Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Organisation: **Australian Bone Marrow Donor Registry (ABMDR)**

Thank you for providing your comments using the template below.

- Rows may be added or deleted as required. Tables may be left blank or deleted if no comments are to be made on other documents.
- 'Reference' indicates the specific section/ subsection/ paragraph where relevant, e.g. In the infectious disease Order, 8(1)(b) would be used to reference requirements for donor interview timeframe in Part 3, Section 8, Subsection (1), paragraph (b).
- 'Issue' invites a short statement to summarise the comment.
- 'Comments' may include a position including justification or an alternative position.
- Additional general comments are also invited on the impact of these standards, as indicated below each table.

Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

SUBMITTING ORGANISATION: Australian Bone Marrow Donor Registry

Reference	Issue	Comment
8(1)(b) page 6	Medical and social history interview within 7 days	The December 2009 draft TGO accommodated the problem of unrelated HPC donor workup which must occur within 30 days of the collection. It appears that there is no reference in this December 2010 TGO to the 30 days. It is not possible to carry this out "no more than 7 days prior to or 30 days after collection" as HPC donors must have had a full medical examination and clearance prior to the patient starting "conditioning" or myeloablative treatment. Conditioning can be anything from 7-10 days prior to the collection. It is essential to obtain this history prior to the collection (not up to 30 days after) to ensure the HPC donor is "cleared" to donate. This paragraph clearly relates to cord blood NOT donors but clarification is needed.
9(2)(a)	Donor sampling and test management	Blood samples cannot be taken "no more than 7 days prior to or 7 days after collection…." For the reasons described above
10(2)(a) page 11	Physical assessment of the donor must take place at the time of donation	This is clearly impractical. At the time of HPC donation is clearly far too late to assess an HPC donor physically
10(4)(a) and (b) page12	Testing of HPC donors	At the time of HPC donation is clearly far too late to perform serology and NAT testing
11(3)	Microbial control	Please note that international transplant centres will wish to transport the product for their patient at the temperature they desire or that they are regulated to do according to their own regulations. If this is mandated it has the potential to stop international export of products from Australia.

11(5)	Product release specifications	Results of microbial testing will not necessarily be known before the product is released in the unrelated HPC setting. Again logistically impossible to provide these results at release.

What is the perceived impact, if any, of implementing these requirements in your organisation? Logistically impossible in the unrelated donor setting.

Other general comments:

This document has completely changed from the draft Dec 2009 document which was potentially workable in the HPC donor setting.

The draft document December 2009 took into account the requirements for the assessment, testing and transport of HPC within 30 days. This document has completely changed, thus making the TGO totally unworkable for HPC collection of HPC, Apheresis and HPC, Marrow restricting assessment, testing and transport of HPC to a period "no more than 7 days prior to or 30 days after collection". The paragraphs allowing for assessment and testing within 30 days have been completely removed.

The ABMDR would like to reiterate the need for an individual risk-benefit approach to regulation in this area given the international exchange of products approaching 50% worldwide. However the proposed mechanism of *"exceptional release"* will result in a huge administrative burden for both TGA and the suppliers of and recipients of all donors and cord blood units.

Standards for human cardiovascular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human ocular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human skin

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments: