Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022

I, Nick Henderson, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 25 March 2022

Nick Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022*.

(2) This instrument may also be cited as TGO 111.

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 2022.	31 March 2022

Note: This table relates only to the provisions of this instrument as originally made.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) British Pharmacopoeia;
(b) European Pharmacopoeia;
(c) export only medicine;
(d) standard;
(e) therapeutic goods;
(f) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

human albumin means albumin derived from humans for:

(a) therapeutic use; or
(b) use as an ingredient or component in the manufacture of therapeutic goods other than a medical device.

5 Standard

The matters specified in this instrument constitute a standard for human albumin.

6 Application

This instrument applies to human albumin, other than human albumin that is:

(a) an export only medicine; or

(b) an ingredient or component in the manufacture of an export only medicine.

7 Requirements

The requirements for human albumin are the requirements specified in an individual or general monograph in the British Pharmacopoeia or the European Pharmacopoeia that is applicable to human albumin, as interpreted in accordance with the General Notices section of the relevant Pharmacopoeia.

8 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Note: See section 8.

Therapeutic Goods Order No. 90 Standard for human albumin

1 The whole of the instrument

Repeal the instrument.