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CSL Biotherapies

26th February 2010

Attention: Dr. Rohan Hammett

Delegate of the Minister for Health and Ageing
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 Dr Hammett,

Consultation on proposed 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*

Thank you for providing CSL with the opportunity to comment on the above referenced Proposed Therapeutic Goods Order.

CSL whilst supportive of the move towards regulation of cellular and tissue therapies believes strongly that Plasma for Fractionation (PFF) should not be included in the list of biological products covered by this particular TGO. The Order as written is clearly designed to introduce regulation to the area of biological product for therapeutic infusion/transplantation and does not take into account the important difference with respect to PFF is so far as it is a starting material for manufacture of previously TGA-assessed and approved pharmaceutical product, and is not a product in its own right. The Order appears to ignore the internationally accepted rigorous safety procedures relating to PFF provided by the Plasma Master File (PMF) system, and imposes requirements in excess of the Pharmacopoeial Monograph for Plasma for Fractionation. This imposes an unnecessary and unacceptable regulatory burden on CSL and its global customers which makes the operation of our plasma fractionation business in Australia difficult and could inevitably result in the diversion of investment overseas.

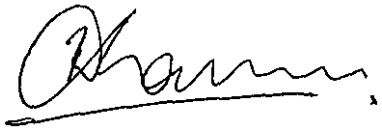
CSL believes that the draft Order as written is unworkable in relation to PFF. The definitions included in the Order are ambiguous and would make compliance monitoring difficult for PFF. The definition of blood components within the proposed Order as being 'therapeutic' clearly implies product that is intended 'for infusion'. PFF does not fall into this category of blood components. The understandable list of conditions for products for therapeutic infusion/transplantation in schedules 1-6 of the draft Order are in many cases not applicable to PFF.

Regulation of PFF in Australia to date has been based on internationally recognised European standards inherent in the PMF system of annual review and in the European Pharmacopoeial standard for Plasma for Fractionation. Plasma for Fractionation is a globally sourced starting material for CSL's plasma fractionation business based in Melbourne. It is essential that the standards applied to it by the TGA are specific to its unique character as a biological starting material and are in line with the existing global standards.

CSL believes that PFF requires a separate TGO to specifically address the needs of this unique material and requests further dialogue with TGA to identify how the effective regulation of PFF can be achieved. The Order as proposed is unacceptable to CSL.

I can be contacted on (03) 9246 5736, fax (03)9246 5465 or e-mail: rory.graham@csl.com.au to discuss the issues in more detail.

Yours sincerely,



Rory Graham
Head of Regulatory Affairs