Introduction

On 17 February 2006 the Minister for Health and Ageing, the Hon. Tony Abbott MP, announced a review of Australia's plasma fractionation arrangements:

> 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.

The Minister appointed Mr Philip Flood AO, former Secretary of the Department of Foreign Affairs and Trade and former Australian High Commissioner to the United Kingdom, as Chairman of the Review Committee. Also appointed to the Committee were Mr Peter Wills AC (Deputy Chairman), Sir Peter Lawler OBE, Professor Graeme Ryan AC, and Associate Professor Kevin A. Rickard AM.

Provisions of Australia–United States Free Trade Agreement (AUSFTA) in relation to Australia's plasma fractionation arrangements

Under the Australia–United States Free Trade Agreement (AUSFTA), the Commonwealth Government agreed to:

- undertake a review of its arrangements for the supply of plasma fractionation services, with this review to be concluded no later than 1 January 2007
- (after completion of the Review) recommend to the state and territory governments that future arrangements for the supply of plasma fractionation services be implemented in accordance with tender processes consistent with Chapter 15 ('Government Procurement') of the AUSFTA.

The AUSFTA requires that, if all Australian state and territory governments are in agreement with the aforementioned recommendation, the Commonwealth Government shall withdraw the reservation in the AUSFTA that currently exempts the procurement of plasma fractionation services from the government procurement provisions in Chapter 15 of the Agreement.

These obligations are set out in an Exchange of Letters forming part of the AUSFTA (see Annex A at conclusion of this report).[1] The Letters also confirm Australia's right to:

- require any producer of blood plasma products or supplier of blood fractionation services to fulfil requirements necessary for ensuring the safety, quality and efficacy of plasma products
- require that blood plasma products for use in Australia be derived from blood plasma collected in Australia.

Conduct of the Review

The Review has been conducted with a view to informing Australia's plasma fractionation arrangements well into the future. At the same time, the Review has been concerned with ensuring that all safeguards remain in place to protect the safety, quality, efficacy, and security of supply, of blood and blood products for Australia.

The Review has assessed the existing arrangements, and alternatives, with respect to products fractionated from plasma collected from voluntary, non-remunerated Australian donors and destined for use in Australia. The possible implications of changes to current tendering processes have also been considered.

The Review Committee has undertaken a number of consultation activities in order to give all interested parties an opportunity to express their views.

Written submissions, from within Australia and from overseas, were received from a range of professional associations, consumer groups, patient support groups, pharmaceutical companies, industry organisations, federal, state and territory government agencies, and interested members of the public. (A complete list of individuals and organisations that provided submissions is included at Annex B.)

1 A facsimile of the original signed correspondence can be found at <http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html>.

At meetings in Canberra and in state capitals, members of the Review Committee consulted with representatives of stakeholder groups. Committee members and Secretariat staff also visited regulatory agencies, agencies with relevant procurement and policy-making responsibilities, industry organisations and private enterprises, in North America and Europe. The views of all state and territory governments were sought, and Australia's regional neighbours with an interest in the Review's terms of reference were invited to contribute their views to the Committee. (A list of persons consulted is provided at Annex C.)

So that the Review had the benefit of specialised and independent advice on the implications of the current plasma fractionation arrangements and on possible options for increasing competition, the Department of Health and Ageing engaged expert opinion with respect to legal considerations and the clinical and scientific environment, and international business environment, surrounding plasma fractionation. The National Blood Authority and the Therapeutic Goods Administration provided valuable input to the Review. Advice from other Commonwealth government agencies, including the Department of Foreign Affairs and Trade, was also obtained.

A team in the Acute Care Division of the Department of Health and Ageing provided Secretariat support to the Review Committee (see Annex E).

National Blood Agreement

The Review took into account the policy objectives and aims of the National Blood Agreement of 1 July 2003, to which the Australian Government and all state and territory governments are party. These objectives and aims are summarised as follows in the Agreement:

1. The primary policy objectives for the Australian blood sector 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.
2. In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:
   (a) to meet international obligations and standards;
   (b) to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma;
   (c) to promote national self-sufficiency;
   (d) to provide products to patients free of charge and based on clinical need and appropriate clinical practice;
   (e) to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards;
   (f) to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sector;

(g) to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector;

(h) to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs;

(i) to ensure public support and confidence in the Australian blood sector; and

(j) to work towards optimal access to blood products and blood related products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction.[2]

Donating blood is Lisa Wilkinson, co-host of Channel 7's Weekend Sunrise. *Photo courtesy of ARCBS.*

2 *National Blood Agreement*, National Blood Authority, Canberra, 2003, p. 2, http://www.nba.gov.au/PDF/national_blood_agreement.pdf. The full text of the Agreement may be accessed at this URL.