Guidelines for Written Submissions and Registrations of Interest

This page contains the guidelines for written submissions and registrations of interest for the Review of Australia's Plasma Fractionation Arrangements.

Terms of Reference

Under the Australia-United States Free Trade Agreement, the Australian Government has committed to undertake a review of its arrangements for the supply of plasma fractionation services for plasma collected in Australia.

The review will focus on the provision of plasma fractionation services following the collection of plasma donated in Australia, on a voluntary basis, to meet Australian demand for plasma derived products.

The Terms of Reference for this review are to:

1. Examine the projected demand for plasma products over the next ten years and the relationship between demand trends and the requirements on supply of plasma fractionation services.

2. Identify appropriate requirements to be met by producers of plasma products or suppliers of plasma fractionation services to ensure the safety, quality and efficacy of such products or services. These requirements shall not create unnecessary obstacles to trade.

3. Identify issues arising as a result of any increase in competition for the provision of plasma fractionation services for Australia and indicate how these issues could best be dealt with through future procurement arrangements.

4. Assess issues under (3) above against the following evaluation criteria: safety, quality, efficacy, security of supply and the potential impact on expenditure under the National Blood Agreement.

In its work the review will:

- be consistent with the policy of providing plasma products to patients free of charge;
- be consistent with the policy of recognising the role of Australia's regulator, the Therapeutic Goods Administration, in regulating the safety, quality and efficacy of plasma products;
- be consistent with the policy objectives and aims of the National Blood Agreement; and
- engage in public consultation to assist with the conduct of work under the Terms of Reference.

The review will report to the Minister for Health and Ageing by 1 January 2007.

Australian & New Zealand
Society of Blood Transfusion Inc

20th JUNE, 2006

To the Secretariat,
Plasma Fraction Review.

Written submissions may address any issues arising under the Terms of Reference. Written submissions may wish to address some of the following questions:

- **1. Demand trends for plasma products**
  - 1.1 Comment on current and projected disease information over the next ten years.

Parvovirus B19 / West Nile Virus / vCJD / SARS like / "The next virus – unknown.

  - 1.2 Comment on current and projected clinical treatment and usage trends over the next ten years.

IVIg will have wider applications. Expectation of more targeted clotting products – FVII concentrate / Fibrinogen concentrate.

  - 1.3 What demand trends are likely to arise for plasma products in Australian in the next ten years?

Increasing demand for Normal IVIg and for some hyperimmune IVIg products.

  - 1.4 What are the current and future supply requirements for Australian plasma products?

High quality, safe and efficacious products. Readily available with guaranteed supply chain. Treated fresh plasma products to reduce risk of viral/bacterial transmission.

  - 1.5 Comment upon whether Australia's capacity to meet demand for plasma products in the next ten years would be effected by Australia moving to a tendering process for plasma fractionation services.

Demand for plasma is increasing especially for IVIg. It is understood that ARCBS could collect more plasma if funded appropriately.

- **2. Regulatory requirements**
  - 2.1 Comment upon whether safety, quality and efficacy requirements for plasma derived products would need to change to preserve Australia's high regulatory standards if there was tendering for plasma fractionation services. If so, how this would occur?

No need for change provided that any current TGA requirements are absolutely satisfied by the fractionator.

Currently there is a lack of readable/compatible barcodes on all overseas products. This is a high risk issue from a safety & quality perspective and increases the possibility of poor or absent product traceability. There is an urgent need to undertake a process to standardise barcoding of all blood products and to require IT system manufacturers to provide the necessary software changes.

- 2.2 Comment upon current requirements for exportation and importation of plasma and plasma products and how they might need to be changed to accommodate offshore fractionation.

No knowledge of current AQIS requirements.
We believe that there would be significant capital costs in large scale transportation of raw and fractionated plasma.

- **3. Increasing competition**
  - 3.1 What are the options for increasing competition in plasma fractionation services in Australia and how could they be implemented?

An updated list of desired products by the clinical community would stimulate manufacturers to make such products available.

  - 3.2 What issues would arise out of increasing competition in plasma fractionation services in Australia?

Assurance of continuity of supply of safe, high quality and efficacious products.

  - 3.3 How could Australia achieve better value for money in procuring plasma fractionation services through increasing competition?

Expanded range of products.

  - 3.4 What is security of supply and how could Australia ensure security of supply if it increased competition in plasma fractionation services?

Security of supply is timely availability of products for clinical treatment of patients. Contracts would need to specifically designed to ensure supply with severe monetary penalties for non compliance.

  - 3.5 What costs would occur from ensuring security of supply if competition was increased in plasma fractionation services?

  - 3.6 How could Australia maintain safe, high quality, efficacious plasma products while increasing competition?

By a strong regulator enforcing Australian requirements under Australian Law.

  - 3.7 What risk mitigation and security measures would need to be implemented to ensure safety, quality, efficacy and security of supply of plasma products if competition was increased?

Contingency plans would need to be built to handle risk mitigation scenarios.

  - 3.8 What are the potential implications for the collection of the plasma starting pool for fractionation which may arise from options for increasing competition?

Australian donors may withdraw from a system where their plasma is 'sold' to a 'foreign' manufacturer. This is a possible extremely high risk scenario.

  - 3.9 Which organisation would be best placed to maintain the national reserve if Australia increased competition for plasma fractionation services?

- 3.10 Would the role or obligations of the National Blood Authority need to change if there was increased competition for plasma fractionation services?

- 3.11 What changes would need to be made to State and Territory legislation if there was increased competition for plasma fractionation services?

Unknown.

- 3.12 What are the potential insurance and indemnity implications of increased competition for plasma fractionation services?

Transportation indemnity insurance costs.
Possible medico-legal if particular product not available.

- 3.13 What delays and costs would occur in obtaining registration from the Therapeutic Goods Administration for finished products manufactured by alternate fractionators located in Australia or elsewhere?

Unknown.

- 3.14 What delays and costs would occur in nominating a domestic sponsor for plasma products manufactured abroad?

Increases complexity of supply chain with anticipated increased costs.

- 3.15 What would be the potential cost implications, including bearing of exchange risks, of increased competition for plasma fractionation services?

Increased transport costs.

Further information

The Terms of Reference and details of the Review Committee are on the Plasma Fractionation Review web-site www.health.gov.au/plasmafractionationreview

Confidentiality

Submissions are provided for the purposes of the Review. If a submitting party considers that information in a submission is confidential, that information must be clearly identified as confidential in the submission. Where such information is inherently confidential, the Commonwealth and the Review Committee will treat the information as confidential, subject to applicable laws.

The Review Committee does not intend to publicly release any submissions prior to the public release of its Report to the Minister.

Ownership and use of submitted documents

Documents are to be submitted on the basis that the submitting party agrees:

- all documents (including paper and electronic copies) submitted will become and remain the property of the Department of Health and Ageing upon submission; and
- any intellectual property rights (including copyright) that exist in the submitted documents will remain with the submitting party; but
- the Review Committee, and anyone assisting the Review Committee, may use the submitted documents for the purposes of the Review, including reproducing the submitted documents, communicating the submitted documents and/or incorporating the submitted documents into the Review's Report to the Minister (either in whole or in part or by paraphrasing).

The terms and conditions in this document will apply unless varied in writing by the Chair of the Review Committee.

Submissions should be sent to the Review Secretariat:

By mail: The Secretary
Review of Australia's Plasma Fractionation Arrangements
Department of Health and Ageing
GPO Box 9848
MDP 47
Canberra ACT 2601
Australia

By email: plasmafractionationreview@health.gov.au

By fax: (02) 6289 7630

Receipt of Submissions

The Review Secretariat will acknowledge receipt of submissions via an email or letter. However, detailed feedback will not be provided at this time.

If you require further information, please contact the Review Secretariat via email plasmafractionationreview@health.gov.au or via 1800 815 855.
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