Australian & New Zealand
Society of Blood Transfusion Inc

The Secretary,
Review of Australia's Plasma Fractionation Arrangements,
Department of Health and Ageing,
GPO Box 9848,
MDP 47,
CANBERRA.
ACT 2601.

10/04/06

Dear Secretariat,

Registration of Interest - Plasma Fractionation Review

The ANZSBT is a professional society who represents health care professionals responsible for the supply and distribution of fractionated blood products within hospitals in Australia [and New Zealand]. This puts the Society in a unique position to represent the views of users in relation to the broader issue of changes in the overall supply chain.

Plasma products are biologicals. Safety and efficacy are critical issues; however there are broader issues which arise in relation to their use. In particular, changes in manufacturing processes can result in the development of adverse reactions in patients who have tolerated other products well.

Given this, we believe that extreme caution should be taken in relation to any proposal that might result in a change in manufacture[r] for products fractionated from Australian plasma, or indeed the introduction of new suppliers in parallel with current arrangements.

We also believe that the review of plasma fractionation should address the fundamental issue of self sufficiency in Australia.

The NBA has recently put in place arrangements that increase availability of fractionated products from overseas. This has alleviated acute shortages of intravenous immunoglobulin. In doing so, issues have arisen in supply of product to patients. These involve both clinical concerns around product sourced from overseas and concerns regarding the certainty of supply of products from one manufacturer of products for individual patients.

The ANZSBT believes that the Review should revisit the question of self sufficiency and the appropriateness of putting medium term plans in place to increase availability of products derived from Australian plasma.

The current arrangement whereby CSL has provided fractionation facilities for Australian plasma for over fifty years has proven to be extremely effective. Any change that might result in increased risk to supply, for whatever reason, should be avoided, unless there is clear evidence that this will be a benefit to patients in Australia.

In this context the close relationship between CSL and the New Zealand Blood Service must also be considered. Any change to the current arrangements in Australia will likely impact adversely on the ability of CSL to maintain its current facility at Broadmeadows. This has consequent impact on New Zealand and other countries with contract fractionation arrangements with CSL.

ANZSBT is concerned with the possibility that Australian plasma might be transported overseas for the purposes of fractionation. This must introduce increased risk to ongoing supply of product. Risks include plasma lost during transportation to the fractionator, reduction in control of GMP environment within overseas fractionators, and delay in or loss of final product being transported back to Australia. During a major pandemic Australia may close it borders to reduce risk.

We struggle to see how these additional risks to an already complex system can be completely avoided. Consequently any change which involves the movement of plasma overseas must impact adversely on the certainty of supply and hence patient care.

The Review documents raise a number of specific questions. The Society is keen to provide a more detailed response that will address these. This will however require further time to develop.

Accordingly we are 'registering our interest' in the Review and will welcome the opportunity to present our views to the Review team in due course. We anticipate our final submission will be completed by the end of June 2006.

Yours faithfully,

Ken Davis
President
ANZSBT

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