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

Organisation: Bayer Australia Limited

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.

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

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: Bayer Australia Limited

Reference	Issue	Comment
4. (2) [page 3] Interpretation in this order	sponsor name and address	· We wish to raise the option of providing reference to a company website for access to product information (PI, CMI) · In situations where the product is not marketed by the sponsor but is distributed by a third party, there should still be the option to include the distributor details on the labelling instead of the sponsor details
6. (2) (c) [page 4] General requirements for label	letter height of not less than 1.5 mm	· Please confirm that abbreviated labelling for small containers are still applicable per TGO 69 · We wish to raise for consideration, the need for labelling exemptions to allow use of letter height < 1.5 mm in certain circumstances where the container is small and cannot accommodate all of the required labelling text at 1.5 mm (even if using abbreviated text on the label)
6. (5) [page 4] General requirements for label	AUST R number	There is no mention in the document regarding the inclusion of the AUST R number on the label – please clarify
6. (5) (g) [page 5] General requirements for label	storage conditions	Please add option of including other storage conditions e.g. excursion / home use situations, and storage after product reconstitution (if applicable)

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

Regarding the general requirements for the label letter height of not less than 1.5 mm, in some cases it is extremely difficult to fit all the required text on the label and meet the 1.5 mm size requirement, due to space constraints from product being packaged in small containers (e.g. vial, syringe labels), even when using abbreviated labelling as permitted by TGO 69 for small containers. Thus, there is a need for some flexibility from TGA, particularly for biologicals, to allow labelling exemptions in some circumstances for small containers where the text size, whilst still legible, falls below 1.5 mm. This approach should be feasible given that the required labelling information is already presented on the outer carton labels, which does not have the same space constraint issues.

For some products, the relatively smaller size of the Australian market means that it may be necessary for companies to use an international label due to the commercial reality of not being able to have production of an Australian specific label. With international labels, it is not always possible to accommodate the 1.5 mm letter height requirement and still fit all the core text. Therefore, flexibility and labelling exemptions will be needed in these situations. Otherwise, we could face product supply issues for the Australian market.

Other general comments:

See above.