Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019

I, Jane Cook, as delegate of the Minister for Health, make the following order.

Dated 22 March 2019

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Authorised Version F2019L00389 registered 25/03/2019

Contents

Authorised Version F2019L00389 registered 25/03/2019

Authorised Version F2019L00389 registered 25/03/2019

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019*.

(2) This instrument may also be cited as TGO 102.

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	31 March 2019.	31 March 2019

Note: This table relates only to the provisions of this instrument as originally made.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 sections 10 and 36 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:
(a) manufacture; and
(b) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

blood means whole blood collected from a single human donor and 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) red cells;
(b) white cells;
(c) platelets;

Authorised Version F2019L00389 registered 25/03/2019

(d) plasma;

but does not include haematopoietic progenitor cells.

Guide means the *Guide to the preparation, use and quality assurance of blood components*, 19th edition, 2017, published by the Council of Europe, as in force or existing immediately before the commencement of this instrument.

Note: The Guide is published by the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe at: www.edqm.eu.

haematopoietic progenitor cells means self-renewing or multi-potent stem cells, or both, capable of maturation into haematopoietic lineages, lineage-restricted pluri-potent progenitor cells, or committed progenitor cells.

HBV means hepatitis B virus.

HCV means hepatitis C virus.

HIV-1 means human immunodeficiency virus.

5 Standard

This instrument constitutes a standard for blood and blood components.

6 Application

(1) Subject to subsection (2), this instrument applies to therapeutic goods that are blood and blood components.

(2) This instrument does not apply to therapeutic goods that are:
   (a) collected by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, in the course of medical treatment and for the purposes of diagnosis of, and testing for, a medical condition;
   (b) manufactured by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, for therapeutic application to a patient under the practitioner's care; or
   (c) manufactured by a blood donation centre for a medical practitioner, registered under a law of a State or Territory, for therapeutic application to a particular patient under the practitioner's care.

7 Requirements

(1) The requirements in relation to blood and blood components are:
   (a) subject to subsection (2), those requirements specified in the Guide; and
   (b) those requirements specified in subsections (3) and (4).

Authorised Version F2019L00389 registered 25/03/2019

(2) The reference to 'tropical areas' in relation to the deferral period for the condition *Tropical infections* in Table 2.2. *Conditions leading to temporary deferral (suspension)* on page 253 of the Guide is to be taken not to include areas within Australia.

Note: For the definition of ***Guide,*** see section 4.

(3) Blood and blood components must only be manufactured from blood where samples of that blood test negative for HBV, HCV and HIV-1, using nucleic acid amplification technology.

(4) Blood and blood components must not be manufactured from a donor:

(a) who lived in, or visited, England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time on or between 1 January 1980 and 31 December 1996; or

(b) who received a transfusion or injection of blood or blood products while in England, Scotland, Wales, Northern Island or the Isle of Man, at any time on or after 1 January 1980.

8 Transitional arrangements

(1) In this section:

former instrument means the Therapeutic Goods Order No. 81 – Standards for Blood and Blood Components, as in force immediately before the commencement of this instrument.

transition period means the period beginning on 31 March 2019 and ending on 30 March 2020.

(2) Despite the repeal of the former instrument by section 9 of this instrument, the former instrument continues to apply for the duration of the transition period, such that the standard for blood and blood components constituted by the former instrument may be conformed with as an alternative to the standard for blood and blood components constituted by this instrument.

9 Repeals

Each instrument that is specified in Schedule 1 to this instrument is repealed as set out in the applicable items in that Schedule.

10 Consequential amendments

Each instrument that is specified in Schedule 2 to this instrument is amended as set out in the applicable items in that Schedule.

Authorised Version F2019L00389 registered 25/03/2019

Schedule 1—Repeals

Note: See section 9.

Therapeutic Goods Order No 81 Standards for Blood and Blood Components

1 The whole of the instrument

Repeal the instrument.

Authorised Version F2019L00389 registered 25/03/2019

Schedule 2—Consequential amendments

Note: See section 10.

Therapeutic Goods (Manufacturing Principles) Determination 2018

1 Section 4 (paragraph b of the definition of *Technical Master File*)

Omit "Therapeutic Goods Order No.81 – Standards for Blood and Blood Components", substitute "*Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019*".

Authorised Version F2019L00389 registered 25/03/2019