Princess
Alexandra Hospital

Queensland Government

5 January 2011

Blood and Tissues Unit
Therapeutic Goods Administration (TGA)

TGA consultation on proposed standards for human blood and blood components, human tissues and human cellular therapy products

Further to the email dated 8 December 10 to the Principal Quality Officer – Stem Cell Transplantation received from the TGA informing that public consultation on proposed standards for human blood and blood components, human tissues and human cellular therapy products had commenced, closing on 2nd February 2010, outlined below are our summary comments and feedback:

1. **NPAAC-HPC Standard currently meets the requirements** for **quality, collection and processing** and should be adopted in total as the sole standard for autologous unmanipulated HPC-A.
2. We note that the **Draft Therapeutic Goods Order (TGO) - Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products** have exempted haematopoietic progenitor cells that are manufactured under the supervision of a registered medical practitioner for therapeutic application to a patient under the practitioner's care under section 6 (3). **NAAT testing** is an excessive and costly requirement for autologous patients.
3. We note that the **Draft TGO – General requirements for the labelling of biologicals** are similar to the labelling requirements as outlined in the current NPAAC-HPC Standard. The amount of information and documentation required at release for autologous HPC-A product is not clear. The AAABB/FACT, etc Circular of Information for the Use of Cellular Therapy Products is provided to clinicians upon request.
4. The **consultation is being carried out in a piece-meal fashion for autologous unmanipulated HPC-A and it is not clear** about which class the TGA is considering for the autologous unmanipulated HPC-A under the proposed Biological Framework and if TGA is still proposing the adoption of European Pharmacopoeia Monographs as the minimum standard for all haematopoietic progenitor cells (HPC) intended for use in haematopoietic reconstitution as proposed during the consultation for the TGO No 75 earlier in 2010.

Yours Sincerely,

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