Therapeutic Goods Order -DRAFT – Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies

Comment and Questions

TGO Reference	Comment and/or Question
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. This is an example where collection of such a donor would require authorisation from the TGA via the "exceptional release" mechanism. When such authority is sought for the exceptional release of product, what would be the mechanism for application for authorisation and what would be the time frame in obtaining authorisation.
Schedule 3, Table 2 (l), Page 11of 19	Where a donor is known, suspected or at risk of being infected with Hepatitis B – the donor is ineligible until the disease is resolved (donor immunized or HepBsAb $\geq$ 100 IU/L). Regarding the value of HepBsAb $\geq$ 100 IU/L. In Hepatitis B Virus Reactivation literature for HPC transplants the cutoff value referred to is commonly $\geq$10 IU/L – see example reference Hepatitis B Virus Reactivation following Allogeneic HSCT, Hammond et al, Biol Blood Marrow Transplant 15: 1049-1059). Can you clarify why the value $\geq$100 IU/L is specified/mandated?
Schedule 4, (8) Page 15, of 19	Can TGA clarify which regulatory body's requirements will be specified as a standard for confirmatory microbiological and virological testing.?
Schedule 4, (9) & (10):	These clauses require storage of donor serum/plasma to facilitate retesting or additional testing at the time of cell infusion (clause 9) and a sample of serum for a minimum of 2 years after the product expiry date (clause 10). Can the TGA clarify the reason that the type of specimen sample required to be stored in clauses 9 & 10 is different. What is the anticipated intent of clauses 9 & 10.
Schedule 5, (1a):	Mandates the use of NAAT for HIV, HCV and (when approved HBV), for all autologous and allogeneic HPC donors. How and when will the requirement to commence routine HBV NAAT testing be communicated to the therapeutic goods manufacturers and what will be required for product in inventory ie. will HBV NAAT testing need to be performed prior to release.

Submitted by XXXXXX

Date: 5/02/2010