TGA Consultation paper:

Revision of TGO 75 Standard for Haematopoietic Progenitor Cells Derived from Cord Blood.
Version 1.0, May 2017

Who we represent:
This submission represents the views of the Legal and Regulatory Affairs (LRA) Sub-committee of the International Society for Cell Therapy - Australia & New Zealand (ISCT ANZ). We represent our membership's perspective to regulatory agencies. ISCT is a global society of clinicians, regulators, technologists, and industry partners with a shared vision to translate cellular therapy into safe and effective therapies to improve patients' lives. The Australian and New Zealand representative group of ISCT has its own elected Vice-President, Secretary, Treasurer and subcommittees. Our committee represents a diverse range of interests: Commercial sponsors, devices manufacturers, conventional hospital-based cell therapy providers, as well as academic and policy specialists with interests in ethics, gene technology and biologicals. The current membership of the ISCT ANZ LRA is as follows:

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Response to the consultation paper:

The *Therapeutic Goods Order No. 75 Standard for Haematopoietic Progenitor Cells Derived from Cord Blood* (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.

1. **Do you support Option 1 or 2 in the consultation paper, which and why?**

   We support Option 2 as this conforms to quality evidence-based science, removes the current 2-tier differential between public and private CBBs in Australia and fosters global harmonisation.

2. **Would manufacturers and CBBs be able to meet the requirements of NetCord-FACT International Standards 6th Edition? If so, what changes would manufacturers and CBBs need to make? If not, what are the impediments?**

   The AusCord unrelated donor Cord Blood Banks are FACT-NETCORD accredited and hence already meet the requirements of NetCord-FACT International Standards 6th Edition.
   We consider that the biggest impact is likely to be on private Cord Blood Banks.

3. **What financial impact (both costs and savings) would implementing the new requirements in the NetCord-FACT International Standards 6th Edition have? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.**

   There will be negligible financial impact to the Australian public CBBs, but likely some increased costs for the private CBB sector to implement the additional requirements.

4. **What period of time would be needed by CBBs to implement the proposed changes? We note that the FACT imposes a 3 month transition period for compliance with new requirements when an updated edition of the NetCord-FACT International Standards is published. This information will be used to inform any transitional arrangements.**

   AusCord CBBs already conform to the 6th Edition requirements and hence a 6 month transition period would be sufficient for public CBBs. A longer period may be required by private CBBs given that changes associated with 3 editions of the FACT-NETCORD standards are likely to need to be addressing.

5. **If the new requirements in the NetCord-FACT International Standards 6th Edition are implemented, how should they apply to previously collected HPC units? For example, should all units collected before the implementation date be exempt from the new requirements, or should the new requirements be imposed on all HPC units for steps that have not yet been performed, e.g. testing performed prior to release? What problems can you foresee?**

   Cord blood banked prior to implementation of the new requirements should be exempt from the new requirements if an appropriate risk assessment is performed and strategies implemented to minimise identified risks (as TGA expects under a requirement for a robust Quality Management Plan).

6. **Is the limited application of the new Order (specifically, HPCs derived from cord blood) appropriate? For example, it is proposed that if HPC units were expanded ex vivo (beyond minimal manipulation) prior to use, then the new Order and standard would not apply.**

   Limiting the Order to minimally manipulated HPC, Cord Blood seems appropriate because (a) this is the intended scope of the FACT-NETCORD standards, and (b) HPC, Cord Blood that undergoes more than minimal manipulation is likely to incur greater risk and hence may necessitate additional regulatory oversight and/or application of alternative standards.

7. **Are there any technological developments occurring in this sector that TGA should be aware of that may impact on the design of the new Order?**

   There are likely to be ongoing technological developments in this sector and consideration could be given to designing the new order to facilitate the collection & assessment of new information as it emerges. Developments in the beyond minimally manipulation are most likely to be covered by other regulatory requirements around the types of manipulations.