Therapeutic Goods Order No. 94 (Standard for Haematopoietic Progenitor Cells derived from Cord Blood) 2017

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 10(1) of the *Therapeutic Goods Act 1989*, make the following order.

Dated 26 September 2017

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name of order

This order is the *Therapeutic Goods Order No. 94 (Standard for Haematopoietic Progenitor Cells derived from Cord Blood) 2017*.

2 Commencement

(1) Each provision of this order 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 order	30 September 2017	

Note: This table relates only to the provisions of this order as originally made. It will not be amended to deal with any later amendments of this order.

(2) Any information in column 3 of the table is not part of this order. Information may be inserted in this column, or information in it may be edited, in any published version of this order.

3 Authority

This order is made under subsection 10(1) of the *Therapeutic Goods Act 1989*.

4 Interpretation

In this order:

Act means the *Therapeutic Goods Act 1989*.

cord blood means the blood remaining in the human placenta and umbilical cord after the umbilical cord has been clamped.

NetCord-FACT International Standards means the document titled *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration*, Sixth Edition, published by NetCord and the Foundation for the Accreditation of Cellular Therapy in July 2016, as in force at that time.

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.

Note 1 A number of expressions used in this order are defined in the Act, including the following:

(a) manufacture;

(b) Register;

(c) standard; and

(d) therapeutic goods.

Note 2 NetCord-FACT International Standards are available for free download from the Foundation for the Accreditation of Cellular Therapy website: *www.factweb.org/forms/store/ProductFormPublic/sixth-edition-netcord-fact-international-standards-for-cord-blood-collection-banking-and-release-for-administration-free-download.*

5 Repeal

This order repeals the instrument specified in Schedule 1.

6 Application

(1) Subject to subsection (2), this order applies to therapeutic goods that are haematopoietic progenitor cells derived from cord blood.

(2) This order does not apply to therapeutic goods that are haematopoietic progenitor cells derived from:

(a) bone marrow;

(b) peripheral blood;

(c) cord blood that is processed beyond minimal manipulation; and

(d) any tissue other than cord blood.

7 Standard

(1) The matters specified in this order constitute a standard for the purposes of subsection 10(1) of the Act in relation to therapeutic goods that are haematopoietic progenitor cells derived from cord blood.

(2) For the purposes of this order, the requirements provided in the NetCord-FACT International Standards are specified as minimum requirements for the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood.

8 Transitional arrangements

(1) In this section –

former standard means the instrument specified in Schedule 1, as in force immediately before the commencement of this order.

transition period means the period beginning on the commencement of this order and ending on 30 September 2018.

(2) Despite the repeal of the former standard made by section 5 of this order, that standard continues to apply for the duration of the transition period in relation to the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood, if the cells comprising those goods were collected before or during the transition period.

Schedule 1 Repeal

(section 5)

Repeal of instrument		
Item	**Instrument name and date of making**	**Register ID**
1	Therapeutic Goods Order No. 75 – Standard for Haematopoietic Progenitor Cells Derived from Cord Blood (1 August 2007)	F2007L03598

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation under the *Legislation Act 2003*. See http://www.legislation.gov.au