

**SENATE SELECT COMMITTEE
ON THE FREE TRADE AGREEMENT
BETWEEN AUSTRALIA AND THE UNITED
STATES OF AMERICA**

**Submission prepared by the Australian Red Cross
Blood Service**

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While ARCBS does not specifically request the opportunity to make a further oral submission at any public hearings of the committee of inquiry, it is ready and happy to do so at the Committee's request.

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EXECUTIVE SUMMARY

The supply and quality of blood and blood products to the Australian community is a matter of significant concern to the public and of fundamental importance to the high standards of the Australian health system.

Australia has always been and continues to be self-sufficient for fresh blood products (for example red blood cells and platelets). For plasma derived products Australia has been largely self-sufficient through the collection of plasma from Australian Red Cross Blood Service (ARCBS) volunteer donors and its fractionation into blood products by CSL Limited. The Australian system is held in high regard internationally.

Australia's system reflects a long standing national policy of self-sufficiency recently re-affirmed by the Commonwealth and also affirmed in the Commonwealth Review of the blood sector by Sir Ninian Stephen in 2001. This policy in turn reflects international policies which call for countries to endeavour to be self-sufficient for blood and blood products. Notably,

- The World Health Assembly in 1975 called for the development of national blood services based on voluntary non-remunerated donation. Australia is a signatory to this resolution;
- The European Union reinforced the principle of self-sufficiency in 1989 (and again in 2003) stating that "member states shall take all necessary measures to promote self-sufficiency in human blood and human plasma";

Self-sufficiency has been considered as being a key goal as it provides:

- Relative protection from new infectious agents entering the plasma supply from overseas countries for example SARS, West Nile Virus and variant Creutzfeldt-Jakob Disease (vCJD);
- Avoidance of the use of paid donors with attendant safety benefits;
- Control over sufficiency in supply;
- Independence from supply issues in world markets where plasma is often considered a commodity
- Avoidance of issues related to trade imbalance and trade deficits; and
- The potential to generate some associated by-products in surplus which Australia could provide to other countries unable to achieve this goal.

Australia also has the benefit of a domestic fractionation plant which:

- Has the capacity to fractionate the plasma volumes required for self-sufficiency in major products;
- Provides significant logistical and contingency benefits; and
- Ensures segregation of Australian plasma from other overseas sources as an additional risk management strategy.

Self-sufficiency is a position desired by many countries and achieved by few. Those who do not achieve it are dependent on countries that have the ability to export plasma and plasma products often through the use of paid donors. Self-sufficiency requires considerable effort to achieve and once lost would not be able to be easily

regained. The Australian Red Cross Blood Service accepts that international plasma sources may provide a critical contingency to manage supply risks. However, the ARCBS, through its volunteer donor base of over 500 000 Australians has proven over more than 50 years that self-sufficiency is achievable and is sustainable for products that continue to be sourced from human plasma. In fact, plasma collection in Australia has risen by over 22% in the last 3 years alone.

The ARCBS notes that in the exchange of side letters on Blood Plasma Products that *“A Party may require that blood plasma for use in its territory be derived from blood plasma collected in the territory of that Party”*. The ARCBS believes that any departure from this position, as a departure from national self-sufficiency, would require careful consideration in the context of Australia’s long standing policy and risk management strategy.

ARCBS further notes that the side letter on Blood Plasma Products also sets out a timeframe for a review of the fractionator of the Australian plasma supply. As the collector and provider of the plasma and ultimate distributor of plasma products for the Australian community, ARCBS would seek assurances from Government that ARCBS will be engaged in this decision making process.

Finally, ARCBS notes the side letter states that Australia shall not require a US applicant wishing to market a plasma product in Australia to demonstrate significant clinical advantage over locally manufactured products. On this point ARCBS would seek to ensure that the consequences of such an open market position are fully recognised in the context of the benefits of self-sufficiency and the confidence and expectations of the Australian public.

1. INTRODUCTION - AUSTRALIAN RED CROSS BLOOD SERVICE (ARCBS) AND ITS ROLE IN THE BLOOD AND PLASMA SECTOR OF THE AUSTRALIAN HEALTH SYSTEM

The Australian Red Cross Blood Service (ARCBS) is today the sole collector of blood from Australia's volunteer blood donors. A not-for-profit community organisation, the ARCBS is a crucial part of the nation's health infrastructure. ARCBS distributes blood and blood products to hospitals 24 hours a day, 365 days a year. It is able to do this only because of the support of generous Australian volunteer blood donors. Approximately half a million Australians (about four per cent of the adult Australian population) make regular donations of blood.

Modern medical practice rarely involves transfusion of whole blood. Rather, only those specific components of blood that are needed in a particular clinical situation are transfused, eg fresh blood components such as red cells or platelets or plasma products/proteins.

Therefore, a fundamental feature of modern blood manufacturing practice is the separation of whole blood - into its cellular components and the liquid portion called plasma.

ARCBS sends the vast bulk of the plasma it collects to CSL Limited for fractionation. The fractionation process extracts the specialised proteins contained in plasma, such as albumin, specific clotting factors, or immunoglobulins. Some fresh plasma is retained by ARCBS for distribution to hospitals.

Although plasma products have a much longer shelf life than fresh components, their manufacture involves a much longer lead time - taking many weeks - and each finished product results from the pooling of many thousands of plasma donations.

The involvement of both the Australian Red Cross and CSL in the blood sector grew out of war. CSL was originally the Commonwealth Serum Laboratories, established in 1916 as a public sector entity to ensure Australia a supply of biological products and reagents (such as vaccines). Since 1994, CSL has been a public company, CSL Limited.

While the bulk of Australia's plasma product needs is met from domestic production, we do import small volumes of some specialised plasma products, sourced from both human and animal plasma. Also, as a nation, Australia does not have the capacity to make plasma product substitutes using recombinant technology (Stephen Review 2001).

Australia also maintains a National Reserve of Plasma Products, a reserve of approximately 3-4 months supply of plasma products to cater for emergencies (eg loss of a batch of plasma during production, failure or accident at the CSL plant, etc).

2. ARCBS RESPONSE TO KEY CLAUSES OF THE AGREEMENT

2.1 *Government Procurement Chapter and Related Side Letters to be Exchanged between the Parties*

ARCBS notes that Paragraph 5 of the Side Letters on Blood Plasma Products states that “*A Party may require that blood plasma products for use in its territory be derived from blood plasma collected in the territory of that Party*”. Further, ARCBS notes that this paragraph provides the opportunity for Australian governments to reaffirm previous commitments to self sufficiency in plasma (see below).

Australia’s proposals to “*undertake a review of its arrangements for the supply of blood fractionation services ... by no later than 1 January 2007*” are also noted.

ARCBS respectfully requests that Australian governments ensure that ARCBS is fully consulted in this review process, given the ARCBS role as a key stakeholder in the sector and our special partnership with blood donors and the community.

2.2 *Side-Letter to the Agriculture Chapter on Bovine Spongiform Encephalopathy (BSE)*

The ARCBS notes that the Parties agree to cooperate in international standard setting bodies in relation to international standards or guidelines relating to food. ARCBS would like to draw attention to the need for international cooperation in relation to standards and practice for blood transfusion services in relation to BSE and its human form, variant Creutzfeldt-Jacob Disease (vCJD). To date, there has been one potential transmission of vCJD in human blood, and there is experimental evidence that this condition may be transmissible by blood. Precautionary measures in the form of donor deferrals for donors who have spent time in BSE-affected countries are now in place in most developed nations.

3. BACKGROUND AND DISCUSSION ON THE ISSUES RAISED BY THE AGREEMENT

3.1 Self sufficiency as a goal for nations

Australia’s blood supply has been founded on the two important principles of:

- Voluntary, non-remunerated donation; and
- Self-sufficiency in products derived from human blood and plasma as far as practicable, rather than routine reliance on imported products.

In relation to self sufficiency in blood and blood products, Australia is fortunate in two respects:

- Firstly, Australia is one of the few countries in the world that has been completely self sufficient in fresh blood components and almost completely self sufficient in plasma products. This has been achieved with totally voluntary, non-remunerated

donors. Each week, 20 000 donations are needed to ensure sufficiency of the supply.

- Secondly, Australia is also now one of only a few countries with a domestic fractionation capacity. CSL Limited, the former Commonwealth Serum Laboratories, fractionates plasma collected by ARCBS from Australian donors to make a number of specialised plasma products. This fractionation is done under contract to the National Blood Authority, acting on behalf of all Australian governments. CSL also undertakes toll fractionation services for other nations in our region which do not have this facility, including New Zealand, Malaysia, Singapore, Hong Kong and Indonesia.

The term “sufficiency” means having enough blood and blood products to meet demand. For many developing countries, this primarily means sufficiency in fresh blood components such as red cells, platelets, and fresh plasma separated from a whole blood donation. On the other hand, most developed countries are also able to ensure sufficiency of the supply of both fresh blood components and the more specialised fractionated products derived from plasma (eg albumin, immunoglobulins).

“Self-sufficiency” means being able to achieve sufficiency through a national blood program without having to source products from other countries. A population donation rate of 50 per 1 000 population is the generally accepted minimum donation rate required for a developed country to meet this objective but this will be influenced by local demand.

Australia is a signatory to a 1975 World Health Assembly (WHA) resolution which sought to promote and protect the health and safety of both blood donors and recipients of blood and blood products through “...*the development of national blood services based on voluntary non-remunerated donation of blood...*” (WHA 1975)

Although national self-sufficiency was not specifically mentioned, both the discussion and the decisions of that WHA meeting implied that developed countries should be able to meet their needs without importing plasma, particularly imports from developing countries. At that time there were significant ethical and humanitarian concerns about the activities of private firms from developed nations collecting plasma in developing countries. This was being done on such a scale that it could interfere with local efforts to establish efficient and safe transfusion services to meet domestic needs in developing countries.

In 1989, the European Economic Community (EEC 1989) reinforced the principle of national self sufficiency through Directive 89/831 of the European Union which states:

“Member states shall take all necessary measures to promote self sufficiency in human blood and human plasma. For this purpose they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations”.

Continuing support for the “objective of Community self-sufficiency” was reiterated by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (European Community 2003).

In Australia, the most recent independent review of the blood banking and plasma product sector (commissioned by the Commonwealth) recommended that *“self sufficiency should remain an important national goal for Australia recognising that it is a national and international obligation and responsibility”* (Stephen Review 2001).

However, the Stephen Review also acknowledged that this goal’s appropriateness and application in Australia should be monitored *“in light of scientific, technological and other developments in transfusion medicine and patient care”*.

3.2 International practices in relation to plasma self sufficiency - risks and benefits of different approaches

For most countries self-sufficiency in plasma products remains an unachievable goal.

Some developed countries, such as Canada, believe that sufficiency rather than self sufficiency is the appropriate objective, and accordingly source their plasma products from other countries (principally the US) rather than pursuing a national goal of self-reliance. While this may be expedient in the short term, or when sufficient supplies of safe, high quality product are available on the international market, such a policy leaves the importing country in a vulnerable position should there be problems with the plasma supply in the sourcing country.

Other countries, such as the US and the Netherlands, collect enough plasma domestically to be completely self sufficient in plasma products derived from that plasma but have more open markets that allow exchange of the finished products between them, thus facilitating product choice for end users. (The US also manages to be a net exporter of plasma products, particularly due to having a very significant paid plasma collection industry).

Australia and New Zealand, on the other hand, have a tradition of meeting their demand for plasma products from domestic plasma collections sent to a single fractionator for processing. This option clearly limits choice for end users but provides for a degree of certainty in relation to the supply of the plasma raw material provided sufficient donors and funding are available to meet domestic demand.

In deciding what approach is in Australia’s national interest, there are several key issues to be considered:

- Potential risks to Australia’s supply if it moves significantly away from its current policy of self sufficiency to a situation of considerable dependence upon supply of plasma products sourced in the US. What would Australia’s position be if a serious new blood-borne disease were to become endemic in the US, thus threatening the safety of US-collected plasma?
 - The US already has reported a case of BSE (while Australia remains BSE-free to date) and in recent years has been the source of a substantial outbreak of West Nile Virus.

- Equally, Australia itself could become the locus of a new blood-borne infection. Clearly, to manage such a risk, Australian governments will need contingency options.
- Building the capacity for national self sufficiency in plasma collection and fractionation arrangements requires a systematic and steady incremental approach
 - with adequate lead times and resources. If Australia's current capacity were wound back too far, it could take a long time to restore if required.
- There are advantages to maintaining the current domestic fractionation arrangements through the CSL Limited facility at Broadmeadows (Victoria). These include:
 - a) its proximity (which has significant logistical benefits given the large volumes of material which must be input and processed); and
 - b) the safety benefits of the local regulatory requirement for complete segregation of fractionation services. This means that domestic plasma fractionation for the manufacture of product destined for the Australian community must be undertaken completely separate from fractionation undertaken for other countries to avoid the potential for cross-contamination.
- Finished plasma products are expensive commodities and a significant shift to imported product could impact on Australia's trade deficit, and be subject to variations in currency exchange rates.
- Australia plays an important leadership role in the Asia Pacific region, and continues to provide a source of technical expertise and support to developing nations in the region. Having a highly developed capacity both in the collection and fractionation of plasma products provides opportunities for sharing this expertise with our less developed neighbours on a humanitarian and a commercial basis, and maintains Australian jobs and technical 'know how'.
- Through its provision of opportunities for members of the Australian community to become blood donors, ARCBS plays an important role in building a sense of community and community responsibility for Australians from all walks of life.
 - Many blood donors are very strongly committed to the process. A policy decision to import significant overseas product, perhaps most of it from paid donors, has the potential to undermine support among the current voluntary, nonremunerated donor pool, with the risk that longstanding donors may give up donating. While such an effect is not likely to be large, there is currently no reliable information on Australian donors' attitudes to this issue. With other pressures on the donor pool, this is just one more factor that could threaten the overall adequacy and security of Australia's blood supply.
 - The extent of community interest and support for blood donation opportunities, while not well researched in a formal sense, can be readily gauged from community reaction when ARCBS has (often reluctantly) closed collection centres. To meet safety or regulatory requirements at an acceptable cost, or for reasons of overall efficiency, ARCBS has sometimes been required to close collection centres. Particularly in smaller regional and remote areas of Australia this has been the source of community unrest and concern. With the recent establishment of the National Blood Authority and an increased focus on overall efficiency of the Service, this situation may become more frequent in the next few years.

3.3 ARCBS capacity to meet domestic demand for plasma

As noted above, Australia (through the ARCBS) has been largely self sufficient in relation to plasma until relatively recently.

ARCBS believes that, given adequate lead times and funding, it has the capacity to meet Australia's likely future demand for plasma for fractionation. This would be assisted by longer planning and budgeting cycles than is currently the case. ARCBS looks forward to working closely and on a collaborative basis with the new National Blood Authority to develop the planning and monitoring tools to enable this to occur and thus provide a better service to Australian patients.

3.4 Competitiveness of ARCBS products

ARCBS acknowledges that it operates as a monopoly supplier and that competition in certain circumstances is beneficial.

The cost of production of the blood and blood products essential to the operation of the Australian health system is growing all the time with new threats to supply, new tests and other developments.

International comparisons of the costs of blood and blood products are difficult due to the different systems of operation in place and differing methods of attributing costs to specific products. For example, some services such as ARCBS assign the costs of collection equally across all major product groups, while others load most or all of these costs onto the red cell.

ARCBS welcomes the opportunity to work collaboratively with the new National Blood Authority on appropriate costing models for the Australian environment and for appropriate international comparisons - in the interests of improving our service to governments and the Australian community. Equally, ARCBS is committed to identifying opportunities to increase its efficiency and cost effectiveness - balanced against community opportunities to donate. This will help to ensure ARCBS products and services are not only of the highest standard but also competitive when viewed against like services internationally.

4. CONCLUSION

In conclusion, ARCBS welcomes the opportunity afforded by the FTA and this inquiry to review existing arrangements within the national blood sector for the benefit of the Australian community. ARCBS would be pleased to elaborate upon any of the issues raised in this submission and their bearing upon the national interest.

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