2. Therapeutic Goods Order No. XX – Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies

This draft TGO details the requirements for screening and testing donors for infectious disease transmission. It applies to autologous and allogeneic donors of blood, HPC and other therapeutic cells, with tables that clearly list the donor groups and applicable requirements.

Comments regarding specific sections of the TGO relevant to the HPC sector:

4. Interpretation, (2):	The abbreviations used for the specific sources of HPC do not conform to the ISBT 128 nomenclature which uses the following: • HPC, Apheresis • HPC, Marrow • HPC, Cord Blood
Schedule 2, (1b):	This clause excludes the use of allogeneic donors who have (i) resided in the UK for more than 6 months between 1980 and 1996, or (ii) have received a blood transfusion or blood components in the UK after 1980. Use of such a donor would require authorisation from the TGA via the "exceptional release" mechanism.
Schedule 4, (9) & (10):	These clauses require storage of donor serum to facilitate retesting or additional testing at the time of cell infusion (clause 9) and a minimum of 2 years after the product expiry date (clause 10).
Schedule 5, (1a):	Mandates the use of NAT for HIV, HCV and (when approved), HIV for all autologous and allogeneic HPC donors. HBV by NAT testing will also need to be introduced when approved.
Schedule 6, (2 a iii):	This clause states that supplies & reagents that come in contact with the HPC must, "if required by the Act", be approved for an equivalent purpose and entered on the ARTG. This could be problematic for items such as DMSO and Dextran-40 since the suppliers do not sell enough of the item in Australia to warrant getting the item listed on the ARTG. The TGA could then prevent use of the item for use in HPC collection or processing. It is unknown at this stage which items this clause would apply to.

TGA consultation on the draft code of GMP for Human blood and blood Components, Human Tissues and Human Cellular Therapies (Dec 2009) & Associated Documents

1. Draft code of GMP

The new draft document is based heavily on the cGMP for blood and tissues (2000). The new document has been restructured into a more logical order and sections that were specific for blood and blood components have been written to be more general and hence applicable to a wider range of cellular therapies.

Sections on screening and testing donors for transmission of infectious diseases have been moved to a separate document, "Therapeutic Goods Order No. XX".

It is still uncertain whether the draft cGMP will apply to the majority of BMT collection and processing facilities. This largely depends on how facilities are classified and whether any exemptions continue to be applied. Class 1 products are likely to require compliance with the NPAAC requirements with inspection by NATA. Class 2 – 4 products will require compliance with the new cGMP, a specific standard (potentially the British Pharmacopeia, the NPAAC requirements or the FACT standards) and the TGA standards for minimising infectious disease transmission. Compliance for Classes 2 - 4 will be assessed by the TGA via submission of a Technical Master File and by audit.