Australia and New Zealand Legal and Regulatory Affairs

Watchdog Update

Australia

New Therapeutic Goods Order for HPC, Cord Blood

The Therapeutic Goods Administration (TGA) recently updated the Therapeutic Goods Order (TGO) applicable to Haematopoietic Progenitor Cells Derived from Cord Blood. The previous TGO (No.75) mandated compliance with the obsolete 3rd Edition of the NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release. The new TGO 94, which came into effect on 30th September 2017, stipulates adherence to the requirements of the 6th Edition NetCord-FACT International Standards for HPCs derived from cord blood. A 1-year transition period has been granted. More details are given in the following [link](#).

ISCT ANZ Regional Meeting Presentation

The ISCT ANZ Regional Branch held a liaison meeting with the Australian Therapeutic Goods Administration (TGA) in Brisbane on 15th September 2017. Slides from the following presentations are available for viewing:

- Dr Tony Manderson’s update on the current TGA regulatory framework and planned changes ([slide link](#))
- Dr Ngaire Elwood’s presentation on the FACT immune effector cellular therapy standards and accreditation process ([slide link](#))