australian biotechnologies

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Administration Officer
Biological Sciences Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir,

Re: Consultation on Proposed Standards for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products.

Please find enclosed document giving Australian Biotechnologies' comments on above proposed Standards.

My contact details are supplied above, please don't hesitate to contact me should you require any further information with regard this submission,

Regards,

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1st February 2011

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

Organisation: Australian Biotechnologies Pty Ltd

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 Biotechnologies Pty Ltd

Reference	Issue	Comment
Page 6; 8. (2)	December 2010	Re-write as follows: *"An interview, where possible, with the next-of-kin/guardian or other knowledgeable historian of a deceased donor and examination of pertinent, available medical documentation to obtain and record the medical and social history of the donor must take place and be recorded at the time of, or no more than 7 days prior to or following collection.*
Page 8; Table 1, (s)	December 2010	Re-write as follows: *"A donor with exposure to particular epidemiological situations (e.g. disease outbreaks) subject to formal alert."*
Page 10; 8. (11) (b)	December 2010	Donor suitability is not totally age dependant – there are factors such as donor age, genetic disposition and environmental conditions which must be taken into account. We would recommend the clause be re-worded as follows: *"The age range of donors from whom specific cells and tissue can be collected must be supported by documented evidence or literature review which justify appropriateness for the intended therapeutic purpose"*

Reference	Issue	Comment
Page 11; 9. (9)	December 2010	Following from discussions held in Sydney (Thursday 27th January 2011) we would suggest that wording be amended to remove "must" and replace with *"should be retested"*. If the word "must" remains even though a Manufacturer can determine otherwise based on formal risk assessment this matter will become contentious between Manufacturers and Auditors.
Page 11; 10. (2) (a)	December 2010	The definition of "Physical Assessment" is as follows: "means a clinical inspection of a living or deceased potential donor to determine suitability of the person to be a donor and may include, but is not limited to, the relevance of any abrasion/laceration, bruise/haematoma, fracture, tattoo, piercing, scars, skin lesion, surgical incision or other distinguishing external feature that may be indicative of a behavious or lifestyle, or suggestive of any risk factor for a relevant communicable disease." 10. (2) (a) states: "A physical assessment of the donor must be conducted by a trained assessor, and must take place • For a living donation at the time of donation, unless specified in the product specific Order. There is nothing documented with regard this inspection in the Musculoskeletal Tissue Standard. NO hospital staff have the time to conduct such an examination. NO FH's will be collected should collecting facilities have to demonstrate compliance to this clause. Australian Biotechnologies suggests you remove Paragraph 10.(2)(a).

Reference	Date	Comment
Page 12; 10. (4) (b)	December 2010	Inconsistent with requirements as specified in 9 (2) (a) on Page 10.
Page 13; Table 3	December 2010	We would suggest that collection facilities be given a choice as to when Syphilis and HTLV-1/2 antibody screening is performed. Some facilities prefer to list this test for the 180-day screen thus saving the costs of performing test if Donor may potentially be lost to program.
Page 14. 11. (2)(a)	December 2010	Would suggest re-writing this paragraph as follows: *"as soon as possible after asystole and commence within 24 hours of asystole provided"* etc. Refer to AATB Standard (12th Edition P.38) which states the same; no time for completion is given. Should it be necessary for TGA to include a "completion time" Australian Biotechnologies suggests that it be at each collection centres discretion based on Risk Assessment performed for each individual case.
Page 14. 11. (3)	December 2010	Historically Musculoskeletal tissue has been transported at "wet ice temperatures" with those temperatures recorded as between 0°C - 10°C for the past 30 years here in Australia with no detriment to the tissue. Can the TGA provide data/rationale to support the change to transport temperatures? For musculoskeletal tissue the temperatures as given are too narrow and should be opened to 0°C - 10°C. This statement should be placed in the tissue specific Standard and should be subject to validations as performed by individual manufacturers.

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

Compliance with the Standard as written (December 2010 draft) will have the following implications for Australian Biotechnologies:

- Para 8 (1) (b) states Interviews with Living Donors must be performed no more than 7 days prior to or 30 days after collection. That requirement will jeopardise Femoral Head collection in NSW. Patients in the Private Sector currently complete their Consent / Medical Questionnaire at their visit with the Surgeon; in some instances this visit may be 2 – 3 weeks prior to surgery. It is not always possible to follow-up with a phone call to all potential Donors prior to surgery.

- Para 11 (2) requires donor tissue collection within 24 hours. The word "commence" must be inserted, if the requirement is to finish within 24 hours the number of donors retrieved in NSW will decrease significantly

Other general comments:

Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: Australian Biotechnologies Pty Ltd

Reference	Issue	Comment
Page 4; 7. (2) (a) & (b)	December 2010	(b) to be deleted and 7. (2) to be worded: *"Musculoskeletal tissue that is to be transported to the manufacturing facility must be packaged using aseptic technique with at least one moisture impermeable barrier and maintained at or below 10°C prior to and during transportation."*
		New (3) to be worded: *"Musculoskeletal tissue which is:* *(a) To be retained in its primary packaging and not subject to any formal processing techniques and/or final Bioburden reduction must be sampled at time of collection using a representative and validated sampling technique to collect surface microorganisms for bioburden determination.* *(b) To be retained in its primary packaging and not subject to any formal processing techniques but is subject to final Bioburden reduction must be sampled at time of collection using a representative and validated sampling technique to collect surface microorganisms for bioburden determination* *(c) To be subject to formal processing techniques must be sampled prior to processing using a documented sampling technique at time of collection to collect surface microorgansims for Bioburden determination."*
		Re-number the rest of 7. General requirements accordingly.

Reference	Issue	Comment
Page 5; 7. (6) (c)	December 2010	Re-word as follows: *"Musculoskeletal tissue that has not been subject to a validated terminal Bioburden reduction process must be sampled post-process, the samples taken must show no microbial growth when tested with a validated sampling method."*

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

Other general comments:

Australian Biotechnologies believes there should be extra responsibility placed on the providers of non-processed, non-irradiated osseous allograft materials. Tissue collected to be supplied in this manner should be subject to (as a minimum)

- Determination of surface Bioburden by the use of a representative and validated sampling technique
- Core sampling of inner tissue by a representative and validated sampling technique

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General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: Australian Biotechnologies Pty Ltd

Reference	Issue	Comment
Page 4; 6. (3)	December 2010	Re-write paragraph as follows: *"When using multiple container collection systems the following information must be included on the outer container containing the blood, cells and tissue:* *(a) Unique identification number/alphanumeric linked to donor;* *(b) Date and time of collection;* *(c) Identification of collection facility;* *(d) Type of starting material for the biological;* *(e) Identification of the person collecting the starting material for the biological (if applicable).*

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

Requirement for all labels to be written in letter height of not less than 1.5 millimetres necessitates re-formatting and printing of Labels already full with pertinent information. More information will now be relegated to Insert Sheet.

Other general comments: