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

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.

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

Reference	Issue	Comment
Section 8, Table 1 (i)	Period of ineligibility	EU only requires 6 months deferral.
Section 8, Table 1 (k)	Criteria and period of ineligibility	The question of imprisonment is not required by EU regulations, and it is therefore not asked in EU blood centres. Only source plasma centres have adopted the question as part of the voluntary industry standards. Currently none of [redacted]'s EU based blood centres include this question in their donor interview process.
Section 8 (5)	Testing and deferral requirements for plasma for fractionation	Criterion (m) from Table 1 is not included in this subsection paragraph as not being required for 'plasma for fractionation'. In the EU/USA, source plasma donors (for fractionation only) are not asked/deferred for Malaria risks. This criterion would have an impact on [redacted]'s ability to supply products to Australia as currently none of [redacted]'s EU or US based source plasma suppliers defer such donors (for plasma for fractionation only).

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

The impact of the proposed donor eligibility criteria as listed above would have some impact on [redacted]'s activities. Additional interview questions would need to be implemented at EU plasma suppliers (with respect to imprisonment for blood donors, and malaria risk for plasma donors), but this would be difficult to do without adequate EU regulations. Furthermore, malaria cannot be transmitted through fractionated plasma products, and there is no scientific justification to introduce a deferral period for plasma donors.

Other general comments:

The December 2010 version of the draft TGO is a big improvement on the previous version (dated Dec 2009). The format of the current draft is much easier to read and understand, and it outlines more clearly where requirements do and don't relate to "plasma for fractionation'. There is also greater harmonisation of requirements between Australia and EU/US in the new draft TGO though as noted above there are still a few discrepancies.