

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* (“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.

Subsection 10(1) of the Act relevantly 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) relevantly provides, without limiting the generality of subsection 10(1) of the Act, that an order establishing a standard for therapeutic goods may be specified by reference to a variety of matters including the quality of those goods and the procedures to be carried out in their manufacture.

The *Therapeutic Goods Order No. 94 (Standard for Haematopoietic Progenitor Cells derived from Cord Blood) 2017* (“Order”) is a new standard under subsection 10(1) of the Act for the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood.

The Order repeals the *Therapeutic Goods Order No. 75 – Standard for Haematopoietic Progenitor Cells Derived from Cord Blood* (“the former standard”) which was due for automatic repeal on 1 October 2017 under the *Legislation Act 2003*. The making of this Order provided the opportunity to expressly repeal the former standard and to make a new standard for therapeutic goods that are haematopoietic progenitor cells derived from cord blood, reflecting international best practice.

Accordingly, the new standard set out in this Order provides that the requirements in 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 (“NetCord-FACT International Standards”) are specified as minimum requirements for the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood. At the time of making this Order, the sixth edition dated July 2016 comprises the most recent edition of that publication.

The Order specifies the benchmark against which therapeutic goods that are haematopoietic progenitor cells derived from cord blood must be uniformly manufactured according to global standards. In specifying the most recent edition of the NetCord-FACT International Standards, the new standard will align Australia’s requirements for the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood with internationally-recognised best practice.

Background

The Australian Government is responsible for determining quality standards for the manufacture of therapeutic goods. This is ordinarily achieved by applying default standards in international pharmacopoeias and otherwise specifying ministerial standards in relation to therapeutic goods.

The former standard commenced in 1 August 2007. It incorporated by reference a document titled, *International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release*, Third Edition, which was published by NetCord and the Foundation for the Accreditation of Cellular Therapy in December 2006. This document has now been superseded, but represented the most recent edition of that publication at the time of making the former standard.

This Order is necessary in the absence of any suitable default standards specifically applying with respect to the manufacture therapeutic goods that are haematopoietic progenitor cells derived from cord blood in monographs of the British, European or United States pharmacopoeias.

Consultation

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the making of this Order, as the matter of determining a standard for therapeutic goods that are haematopoietic progenitor cells derived from cord blood does not have more than minor regulatory impacts on business, community organisations or individuals (OBPR ID 22634).

However, prior to the making of this Order, the Therapeutic Goods Administration (“TGA”) conducted public consultation in May 2017 on the proposed options for developing a new standard for therapeutic goods that are haematopoietic progenitor cells derived from cord blood. The consultation provided an opportunity for interested parties, including targeted stakeholders, to comment on whether the former standard should be remade prior to sunseting, or repealed and replaced with a new standard, incorporating by reference the sixth edition of the NetCord-FACT International Standards.

Written submissions were received from numerous interested parties, including both public and private cord blood banks, specialist colleges and societies. These submissions all favoured the latter option to repeal and replace the former standard, notwithstanding the cost that may be associated with conforming to the sixth edition of the NetCord-FACT International Standards.

Details of the Order are set out in [Attachment A](#).

The Order is compatible with 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 B](#).

The Order is a disallowable legislative instrument and commences on 30 September 2017.

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

Section 1 – Name

This section provides that the name of the Order is the *Therapeutic Goods Order No. 94 (Standard for Haematopoietic Progenitor Cells derived from Cord Blood) 2017*.

Section 2 – Commencement

This section provides that the Order commences on 30 September 2017.

Section 3 – Authority

This section provides that the legislative authority for making the Order is subsection 10(1) of the *Therapeutic Goods Act 1989* (“Act”).

Section 4 – Interpretation

This section provides definitions for certain terms used in the Order that are not otherwise defined in the Act. The definitions for the terms “cord blood” and “haematopoietic progenitor cells” are adopted from the NetCord-FACT International Standards with only minor drafting modifications. Despite these changes, the definitions are intended to be consistent with the definitions for the same terms in the NetCord-FACT International Standards.

Importantly, the term “NetCord-FACT International Standards” means the document titled *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration*, Sixth Edition, which was published by NetCord and the Foundation for the Accreditation of Cellular Therapy in July 2016. This document is incorporated by reference as in force in July 2016, which comprised the most recent edition of that publication existing at the time of making this Order.

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

Section 5 - Repeal

This section repeals the instrument specified in Schedule 1 to this Order.

Section 6 – Application

This section provides that the Order applies to therapeutic goods that are haematopoietic progenitor cells derived from cord blood. However, it does not apply to therapeutic goods that are haematopoietic progenitor cells derived from bone marrow, peripheral blood, cord blood beyond minimal manipulation and any tissue other than cord blood.

Section 7 – Standard

Subsection 5(1) provides that the matters specified in this Order constitute a standard for therapeutic goods that are haematopoietic progenitor cells derived from cord blood. This is consistent with subsection 10(1) of the Act.

Subsection 5(2) provides that the requirements 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. These requirements are recognised as international best practice for the collection, banking and release of therapeutic goods that are haematopoietic progenitor cells derived from cord blood. This document represents the current international benchmark and exceeds the standard specified in the *Therapeutic Goods Order No. 75 – Standard for Haematopoietic Progenitor Cells Derived from Cord Blood* (“the former standard”), which is repealed pursuant to section 5 of this Order.

Section 8 – Transitional arrangements

Subsection 8(1) provides that the term “former standard” means the instrument specified in Schedule 1 as in force immediately before the commencement of this Order. In addition, the term “transition period” means the period beginning on the commencement of this Order (being, 30 September 2017) and ending on 30 September 2018.

Subsection 8(2) establishes the transitional arrangements. Despite the repeal of the former standard in section 5 to this order, this subsection provides that the former 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 prior to or during the transition period.

The purpose of this subsection 8(2) is to provide a twelve-month transition period from the former standard to the new standard in relation to those goods described in subsection 8(2), after which time any subsequent step of manufacture must comply with the requirements of the new standard.

Schedule 1 – Repeal

This Schedule specifies the former standard, which was made on 1 August 2007, and is identified by reference to the Federal Register of Legislation instrument identification number F2007L03598.

Statement of compatibility with human rights

This statement is prepared in accordance with subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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

The *Therapeutic Goods Order No. 94 (Standard for Haematopoietic Progenitor Cells derived from Cord Blood) 2017* is 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 legislative instrument

This instrument is made under subsection 10(1) of the *Therapeutic Goods Act 1989* (“Act”) by a delegate of the Minister for Health. The purpose of the Order is to repeal the *Therapeutic Goods Order No. 75 – Standard for Haematopoietic Progenitor Cells Derived from Cord Blood* (“the former standard”) and to determine a new standard for therapeutic goods that are haematopoietic progenitor cells derived from cord blood.

The former standard was due to have been automatically repealed on 1 October 2017 in accordance with the *Legislation Act 2003*. The making of this Order provided the opportunity to expressly repeal the former standard and to make a new standard reflecting international best practice.

The instrument is specified by reference to procedures to be undertaken in the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood. This is achieved by adopting the requirements in 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 (“NetCord-FACT International Standards”) as minimum requirements. At the time of making the instrument, the sixth edition dated July 2016 comprised the most recent edition of that publication.

In specifying the sixth edition of the NetCord-FACT International Standards, the instrument aligns Australia’s requirements for the manufacture of therapeutic goods that are haematopoietic progenitor cells derived from cord blood with international best practice. Specifically, the instrument requires therapeutic goods that are haematopoietic progenitor cells derived from cord blood to be manufactured according to recognised global standards.

The instrument applies to haematopoietic progenitor cells derived from cord blood. However, it does not apply to haematopoietic progenitor cells derived from bone marrow, peripheral blood, cord blood that is processed beyond minimal manipulation and any tissues other than cord blood. The definitions provided in the instrument for the terms “cord blood” and “haematopoietic progenitor cells” are adopted from the NetCord-FACT International Standards with only minor drafting modifications. Despite these changes, the definitions are intended to be consistent with the definitions for the same terms in the NetCord-FACT International Standards.

The instrument includes transitional arrangements, which ensure that the former standard continues to apply for the duration of the transition period in relation to the manufacture of haematopoietic progenitor cells derived from cord blood, if the cells comprising those goods were collected prior to or during the transition period.

Human rights implications

This instrument does not engage any of the applicable rights or freedoms.

Conclusion

This instrument is compatible with human rights as it does not raise any human rights issues.

Larry Kelly, delegate of the Minister for Health