragraph 32A(1)(b) of the Act), and things that are not, biologicals for the purposes of the Act.

The Specified Things Instrument provides a single snapshot of products for which the Secretary has, by legislative instrument, specified things for the purposes of subsections 32A(2) and (3) of the Act. It also repeals the previous Therapeutic Goods (Things that are not Biologicals) Determination No. 1 of 2011 (“the 2011 Determination”), and the *Therapeutic Goods (Things that are Biologicals) Specification 2019* (“the 2019 Specification”), the former of which would otherwise sunset on 1 October 2021.

The *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021* (“the Repeal Instrument”) is made under section 10 of the Act, for the purpose of repealing the following legislative instruments that would otherwise sunset on 1 October 2021:

- Therapeutic Goods Order No. 83 Standards for human musculoskeletal tissue (“TGO 83”);
- *Therapeutic Goods Order No. 84 Standards for human cardiovascular tissue* (“TGO 84”);
- Therapeutic Goods Order No. 85 Standards for human ocular tissue (“TGO 85”);
- Therapeutic Goods Order No. 86 Standards for human skin (“TGO 86”);
- Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals* (“TGO 87”); and
- *Therapeutic Goods Order No. 88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products* (“TGO 88”).

The *Therapeutic Goods (Consequential Amendments—TGO 108) Instrument 2021* (“the Consequential Amendment Instrument”) is made under sections 10 and 36 of the Act, for the purpose of making minor, consequential amendments to update two other instruments, the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020* and the *Therapeutic Goods (Manufacturing Principles) Determination 2020*. The amendments replace references in each of those instruments to TGO 88 with references to the new TGO 108.

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.

Taken together, TGO 83, TGO 84, TGO 85, TGO 86, TGO 87 and TGO 88 formed minimum safety and quality related requirements to be followed in relation to the collection, manufacture, transport and storage of particular kinds of human cells and tissues, and overarching requirements relating to the labelling of biologicals generally and, in the case of TGO 88, requirements relating to donor selection and testing for minimising infectious disease transmission via human tissues, human cellular therapy products and blood and blood components.

These instruments are repealed in the Repeal Instrument. However, the standards constituted by the instruments for the manufacture of therapeutic goods that comprise, contain or are derived from human cells or tissues are reproduced in new TGO 107, TGO 108 and TGO 109.

TGO 107 sets out labelling requirements for biologicals and has the effect of replacing TGO 87, principally without introducing new regulatory requirements. This order does not apply to biologicals mentioned in item 13 of Schedule 5A to the *Therapeutic Goods Regulations 1990*, and only the requirements specified in subsections 9(3) and 10(2) apply in relation to biologicals exported from Australia.

TGO 108 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, or blood or blood

components (including plasma). TGO 108 has the effect of replacing TGO 88, principally without introducing new regulatory requirements. It 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.

TGO 109 sets out general and specific requirements relating to all biologicals, human musculoskeletal tissue products, human cardiovascular tissue products, human ocular tissue products, human skin products and human amnion products, and has the effect of replacing TGO 83, TGO 84, TGO 85 and TGO 86, principally without introducing new regulatory requirements. The new orders are also designed to update a small number of technical requirements and improve the presentation and accessibility of requirements for these products, compared to the earlier instruments.

The Specified Things Instrument is made under subsections 32A(2) and (3) of the Act, and similarly has the effect of replacing (without significant modification) the 2011 Determination, while also repealing the 2011 Determination. The Specified Things Instrument also repeals and replaces the 2019 Specification, again without modification. In replacing both of these instruments, the Specified Things Instrument provides a single snapshot of products for which the Secretary has exercised the power under subsection 32A(2) of the Act to specify things that are biologicals (where those things also satisfy paragraph 32A(1)(b) of the Act), and the power under subsection 32A(3) of the Act to determine things that are not biologicals, for the purposes of the Act.

The Consequential Amendment Instrument makes a small number of minor, consequential amendments to update references to TGO 88 in the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020* and the *Therapeutic Goods (Manufacturing Principles) Determination 2020* with references to the new TGO 108.

### **Human rights implications**

Taken together, the standards and instruments engage 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 standards take 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 standards apply to products derived from human cells and tissues by specifying minimum requirements in relation to the screening, collection, manufacture and labelling of such products, and the materials that are used to manufacture them. This is particularly critical to ensure the safety of such products and biologicals from the risk of the transmission of infectious diseases in connection with these high-risk therapeutic goods that are for use in a recipient.

The Specified Things Instrument also supports the right to health by providing a single snapshot of things for which the Secretary has identified are biologicals (where those things also satisfy paragraph 32A(1)(b) of the Act), or are not biologicals, for the purposes of the Act.

### **Conclusion**

The standards and instruments are compatible with human rights because they promote the right to health in Article 12 of the ICESCR and otherwise do not raise any other human rights issues.