ABMDR
Australian Bone Marrow Donor Registry

9 February 2010

Blood and Tissues Unit
Standards and Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir or Madam,

The AusCord network of public cord blood banks, representing the BMDI Cord Blood Bank, Sydney Cord Blood Bank and the Queensland Cord Blood Bank, appreciate the opportunity to comment on the ***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***, as published by the Therapeutic Goods Administration (TGA) under ***THERAPEUTIC GOODS ACT 1989*** **Section 10** (December 2009).

The AusCord public cord blood banks support a continuous effort to improve the quality and safety of the cord blood products manufactured for therapeutic use, especially those related to screening and testing of infectious disease markers. AusCord appreciates this opportunity to increase product safety and move towards international harmonisation. We also commend the TGA for recognizing that haematopoietic progenitor cells derived from cord blood (HPC-C) are significantly different to other cellular therapies in regards to minimising infectious disease transmission since testing is performed on the mother of the baby (a "surrogate" donor) in addition to testing of the cord blood which represents the baby (donor). We have commented on six areas of the draft where we feel HPC-C may require a different approach and/or clarification is needed to appropriately interpret the standard for HPC-C.

*Comment 1 in relation to:* **Schedule 2 paragraph (1)(b)(i)**

We seek clarification that this standard is relevant only to the donor, which in the case of HPC-C is the baby who has not yet lived at the time of donation and therefore will never have lived in or visited England, Scotland, Wales, Northern Ireland or the Isle of Man. This information is currently obtained from mothers of infant donors and the answer is disclosed to Clinical

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Programs at the time of HPC-C request for transplantation, however a mother who has 'lived in or visited England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of six months or more, between 1 January 1980 and 31 December 1996 inclusive' would not exclude her baby's cord blood donation. The TGA is asked to clarify that this interpretation of the standard and current approach is appropriate.

*Comment 2 in relation to:* **Schedule 1, Table 1:Schedule 2 to 6 requirements for products manufactured from a particular donor group, 4. Living Donor, Allogeneic, HPC-C**

Suggest that "Compliance with requirements set out in Schedule 3" should also include paragraph(2)(d) as an exemption for HPC-C. Schedule 3 paragraph (2)(c) covers the appropriate interview and confirmation of medical and social history with the mother of the donor for HPC-C and paragraph (2)(d) is duplication of (2)(c) for HPC-C. It is also suggested that Schedule 3 paragraph (2)(c) allow the interview confirmation provided in writing by the donor, if possible, at the time of donation, or "within 14 days of donation" to allow the confirmation to occur in the days prior to or after the birth of the donor baby during the hospital stay. This would be consistent with Schedule 4 paragraph (2)(c) allowing the blood sample from the mother of the donor baby be taken within 7 days (before or after) the cord blood collection.

*Comment 3 in relation to:* **Schedule 1, Table 1: Schedule 2 to 6 requirements for products manufactured from a particular donor group, 4. Living Donor, Allogeneic, HPC-C**

Suggest that "Compliance with requirements set out in Schedule 4" should also include clause (10) as an exemption for HPC-C. Schedule 4 clause (10) is not relevant to HPC-C since the dedicated samples taken at the time of donation from the donor (baby) is cord blood plasma and serum is not obtained. In addition, the 180 day blood sample is from the mother not the donor baby.

*Comment 4 in relation to:* **Schedule 5 paragraph (2)(b)**

Suggest that "rare cell or tissue type" is defined. The AusCord public cord blood banks are of the view that all HPC-C should be classified as from a "donor of a rare cell or tissue type" since cord

blood from one individual can never be recollected and at the time of collection the rarity of the tissue typing is not known. Further, the tissue type uniqueness and rarity can only be evaluated at the time of transplant request in conjunction with the tissue typing of the recipient, which relates to ethnicity as well as the other sources of HPC products that are available and suitable for that patient at that time. In many cases, a seemingly common tissue type HPC-C product is the only available product suitable for transplantation to a recipient in need, which then would make that HPC-C rare. In order to determine if an HPC-C product is a rare tissue type, the HPC-C must be banked, listed on search registries and evaluated by Clinical Programs and analysed with recipient patient tissue typing. We suggest that this paragraph clarify that HPC-C products classify as "donor of a rare cell or tissue type" which will allow for initial maternal sample testing by NAAT for HIV, HCV and HBV (when available) if attempts at repeat sampling and serological testing of the mother of the donor have been unsuccessful.

C*omment 5 in relation to:* **Schedule 5, Table 4: Donor testing requirements**

We seek clarification of AusCord's interpretation of the Serology Initial sample-ID testing for HBcAb. Serology Initial sample-ID testing- HBcAb has a superscript "2" which reads HBcAb reactive sample is acceptable if HBsAb is ≥ 100 IU/L or if recipient is known to be immune to HBV. The line of the table for Allogeneic HPC-C has "–$X^c$" which is defined below the table as meaning that "for HPC-C unit, the maternal samples may be acceptable if reactive for HBcAb provided it satisfies the criteria given in superscript'2' or if Hep B antigen negative when tested by DNA". Please clarify that HPC-C are acceptable if HBcAb is positive and Hep B antigen negative when tested by DNA regardless of whether HBsAb results are ≤ or ≥ 100 IU/L.

*Comment 6: General comment in relation to:* **ISBT 128 Standard Terminology**

We draw attention to the new ISBT 128 Standard – *Standard Terminology for Blood, Cellular Therapy and Tissue Product Descriptions For Use with Product Description Code Database Version 3.34*, effective February 2010 which states that the Abbreviation for HPC, Cord Blood Is now HPC(CB) (with no spaces before the parentheses in these abbreviations). This has changed from HPC, CB. The recently released Fourth Edition of the *NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration* require the use of ISBT 128 terminology. All FACT-accredited Cord Blood Banks are required to comply with Version 4 of the FACT Standards by 31 March 2010, which will therefore require the AusCord

Cord Blood Banks to update their terminology accordingly. We therefore request that the TGA consider changing the terminology in this TGO to HPC(CB) to agree with the recommended international standard terminology.

The AusCord cord blood banks look forward to working with the TGA to explore ways to ensure that cord blood banks comply with the most appropriate standards for minimising infectious disease transmission. If you have any questions regarding the above comments, please do not hesitate to contact Anthony Montague at amontague@abmdr.org.au or on (02) 9229 4317.

Yours sincerely,

*Approved for electronic submission.*

Pamela Clark, Director, Sydney Cord Blood Bank

Ngaire Elwood, Director, BMDI Cord Blood Bank

Robyn Rodwell, Director, Queensland Cord Blood Bank at the Mater

Anthony Montague, National Cord Blood and Quality Manager, ABMDR