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February 26, 2010

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

By email: biologicals_consultation@tga.gov.au

Dear Sir,

Re: Draft TGO – Standards for Minimising Infectious Disease Transmission

New Zealand Blood Service (NZBS) submitted comments on the draft Standards for Minimising Infectious Disease Transmission on 11 Feb 2010. However, due to the receipt of new information, we wish to submit this late comment and request that it will be considered along with our previous submission.

It has just been brought to our attention that this standard might be applied to all plasma for fractionation supplied to CSL Bioplasma from overseas. In this case it would apply to the plasma sent to CSL Bioplasma by NZBS even though the product manufactured from the plasma is all returned to New Zealand for use.

NZBS requests clarification on this issue as the requirement is not explicit anywhere in the document nor is the NZ regulator, Medsafe, aware of it. Schedule 2, Policy, implies the document is only applicable in Australia. It refers to Commonwealth, State and Territory laws which will not be applicable in other countries. Clause 1 (a) refers to eligibility requirements for donors who have resided/travelled outside Australia. Overseas suppliers will be concerned with eligibility of donors who have resided/travelled outside their own country.

NZBS has serious concerns about the possibility of an Australian standard being imposed on other countries sending their plasma for fractionation, particularly when the standard is no longer based on the primary reference standard. The primary reference standard for donor selection in Australia, NZ and many other countries is currently the Council of Europe (CoE) Guidelines. However, we have noted that some of the requirements in the draft standard now exceed those of the CoE. An example of this is the requirement to defer inmates of prisons. This is not a CoE requirement.

In the event that the standard is applied to overseas plasma fractionated by CSL Bioplasma, this will need to be made explicit in the document and the wording in Schedule 2 revised to reflect this. The testing requirements for plasma for fractionation will also need to be made clearer. The terms “plasma for fractionation” or “plasma for further manufacture” have not been used in the document. Table 4 includes a column for “Plasma Only” which has different testing requirements from blood components. Our assumption is that “Plasma Only” means “Plasma for fractionation” but it is not defined. “Plasma Only” is a misleading term as some blood services collect apheresis plasma which is used for clinical product.

We would be grateful if you would consider these comments as part of our previous submission.

Yours sincerely,

Meredith Smith
National Manager Quality and Regulatory Systems