

Briefing Paper for AFAO members

25 May 2006

PLASMA FRACTIONATION REVIEW

Introduction

The Department of Health and Ageing is currently conducting a review of Australia's plasma fractionation services. This briefing paper will provide an overview of Australia's fractionation arrangements and the purpose of the review, and outline AFAO's involvement to date.

Why are Australia's arrangements for plasma fractionation being reviewed?

The Australian Government is required under the Australia-United States Free Trade Agreement (AUSFTA) to conduct a review of arrangements for the provision of plasma fractionation services. The side-letter on plasma fractionation services was the result of negotiations between both governments. Applying competitive tendering to fractionation arrangements would be consistent with chapter 15, the Government Procurement chapter, of the AUSFTA.

What is plasma fractionation?

Plasma is the liquid component of blood in which the blood cells are suspended. Plasma fractionation is the large-scale separation of plasma into a number of proteins for medical use. Plasma products are used mainly to treat trauma patients, provide protection against infection for a variety of conditions, and treat haemophilia and other bleeding disorders.

What are the current arrangements for plasma fractionation in Australia?

The Australian blood supply system is based on goodwill. Donation of blood is voluntary and no payments are made to donors, nor are recipients charged for supplies of blood or blood products.

The Australian Red Cross Blood Service (ARCBS) is the sole collector of blood for plasma fractionation in Australia and the major distributor of plasma products. CSL Limited is the sole domestic fractionator of plasma collected in Australia. The Therapeutic Goods Administration regulates the safety, quality and efficacy of plasma products.

In Australia, most plasma-derived products are currently purchased through a single-supplier arrangement between the National Blood Authority (NBA), acting on behalf of all nine Australian jurisdictions, and CSL Limited. These products are sourced from the domestic blood supply and are manufactured in Australia. Plasma products are imported only when domestic supply cannot meet clinical need.

The National Blood Agreement between the Australian Government and all state and territory governments provides the framework for funding and policy making for Australia's supply of blood and blood products, including



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plasma products.

The primary policy objectives of the National Blood Agreement are:
(a) to provide an adequate, safe, secure and affordable supply of blood products, blood-related products and blood-related services in Australia; and
(b) to promote safe, high quality management and use of blood products, blood-related products and blood-related services in Australia.

There will be no change in Australia's blood collection arrangements. The review is concerned with plasma fractionation services for plasma supplied by donors in Australia, as opposed to the collection of plasma.

What is the focus of the review and what is its scope?

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.

AFAO's involvement in the review

In late April 2006, the Plasma Fractionation Review made attempts to contact several AIDS Councils for either written submissions or registrations

of interest in the review. AFAO registered an interest in the review in May 2006 and presented to the review committee on 17 May 2006.

Areas of interest/concern presented to the Review Committee

AFAO's interest in the review derives from our primary concern that Australia's blood supply, and the supply of blood products, remain safe and of a high quality. Particularly, our interest relates to ensuring that blood products are free from any possibility of contamination with HIV or other blood borne viruses.

Internationally, Australia has an enviable record in terms of HIV prevention, treatment and care. This includes high standards and procedures for ensuring a safe supply of blood products.

A tendered, competitive process for plasma fractionation may decrease the safety of the plasma product supply through:

- Increased financial incentive to "cut corners" – commercial interest will compete with principles of safety.
- External safety review arrangements can create environments where events which potentially affect quality go unreported
- Additional transport arrangements may have a negative impact on product safety
- Decreasing the effective ability of Australian regulators to inspect and ensure product safety

Of particular concern to AFAO is the definition of what constitutes an "unnecessary" obstacle to trade (as referenced in the second point of the terms of reference). Australia currently has high safety and quality benchmarks. Will Australia be able to continually demand gold standard safety and quality standards without these standards being considered as adding "unnecessarily" obstacles and conditions to trade? In addition, will the development and enhancing of safety measures be negatively affected? Who defines if a safety restriction or direction presents an unnecessary obstacle to trade?

If fractionation services were opened up to competitive tendering and moved off shore, AFAO's key concern would be in ensuring that current quality and safety standards were in no way compromised. This would include the way in which standards are monitored and that offshore safety standards be consistent over the long term.

In addition, there is a valid concern that contracting of fractionation services offshore may have a negative impact on the altruistic motivations of blood donors. Another concern that should be considered as part of the review is the likely preference of consumers for Australian manufactured products. There currently exists a preference borne from having greater confidence in the safety of products that are fractionated in Australia.

Result

Our presentation was well received by the Review Committee, who strove to guarantee that at no point in time would Australia's existing safety standards be compromised.

The review is scheduled to continue for the rest of the year and will report to the Minister for Health and Ageing by 1 January 2007. The Minister is under no obligation to follow any recommendations made by the review.