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

Organisation: Bone Marrow Transplant Society of Australia and New Zealand Incorporated___

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: Bone Marrow Transplant Society of Australia and New Zealand Incorporated

Reference	Issue	Comment
6(3)	Concerning exemptions	See below

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

Other general comments: Our comments concern the exemptions to this proposed standard in particular the exemptions concerning human

Blood, blood components and haematopoietic progenitor cells. It is our understanding that the exemptions listed under 6 (3) (see below) effectively exclude all haematopoietic progenitor cell products for infusion collected by Australian registered medical practitioners those supervised by them or by a blood donation centre. If that is correct this standard will not impact on products collected in Australia. Our society would emphasise the importance of this exemption given the particular nature of haematopoietic stem cell transplantation (in particular the potential for products to be acceptable that would be excluded on the basis of this standard such as products from Hep C positive sibling donors). If there were to be any change to this exemption our society would expect to be consulted.

The standard does not address the product collected out-side of Australia, we would expect that to be exempt also?

6. Exemptions

The requirements of this Order do not apply to the following:

(1) vascularised organs and associated tissue for direct organ transplant;

(2) biopsied cell or tissue samples taken for *in vitro* diagnosis and not for manufacture and/or reintroduction or transplant to a recipient;

(3) human blood, blood components and haematopoietic progenitor cells that are:

(a) collected by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, in the course of medical treatment and for the purposes of diagnosis of, and testing for, a medical condition; or

(b) manufactured by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, for therapeutic application to a patient under the practitioner's care; or

(c) manufactured by a blood donation centre for a medical practitioner who is registered under a law of a State or Territory, for therapeutic application to a particular patient under the practitioner's care