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

made under section 10 of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 9 March 2022

Includes amendments up to: F2022L00284

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021* that shows the text of the law as amended and in force on 9 March 2022 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name

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

(2) This instrument may also be cited as TGO 108.

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 section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) export only medicine;
(b) manufacture;
(c) medicine;
(d) Register;
(e) standard;
(f) supply;
(g) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

allogeneic use, in relation to an HCT product, means administration to, or application in the treatment of, a person other than the person from whom the HCT materials used in the manufacture of the product were collected.

asystole, in relation to a donor of HCT materials, means the reference time for cardiac death, being:

(a) the documented pronounced time of death; or

(b) if death is not witnessed—the last time the donor was known to be alive; or

(c) if the donor of the HCT materials is also a solid organ donor—the cross-clamp time.

autologous use, in relation to an HCT product, means administration to, or application in the treatment of, the person from whom the HCT materials used in the manufacture of the product were collected.

blood means whole blood collected from a single human donor and that is:

(a) used for infectious disease testing; or

(b) processed either for transfusion or further manufacturing.

blood components means any of the following therapeutic components of blood that can be prepared by centrifugation, filtration or freezing using conventional methodologies in blood establishment:

(a) plasma;

(b) platelets;

(c) red cells;

(d) white cells;

but does not include haematopoietic progenitor cells.

directed allogeneic use, in relation to an HCT product, means allogeneic use for which all of the following paragraphs apply:

(a) the HCT materials used in the manufacture of the product are collected by, or under the professional supervision or direction of, a medical or dental practitioner; and

(b) the product is manufactured for administration to, or application in the treatment of, a designated patient who has a pre-existing condition by, or under the professional supervision or direction of, a medical or dental practitioner; and

(c) the medical or dental practitioners mentioned in paragraphs (a) and (b) are registered in a State or internal Territory.

faecal microbiota transplant product has the same meaning as in the Regulations.

haematopoietic progenitor cells means primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells.

HBsAg means hepatitis B surface antigen.

HBV means hepatitis B virus.

HCT materials means one or more of the following that are collected from a donor for use in the manufacture of an HCT product:

(a) human cells (including haematopoietic progenitor cells);
(b) human tissues;
(c) blood;
(d) blood components (including plasma).

HCT products means therapeutic goods that comprise, contain or are derived from HCT materials.

HCV means hepatitis C virus.

HIV-1 means human immunodeficiency virus type 1.

HIV-2 means human immunodeficiency virus type 2.

HPC(CB) means haematopoietic progenitor cells obtained from cord blood.

HTLV-1 means human T-lymphotropic virus type 1.

HTLV-2 means human T-lymphotropic virus type 2.

human musculoskeletal tissue includes bone, cartilage, fascia lata, ligament, muscle, and tendon.

in-house IVD medical device has the same meaning as in the MD Regulations.

IVD medical device has the same meaning as in the MD Regulations.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

NAT means nucleic acid amplification testing.

Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic Goods Administration has the same meaning as in the Regulations.

5 Standard

The matters specified in this instrument constitute a standard for HCT products in relation to donor screening.

6 Application

This instrument applies to HCT products, other than:

(a) a faecal microbiota transplant product; or
(b) a sample of human cells or human tissues:
    (i) biopsied for in vitro diagnostic examination; and
    (ii) not for further manufacture, or reintroduction or transplant to a person; or
(c) an HCT product for which all of the following subparagraphs apply:

(i) the product is manufactured for autologous use only; and

(ii) the HCT materials used in the manufacture of the product are collected by, or under the professional supervision or direction of, a medical or dental practitioner; and

(iii) the product is manufactured for administration to, or application in the treatment of, a patient by, or under the professional supervision or direction of, a medical or dental practitioner; and

(iv) the practitioners mentioned in subparagraphs (ii) and (iii) are registered in a State or internal Territory.

7 Transitional arrangements

(1) In this section:

former instrument means 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*, as in force immediately before the commencement of the repeal instrument.

repeal instrument means the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*.

transition period means the period beginning on 30 September 2021 and ending on 30 September 2022.

(2) Despite the repeal of the former instrument by the repeal instrument, the former instrument continues to apply for the duration of the transition period, such that the standard for human cell and tissue products constituted by the former instrument may be conformed with as an alternative to the standard for human cell and tissue products constituted by this instrument.

8 Special transitional arrangements for cornea only manufacturers

(1) In this section:

cornea only manufacturer means a manufacturer who, in relation to a deceased donor:

(a) collects human ocular tissue from the donor for the purpose of corneal transplantation and not any other purpose; and

(b) does not collect any other tissue from the donor for any other purpose.

repeal instrument means the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*.

special transitional requirements means the requirements specified in subsection (3) in relation to the testing of blood samples taken from a donor of human ocular tissue.

special transition period means the period beginning on 30 September 2021 and ending on 30 September 2024.

(2) The special transitional requirements apply to a cornea only manufacturer for the duration of the special transition period, such that those requirements may be complied with as an alternative to the blood sample testing requirements specified in paragraph 11(6)(b) and subsection 11(7) of this instrument.

(3) Blood samples of a deceased donor of human ocular tissue collected in accordance with paragraph 11(6)(a) must be serology tested for HIV-1, HIV-2, HCV and HBsAg.

Part 2—Requirements

9 General requirements

(1) An HCT product must be manufactured in accordance with procedures that mitigate the risk of infectious disease transmission.

(2) An HCT product must not be released for supply, unless the applicable screening procedures and requirements specified in this instrument are satisfied.

(3) Acceptance criteria based on microbial specifications must be applied to HCT materials used in the manufacture of an HCT product.

General requirements relating to testing of blood samples

(4) Blood samples of a donor of HCT materials must be tested:
  (a) as soon as practicable after the blood sample is taken; or
  (b) in accordance with the timeframe specified by the manufacturer of the IVD medical device or the in-house IVD medical device that is used for testing the sample; or
  (c) where testing is conducted outside of Australia—within a timeframe that is validated by the testing laboratory.

(5) Blood samples must be tested using IVD medical devices or in-house IVD medical devices that:
  (a) use the most appropriate methodology available that is validated for testing the samples (including cadaveric samples); and
  (b) where testing is conducted in Australia—are either included in the Register or exempt from the requirement to be included in the Register, or are the subject of an approval or authority under the Act; and
  (c) where testing is conducted outside of Australia—are:
    (i) approved by a relevant regulatory authority in the country in which the testing is conducted; and
    (ii) used in a facility that has been approved for such testing by a relevant regulatory authority in the country in which the testing is conducted; and
    (iii) considered acceptable by the Therapeutic Goods Administration.

(6) Where the testing of a blood sample is conducted by a laboratory that is not under the direct control of the manufacturer of the relevant HCT product:

(a) the testing must be conducted under a contract between the manufacturer and the laboratory; and

(b) the contract mentioned in paragraph (a) must clearly set out the responsibilities of the manufacturer and the laboratory, and include arrangements to ensure that information relating to matters in this section and any other relevant details relating to the IVD medical devices or in-house IVD medical devices used for such testing can be obtained from the laboratory.

(7) The testing of blood samples must take into account all factors that may cause plasma dilution.

(8) Where plasma dilution is suspected at a level sufficient to alter the test results in relation to a blood sample, and a pre-infusion sample is unavailable for testing, then:

(a) an algorithm must be applied to assess the extent of plasma dilution; and

(b) the extent of plasma dilution must be less than 50 per cent, unless use of samples with more than 50 per cent plasma dilution is validated by the manufacturer of the IVD medical devices or in-house IVD medical devices used for testing the sample.

(9) Records must be maintained in relation to the following:

(a) the tests performed in relation to blood samples and the results of those tests; and

(b) the IVD medical device or in-house IVD medical device used for testing the samples; and

(c) any test modifications; and

(d) any evaluations of, or anomalies in, test results.

(10) Procedures must be implemented for notifying a donor of HCT materials, a relevant health practitioner, a relevant hospital and any other relevant organisation, of a test result in relation to the donor that is indicative of a disease or carrier state.

10 Medical and social history of donors

Living donors

(1) A medical and social history in relation to a living donor of HCT materials, covering the ineligibility criteria for donor selection specified in Schedule 1 and any other relevant matters, must be obtained by interview.

(2) The interview must be:

(a) conducted by an interviewer who is:

(i) appropriately qualified and trained; and

(ii) an employee of, or under a contract with, a person engaged in the collection of HCT materials or the manufacture of the HCT product; and

(b) held face-to-face (to the extent that it is possible in the circumstances) with the donor or the donor's guardian or next of kin; and

(c) conducted within 30 days before or 30 days after the collection of the HCT materials, and

(d) documented.

Deceased donors

(3) A medical and social history in relation to a deceased donor of HCT materials, covering the ineligibility criteria for donor selection specified in Schedule 1 and any other relevant matters, must be obtained and documented within 7 days before or 7 days after the collection of the HCT materials, by:

(a) both:

(i) an interview with a person who is sufficiently informed about the donor's medical and social history; and

(ii) an examination of relevant documentation in relation to the donor; or

(b) where the interview mentioned in subparagraph (3)(a)(i) is not possible—an examination of the donor documentation to ensure there is sufficient evidence to determine the acceptability of the donor's medical and social history.

Example: A person who is sufficiently informed about a deceased donor's medical and social history may include the donor's treating physician, next of kin or closest available relative, a member of the donor's household, or a person with a relationship with the donor, such as a carer, friend or partner.

Donors of HCT materials used exclusively for plasma fractionation

(4) The periods of ineligibility specified in column 3 of items 2, 4, 13, 16 to 19, and 23 to 26 of the table in Schedule 1 do not apply in relation to a donor of HCT materials that are used exclusively for plasma fractionation in the manufacture of HCT products.

(5) The periods of ineligibility specified in column 3 of items 1 to 7 and column 3 of items 9 to 26 of the table in Schedule 1 do not apply in relation to a donor of HCT materials that are used exclusively for plasma fractionation in the manufacture of an export only medicine.

Donors of HCT materials that are human ocular tissue only

(6) The periods of ineligibility specified in column 3 of items 16 to 19 of the table in Schedule 1 do not apply in relation to a donor of HCT materials that are human ocular tissue only.

Change in circumstances of donor

(7) Where the circumstances of a donor of HCT materials used in the manufacture of an HCT product change in relation to the ineligibility criteria for donor selection specified in Schedule 1, the relevant aspects of the medical and social history of the donor must be reviewed by the manufacturer of the HCT product with respect to those changes, before the HCT product is released for supply.

Screening requirements

(8) An HCT product must not be released for supply, unless the medical and social history of a donor is reviewed and evaluated in accordance with this section.

(9) Where a donor meets any of the medical and social history criteria specified in column 2 of an item of the table in Schedule 1, the donor must be subjected to the period of ineligibility specified in column 3 of that item, in relation to the collection of HCT materials from that donor for use in the manufacture of HCT products.

Screening in relation to donors less than 18 months old

(10) If the donor is less than 18 months old, a medical and social history in relation to the donor's birth mother, covering the ineligibility criteria for donor selection specified in column 2 of items 1 to 7, 11 to 13, 17 and 20 of the table in Schedule 1 must be obtained.

(11) Where the donor's birth mother meets the medical and social history criteria specified in column 2 of item 1 to 7, 11 to 13, 17 or 20 of the table in Schedule 1, then the donor must be subjected to the period of ineligibility specified in column 3 of that item, in relation to the collection of HCT materials from the donor.

Screening in relation to donors who have consumed breast milk

(12) If the donor has consumed breast milk from a person (the ***relevant person***) within the previous six months, a medical and social history in relation to the relevant person, covering the ineligibility criteria for donor selection specified in column 2 of the items 1 to 7, 11 to 13, 17 and 20 of the table in Schedule 1 must be obtained.

(13) Where the relevant person meets the medical and social history criteria specified in column 2 of item 1 to 7, 11 to 13, 17 or 20 of the table in Schedule 1, then the donor must be subjected to the period of ineligibility specified in column 3 of that item, in relation to the collection of HCT materials from the donor.

HCT products that are manufactured for directed allogeneic use

(14) Subsections (9), (11) and (13) do not apply in relation to HCT products that are manufactured for directed allogeneic use where the medical or dental practitioner who is responsible for the administration to, or application in the treatment of, the designated patient is provided the complete medical and social history of the donor of the HCT materials, including (where applicable) the medical and social history of the donor's birth mother or the relevant person.

11 Blood samples—taking and testing

(1) Blood samples must be:
  (a) taken from a donor of HCT materials; and
  (b) tested for the purpose of donor screening.

(2) Blood samples must be taken using aseptic procedures.

Blood samples—living donors of HCT materials other than materials used exclusively for plasma fractionation

(3) Subject to subsections (4) and (5) blood samples of a living donor of HCT materials must:
  (a) be taken within 7 days before, or 7 days after, the collection of the HCT materials from the donor; and
  (b) undergo both NAT and serology testing in accordance subsection (7).

(4) Where an HCT product is able to be stored for more than 180 days without compromising the quality, safety or efficacy of the product, blood samples of a living donor of the HCT materials used in the manufacture of the product may instead:
  (a) be taken:
    (i) within 7 days before, or 7 days after, the collection of the HCT materials from the donor; and
    (ii) at least 180 days after the collection of the HCT materials from the donor; and
  (b) undergo serology testing in accordance with subsections (8) and (10).

Blood samples—living donors of HCT materials used exclusively for plasma fractionation

(5) Blood samples of a living donor of HCT materials that are used exclusively for plasma fractionation must:
  (a) be taken within 7 days before, or 7 days after, the collection of the HCT materials from the donor; and
  (b) undergo both NAT and serology testing in accordance subsection (11).

Blood samples—deceased donors of HCT materials

(6) Blood samples of a deceased donor of HCT materials must:
  (a) be taken:
    (i) in accordance with subsection 9(4); or
    (ii) within 7 days before the collection of the HCT materials; and
  (b) undergo NAT and serology testing in accordance with subsection (7).

Testing—living and deceased donors of HCT materials

(7) Subject to subsection (9), the following testing must be conducted in relation to blood samples taken in accordance with paragraphs (3)(a) or (6)(a):
  (a) serology testing for HIV-1, HIV-2, HCV, HBsAg, HTLV-1, HTLV-2, and syphilis (*Treponema pallidum*); and
  (b) NAT for HIV-1, HIV-2, HBV, and HCV.

(8) Subject to subsection (9), the following testing must be conducted in relation to blood samples taken in accordance with subparagraph (4)(a)(i):

(a) serology testing for HIV-1, HIV-2, HCV, HBsAg, HTLV-1, HTLV-2, and syphilis (*Treponema pallidum*).

(9) Serology testing for HTLV-1 and HTLV-2 is not required if a risk assessment, in relation to the type of the HCT materials and the geographical history of the donor, is undertaken, which demonstrates that:

(a) the risk of transmission of HTLV-1 and HTLV-2 from the donor is mitigated in the absence of donor testing; and

(b) the donor, the parents of the donor, and the sexual partners of the donor, originate from a low risk area; and

(c) the HCT materials is not a viable leukocyte-rich cell or tissue.

(10) The following testing must be conducted in relation to blood samples taken in accordance with subparagraph (4)(a)(ii):

(a) serology testing for HIV-1, HIV-2, HCV, and HBsAg.

Testing—living donors of HCT materials used exclusively for plasma fractionation

(11) The following testing must be conducted in relation to blood samples taken in accordance with paragraph (5)(a):

(a) serology testing for HIV-1, HIV-2, HCV, and HBsAg; and

(b) NAT for HIV-1, HIV-2, HBV and HCV.

Testing in relation to donors less than 18 months old

(12) If a donor of HCT materials is less than 18 months old, then the donor's birth mother must be subjected to the same testing requirements that are applicable to the donor, as set out in subsections (1) to (11).

(13) In the case of a donor of the HCT materials that are HPC(CB) only, the applicable testing requirements in this section apply only in relation to the donor's birth mother.

Note: An infant donor of HPC(CB) only is not required to be tested in accordance with this section.

Testing in relation to donors who have consumed breast milk

(14) If a donor has consumed breast milk from a person (the ***relevant person***) within the previous six months, then the relevant person must be subjected to the same testing requirements that are applicable to the donor, as set out in subsection (1) to (11).

Assessment of testing results

(15) An HCT product must be placed in quarantine, and must not be released for supply, until the results of the testing mentioned in subsections (1) to (14) are assessed.

(16) If the testing of a blood sample demonstrates a reactive result, then the relevant HCT product must not be released for supply.

(17) Subsection (16) does not apply to an HCT product that is manufactured for directed allogeneic use where the medical or dental practitioner who is responsible for the administration to, or application in the treatment of, the designated patient is notified about the testing results.

Serum or plasma of blood samples

(18) The serum or plasma of a blood sample taken from a donor of HCT materials in accordance with subsection (3), (4) or (6) must be:

(a) archived at or below minus 25°C, or in accordance with conditions that are validated or recommended by the manufacturer of the IVD medical device or in-house IVD medical device used for testing the samples; and

(b) retained for a minimum of two years after the expiry date of the relevant HCT product, or for a period that is validated on the basis of validated data or documented evidence from relevant scientific literature.

(19) If:

(a) an HCT product has not been released for supply; and

(b) following the testing of a blood sample in relation to the product, a protocol or methodology for the testing changes;

then, the archived serum or plasma of the blood sample must be tested in accordance with the new protocol or methodology before the product is released for supply, unless the testing is not required on the basis of a risk assessment.

12 Physical assessment

(1) A physical assessment must be conducted in relation to a donor of HCT materials (other than a donor of HCT materials used exclusively for plasma fractionation in the manufacture of an export only medicine) as follows:

(a) in the case of a living donor (other than a living donor of human musculoskeletal tissue only)—at the time of the collection of the HCT materials; or

(b) in the case of a living donor of human musculoskeletal tissue only—within 30 days before or 30 days after the collection of the tissue; or

(c) in the case of a deceased donor—before the collection of the HCT materials.

(2) A physical assessment must:

(a) include a clinical inspection of any physical features or characteristics of a donor (such as an abrasion, laceration, bruise, haematoma, fracture, tattoo, piercing, scar, skin lesion, or surgical incision) that may indicate that the donor poses a risk of infectious disease transmission; and

(b) be conducted by a person who is:

(i) appropriately qualified and trained; and

(ii) an employee of, or under a contract with, a person engaged in the collection of HCT materials or the manufacture of HCT products; and

(c) demonstrate that the donor does not pose a risk of infectious disease transmission.

Schedule 1—Ineligibility criteria for donor selection

Note 1: See section 10.

Note 2: The testing mentioned in column 3 of each item of this table (if any) must comply with the general requirements specified in subsections 9(4) to (10).

Ineligibility criteria for donor selection

Column 1	Column 2	Column 3
Item	**Medical and social history criteria**	**Period of ineligibility**
1	a person who is infected with: (a) HCV; (b) HIV-1; or (c) HIV-2	permanently ineligible
2	a person who is infected with: (a) HTLV-1; or (b) HTLV-2	permanently ineligible
3	a person who has potentially been exposed to: (a) HCV; (b) HIV-1; or (c) HIV-2	ineligible until such time as the person is demonstrated not to be infected
4	a person who has potentially been exposed to: (a) HTLV-1; or (b) HTLV-2	ineligible until such time as the person is demonstrated not to be infected
5	a person who is infected with, or has potentially been exposed to, HBV	ineligible until such time as the person is demonstrated to be: (a) immune from HBV infection; or (b) not infected with HBV, as confirmed by NAT
6	a person who has received an injection of any substance in connection with a use that is not a: (a) therapeutic use; or (b) cosmetic use where the injection is delivered as part of a procedure that is conducted under the professional supervision or direction of a medical or dental practitioner	ineligible for a period of at least 5 years from the last injection received by the person
7	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.	permanently ineligible

Ineligibility criteria for donor selection		
Column 1	**Column 2**	**Column 3**
Item	**Medical and social history criteria**	**Period of ineligibility**
8	a person who is at risk of prion disease because the person has been, or has potentially been, exposed to the putative causative agent of one of the family of pathogenic transmissible spongiform encephalopathies, including: (a) genetic (familial) exposure; (b) environmental exposure, including living in or visiting England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time between 1 January 1980 and 31 December 1996; or (c) iatrogenic exposure, including receiving a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man at any time on or after 1 January 1980	permanently ineligible
9	a person who has been a recipient of human pituitary-derived hormone	permanently ineligible
10	a person who has experienced any of the following events, which may give rise to a risk of acquiring a blood borne transmissible infection: (a) mucosal splash with blood; (b) needle stick injury; (c) tattooing; (d) body piercing; or (e) acupuncture or dry-needling, unless performed using sterile, single-use needles	(a) where the person tests negative for HCV using NAT—ineligible for a period of at least 4 months from the event; or (b) where the blood samples of the person has undergone serology testing in accordance with subsection 11(4), and the donated tissue was placed in quarantine in accordance with subsection 11(15)—no ineligibility period applies; or (c) in all other circumstances—ineligible for a period of at least 6 months from the event
11	a person who has been a recipient of allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues that did not conform with this instrument	(a) where the person tests negative for HCV using NAT—ineligible for a period of at least 4 months from the date the person received the allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues;

Ineligibility criteria for donor selection		
Column 1	**Column 2**	**Column 3**
Item	**Medical and social history criteria**	**Period of ineligibility**
		(b) in all other circumstances—ineligible for a period of at least 6 months from the date the person received the allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues
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
13	a person who has been imprisoned for a consecutive period of 72 hours or longer	ineligible for a period of 12 months from the date of release of the person from prison
14	a person who has a symptomatic infection, fever or infectious illness	ineligible for a period of at least 2 weeks from the date of full recovery of the person
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 country 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.
16	a person who has lived in a malaria endemic region for a continuous period of 6 months or more at any time	(a) where HCT materials donated by the person are subject to: (i) terminal sterilisation that is validated to ensure a maximal sterility assurance level of 10^{-6}; or (ii) $\geq$ 25 kGy of gamma irradiation; no ineligibility period applies; or (b) where an immunological test

Ineligibility criteria for donor selection		
Column 1	**Column 2**	**Column 3**
Item	**Medical and social history criteria**	**Period of ineligibility**
		is performed at least 4 months after the return of the person from the malaria endemic region (an ***immunological test***)—ineligible until such time as the immunological test demonstrates a negative result; or (c) in all other circumstances, including where the immunological test demonstrates a positive result—permanently ineligible
17	a person (other than a person mentioned in item 16) who has visited a malaria endemic region	(a) where HCT materials donated by the person are subject to: (i) terminal sterilisation that is validated to ensure a maximal sterility assurance level of 10^{-6}; or (ii) ≥ 25 kGy of gamma irradiation; no ineligibility period applies; or (b) where an immunological test is performed at least 4 months after the return of the person from the malaria endemic region (an ***immunological test***)—ineligible until such time as the immunological test demonstrates a negative result; or (c) where an immunological test demonstrates a positive result—ineligible for a period of 3 years from the date of the test result; or (d) in all other circumstances—ineligible for a period of 12 months commencing from the return of the person from the malaria endemic region
18	a person who has or has had malaria	(a) where HCT materials donated by the person are subject to:

Ineligibility criteria for donor selection		
Column 1	**Column 2**	**Column 3**
Item	**Medical and social history criteria**	**Period of ineligibility**
		(i) terminal sterilisation that is validated to ensure a maximal sterility assurance level of 10^{-6}; or (ii) ≥ 25 kGy of gamma irradiation; no ineligibility period applies; or (b) where an immunological test is performed at least 4 months after the later of the cessation of treatment or the person's last symptoms (an ***immunological test***)—ineligible until such time as the immunological test demonstrates a negative result; or (c) where an immunological test demonstrates a positive result—ineligible for a period of 3 years from the date of the test result; or (d) in all other circumstances—permanently ineligible
19	a person who has or has had an undiagnosed febrile illness, with symptoms consistent with malaria during, or within 6 months of return from, a visit to a malaria endemic region	(a) where HCT materials donated by the person are subject to: (i) terminal sterilisation that is validated to ensure a maximal sterility assurance level of 10^{-6}; or (ii) ≥ 25 kGy of gamma irradiation; no ineligibility period applies; or (b) where an immunological test is performed at least 4 months after the later of the cessation of treatment or the person's last symptoms (an ***immunological test***)—ineligible until such time as the immunological test demonstrates a negative result; or

Ineligibility criteria for donor selection		
Column 1	**Column 2**	**Column 3**
Item	**Medical and social history criteria**	**Period of ineligibility**
		(c) where an immunological test demonstrates a positive result—ineligible for a period of 3 years from the date of the test result; or (d) in all other circumstances—ineligible for a period of 3 years from the later of the cessation of treatment or the person's last symptoms
20	a person with an active infection that would render HCT materials collected from that person unsuitable for use in the manufacture of HCT products	ineligible until such time as the person is demonstrated no longer to be infected
21	a deceased person who, within 12 months prior to asystole, has been a recipient of allogeneic HCT materials or an allogeneic organ that did not conform with this instrument	permanently ineligible
22	a deceased person whose cause of death is unknown	ineligible until such time as a post-mortem examination of the person provides sufficient information to conclude that the death of the person was not caused by a transmissible disease
23	a person who has been vaccinated with a live vaccine that contains attenuated bacteria or viruses, other than a vaccine mentioned in item 24	ineligible for 4 weeks
24	a person who has been vaccinated with a live vaccine against smallpox	ineligible for 8 weeks
25	a person who has been vaccinated with a live vaccine that contains sera of animal origin	ineligible for 12 weeks
26	a person who has been vaccinated with an unknown vaccine	ineligible for 12 months

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021	28 Sep 2021 (F2021L01326)	30 Sep 2021	s 7-8
Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Amendment Order 2022	8 Mar 2022 (F2022L00284)	9 Mar 2022	—

Endnote 4—Amendment history

Provision affected	How affected
Sch 1	am F2022L00284