

Australian Government

Department of Health and Ageing Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

THERAPEUTIC GOODS ORDER NO. 75

STANDARD FOR HAEMATOPOIETIC PROGENITOR CELLS DERIVED FROM CORD BLOOD

I, DAVID GRAHAM, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

1. REVOKE Therapeutic Goods Order No 73 "Standards for haematopoietic progenitor cells derived from cord blood" (TGO73) made on 8th June 2005; and

2. DETERMINE that the matters specified in this Order constitute a standard for haematopoietic progenitor cells derived from cord blood.

In this order:

Definitions

"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;

"cord blood" means blood collected from human placental and umbilical cord blood vessels;

Standards and requirements:

Haematopoietic progenitor cells derived from cord blood

1. Haematopoietic progenitor cells derived from cord blood must meet the requirements of the document entitled "*International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release*" Third edition, dated December 2006, published by the Foundation for the Accreditation of Cellular Therapy and NetCord.

This Order commences from the day after it is registered on the Federal Register of Legislative Instruments.

Dated this first day of August 2007

David Graham Delegate of the Minister for Health and Ageing