



Australia and New Zealand Legal and Regulatory Affairs

Watchdog Update



TGA

Australian regulatory guidelines for biologicals (ARGB)

These guidelines explain which products are covered by the regulations, how to manage the transition period over the three-year grace period in which manufacturers are required to work towards meeting the requirements, as well as instructions on how to complete an application so that the process goes quickly. The guide comprises 3 main sections and 14 appendices.

A new version of Part 1 of the ARGB, “Introduction to the Australian Regulatory Guidelines for Biologicals” was released in June 2017. This update includes live animal cells, tissues and organs into the biologicals framework.

<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>

Consultation paper: Revision of TGO 75 Standard for Haematopoietic Progenitor Cells Derived from Cord Blood (closing date 7th July 2017).

The Therapeutic Goods Administration (TGA) recently sought comments on the following consultation paper: Revision of TGO 75 Standard for Haematopoietic Progenitor Cells Derived from Cord Blood (closing date 7th July 2017).

Therapeutic Goods Order No. 75 (TGO 75) requires conformance with the now obsolete 3rd Edition of the International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release (NetCord-FACT International Standards 3rd Edition). TGO 75 is due for automatic repeal on 1/10/2017 and hence the TGA is proposing two options for the replacement Order: Option 1 continues the current requirement to meet NetCord-FACT International Standards 3rd Edition; Option 2 stipulates adherence to the requirements of the NetCord-FACT International Standards 6th Edition for HPCs derived from cord blood.

The three AusCord public Cord Blood Banks are currently FACT accredited and TGA licensed, and hence are operating to meet the requirements of both the 3rd and 6th Edition NetCord-FACT International Standards. The private CBB in Australia is not currently FACT accredited and hence the biggest impact of Option 2 is likely to be on the private Cord Blood Bank.