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

Organisation: Centre for Blood Cell Therapies, Peter MacCallum Centre

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: Centre for Blood Cell Therapies, Peter MacCallum Centre

Reference	Issue	Comment
8 (3)	Donor medical and social history criteria	The periods of ineligibility specified in Table 1 apply only to allogeneic donors, but all questions must be asked for autologous donors as well, even though there are no periods of ineligibility. This is a burdensome requirement for autologous donors, and, in settings where this is no doubt that the intended procedure would go ahead, raises questions of compliance with patient privacy requirements. It would be hard to justify this approach for an autologous product that is manufactured in isolation and released fresh (without storage). In the autologous setting, a risk-based approach would allow a subset of these questions to be asked.
Table 1 (s)	Exposure to epidemiological situations (eg disease outbreaks).	"Deferral consistent with the epidemiological situation and these deferrals should be notified to the Head of the Office of Scientific Evaluation of the Therapeutic Goods Administration." It is not clear if this clause refers to 'declared' outbreaks (eg dengue fever in Queensland) or if it is expected to be determined by the manufacturer or other relevant party. Is notification of deferral expected to be for each individual patient, or does it refer to the actions being taken in response to a particular situation? A risk-based approach should be adopted for autologous donors.
8 (11) (a & b)	Age of donor & safety and efficacy of product	It is not clear how these requirements relate to minimising infectious disease transmission. The requirements have the potential to limit the accessibility to life-improving or -extending treatments in patient cohorts that are already under represented in clinical trials. There should be a simple mechanism for allowing medical justification by a treating physician in cases where the product represents the best option for treatment, especially when the condition is life-threatening or life-disabling.

11(3)	Transport conditions Time and temperature requirements	· The relevance of 72 hours as a maximum transport duration is not clear. (eg frozen product being shipped overseas in a mechanical freezer). · 3 different temperature ranges are specified. Are these the only temperature ranges within which product can be transported? Or, does the 72 hour maximum apply only to these ranges and not to product that can be transported at ambient temperatures? · The temperature ranges are not necessarily relevant to many products which may have broader or narrower ranges, or indeed, combined ranges.

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

· The requirement to implement donor questionnaires for autologous donors will have a major impact, especially for donors collected off-site. The need to develop and manage donor questionnaires could restrict treatments to major centres only, and for autologous donors there appears to be no genuine clinical justification for this restriction.

Other general comments:

· The simplified layout makes this version of the standard much easier to follow than the earlier draft.

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: Centre for Blood Cell Therapies, Peter MacCallum Centre

Reference	Issue	Comment
6 (5) (d)	Requirements for primary pack label	· It is not clear if the requirement to include the sponsor's name and address on the container and primary pack label allows for an abbreviated address to be used. With a small container (eg 1 mL syringe) there is limited space, unless the label is folded back on itself. Folding the label makes it more difficult to read and can reduce the contact area with the container, resulting in a less securely attached label. It would be preferable if (c) and (d) are also included in the exclusions listed in 6 (6). · A mandatory requirement for items (a) and (b) only would allow unambiguous identification of the product and its intended recipient, in a form that is easily checked and reconciled with other batch paperwork and clinical records. The need to allow for an absolute minimum for product identification on the container and primary pack label is paramount when one considers export requirements when multiple languages may also have to be allowed for on the primary and secondary labels. · The clause as written does not distinguish between primary pack and container. Splitting these requirements would permit different minimum requirements for each type of label.

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

· No perceived impact for current products.

Other general comments:

· No additional comments.