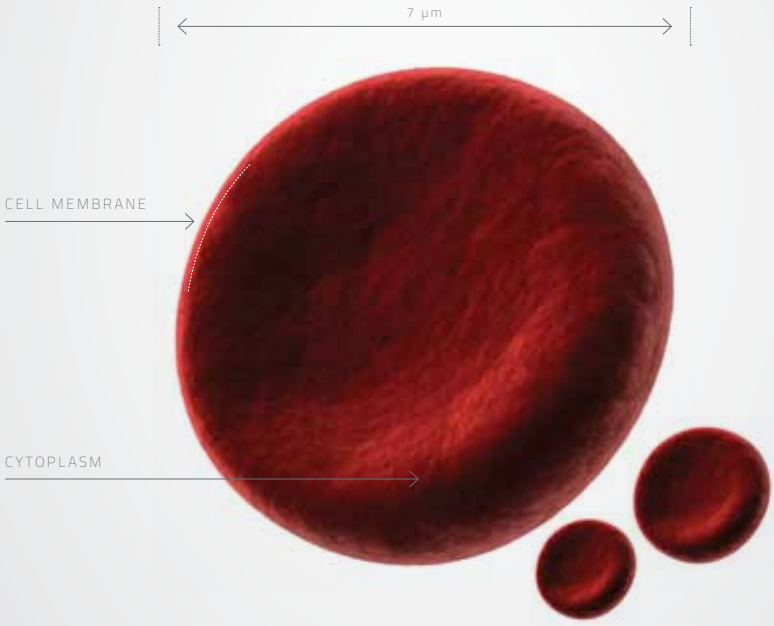
NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT 2009–2010

SAVING & IMPROVING
AUSTRALIAN LIVES
THROUGH A WORLD-CLASS
BLOOD SUPPLY

MATURE RED BLOOD CELL [7 MICROMETRES]



BLOOD FACTS

- There are about 5 billion red blood cells in 1 ml of human blood
- More than 98% of the oxygen in the blood is carried on the haemoglobin in the red cells
- Mature red blood cells do not have a nucleus and do not contain mitochondria or genetic materia

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› AT REST, EACH MINUTE ABOUT 25 TRILLION RED BLOOD CELLS ARE PUMPED BY THE HEART THROUGH THE LUNGS TO PICK UP OXYGEN

› EACH MILLILITRE OF ARTERIAL BLOOD CONTAINS ABOUT 0.2 ML OF OXYGEN

THE NATIONAL BLOOD AUTHORITY

THE NBA IS AN AUSTRALIAN GOVERNMENT AGENCY WITHIN THE HEALTH AND AGEING PORTFOLIO. WE ARE AN INDEPENDENT STATUTORY AGENCY THAT ACTS ON BEHALF OF THE AUSTRALIAN AND ALL STATE AND TERRITORY GOVERNMENTS. WE OPERATE UNDER THE *PUBLIC SERVICE ACT 1999* AND THE *FINANCIAL MANAGEMENT AND ACCOUNTABILITY ACT 1997*.

OUR VISION

Our vision is saving and improving Australian lives through a world-class blood supply.

OUR MISSION

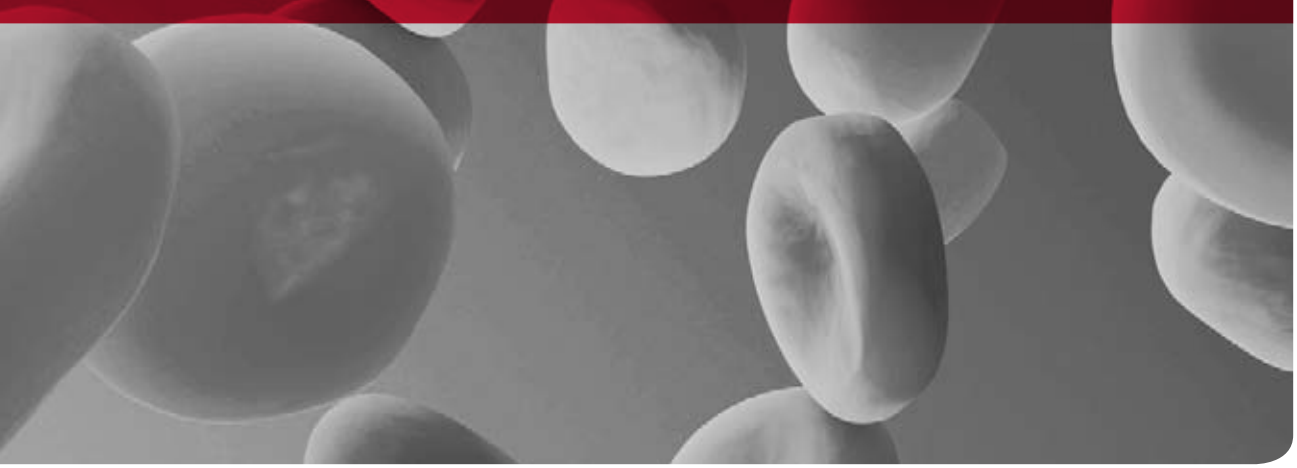
To secure a quality blood supply through world leading contractual arrangements, promote safe, high quality management and use of blood and blood products in Australia, and drive continual performance improvement across the sector.

OUR ROLE

Our role is to coordinate national blood supply and demand planning, to purchase blood and blood products to meet clinical need on behalf of all Australian governments, and to develop and implement national strategies to encourage better use of blood and blood related products.

OUR EXPENDITURE

The NBA employed around 48 staff in Canberra. Our Principal Medical Officer, works from Melbourne. In 2009–10 health ministers approved $910.8 million to procure and manage the supply of blood, blood related products and services.



MAJOR ACHIEVEMENTS **2009–10**

- Won the 2010 United Nations Public Service Award in the category of Advancing Knowledge Management in Government.
- Signed a new agreement with CSL Limited to maintain a safe, secure and affordable supply of domestically produced blood plasma products.
- Won the Comcover Award for Excellence in Risk Management.
- Implemented a pilot project for a national electronic Order and Receipting Blood System.
- Completed a public consultation of the critical bleeding module on the Patient Blood Management guideline designed to assist in the management of patients with life threatening bleeding.
- Agreed to output based funding principles with the Blood Service, and a 12 month extension of the current Deed.
- Developed a Stewardship statement for use of blood and blood products by Approved Health Providers.
- Commenced review of the *Criteria for the clinical use of intravenous immunoglobulin in Australia*.
- Improved data capture and analysis to provide greater insight on the management, administration and use of blood and blood products.
- Completed stage 2 of the review of distribution arrangements of plasma and recombinant products.
- Published the second Australian Haemovigilance Report 2010 which aims to increase the sector's understanding of transfusion related adverse events.

LETTER OF TRANSMITTAL

The Hon. Nicola Roxon MP
Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Minister,

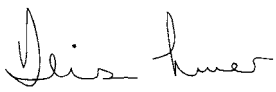
I am pleased to present to you the annual report of the National Blood Authority and the National Blood Authority Board for the financial year ending 30 June 2010, as required under sub-section 44(2) of the *National Blood Authority Act 2003*.

This annual report details the National Blood Authority's performance against the Agency Outcomes and Programs of the *Health and Ageing Portfolio Budget Statements 2009–10*.

This document has been prepared in accordance with sub-sections 44(1) and 44(2) of the *National Blood Authority Act 2003* and the guidelines approved by the Joint Committee of Public Accounts and Audit referred to in sub-sections 63(2) and 70(2) of the *Public Service Act 1999*. These guidelines are applied as a matter of policy to prescribed agencies, including the National Blood Authority, under section 5 of the *Financial Management and Accountability Act 1997*. I certify that all of the requirements specified in the 2010 edition of the Prime Minister and Cabinet *Requirements for Annual Reports* have been addressed.

I am satisfied that the National Blood Authority has prepared fraud risk assessments and control plans that meet the specific needs of the agency and comply with the *Commonwealth Fraud Control Guidelines*.

Yours sincerely



Dr Alison Turner
General Manager and Chief Executive Officer
National Blood Authority

1 October 2010

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APPENDIX TABLES

USER GUIDE

About this report

This annual report outlines the National Blood Authority's performance and achievements in the financial year ending 30 June 2010. It also includes the National Blood Authority Board report for the same period, as required under section 44(2) of the *National Blood Authority Act 2003*.

The annual report was prepared in accordance with the Department of Prime Minister and Cabinet's 2010 requirements for annual reports and was written to inform stakeholders, including governments and the community, of the ways in which the roles and responsibilities of the NBA have been implemented.

The report is divided into eight parts:

Part One : Our role and governance

Part One provides a summary of the NBA's key activities and outlines our major achievements, as well as issues and challenges faced during 2009–10 and the outlook for 2010–11. It consists of the NBA General Manager's review, a report from the Chair of the NBA Board, biographies of our board members, a report from our Principal Medical Officer, and overviews of the NBA and the Australian blood sector.

Part Two : Performance by outcome and program

Part Two summarises the NBA's outcome and program structure in 2009–10 and our performance against the quantitative deliverables and indicators established in the Portfolio Budget Statements 2009–10.

Part Three : Strategic directions

Part Three contains an assessment of how the NBA performed in the three key strategic directions identified in the Portfolio Budget Statements 2009–10: to ensure the supply of required blood and blood products through efficient supply planning and budgeting, and effective procurement and management of product availability; to implement blood sector policy for the management of risk and sector performance improvement; and to facilitate appropriate patient blood management and safe use of blood products.

Part Four : Sector information management initiatives

This new section of our report provides information about the NBA's national information management and reporting strategies for the blood sector.

Part Five : Horizon scanning

Part Five describes external influences that could affect the way the NBA does business in the future. It provides a summary of the core developments we have monitored during 2009–10, including factors that may affect global supply, demand and pricing, safety issues and international regulatory trends.

Part Six : Our management arrangements

Part Six describes how we manage our affairs. It includes information on corporate governance, planning and service delivery, and people management. It includes our audit arrangements and how we manage risk and fraud. Finally, information is provided on our budget and financial management arrangements.

Part Seven : Our accountability

Part Seven specifies how the NBA complies with a range of external policies. These include purchasing, asset management, the Commonwealth Disability Strategy, occupational health and safety, productivity gains, ecologically sustainable development and freedom of information.

Part Eight : Financial statements

Part Eight presents the NBA's financial statements for the year ending 30 June 2010.

Appendices

The appendices contain government objectives under the National Blood Agreement, which encompasses the work of the NBA, the NBA's Resource Statement, lists of fresh blood components and plasma-derived and recombinant plasma products supplied under contract, further details of fresh blood component supply distribution across Australia, an erratum, a glossary of acronyms and terms, and general and compliance indices.

PART ONE
OUR ROLE AND GOVERNANCE

APPROXIMATE OVERALL PROPORTIONS OF BLOOD GROUP TYPES IN THE AUSTRALIAN POPULATION:

- GROUP O POSITIVE 40%
- GROUP O NEGATIVE 9%
- GROUP A POSITIVE 31%
- GROUP A NEGATIVE 7%
- GROUP B POSITIVE 8%
- GROUP B NEGATIVE 2%
- GROUP AB POSITIVE 2%
- GROUP AB NEGATIVE 1%

- POPULATIONS OF DIFFERENT ETHNIC ORIGINS HAVE DIFFERING BLOOD GROUP PROFILES

PART ONE PROVIDES A SUMMARY OF THE NATIONAL BLOOD AUTHORITY'S KEY ACTIVITIES AND OUTLINES OUR MAJOR ACHIEVEMENTS AS WELL AS ISSUES AND CHALLENGES FACED DURING 2009–10. IT CONSISTS OF THE NBA GENERAL MANAGER'S REVIEW, A REPORT FROM THE CHAIR OF THE NBA BOARD, BIOGRAPHIES OF OUR BOARD MEMBERS, A REPORT FROM OUR PRINCIPAL MEDICAL OFFICER, AND OVERVIEWS OF THE NBA AND THE AUSTRALIAN BLOOD SECTOR.

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1.1 GENERAL MANAGER'S REVIEW

Alison Turner, BVSc, MSc, FAICD, was appointed General Manager and Chief Executive Officer of the NBA in August 2003. From 1997 to 2003 she was Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority. Before that she had held a number of senior government positions in the health and primary industries sectors and had represented Australia internationally. Alison has been a director of government and not-for-profit organisations and is currently a councillor of the Australian Institute of Public Administration (ACT).

Introduction

The National Blood Authority has always aspired to excellence in carrying out our tasks. We open our methods to challenge by involving external parties in their design and implementation, we consult widely and we use the expertise of the NBA Board for the most complex matters. That doesn't mean our execution is always perfect or that we never make mistakes, but our quality framework means that we capture information on what we have learned and do even better next time.

The NBA has always believed that developing and maintaining the organisational capability to do our work well is a top priority. In particular, it is crucial for us to have access to high-quality information so that the NBA can be a well-informed purchaser and program manager. To that end, over the last six years we have built a very effective private and civil network that provides us with the information we need to maintain our high standard of work. It was therefore a very exciting day for us in June when the NBA's work in this area was recognised by our winning the 2010 United Nations Public Service Award in the knowledge management category.

This award capped another exciting year for the NBA. During the year our key focus has been on building capacity for data collection, analysis and measurement, both within the NBA and in the wider blood sector. A major hurdle faced by the blood sector in managing itself effectively is lack of performance measurement, both administrative and clinical. While there is still a long way to go, the new NBA organisational structure and the fantastic contribution of our staff have allowed us to end the financial year with a significantly improved quantity and quality of information and data on the sector.

Maintaining the high standard of our work requires constant and undiminishing effort. The NBA will need to stay vigilant in the future so that it can respond effectively to the ever-changing external environment, as governments implement broader health reforms.

Highlights of 2009–10

Supply of blood and blood products

Among the NBA's key functions are the development and management of the National Supply Plan and Budget and the management of contracts for blood and blood related products. In 2009–10, governments spent $872.8 million on blood and blood related products which are supplied free of charge to Australian patients.

In 2009–10 our current contracts with major suppliers CSL Limited and the Australian Red Cross Blood Service (the Blood Service) both expired. The NBA put a great deal of effort into negotiating the successful renewal of the contracts. In December 2009 we signed a new agreement with CSL Limited. Subject to a review in 2014, the agreement will run until 31 December 2017. Over that period this will ensure a secure supply of plasma products and services and provide improved value for money for governments.

Other major achievements in this area included:

- successfully ensuring that blood products were available at all times to meet clinical need
- reaching agreement with the Australian Red Cross Society and the Blood Service on the principles of an output based funding model, to be implemented from 1 July 2010, and on the extension of the current Deed of Agreement for a further year
- reaching agreement with Octapharma to extend the existing contract for the supply of imported intravenous immunoglobulin until December 2011, with improved value for money
- extending the contracts for diagnostic reagent products until June 2011
- completing the 2010–11 National Supply Plan and Budget with a higher level of jurisdictional engagement on clinical demand than in previous years. The plan was approved by the Jurisdictional Blood Committee in December 2009 and received ministerial approval in April 2010
- achieving savings to governments of $22 million, compared to the prices that governments would have otherwise incurred before the establishment of the NBA.

Risk and sector improvement

The NBA continues to give high priority to our obligation to manage blood sector risks, especially those related to supply security. We do this by ensuring that responsibility and accountability lie with those best placed to manage risk. There were several highlights in this area during the year:

- The NBA was awarded the 2009 Australian Government Comcover Award for Excellence in Risk Management for the National Blood Supply Contingency Plan.
- An annex to the National Blood Supply Contingency Plan, dealing with the management of transfusion-transmitted infections in the blood supply, was drafted.
- Agreement was reached with the Blood Service on the need to standardise stock holdings for fresh blood components to assist in identifying appropriate trigger points for the National Blood Supply Contingency Plan and enabling improved reporting.

The NBA restructured its organisation in 2009 to enhance our capacity to capture and analyse data and provide insight into the management, administration and use of blood and blood products. Significant progress was made during the year on data capture that will allow us to deliver more robust and accurate reports to jurisdictions on product use, the balance between supply and demand throughout the year, and intensive management of products in short supply where this is necessary.

A number of projects are under way within the NBA to improve the overall efficiency of the sector, particularly to enhance affordability and risk minimisation:

- We implemented a pilot project to develop a national electronic ordering and receipting blood system for use by blood banks in ordering products from suppliers.

- The Jurisdictional Blood Committee endorsed the recommendations of the review of the distribution of plasma and recombinant products. Governments will make a final decision in late 2010 following further consultation with stakeholders and suppliers and detailed analysis of costs, benefits and risks.
- A further 22 recommendations of the Blood Service KPMG business review were implemented.
- The Jurisdictional Blood Committee approved the Statement on National Stewardship Expectations for health providers of blood and blood products and the Statement of Expectations for the Australian Red Cross Blood Service 2010–11 to 2012–13. Both of these statements will be considered by Ministers in the coming year.

Appropriate use of blood

In the past, reviews have identified scope for improvement in the way blood products are used in the clinical setting in order to achieve better patient outcomes and reduce wastage and costs. A key feature of the NBA's work in this area is the high level of involvement of clinical experts in all of our activities.

A major milestone was reached this year with the completion of Australia's second national Haemovigilance Report. The report is a valuable resource that helps us to understand the risks associated with transfusion. The importance of detailed information on the types of risks associated with blood transfusion and how frequently these risks present themselves cannot be overstated.

Other major achievements in this area during the year included:

- The first module of the *Patient blood management guideline*, on critical bleeding/massive transfusion, was released for public consultation. The review of the National Health and Medical Research Council/Australia and New Zealand Society of Blood Transfusion guidelines for patient blood management will produce up-to-date, best practice and evidence-based information on when and how to use fresh blood components.
- Governance arrangements for the National Patient Blood Management Program were established and a program of activities to support patient blood management initiatives at the local level, both public and private, is under development. The management of iron deficiency anaemia is an initial focus of activity.
- NBA support for education projects initiated by states has continued to bear fruit: the BloodSafe e-Learning website continues to be popular. The website is supported by a national advisory committee and the content is being expanded and updated.
- The first intake of students to the redeveloped Graduate Certificate in Transfusion Practice commenced early in 2010. The course, supported by the Jurisdictional Blood Committee, is the only formal transfusion-specific tertiary qualification in Australia.

Financial results

The NBA continues to perform well within our budgetary allocation and our end of year result was a surplus of $49,000. We have agreement from governments to carry forward prior years' operating surpluses for a limited period, which will allow us to maintain close to current activity levels and staffing during that time.

Corporate development

The restructure of the NBA in July 2009 led to some disruption within the organisation and, as a result, a number of staff left the NBA. However, new people came to the organisation bringing valuable skills. Many of the staff that remained with the NBA took on tasks that were unfamiliar to them. I am very proud of the way staff members were prepared to work even harder to learn new skills and at the same time assist their colleagues undertaking unfamiliar duties.

New cross-NBA committees were established so that we could share experiences and provide a consistent NBA-wide approach to key tasks and new functions. By the end of 2009–10, the organisation has settled down and our capacity to deliver our extensive range of programs and activities had substantially increased.

During the year the NBA management and Board made major contributions to the Administrative Review of the national blood arrangements. Later in the year, when the recommendations of the review became available, the NBA worked with the Jurisdictional Blood Committee to develop an implementation strategy.

The Jurisdictional Blood Committee agreed to delay the development of our third Corporate Plan until we knew the outcome of the review and could be guided by its recommendations. The new Corporate Plan will be finalised early in 2010–11. A range of new strategies will focus on the capture and analysis of relevant data to drive enhanced performance of the blood sector and improve integration with the wider health sector.

Outlook for 2010–11

We expect that 2010–11 will be another busy year.

The recommendations of the Administrative Review of the national blood arrangements will inform our efforts to respond to pressures and changes in the hospital sector. We will work with jurisdictions and focus on engagement with stakeholders to improve policy development outcomes.

One of our major priorities will be to further develop our data collection and analysis capacity and extend systems currently under development to the national level. The progress we have made so far, especially during 2009–10, gives us confidence that these activities will allow us to assist the states and territories and obtain robust data to inform our decision-making for the overall improvement of the sector.

Also high on our priority list will be the implementation of the three-year output based funding model for the Blood Service.

A new deed, to commence on 1 July 2011, needs to be negotiated with the Australian Red Cross Society. New contracts will be required for the supply of imported plasma and recombinant blood products (including intravenous immunoglobulin), for diagnostic reagents and for out-sourcing actuarial and other services associated with the National Managed Fund.

In the area of clinical development, we will publish modules of the *Patient blood management guideline* and the outcomes of the review of the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia*.

In all of these activities we will continue to rely on the expert advice of our stakeholders. Their willingness to contribute their time and advice to our many committees and working groups is a major reason that the NBA is able to continue to perform at such a high level. The names of some of these valuable colleagues are listed in Part 3 of the report, in which our performance is described in greater detail.

I would like to take this opportunity to publically congratulate our long-serving Board member Dr Peter Lewis-Hughes, who was made a Member of the Order of Australia in the 2010 Australia Day Honours List in recognition of his services to public and medical administration in Queensland, particularly through the reform of the pathology service delivery system.

Dr Alison Turner
General Manager and Chief Executive Officer
National Blood Authority

NBA WINS 2010 UN PUBLIC SERVICE AWARD

We are delighted that the NBA won the 2010 United Nations Public Service Award in the category of advancing knowledge management in government. The United Nations Public Service Awards are 'the most prestigious international recognition of excellence in public service'. The aim of this annual award is to promote the role, professionalism and visibility of public services worldwide.

We described how a small agency with limited resources has built a sustainable knowledge network which has supported and enabled the acquisition of knowledge in a cost effective manner and built organisational capability. We demonstrated how this knowledge network benefits citizens through a more secure supply of high quality, safe blood products, improved value for money, more choice for patients and improvements in the appropriate use of products.

The knowledge network is part of the NBA's comprehensive corporate capability strategy. This strategy is built to achieve excellent capabilities in the areas of:

- consolidating the quality and volume of knowledge available to the NBA through its private and civic knowledge networks
- enabling staff to apply processes and knowledge
- enhancing our engagement with citizens and stakeholders
- increasing the capacity to adapt and develop the organisation
- refining business systems and processes
- improving our capacity to manage and measure performance.

The knowledge network was designed in recognition of the need to access and utilise, in a sustainable way, the knowledge that already exists in the private and civil sectors of the blood sector. The network enables us to identify multiple sources of knowledge and form alliances with people working in relevant areas including clinicians, patient user groups and business analysts. The NBA's private knowledge network partners now include the domestic, public and private hospital and pathology sector, recombinant and international plasma manufacturers, logistics experts , the commercial plasma industry and business analysts

advising the investment industry. Our clinical network partners include local and international professional organisations, clinicians, blood scientists, nurses, patient representative groups and the Australian Red Cross Blood Service. Our international government networks extend into Europe, Asia, Canada, USA and South America and include both public and private institutions.

This strategy has been key to our success in delivering enhanced value for money and security of supply by providing access to the most significant and current information and developments across the global and domestic sectors relevant to our business, thus informing our decision-making.

To illustrate the extent of our knowledge network, in this year's annual report we have chosen to highlight and acknowledge our clinical partners. Readers should refer to Part 3 of the report (pages 70–83) to see the breadth of our clinical engagement.

The NBA's approach to developing our knowledge networks strongly aligns with contemporary thinking on public service reform, including engaging citizens in program design, incorporating non government expertise, strengthening workforce development and ensuring agency agility, capability and effectiveness. All these elements have been key elements contributing to NBA's success.

We are proud that the work of the NBA in this area has been strongly endorsed internationally and look forward to building on this success and our continual engagement with our highly valued knowledge network.

THE AUSTRALIAN AMBASSADOR TO SPAIN, HER EXCELLENCY MS ZÓRICA MCCARTHY, DR TURNER AND MR STONE RECEIVING THE UN PUBLIC SERVICE AWARD

1.2 NATIONAL BLOOD AUTHORITY BOARD

The NBA Board was established under the National Blood Authority Act 2003, with four functions:

1. to participate in consultation with the Australian Government Minister for Health and Ageing about the performance of the NBA's functions
2. to provide advice to the General Manager about the performance of the NBA's functions
3. to liaise with governments, suppliers and other stakeholders about matters relating to the NBA's functions
4. to perform such other functions (if any) as specified in a written notice given by the Minister to the Chair.

Board members are selected by the Australian Health Ministers Conference. They are appointed by the Australian Government Minister for Health and Ageing to serve a term not exceeding four years and are eligible for reappointment. The Board is required under section 44(2) of the *National Blood Authority Act 2003* to report on its activities on an annual basis.

MEMBERS OF THE NBA BOARD AT A MEETING IN CANBERRA

1.2.1 NBA Board Chair's report

Mr Garry Richardson has extensive experience in the health and financial services sectors and is a Fellow of the Australian Institute of Company Directors. Before retiring from his executive career at the end of 1997, Mr Richardson was Managing Director of National Mutual Health Insurance Pty Ltd (now known as BUPA Australia) for seven years. He was concurrently Vice President of the Australian Health Insurance Association and Board Member of the International Federation of Health Funds (based in the United Kingdom).

Since retiring, Mr Richardson has been appointed to several boards in the state, Commonwealth, private and not-for-profit sectors. At present, in addition to being Chair of the National Blood Authority Board (since May 2007), he serves as Chair of Health Super Pty Ltd (since January 2001) and Independent Chair of the City of Stonnington's Audit Committee (since 2000).

Mr Richardson was appointed as Chair of the NBA Board in May 2007.

This is my third report as Board Chair and I am pleased to note that the NBA has continued to make very good progress on the activities that were the focus of the Board's attention this year.

Key focus in 2009–10

During 2009–10 the Board conducted five meetings. The Board also held its annual meeting with the Australian Red Cross Blood Service (the Blood Service) Board in October 2009. The following outlines the key achievements of the NBA Board over the past year.

Fresh blood management

The NBA Board has continued to guide the NBA's relationship with the Blood Service in the pursuit of organisational efficiencies while maintaining high standards of quality and safety. We focused on providing strategic advice to help the NBA progress the key recommendations of the 2008 Blood Service business study, in particular:

- *Development and design of the principles and operations of an output based funding model:* The NBA Board has continued to oversee the project which aims to ensure that the supply of blood is based on efficient and transparent costs that will provide incentives to the Blood Service for ongoing efficiency and continuous improvement. The project is also a key mechanism to link supply practices to clinical demand. I am pleased that, following the detailed work of NBA and Blood Service staff, the principles for output-based funding were endorsed by the Blood Service and Australian Red Cross Society boards. The model will now be applied to Blood Service products and services from 1 July 2010, with a review of the cost attribution model within the first 12 months.

- *Incorporation of government priorities into the Blood Service strategic and business planning:* The October 2009 meeting of the NBA and the Blood Service boards in Canberra provided a productive forum for explanation and discussion of government developments and priorities. The discussion focused on the Administrative Review of the national blood arrangements, the health reform agenda, progress with the implementation of the Blood Service Business Study, and developments within the Blood Service.

Plasma and recombinant supply management

A highlight of the past year has been the execution of the new CSL Australian Fractionation Agreement on 23 December 2009. The NBA Board provided policy guidance to the NBA on the development of the agreement, with a key focus on risk management. The final satisfactory outcomes can be largely attributed to intensive financial and market analysis by the NBA.

One of the NBA's most significant procurement arrangements is for imported intravenous immunoglobulin (IVIg) to supplement the domestic supply. With the current contract set to expire on 31 December 2010, the NBA Board provided advice to the General Manager on potential procurement options beyond December 2010.

Sector improvement

The NBA Board has been involved with two long-term projects that have been designed to increase the affordability and performance of the sector:

- *Review of distribution arrangements for plasma and recombinant products:* The aim of the review is to examine current distribution arrangements for fractionated and recombinant blood products and identify areas of improvement. At our meeting in April 2010, the NBA Board advised that a phased approach should be taken to implementing any change so that the approach can be evaluated and refined. This will enable governments to move towards a consistent national implementation of a new model.
- *Criteria to assess applications for changes or additions to blood products:* Over the last few years, a key priority for the NBA Board has been to establish clear criteria to assess applications for changes or additions to blood products to the National Product Price List. In 2009–10 the Board endorsed a multi-criteria analysis framework, a major element of which is the economic assessment of proposals, as the primary assessment tool. The Department of Health and Ageing 2010–11 budget measure will ensure the availability of expertise to undertake this economic analysis. The Board will retain a focus on this area, mindful of the need to balance all priorities and policy objectives within the National Blood Agreement when considering changes to the National Product Price List and the supply plan.

Risk mitigation

The NBA Board continued to oversee measures to mitigate risks to blood supply security. In particular, we focused on considerations arising from:

- contractual reforms and negotiations
- the NBA's horizon-scanning program, which monitors international and domestic developments that may influence the management of blood and blood products in Australia. A summary of these issues is contained in Part 5 of this report. The Board has remained alert to the implications for IVIg of the research into Alzheimer's, variant Creutzfeldt-Jakob disease, and emerging diseases.

Enhancing national data management

The NBA Board is very aware that the efficient management of the sector requires good quality information on where and how blood is used. To facilitate improvements in the NBA's data collection and management processes, the Board endorsed a review of the NBA's information and communication technology systems. The review focused on governance and management arrangements and was finalised in July 2009.

A key outcome of the review was the consolidation of the NBA's ICT functions and sector data projects into a single expert team. The Board also supported work on the implementation of the Sector Information Management and Data Strategy, noting the excellent progress made in a range of national system developments, including:

- increased data entry and quality for the revamped Australian Bleeding Disorders Registry system, providing information on clotting factor product orders, use and outcomes
- work with Queensland system developers on the proof of concept trial for the Ordering and Receipting Blood System, now under way in several states to evaluate the feasibility of expanding the system into a national one
- expansion and use by the NBA of the Integrated Data Management System as the primary contract management system, noting that electronic feeds from all suppliers are now loaded into the system, including delivery details for all product deliveries, expiries and supplier inventory holdings
- commissioning a business intelligence capability to support all systems and link the disparate sources of data in each system in order to improve consistency and the quality of data reporting.

This work positions the NBA to add real value to the performance analysis of the sector and will enable a consistent national approach to continuous improvement.

Governance

Governance arrangements for the sector were considered as part of the Administrative Review of the national blood arrangements 2009. The Board provided considerable input to the review through Mr Ken Barker, as a member of the Review Management Committee, and commented at each stage of the review process. The review was completed in December 2009. The Board will play a continuing role in guiding the NBA's implementation of relevant recommendations arising from the review.

Corporate Plan for 2010–12

The current NBA Corporate Plan was extended until the outcomes of the Administrative Review of the national blood arrangements 2009 were known. When the review was finalised, the Board recommended that the next Corporate Plan should be based on a two-year timetable. The Board agreed that the two core priorities for the NBA for the period would be to:

- further improve the integration and synergies between the blood sector and the wider health sector
- Support reforms to ensure that Australia's blood sector remains at the forefront of international better practice in all facets of production, management and appropriateness of use.

The plan identifies those items of highest priority for jurisdictions. The Board will work with the NBA to ensure adequate and timely delivery of results to meet these expectations.

National Blood Authority performance

A key role of the Board is to provide the General Manager with advice about the performance of the NBA. I am pleased to report that the NBA has again performed strongly during the 2009–10 year, achieving 91 per cent completion of activities from its 2009–10 Operational Plan.

On behalf of the Board, I would like to heartily congratulate the NBA on receiving the 2010 United Nations Public Service Award for advancing knowledge management in government. Australia has won a UN public service award on only three previous occasions. The award is a testament to the dedication of NBA staff.

2010–11 priorities

The Board acknowledges that a key challenge for the NBA in 2010–11 will be to ensure that the blood sector continues to operate in an efficient manner and has enhanced flexibility to respond to the requirements of the health sector.

The key activities that the Board will focus on in 2010–11 include:

- government's relationship with the Australian Red Cross Society and deed negotiations with the Blood Service
- procurement strategies for imported IVIg, other imported plasma and recombinant products and diagnostic products
- the ongoing capability requirements of the NBA
- the impact of and synergies with the broad health sector reform agenda
- the development of data and performance indicators to demonstrate the performance of the sector and increase capacity to undertake comparative analyses with the wider health sector.

I would like to acknowledge the advice and support of my fellow Board members during the course of the year. I would also like to thank Associate Professor David Cooper for his contribution to the work of the Board. Associate Professor Cooper resigned from the Board in October 2009 after two and a half years of service.

Garry Richardson
Chair
National Blood Authority Board

1.2.2 Members of the National Blood Authority Board

MR KEN BARKER

Financial Expert

In July 2009 Mr Ken Barker retired from full-time employment as Chief Financial Officer with New South Wales Health. In that position Mr Barker was responsible for controlling and monitoring recurrent expenditure and revenue, establishing New South Wales Health's financial management policy and strategy, and overseeing the business management services involving insurance, risk management, taxation, benchmarking of public hospital support services and independent financial review of public and private sector initiatives.

Mr Barker worked for New South Wales Health for 24 years and had some 42 years of experience in the New South Wales Government. He is now director of his own company, which specialises in financial management and strategic advice, mainly to government agencies. He is also a member of a number of state government governance boards and of several New South Wales agency audit and risk committees.

In relation to Australia's blood sector, Mr Barker has been involved from the government financial perspective in the former New South Wales Blood Transfusion Service, nationalisation and establishment of the Australian Red Cross Blood Service, establishing national indemnity arrangements for blood and blood products, providing input into defending claims for blood-acquired HIV in New South Wales, providing input into the Stephen Review of the Australian Blood Banking and Plasma Product Sector, establishing the National Blood Authority, and the 2008 KPMG business study of the Blood Service.

Mr Barker was appointed to the NBA Interim Board and has served as a full Board member since the inception of the NBA. He served as Chair of the NBA Audit Committee from 2003 to 2007.

MR ROB CHRISTIE

Community Representative

Mr Rob Christie has a long history of community service and experience as a health consumer representative in Australia in connection with blood and blood related products and the needs of patients with bleeding disorders and their families.

Mr Christie's commitment to the blood sector has resulted in his appointment as Life Governor and Board member of Haemophilia Foundation Australia since 1997. He spent four years as its National President, was Vice President of Haemophilia Foundation South Australia and Board member from 1995 to 2008, was a member of the Coagulation User and Advisory Group with the Australian Red Cross South Australia. He has also been a member, since 1995, and Vice-President, since 2004, of the Finance of the World Federation of Hemophilia, Montreal, Canada.

Mr Christie was appointed Community Representative on the NBA Board in May 2007.

DR STEPHEN CHRISTLEY

State and Territory Representative

Dr Stephen Christley is Chief Public Health Officer and Executive Director of Public Health and Clinical Coordination in the South Australian Department of Health. Before this appointment, he was the Chief Executive Officer of three separate area health services in New South Wales over 12 years. He is a medical practitioner and has previously worked in rural, public health and community settings.

Dr Christley's interests are public health, health system improvement, and safety and quality. He has been a member of a number of research fundraising foundation boards. He is also a member of the Clinical, Technical and Ethical Principal Committee.

Dr Christley was appointed State and Territory Representative on the NBA Board in March 2009.

DR PETER LEWIS-HUGHES AM

State and Territory Representative

Dr Peter Lewis-Hughes joined the Commonwealth Department of Health in 1986, working in the Australian Capital Territory and Queensland until 1995, when he was recruited by Queensland Health. His role with Queensland Health was to implement structural reform agendas in key services such as pathology, biomedical engineering services and public health and forensic laboratory sciences. Following the Forster Review of Queensland Health in 2005, he was appointed Executive Director of Clinical and Statewide Services with responsibility for development and reform of the Queensland Health blood program, radiology services, medication services and the oral health program. With wide-ranging experience in the health care industry at Australian government and state levels, Dr Lewis-Hughes is especially interested in contemporary health issues as they relate to strategic and business planning for clinical services across Queensland. In 2009 he received a Queensland Health Australia Day Achievement Award for Clinical and Statewide Services. Later that year Dr Lewis-Hughes left Queensland Health but continues to provide advice on all aspects of health policy, service delivery, review and reform.

In 2010 his contribution to clinical administration and services to public pathology were nationally recognised in the Australia Day honors list and he was made a Member of the Order of Australia.

Dr Lewis-Hughes was appointed Public Health Expert on the NBA Board in 2003 and State and Territory Representative in 2007.

MS MARY MURNANE

Australian Government Representative

Ms Mary Murnane is currently Deputy Secretary of the Australian Government Department of Health and Ageing. Ms Murnane joined the Commonwealth Department of Social Security in 1984 and since that time has had a broad range of responsibilities. Her current responsibilities as Deputy Secretary include the Office of Health Protection, including Health Emergency, the Regulatory Policy and Governance Division and a special focus on the Therapeutics Goods Administration, the Office of the Gene Technology Regulator, Food Standards Australia and New Zealand, food policy, medical and biological research policy, the National Blood Authority, ageing and aged care, and palliative care.

Ms Murnane also chairs the Australian Health Protection Committee, which advises the Australian Health Ministers Advisory Council on emergency preparedness. This committee manages the emergency health component of national emergencies, liaises with other Commonwealth and state emergency-handling structures, and interfaces with exercises, leadership and coordination roles in national emergencies requiring a health response.

Ms Murnane was appointed as the Australian Government Representative on the NBA Board in March 2009.

ASSOCIATE PROFESSOR DAVID COOPER

Public Health Expert (until October 2009)

At the time of his Board membership, Associate Professor David Cooper was Regional Medical Director Australasia with International SOS, a company providing medical, security and assistance services across the world. He has extensive experience in emergency and disaster medicine.

Among Associate Professor Cooper's previous appointments have been Foundation Chair of Disaster Response and Preparedness, Charles Darwin University/National Critical Care and Trauma Response Centre, Royal Darwin Hospital; Acting Deputy Chief Health Officer, New South Wales Health; and Director of the New South Wales Health Counter Disaster Unit.

His interest in the blood sector related to the safe management of blood and blood related products in critical care and emergency medicine and in disaster settings.

Associate Professor Cooper was appointed Public Health Expert member of the NBA Board in May 2007 and resigned in October 2009.

1.3 PRINCIPAL MEDICAL OFFICER'S REPORT

Dr Chris Hogan is a consultant haematologist and brings to the NBA long-term sub-specialist expertise and experience in transfusion medicine, from both the clinical and the laboratory perspectives. He retains his part-time position as consultant haematologist at Royal Melbourne Hospital. Dr Hogan is also a member of the Education Committee of the Australian and New Zealand Society of Blood Transfusion. He began working as the NBA's first Principal Medical Officer in August 2008.

This moment in the NBA's history represents something of a threshold. The establishment tasks of reviewing, revising and initiating major contractual arrangements for a safe, secure and affordable blood supply are now embedded. Major infrastructural projects in regard to the supply chain, the development of new principal sites for the Blood Service, contingency planning and data resourcing and gathering are advancing well.

The second set of objectives for the NBA, arising directly from the National Blood Agreement, concern its stewardship responsibilities for the appropriate use of blood and blood products: 'to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia'. In this regard, during 2009–10 the NBA has driven forward a range of relevant projects and initiatives.

The *Criteria for the clinical use of IVIg in Australia* are now undergoing formal review. The creation of the suite of National Health and Medical Research Council/Australian and New Zealand Society of Blood Transfusion *Patient blood management guidelines*, which will replace the 2001 *Clinical practice guidelines on the use of blood components*, is well under way. These new guidelines will be clinical scenario based, not product based. The consultative draft of the critical bleeding module of these guidelines has already been released. Peri-operative, medical, intensive care, obstetric, paediatric and neonatal sections are soon to follow. A major NBA national Patient Blood Management Project, which includes a focus on overall anaemia management and transfusion alternatives consistent with a number of related international practice initiatives, has also commenced.

Monitoring and analysis of blood transfusion-related adverse events has taken a major step forward with the implementation of the Australian National Haemovigilance Program and reporting under the auspices of NBA's Haemovigilance Advisory Committee. A standardised national haemovigilance data dictionary has been created. Australia is now a full member of the International Haemovigilance Network, and the second national *Australian Haemovigilance Report*, with amalgamated, standardised national data, became available.

Blood and blood product ordering, audit interfaces and tools, including the Australian Bleeding Disorders Registry have been implemented, and governments will soon decide on the national approach to the Ordering and Receipting Blood System. The NBA's new business intelligence capabilities, which integrate various sources and streams of product and transfusion-related data, offer new opportunities for transfusion-related data analysis and review in the future.

The ultimate aim is to have a blood supply system that is driven by the details of informed clinical demand and, importantly, by patient outcome data.

I wish to thank Dr Turner, the NBA Executive Team and all the NBA staff for their hard work, support and enthusiasm throughout the year. I am very grateful to all of my clinical colleagues, in various parts of the health sector, for their major contributions to key NBA projects, and for their expert guidance, input and advice. Finally, I would like to acknowledge Dr Joanne Pink, Chief Medical Officer of the Blood Service, for her ongoing commitment to collaboration and partnership between our organisations.

Dr Chris Hogan
Principal Medical Officer
National Blood Authority

1.4 AGENCY OVERVIEW

The National Blood Authority, an Australian Government agency within the Health and Ageing portfolio, is responsible for contributing to ensuring the adequate, safe, secure and affordable supply of blood and blood related products.

The *National Blood Authority Act 2003* and the National Blood Agreement outline the role of the NBA. The NBA:

- works with jurisdictions to determine the clinical requirements for blood and blood products to meet national needs, and develops an annual supply plan and budget
- negotiates and manages national contracts with suppliers of blood and blood products to obtain the products needed
- assesses blood supply risk and engages in contingency planning for risks arising in the sector and impacting on the sector
- supports the work of the jurisdictions to improve the way blood products are used—including by developing and facilitating strategies and programs that will improve the safety, quality and effectiveness of blood usage, particularly in the areas of national standards, guidelines and data provision
- provides expert advice to support government policy development, including on identification of emerging risks, developments, trends and new opportunities
- manages the evaluation of proposals for blood sector improvements, including proposals for new products, technologies and system change
- provides secretariat support to the Jurisdictional Blood Committee.

The NBA has developed a business delivery model that is underpinned by a high level of expertise in both the global and the domestic blood sector. As a result, the NBA is a well-informed purchaser and policy advisor. In addition, the NBA has built extensive and effective networks of clinical and blood sector experts and information flows so that the agency can maintain awareness of the clinical and business environments and how they may change in the future.

The NBA's priorities and processes are to a large extent determined by the National Blood Agreement, which was approved by the Australian Health Ministers Conference in November 2002. The policy objectives of the National Blood Agreement are summarised in Appendix A1.

1.5 THE AUSTRALIAN BLOOD SUPPLY CHAIN

To understand how these functions are implemented, this section provides a brief description of the blood sector and the overall governance framework for the sector.

What are blood products and how are they used?

Fresh blood contains red blood cells, white cells and platelets suspended in a straw-coloured liquid known as plasma. When a blood donor gives blood, they can provide this as a whole blood donation, a plasma only or a platelet only donation.

While whole blood transfusions are still used in certain circumstances today, it is a more generally accepted practice to administer the separated, concentrated components of blood, as in most cases these can be stored for longer periods and delivered more rapidly than whole blood. Processing blood into components provides tailored treatment for patients and maximises the use of blood donations.

Fresh blood products (red cells, platelets and fresh frozen plasma) are used in the treatment of medical conditions such as cancer and heart, stomach, bowel, liver and kidney disease. Fresh products are also used during and after surgery and to treat people who suffer traumatic incidents such as accidents and burns.

Many blood products are made from the plasma component of blood. Plasma contains a large number of proteins, each of which performs a different role within the blood. Since the 1940s, it has been possible to extract different proteins from plasma on a large scale. This is commonly referred to as plasma fractionation. In Australia, CSL Limited carries out these fractionation processes on plasma collected by the Blood Service and provides blood products to meet the needs of the Australian health sector.

Proteins isolated by fractionation processes are made into products to treat specific diseases. For example, albumin is used to replace blood or fluid lost by a patient following trauma, such as a car accident or major burns. Clotting factors such as Factor VIII and Factor IX are used to treat haemophilia A and B.

Immunoglobulins are one of the most important mechanisms the body has to protect itself against infections. If the patient has depleted quantities of immunoglobulins in their blood, immunoglobulin concentrates can be used to replace them. Immunoglobulin concentrates are widely used, for example, in the treatment of immune deficiencies in cancer patients undergoing chemotherapy, in a range of debilitating conditions or for immune disorders.

Some blood products are manufactured from non-human components using genetic engineering methodologies. These are called recombinant products and are alternatives to some fractionated plasma products. The different types of blood products are illustrated in Figure 1.1.

FIGURE 1.1 *Blood and its components*

Blood sector funding

Australia's blood sector is funded by the Australian and state and territory governments, with contributions of 63 per cent and 37 per cent respectively. In 2009–10, governments provided $872.8 million to cover actual demand for blood and blood related products (see Table 1.1). Since the establishment of the NBA, governments have spent $4,613.2 million on blood and blood related products. Table 1.2 shows government funding for the operation of the NBA over the same period.

TABLE 1.1 *Government funding for the supply of blood and blood related products, 2003–04 to 2009–10*

YEAR	AMOUNT ($M)	GROWTH (%)
2003–04	$460.5	–
2004–05	$536.8	16.6
2005–06	$577.4	7.6
2006–07	$639.4	10.8
2007–08	$719.5	12.5
2008–09	$806.8	12.1
2009–10	$878.8*	8.9
Total	**$4,619.2**	**11.4 (average)**

* Does not include $6 million of interest monies allocated by the Commonwealth to the Special Account

TABLE 1.2 Government funding for the operation of the NBA, 2003–04 to 2009–10

YEAR	AMOUNT ($M)	GROWTH (%)
2003–04	$7.4	–
2004–05	$8.4	12.7
2005–06	$10.4	24.1
2006–07	$10.1	-2.6
2007–08	$9.6	-4.8
2008–09	$9.2	-4.9
2009–10	$8.9	-3.3

Blood sector stakeholders

The NBA manages the national planning and purchasing of blood and blood related products in close cooperation with a number of stakeholders. The roles and responsibilities of the key stakeholders in the Australian blood sector are outlined below.

Australian, state and territory governments

As signatories to the National Blood Agreement, the Australian, state and territory governments are responsible for:

- establishing the policy framework and specific policies relating to the national blood supply
- overseeing the NBA's management of the blood supply arrangements
- fostering the development and implementation of best-practice systems to promote efficient use and minimal wastage of blood and blood related products
- providing information on demand for blood and blood related products
- managing local issues.

Therapeutic Goods Administration

The Therapeutic Goods Administration is the regulator for blood and blood related products in Australia. It is responsible for:

- regulating the efficacy and safety of blood and blood related products under the *Therapeutic Goods Act 1989*
- auditing supplies against good manufacturing practice
- issuing product recalls
- issuing modifications to safety standards
- issuing directives such as those relating to donor deferral.

Suppliers of blood and blood products in Australia

The NBA contracts with a number of suppliers for the provision of blood and blood related components and products including:

- the Blood Service, which collects fresh blood from voluntary donors
- CSL Limited, which fractionates plasma from blood collected by the Blood Service and supplies a range of plasma products.

During the year, the NBA has held contracts with suppliers for the provision of blood and blood related products under standing offer arrangements with:

- CSL Limited, Octapharma Australia Pty Ltd and Lateral Grifols Pty Ltd for the provision of overseas-sourced intravenous immunoglobulin (IVIg)
- Baxter Healthcare Pty Ltd, Wyeth Australia Pty Ltd and Novo Nordisk Pharmaceuticals Pty Ltd, for the provision of a range of imported plasma-derived and recombinant blood products
- CSL Limited, Lateral Grifols Pty Ltd, Ortho-Clinical Diagnostics Inc (USA) and Abacus ALS (formerly Australian Laboratory Services), for the supply of diagnostic reagents.

Figure 1.2 shows the location of these stakeholders in the blood supply chain.

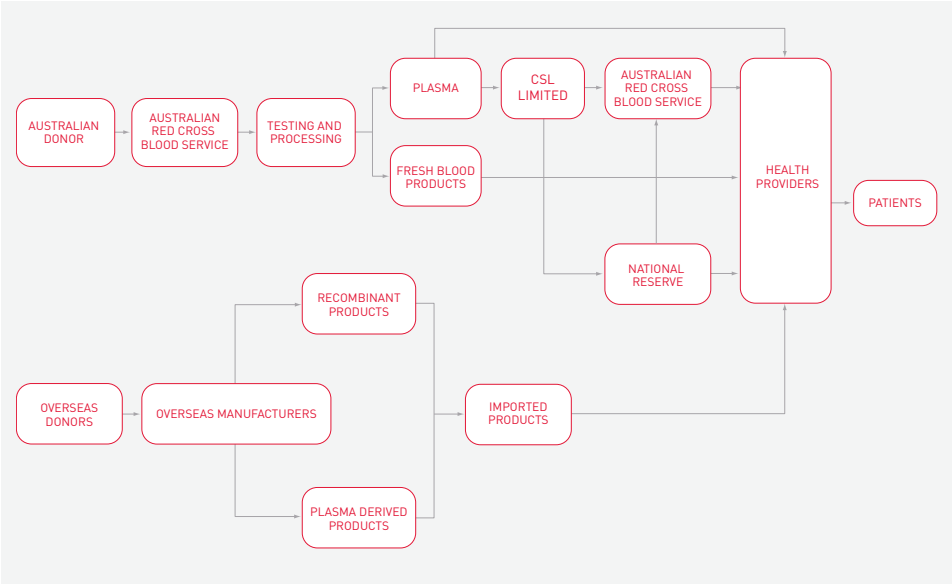


FIGURE 1.2 *The Australian blood supply chain*

Blood sector governance

The key governing bodies in the Australian blood sector and their roles and relationships with each other are set out in the National Blood Agreement and the *National Blood Authority Act 2003*, and illustrated in Figure 1.3.

Australian Health Ministers Conference

The Australian Health Ministers Conference is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates. In 2009–10 health ministers:

- noted a progress report on the implementation of the recommendations of the report on the Blood Service KPMG business study
- approved the 2010–11 National Supply Plan and Budget
- approved the terms of reference and associated arrangements for an administrative review of the national blood arrangements.

Minister for Health and Ageing

Under the National Blood Authority Act 2003 the Minister for Health and Ageing, the Hon Nicola Roxon MP, is responsible for issuing policy principles, the appointment of the NBA Board and General Manager and for determining additional functions of the NBA. The Minister carries out these statutory roles with endorsement from all health ministers in the Australian Health Ministers Conference. The Hon Mark Butler, Parliamenatry Secretary to the Minister for Health and Ageing had executive responsibility for the NBA within the Australian Government health portfolio.

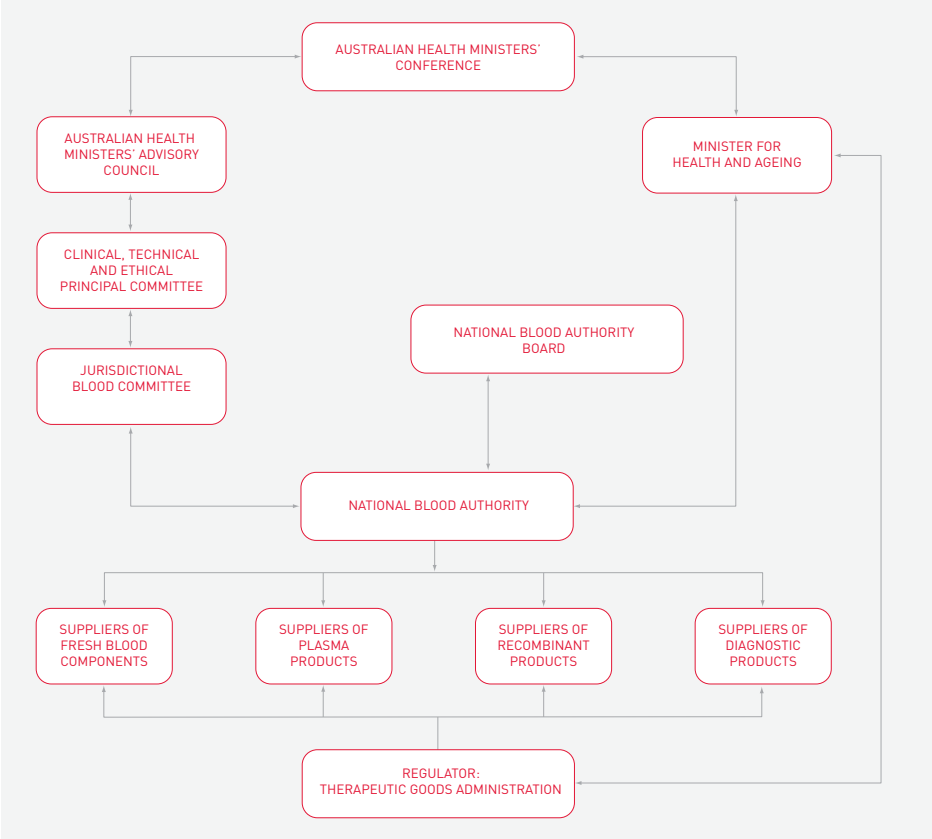


FIGURE 1.3 *Governance structure of the Australian blood sector*

Australian Health Ministers Advisory Council

The Australian Health Ministers Advisory Council provides support to the Australian Health Ministers Conference. It advises the health ministers on strategic matters relating to the coordination of health services across the nation and, as necessary, with New Zealand. The council considers blood sector matters referred to it by the Jurisdictional Blood Committee through the Clinical, Technical and Ethical Principal Committee and reports, as necessary, to the Australian Health Ministers Conference. The council has no statutory power and decisions are reached by consensus.

Clinical, Technical and Ethical Principal Committee

The Clinical, Technical and Ethical Principal Committee was established in 2006 to provide advice to the Australian Health Ministers Advisory Council on a range of issues, such as:

- clinical, technical and medico-ethical developments that are likely to affect more than one jurisdiction
- options for ongoing coordination of the clinical and technical services that are managed on a national basis
- the appropriateness, effectiveness and safety of clinical and technical developments and any policy implications arising from such issues
- the impact of clinical and technical developments on the delivery and management of health care and other services
- the impact of these developments outside the health care sector.

Jurisdictional Blood Committee

Australian, state and territory governments are represented on the Jurisdictional Blood Committee which was established by the National Blood Agreement in 2003. The committee is the conduit between governments and the NBA. It represents the Australian, state and territory governments' positions on blood policy, demand, supply planning and product distribution, funding and evidence-based approaches to emerging products, services and technologies. It oversees the NBA's role in blood supply contracting. It is also the primary body responsible for providing advice and support on these matters to the Australian Health Ministers Conference through the Clinical, Technical and Ethical Principal Committee (of which it has been a subcommittee since September 2006) and the Australian Health Ministers Advisory Council. Members of the committee serve on various NBA committees and working groups and are a highly respected and valuable source of advice and expertise.

The members of the committee at 30 June 2010 were:

Ms Mary McDonald (Chair)	Commonwealth
Ms Joan Bedford	Western Australia
Ms Donna Burton	Commonwealth
Ms Nicole Cameron	Northern Territory
Dr Gina Clare	Queensland
Mr Bill Heiler	New South Wales
Ms Susan Ireland	South Australia
Dr Eddie O'Brien	Australian Capital Territory
Mr Tony Sansom	Tasmania

As at 30 June 2010 Victoria was represented by Ms Karen Botting as a proxy.

Outcome and program structure

The NBA's performance obligations are determined by the Agency Outcome and Program Group, as reported in the Department of Health and Ageing Portfolio Budget Statements 2009–10. Parts 2, 3 and 4 provide details on the NBA's performance against these key performance indicators and other specific activities in 2009–10.

PART TWO
PERFORMANCE BY OUTCOME AND PROGRAM

1 UNIT OF FRESH WHOLE BLOOD IN COAGULANT

- HAEMOGLOBIN CONTENT >45G/UNIT
- BAR CODES CONTAIN INFORMATION ABOUT THE SOURCE OF THE DONATION AND OTHER MANUFACTURING DETAILS

PART TWO SUMMARISES THE NATIONAL BLOOD AUTHORITY'S PORTFOLIO BUDGET STATEMENTS OUTCOME AND PROGRAM STRUCTURE IN 2009–10 AND OUR PERFORMANCE AGAINST QUANTITATIVE DELIVERABLES AND INDICATORS SET OUT IN THE PORTFOLIO BUDGET STATEMENTS.

2

2.1 SUMMARY OF AGENCY PBS OUTCOME AND PROGRAM STRUCTURE

The National Blood Authority operates as a single agency outcome and single program, as specified in the Department of Health and Ageing Portfolio Budget Statements 2009–10.

OUTCOME 1	PROGRAM 1.1
Access to a secure supply of safe and affordable blood products, including through national supply arrangements and coordination of best practice standards within agreed funding policies under the national blood arrangements.	National blood agreement management.

2.2 PERFORMANCE AGAINST QUANTITATIVE DELIVERABLES AND INDICATORS

The Portfolio Budget Statements specified deliverables and key performance indicators for assessing the NBA's performance. Tables 2.1 and 2.2 show our performance against quantitative deliverables and key performance indicators, respectively.

TABLE 2.1 Quantitative key performance indicators for Program 1.1

QUANTITATIVE INDICATORS	2009–10 BUDGET TARGET	2009–10 ACTUAL PERFORMANCE	COMMENTS
Supply of blood and blood products			
Cost-effectiveness of the management of the National Blood Agreement. Measured by comparison of administration costs with the national supply plan and budget.	1.4%	1.02%	The cost of managing the National Blood Agreement has remained well within the target figure
Variance between actual and NBA estimated total demand for supply of products.	<5%	3.2%	Final actual demand showed very small variance to the plan approved by ministers.
Risk management and sector performance improvement			
Number of days the National Blood Supply Contingency Plan is activated for plasma and recombinant products.	0	0	The National Blood Supply Contingency Plan was not required to be activated for plasma and recombinant products in 2009–10.

TABLE 2.2 Quantitative deliverables for Program 1.1

QUANTITATIVE DELIVERABLES	2009–10 BUDGET TARGET	2009–10 ACTUAL PERFORMANCE	COMMENTS
Supply of blood and blood products			
Number of blood supply contracts managed	13	14	The NBA managed 14 blood and blood related supply contracts throughout 2009–10. There were some changes in the specific contracts during the year.
Appropriate patient blood management and safe use of blood and blood products			
Number of National Health and Medical Research Council product guidelines produced	2	0	Program delayed due to systematic reviewer closing its business and the need to engage new provider. Guidelines on track for issue in 2010–11.

Assessment against qualitative deliverables and key performance indicators are highlighted in the detailed accounts of the NBA's activities contained in Parts 3 and 4.

Part 3 describes our work in supply planning, managing blood and blood related supply contracts and arrangements, our risk management strategies, the ways we are driving sector performance improvement, and how we are monitoring and improving the use of blood and blood products.

PART THREE
STRATEGIC DIRECTIONS

HIGH VOLUME CENTRIFUGE IN ACTION
AT THE BLOOD SERVICE

- SPINS AT A VARIOUS SPEEDS TO A MAXIMUM OF 4500 REVS PER MINUTE TO SEPARATE WHOLE BLOOD INTO ITS COMPONENTS
- 6 PLACE SWING OUT WIND SHIELD ROTOR
- SET OF 6 CARRIERS TO CARRY 1 BLOOD BAG EACH

PART THREE CONTAINS AN ASSESSMENT OF HOW THE NATIONAL BLOOD AUTHORITY PERFORMED AGAINST THE THREE KEY STRATEGIC DIRECTIONS IDENTIFIED IN THE PORTFOLIO BUDGET STATEMENTS 2009–10: TO ENSURE THE SUPPLY OF ALL REQUIRED BLOOD AND BLOOD PRODUCTS THROUGH EFFECTIVE PROCUREMENT AND MANAGEMENT OF PRODUCT AVAILABILITY; TO IMPLEMENT BLOOD SECTOR POLICY FOR THE MANAGEMENT OF RISK AND SECTOR PERFORMANCE IMPROVEMENT; AND TO FACILITATE APPROPRIATE PATIENT BLOOD MANAGEMENT AND SAFE USE OF BLOOD PRODUCTS.

3

3.1 SUPPLY OF BLOOD AND BLOOD PRODUCTS

The NBA delivers security of supply of blood and blood products through:

- developing and monitoring the National Supply Plan and Budget
- procuring and managing blood supply contracts and arrangements, including for fresh blood components, local and imported plasma-derived and recombinant products and diagnostic reagents
- evaluating proposals to change products on the National Product Price List determined by the Australian Health Ministers Conference.

KEY PERFORMANCE INDICATOR	MEASURED BY
Management and coordination of Australia's blood supply in accordance with the National Blood Agreement between the Australian, state and territory governments.	The level of satisfaction expressed by all funding jurisdictions with planning, management and coordination of blood supply in 2009–10: 80 per cent of respondents were fully satisfied and 20 per cent were unsure.

National Supply Plan and Budget

During 2009–10, 100 percent of demand was met at all times and there were no reported shortages of product provided through the national supply plan.

The NBA's key role is to coordinate the annual National Supply Plan and Budget, along with the National Product Price List, for approval by health ministers. This is achieved by:

- working with jurisdictions to establish the demand for products
- collecting data on product issued and reporting to jurisdictions against the approved supply plan
- making continual improvements to the supply planning process, taking into account demand information
- intensively managing products if they are in short supply.

The NBA streamlined the development of the National Supply Plan and Budget during the year. In particular we enhanced our capacity for data collection and subsequent analysis, including analysis of demand factors at a jurisdictional level. For example, jurisdictions accepted a new methodology for assessing variations within the year for clotting factors. The end-of-year analysis for 2009–10 indicated that, for many products, this modelling resulted in minimal variance against actual issues. The model should provide greater accuracy in planning future demand.

In response to a satisfaction survey conducted with the Jurisdictional Blood Committee, jurisdictions have also identified several areas of improvement that we will pursue in 2010–11, including development of clear variance tolerances.

The National Supply Plan and Budget for 2010–11 was endorsed by the Jurisdictional Blood Committee in December 2009 and approved by the Australian Health Ministers Conference in April 2010.

The 2009–10 budget approved by health ministers for the supply and management of blood and blood related products and services was $910.8 million, of which $456.1 million was for fresh blood products and plasma collection and $426.9 million for plasma and recombinant products. Figure 3.1 shows the allocation of this funding to each product category. The list of products the NBA purchased from suppliers to meet this demand is provided in Table 3.1.

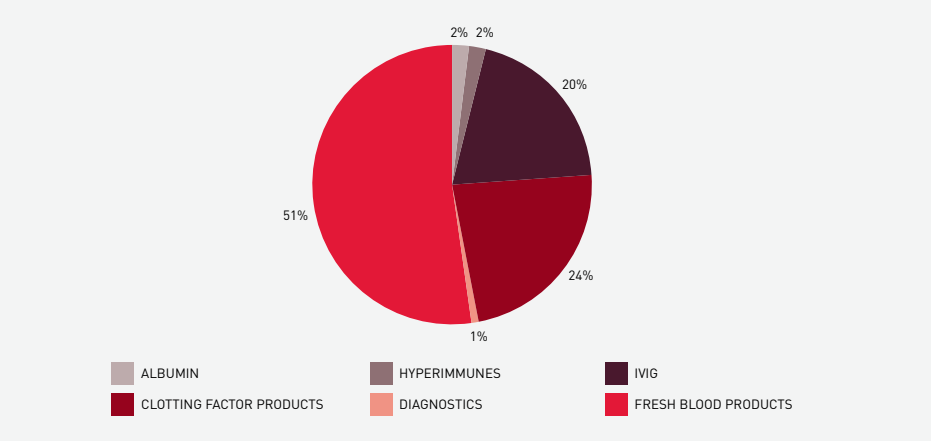


FIGURE 3.1 *Funding by product category, 2009–10*

TABLE 3.1 Blood and blood related products purchased, by supplier, 2008–09 and 2009–10

SUPPLIER	PRODUCTS PURCHASED	2008–09 ($M)	2009–10 ($M)
CSL Ltd	Plasma products – albumin products – immunoglobulin products (including IVIg and hyperimmune products) – plasma-derived clotting factors Diagnostic reagent products – blood grouping sera – reagent red cell products Imported Blood Products – Factors XI and XIII – IVIg standing offer Management of National Reserve	162.09	186.16
Australian Red Cross Blood Service	Fresh Blood Products – whole blood – red blood cells – platelets – clinical fresh frozen plasma – cryoprecipitate – plasma for fractionation	432.62	456.12
Baxter Healthcare Pty Ltd	Imported Blood Products – Recombinant Factor VIII – Protein C – Factor VII concentrate – Factor Eight Inhibitor Bypass Agent (FEIBA) – WinRho	84.09	90.62
Wyeth Australia Pty Ltd	Imported Blood Products – Recombinant Factor VIII – Recombinant Factor IX	48.65	48.94
Novo Nordisk Pharmaceuticals Pty Ltd	Imported Blood Products – Recombinant Factor VIIa	17.40	26.42
Octapharma Pty Ltd	Imported Blood Products – IVIg Standing Offer	46.90	48.69
Lateral Grifols Pty Ltd (formerly DiaMed Australia Pty Ltd)	Diagnostic Reagent Products – blood grouping sera – reagent red cell products	0.92	0.81
Ortho-Clinical Diagnostics (Johnson & Johnson Company)	Diagnostic Reagent Products – blood grouping sera – reagent red cell products	0.47	0.43
Abacus ALS Pty Ltd	Diagnostic Reagent Products – blood grouping sera – reagent red cell products	0.04	0.04
TOTAL		**793.18**	**858.23**

In consultation with jurisdictions, in February 2010 the NBA reviewed the National Supply Plan and Budget as part of the mid-year review process for 2009–10. This provided an opportunity for jurisdictions to review and adjust their funding requirements in the light of the demand observed in the preceding six months.

The total cost of products issued to all jurisdictions for 2009–10 amounted to $860.4 million. This represents an increase of $46.4 million compared with 2008–09. As shown in Figure 3.2, in 2009–10 there was a significant reduction in issues of product against the plan although it should be noted that in 2009–10, the plan reflected higher supply levels which had been predicted on the basis of the level of deliveries in 2007–08, and the mid-year analysis of 2008–09.

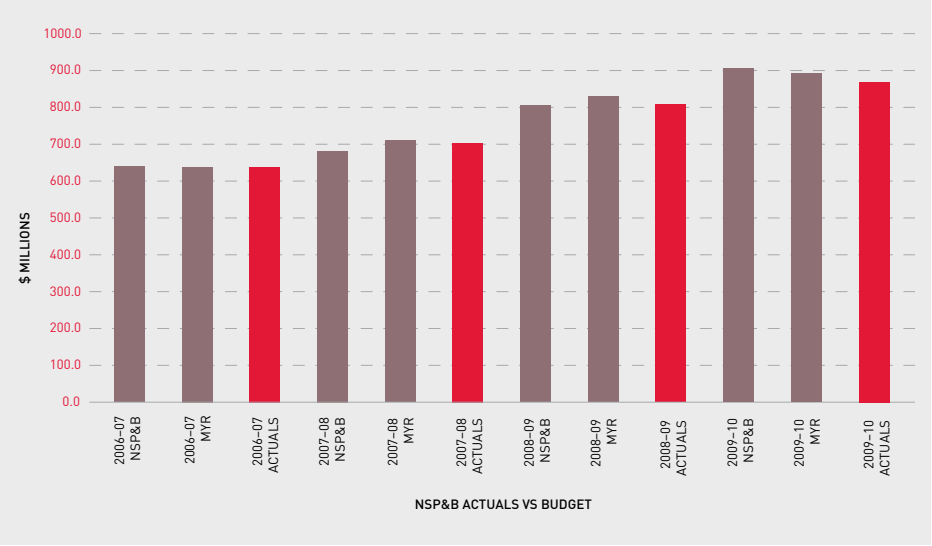


FIGURE 3.2 *Actual issues performance against the National Supply Plan and Budget and the mid-year review, 2006–07 to 2009–10*

Fresh blood

In the seven years to 2009–10, funding for fresh blood and plasma collections has increased from $247.8 million to $456.1 million. Of this, $91.4 million is due to price increases, which have averaged 7.5 per cent a year. Increased demand for fresh products—principally red cells, platelets and plasma for fractionation—has been running at 4.7 per cent a year, resulting in additional expenditure of $57.8 million. A further $63.6 million is a consequence of the introduction of government-approved quality and safety measures such as universal leucodepletion of platelets and red cells, and bacterial testing for platelets. These safety measures have resulted in an additional increase in expenditure averaging 5.2 per cent a year. The combined effect of these measures on expenditure can be seen in Figure 3.3.

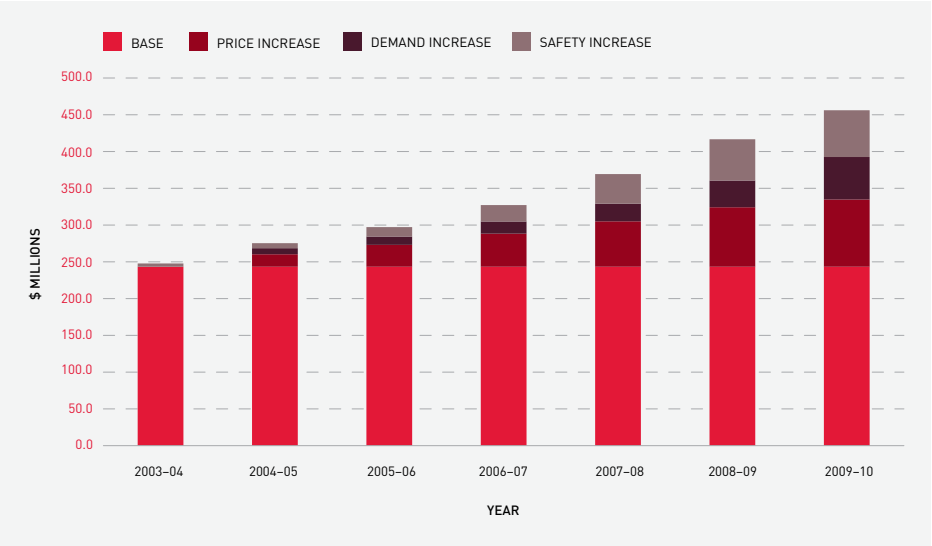


FIGURE 3.3 *Fresh blood expenditure: increases 2003–04 to 2009–10*

The actual supply of fresh blood products for 2009–10 compared with the annual supply estimates agreed by the Australian Health Ministers Conference is highlighted in table 3.2.

TABLE 3.2 *Variance between actual supply of fresh blood components and the annual supply estimates*

		2009–10 NATIONAL OUTCOMES		
		Issues	**Unit variation on supply plan**	**% Variation on supply plan**
Total red cells	Units	795,892	-15,485	-1.9%
Total platelets	Units	128,495	6,920	5.7%
Total clinical FFP	Units	160,813	7,478	4.9%
Plasma for fractionation to CSL	kgs	452,422	1,421	0.3%

Issues of red cells

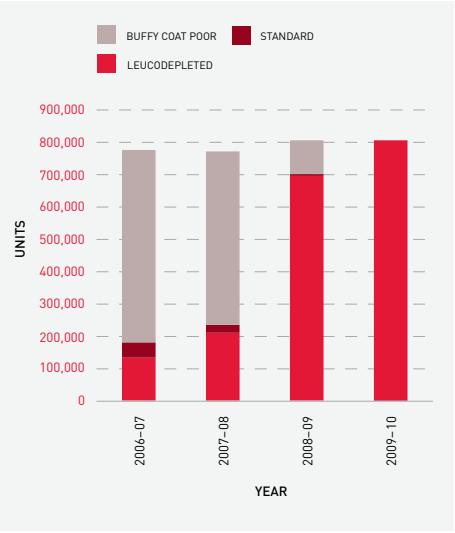


FIGURE 3.4 *Product mix of red cells issued by the Blood Service, 2006–07 to 2009–10*

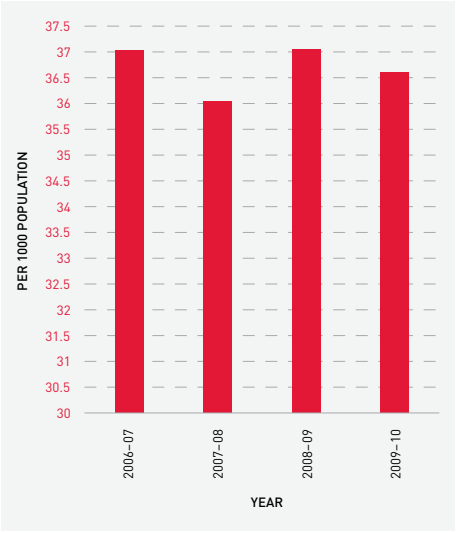


FIGURE 3.5 *Red cells issued per 1000 head of population, 2006–07 to 2009–10*[1]

[1] Calculations using per 1000 head population in all graphs may differ from previous year reporting reflecting the move to a new standardised data source.

In 2009-10, almost all red cells issued were leucodepleted, as is illustrated in Figure 3.4. The volume of red cells issued in 2009-10 was 1.9 per cent less than the National Supply Plan and Budget and demonstrated very minor growth of 0.3 per cent from 2008-09. This minor growth also resulted in a reduction in issues per 1000 head of population from 37 to 36.55, as illustrated in Figure 3.5. For the majority of 2009–10 inventory days remained high for all blood types. Clinical factors that are considered to be currently influencing demand include an increased use of massive transfusion protocols which reduce the volume of red cells used. There was a strong view from all jurisdictions that activities at a state level focusing on reducing red cell demand were starting to take effect.

Issues of platelets

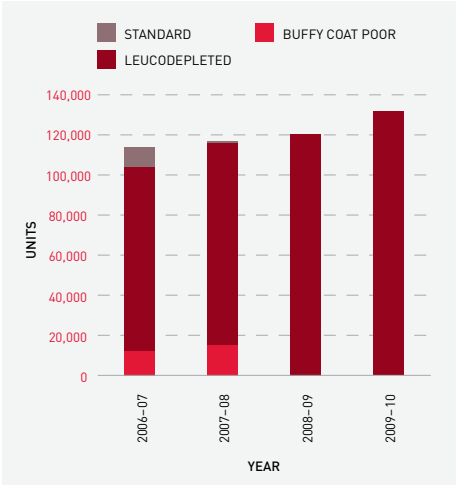


FIGURE 3.6 *Product mix of platelets issued by the Blood Service, 2006–07 to 2009–10*

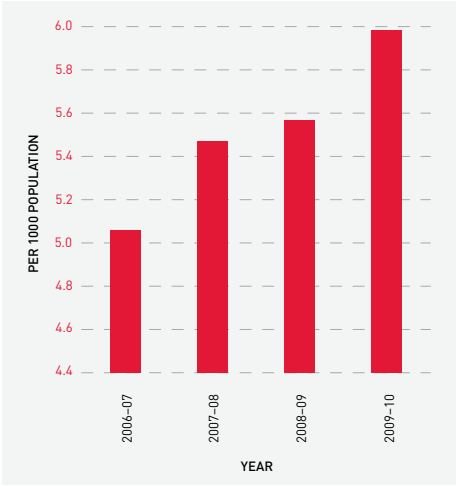


FIGURE 3.7 *Platelets issued per 1000 head of population, 2006–07 to 2009–10*

By contrast, total platelet issue for 2009–10 was six per cent higher than the 2009–10 National Supply Plan and Budget and 8.7 per cent higher than usage in 2008–09. All platelets issued in the year were leucodepleted as illustrated in Figure 3.6. Issues of platelets per 1000 population increased by approximately 8 per cent compared with a 5.56 per cent increase the previous year as illustrated in Figure 3.7. The major change in demand during 2009–10 has been in the mix of whole blood pooled and apheresis platelets: while the plan allowed for a ratio of 55 per cent whole blood pooled to 45 per cent apheresis, the actual issues were 62 per cent whole blood pooled to 38 per cent apheresis. This represents a variation in the estimated demand from Approved Health Providers and is an ongoing focus of discussions with jurisdictions as to the most appropriate balance between clinical requirements and cost impact. Jurisdictional views on the drivers of demand for platelets included an increased use of platelets in massive transfusion protocols, and increases in major surgery in older age groups.

During 2009–10, extensive work was undertaken to develop a more effective model for funding fresh blood components, and this is expected to deliver savings to governments from 2011–12 onward. Details of various aspects of the NBA's contractual arrangements with the the Blood Service in 2009–10 are provided at pages 44 to 53.

The focus of the NBA and the Jurisdictional Blood Committee on improving data on issues of product, and, ultimately, establishing a nationally consistent approach to monitoring the fate-of-product, will provide the core platform from which major initiatives to guide appropriate use and minimise demand increases can be based. Other activities such as the development of principles and guidelines, and improved inventory management are given in pages 47 to 51.

Plasma and recombinant products

Unit price growth for plasma-derived and recombinant blood products has been minimal in the context of international prices. However, strong average growth of 11 per cent per year over the last seven years for haemophilia products and 12 per cent per year for intravenous immunoglobulin (IVIg) has led to increased expenditure on these products. Despite this, the effect of the NBA's continuing commitment to value for money can be seen in Figure 3.8; there has not been any significant increase in prices paid for these products since the inception of the NBA. Figure 3.8 also shows annual savings achieved by current commercial contracts compared with indexed costs of arrangements before the establishment of the NBA.

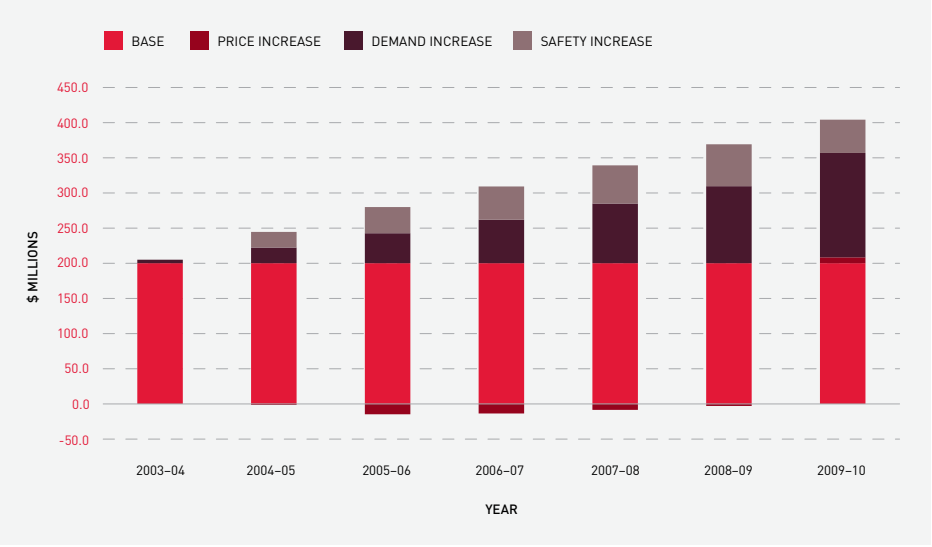


FIGURE 3.8 *Plasma-derived and overseas product expenditure increases, 2003–04 to 2009–10*

Details of the management of plasma-derived and recombinant products are provided a pages 53 to 60.

Issues of clotting factors

There has been considerable growth in supply of recombinant Factor VIII since the change in funding policy in 2004–05, resulting in a competitive market with keen interest from further suppliers. However, in 2009–10 some 14 million fewer IU (international units) were issued compared to the demand anticipated in the plan. There was also a decline of 17 per cent in the amount of plasma-derived FVIII issued in 2008–09. This variation to some extent reflects an adjustment to the over-estimates in the 2008–09 supply plan.

More significantly, however, a range of factors influence the demand for FVIII, including the effects of ageing and increasing longevity of the patient population, more effective treatment with increasing prophylaxis and tolerisation, ability of patients to make wider lifestyle choices, and general increase in body mass. However, particular factors which may influence an apparent slowing in the demand growth rate may include the relative effectiveness of prophylaxis against previous on-demand treatment, oversight and standardisation of treatment regimes, current clinical studies and trials, a reduction in the number of patients on tolerisation, and increasingly sophisticated pharmacokinetic dosing indicators.

Total Factor VIII supply increased moderately by 2.1 per cent over that supplied in 2008–09 (see Figure 3.9), with an increase in issues per 1000 head of population of just 0.6 per cent compared to 3.6 per cent in the previous year (see Figure 3.10).

Advate continues to dominate the market for recombinant Factor VIII (see Figure 3.11).

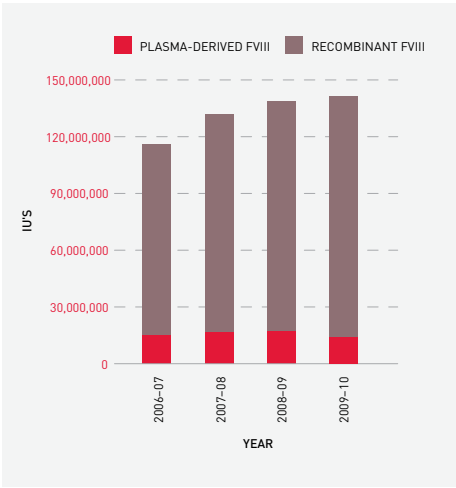


FIGURE 3.9 *Issues of Factor VIII products, 2006–07 to 2009–10*

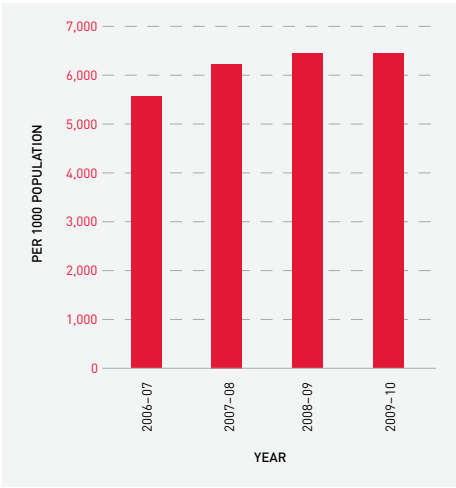


FIGURE 3.10 *Issues of total Factor VIII per 1000 head of population, 2006–07 to 2009–10*

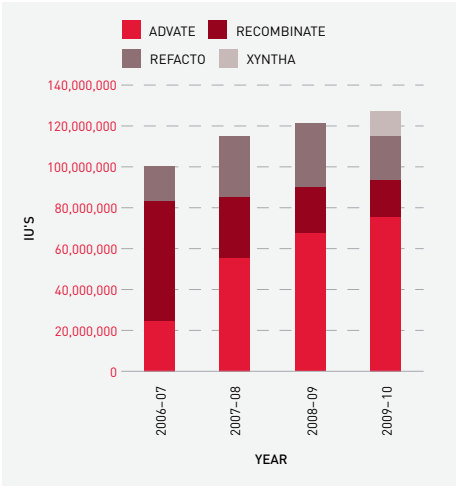


FIGURE 3.11 *Market share of recombinant Factor VIII issues, 2006–07 to 2009–10*

The increase in total demand for Factor IX products observed in previous years continued in 2009–10 across both plasma-derived and recombinant products (see Figure 3.12). Figure 3.13 shows an increase in this year's demand of two per cent to 1,147 units issued per 1000 head of population. This increase is thought to reflect the demand for product as paediatric patients grow (with consequent increase in body mass, size and potential for injury), combined with a population of patients living longer.

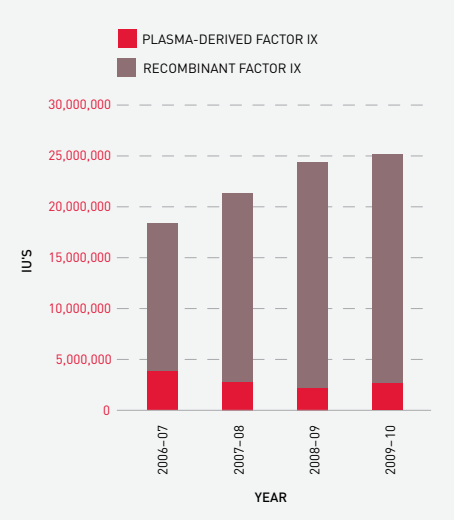


FIGURE 3.12 *Issues of Factor IX products, 2006–07 to 2009–10*

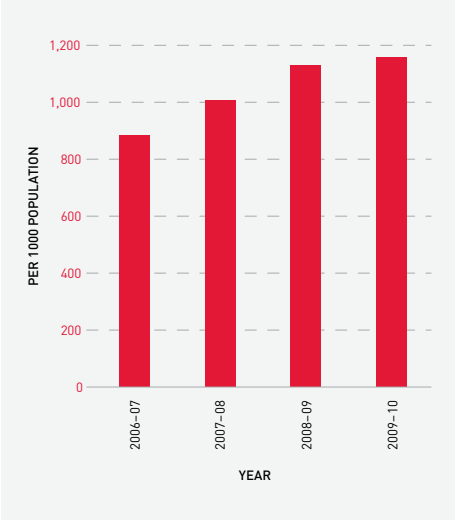


FIGURE 3.13 *Issues of Factor IX products per 1000 head of population, 2006–07 to 2009–10*

Issues of recombinant Factor VIIa (rFVIIa), for treatment approved under the national blood arrangements, increased significantly in 2009–10 (see Figure 3.14). FEIBA also showed a moderate increase in demand in the reporting year (see Figure 3.15). Demand for rFVIIa and FEIBA is complex; a small number of patients using the products leads to demand being dependent on the health status of very few patients. In 2009–10 the Australian Haemophilia Centre Directors' Organisation agreed to work with the NBA to develop a risk-based model of likely demand for rFVIIa and FEIBA based on the analysis of trends in inhibitors.

The release of the Australian Bleeding Disorders Registry 2009–10 Annual Report, scheduled for late 2010, will provide improved insights into patterns of use of these products.

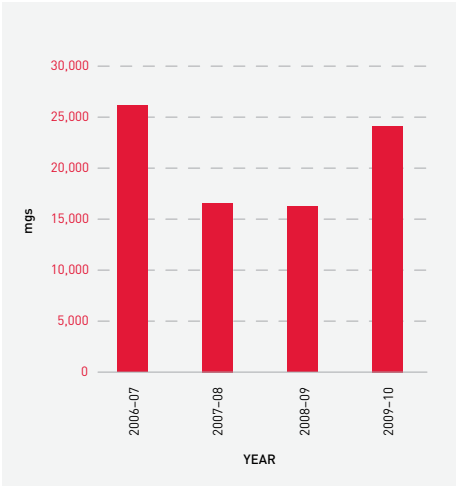


FIGURE 3.14 *Issues of recombinant Factor VIIa, 2006–07 to 2009–10*

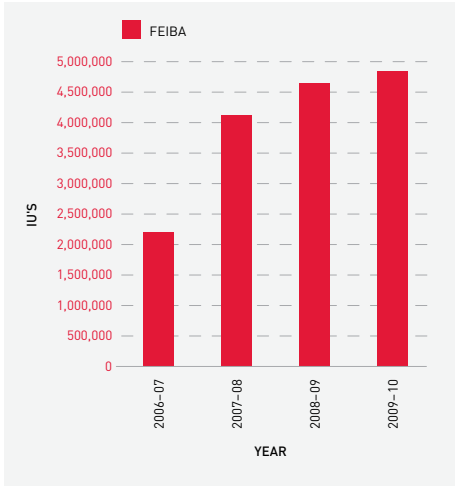


FIGURE 3.15 *Issues of FEIBA, 2006–07 to 2009–10*

Issues of Intravenous immunoglobulin (IVIg)

The overall rate of growth in issues of IVIg increased during 2009–10, from a planned rate of 10.3 per cent to an actual rate of 11.6 per cent. This was a higher rate of growth than 2008–09, but still noticeably lower compared to previous years (13.9 per cent in 2006–07 and 13.4 per cent in 2007–08— see Figure 3.16). Nevertheless, the issue of IVIg per 1000 head of population increased from 109.8 grams in 2008–09 to 120.7 grams in 2009–10 as illustrated in Figure 3.17. There are thought to be several factors contributing to this trend including: the increasing weight of the population, which necessitates higher dosage requirements per patient; and increases in the number of episodes of treatment. Research currently underway in the United Kingdom on adjusting dosage rates to body weight could influence future patterns of demand; this is being monitored closely in Australia.

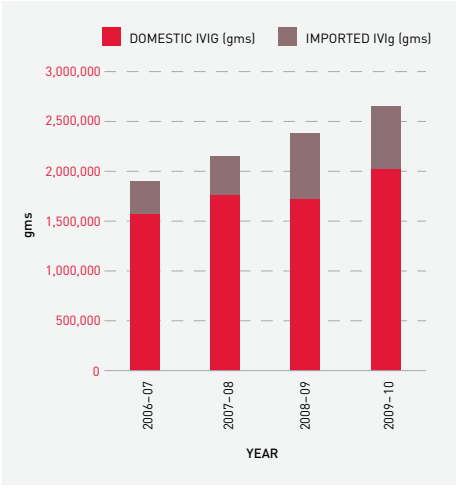


FIGURE 3.16 *Issues of IVIg products, 2006–07 to 2009–10*

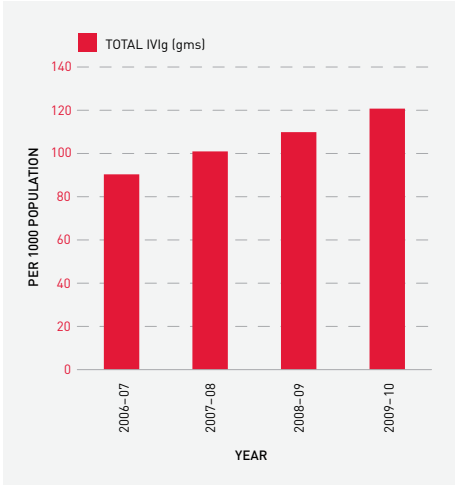


FIGURE 3.17 *Issues of IVIg over 1000 population, 2006–07 to 2009–10*

It would appear that demand for IVIg in some indications decreased following the implementation of the *Criteria for the clinical use of intravenous immunoglobulin in Australia* early in 2008. For example, issues for some indications such as Specific Antibody Deficiency has decreased by almost 50 per cent since 2008–09, and there has been a steady decreasing trend in the proportion of use to treat idiopathic thrombocytopenic purpura (ITP) in adults and Guillian-Barré syndrome. The proportion of use to treat primary immunodeficency diseases decreased from 2008–09. However, the relative proportions used for acquired hypogammaglobulinaemia and chronic inflammatory demyelinating polyneuropathy continued to increase. This is illustrated in Figure 3.18 which graphs the top ten uses of IVIg by indication per year.

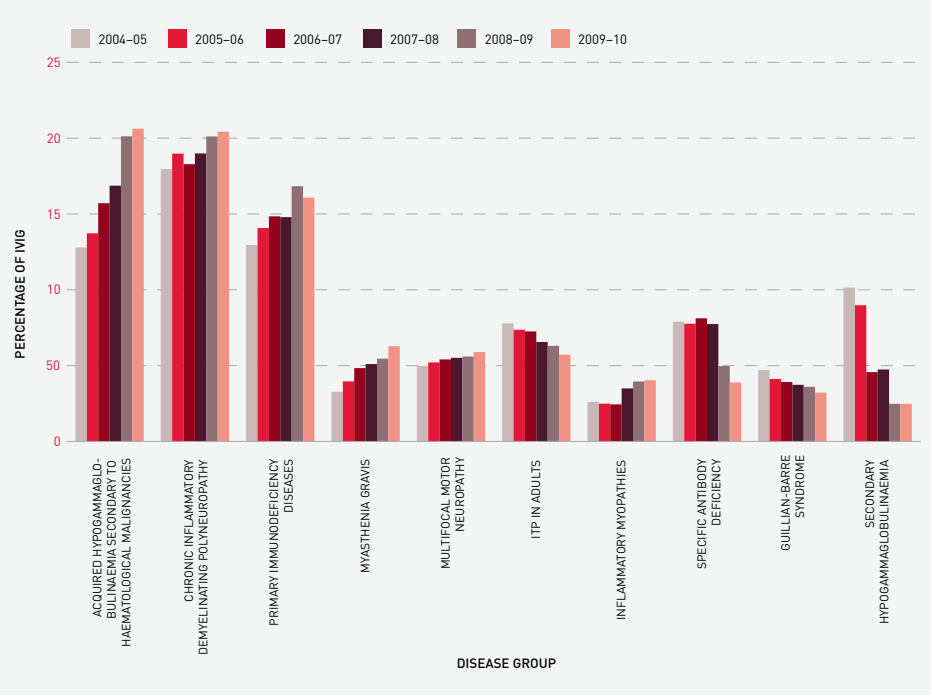


FIGURE 3.18 *Top 10 uses of IVIg, 2004–05 to 2009–10 by disease group*

Management of blood supply contracts and arrangements

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Manage the performance of contracted suppliers through 2009–10 through monitoring outputs and key performance indicators, and auditing supplier reports.	Largely met. Monitoring and evaluation of supplier key performance indicators confirms: • strong achievement by the Blood Service against all key performance indicators • achievement by CSL Limited against all targets; reporting against new agreement key performance indicators in transition • minor issues with shelf life on delivery and in-country reserve levels by other suppliers although no impact on patients; this will be carefully monitored in 2010–11 to ensure improvement.

A key challenge has been to demonstrate value for money in accordance with the objectives of the National Blood Agreement in an environment in which the NBA deals with a sole or limited range of suppliers.

In 2009–10 the NBA managed 14 blood and blood product supply contracts and arrangements. The NBA entered into one new contract during the year with CSL Limited, and seven existing contracts were subject to variation and extension. NBA performance in this key strategic area ensures continued supply security, value for money and affordability of the blood supply. Activities included:

- management of Australia's fresh blood component requirements through:
  - the Deed of Agreement with the Australian Red Cross Society, including negotiation of an extension, to 30 June 2011
  - continued implementation of the business study recommendations and related business improvement projects required of the Blood Service by ministers
  - development of an output based funding model for implementation on 1 July 2010
  - finalisation of the funding agreement for the Victoria and Tasmania principal blood manufacturing site
- management of Australia's plasma product and recombinant product requirements through:
  - management of the Plasma Products Agreement with CSL Limited, and negotiation and management of the new the CSL Australian Fractionation Agreement, operating from 1 January 2010
  - management and extension of contracts for the provision of imported plasma and recombinant products
  - management and agreement to extend contracts for the provision of diagnostic reagents required by the sector
  - preparation for new tender processes for imported plasma and recombinant products, and diagnostic reagents.

Management of fresh blood supply arrangements

The NBA manages the relationship with the Blood Service—the sole supplier of fresh blood components in Australia—and is responsible for negotiating and managing the Deed of Agreement with the Australian Red Cross Society. The NBA also manages a number of projects involving the Blood Service and provides secretariat and project management support for the National Managed Fund (see page 52).

Australian Red Cross Blood Service funding and product mix

Actual funding for the Blood Service increased from $417.2 million in 2008–09 to an agreed budget of $456.1 million in 2009–10 (see Table 3.3).

TABLE 3.3 Blood Service: annual funding 2003–04 to 2009–10

YEAR	AMOUNT ($M)	% GROWTH
2003–04	$247.8	–
2004–05	$277.0	11.8
2005–06	$297.7	7.5
2006–07	$327.1	9.9
2007–08	$369.1	12.8
2008–09	$417.2	13.0
2009–10	$456.1	9.3
Total	**$2,392.0**	**10.7 (average)**

Australian Red Cross Blood Service supply performance

Supply performance requires the Blood Service to both manage the requirement for donors in an efficient and targeted manner and to convert product received from these donations in the most efficient manner. Governments require the Blood Service to place a priority on developing approaches for increasing its performance in both areas.

The Blood Service continued to perform well against all of the key performance indicators specified in the Deed. Some indicators of particular interest this year are summarised in Table 3.4.

TABLE 3.4 Blood Service: selected key performance indicators, 2009–10

DOMAIN	INDICATOR	PLANNING PARAMETER	ANNUAL RESULT
Donor management	Size of donor base:		
	• Whole blood	525,259	513,803
	• Apheresis plasma	58,802	60,357
	• Apheresis platelet	12,126	11,149
	Frequency of donation, by type		
	• Whole blood	1.97	1.96
	• Apheresis plasma	4.97	4.51
	• Apheresis platelet	3.49	3.35
Supply chain management	Efficiency of collection (conversion to supply)		
	• Whole blood	77.7%	78.1%
	• Apheresis plasma	97.2%	97.1%
Quality and level of service	Overall Approved Health Provider satisfaction with Blood Service	65%	82%
Governance and accountability	Deed reporting requirements	100%	100%

The quantity of plasma for fractionation collected met the annual supply requirement (see Table 3.5). The increase in collections of plasma in 2009–10 was largely achieved through the implementation of the new Council of Europe guidelines introduced in January 2009, which allow for the total average plasma collected from each apheresis donation to be increased. However, the transition to this larger volume has not been as rapid as had been planned, as the Blood Service had to trial variable volumes to meet the optimal amount for their donors. To maintain this increased volume, the Blood Service is now trialling a saline replacement program.

TABLE 3.5 Blood Service plasma volumes collected, 2003–04 to 2009–10

YEAR	VOLUME COLLECTED (TONNES)	VARIATION FROM PREVIOUS YEAR
2003–04	294,521	
2004–05	308,068	4.6%
2005–06	308,348	0.1%
2006–07	329,346	6.8%
2007–08	352,781	7.1%
2008–09	390,707	10.8%
2009–10	452,422	15.8%

Deed of Agreement between the National Blood Authority and the Australian Red Cross Society

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Continue and improve the supply of blood and blood products by agreeing future contractual arrangements with the Australian Red Cross Blood Service by June 2010.	Met. Current deed extended to 30 June 2011. Output based funding model developed, and agreed on 30 June 2010 for implementation from 1 July 2010.

The current Deed of Agreement, with the agreement of the Jurisdictional Blood Committee and the Minister for Finance and Deregulation, was again extended for 12 months from 1 July 2010 to 30 June 2011 to enable the development and implementation of the output based funding model. This had been a key recommendation of the business study.

During 2009–10, work commenced on requirements for the new deed. It is expected that the new deed, to be negotiated during 2010–11, will have a significantly longer term than the current deed. Other associated documents, such as the output-based funding principles, will have durations appropriate to their specific purposes.

Achieving improvements identified by the Australian Red Cross Blood Service KPMG business study

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Implement the recommendations of the independent business study of the Australian Red Cross Blood Service by June 2010.	Met. 33 of the 35 recommendations met, either directly or in the output-based funding model.

On 22 July 2008 the Australian Health Ministers Conference agreed on a combined government response and implementation strategy for the recommendations of the Blood Service KPMG business study. The Australian Health Ministers Conference also directed the Jurisdictional Blood Committee to present progress reports on the implementation of agreed recommendations.

The Australian Red Cross Society and the Blood Service confirmed their commitment to implementing the business study recommendations, which cover five broad areas:

- reviewing Blood Service financial governance arrangements
- improving Blood Service efficiency and effectiveness through better planning
- improving Blood Service financial and capital management
- implementing an output based funding model
- preparing safety business cases.

Progress on improvements recommended in the business study recommendations has been sound, with 33 out of the 35 items completed; those completed this year were directly relevant to negotiating the terms of the output based funding model (see below). A progress report was noted by health ministers in September 2009 and a final scorecard report will be considered by health ministers early in 2010–11.

Savings from operational efficiencies achieved within the Blood Service in 2009–10 included one-off savings and recurrent savings. It has been agreed that funds generated from recurrent operational efficiencies in 2009–10 and 2010–11 will be returned to the jurisdictions in 2011–12 by way of lower product prices. In 2009–10, $3.6 million was achieved in recurrent savings from Blood Service workforce planning initiatives, as part of the change program funding initiatives; this program will continue into 2010–11.

Developing an output based funding model for the Australian Red Cross Blood Service

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Finalise details of the output based funding model for the Australian Red Cross Blood Service contract by June 2010.	Met. Agreement signed on 30 June 2010.

The Business Study identified 10 recommendations which directly relate to the development and implementation of an output based funding model.

The principles for the output based funding model were drafted and agreed with Blood Service management, including agreement on a number of core issues such as an indexation and efficiency dividend, the product and services list, and the financial management risk framework. Final agreement with the Australian Red Cross Society and the Blood Service was achieved in June 2010, with the model to be implemented from 1 July 2010.

Further work will be undertaken in 2010 on the payment regime, funding of the Blood Service's Transfusion Medicine Services, business rules for ordering and delivery, and acceptance of products including product substitution rules. There will also be an independent review of the product cost attribution.

Statement of Expectations for the Australian Red Cross Blood Service 2009–12

During 2009–10, following consultation with the Blood Service, the NBA developed a statement that sets out governments' expectations from their continuing partnership with the Blood Service for a three-year period; this will align with the period covered by the output based funding model. The statement builds on the current deed and the expectations arising from the business study outcomes, and will inform the development of the next deed. It also sets out governments' overarching principles, goals and policies and contains a set of management and accountability principles. The statement will be considered by health ministers early in 2010–11.

The Australian Red Cross Blood Service Strategic Capital Investment Plan

Under the deed, the Blood Service is provided with an agreed capital budget, set at 10 per cent of total operational funds provided. For 2009–10 the actual sum was $41.2 million. Table 3.6 shows the value of the approved annual capital plans from 2006–07 to 2009–10.

TABLE 3.6 Blood Service annual capital plan funding, 2006–07 to 2009–10

2006–07	2007–08	2008–09	2009–10
$29.58 million	$32.96 million	$38.00 million	$41.21 million

These funds are required to be managed through the Strategic Capital Investment Plan. The plan details the capital expenditure that is expected to be required to sustain fixed assets, including to replace assets such as vehicles, laboratory equipment and premises (for example, refurbishments, relocations and new collection sites). The Strategic Capital Investment Plan, which covers a three-year period, is prepared by the Blood Service annually and submitted to the Jurisdictional Blood Committee. Key capital investments funded by governments through the Strategic Capital Investment Plan during 2009–10 include:

- Asset replacement programs
  - collection equipment
  - laboratory and testing equipment
  - office/administrative equipment
  - donor mobiles
  - information and communication technology equipment
  - premises, plant and equipment
  - software upgrades
- Other allocations
  - next generation National Blood Management System
  - Corporate Information Management and Reporting System
  - finance facility costs for fit-out of the new Queensland principal manufacturing site
  - Laboratory Information Management System.

The Blood Service has undertaken extensive work on asset management during 2009–10. It has established a regular review process as a more reliable mechanism for management assurance of its asset replacement program. The NBA monitors the maintenance program for these assets as part of its annual review and through quarterly meetings of NBA and Blood Service Chief Financial Officers.

In addition to the approved annual capital plans, governments agreed to fund, as appropriate, the redevelopment of the principal manufacturing sites in New South Wales and Victoria in order to update and improve the efficiency of the manufacturing capacity of the Blood Service.

The New South Wales and Australian Capital Territory principal site

In April 2008 the Australian Health Ministers Conference gave policy approval for additional funding for the Blood Service to meet building leases and fit-out for a new principal blood-manufacturing site for New South Wales and the Australian Capital Territory.

The three-storey facility will be located at Green Square, a suburb between the Sydney central business district and Kingsford-Smith Airport. Construction began in late June 2009. When completed, the development will comprise 12,450 square metres of purpose-built manufacturing space, at a cost of approximately $188 million. The new facility will be responsible for processing and distributing blood and blood components in New South Wales and the Australian Capital Territory.

The project is tracking to plan, with practical completion expected in January 2011.

OUTPUT BASED FUNDING FOR THE BLOOD SERVICE

DR PIP HETZEL, NATIONAL OPERATIONS MANAGER OF THE BLOOD SERVICE, PRESENTING TO THE JURISDICTIONAL BLOOD COMMITTEE ON INVENTORY LEVELS AND DONOR MANAGEMENT

An output based funding model for the Blood Service moves the financial relationship with the Blood Service to a more accountable basis and aligns this relationship to one more akin to a standard supplier arrangement.

Historically, the Blood Service has been funded on a grant basis (an input model) where Australian governments paid a monthly fee that met the total annual costs of the Blood Service.

During 2009–10, the NBA and the Blood Service worked together to negotiate and develop the details required to support the new model which had been supported in the 2008 KPMG Business Study. The shared and collaborative approach to this project has produced agreed:

- definitions for all products and services to be delivered
- creation of the product costing and attribution processes in year one
- translations of standard product level costs to product prices
- determinations for revenue budgets and cash flows
- risk management arrangements.

The output based funding model has been developed with the objective of a producing a number of key benefits including:

- providing incentives to the Blood Service to increase overall operational efficiency
- increasing incentive for users of products to order only what they need
- providing certainty and forward looking financial management and pricing
- delivering more accurate funding and reduced cross subsidies.

The new funding regime will improve systems accountability and provide greater transparency for jurisdictional budgets. In turn, the model will require hospitals to have greater discipline in their ordering practices.

Agreement was reached on the model in June 2010, and it will be implemented in 2010–11 as part of the Deed of Variation with the Blood Service. The process will have three review points during 2010–11 so that the new Deed, to be negotiated during that year, includes any refinements of the model. The model has a three-year duration and will be reviewed and renegotiated at the end of that time.

The Victoria and Tasmania principal site

In December 2008 health ministers approved in-principle additional funding for the Blood Service over 20 years to meet the costs of building and outfitting leases for a new principal blood-manufacturing site in Melbourne. In May 2009, the Treasurer announced in the 2009–10 Federal Budget that the Australian Government contribution of $120 million for this project (out of a total of $212 million) would be provided as capital over two years through the Health and Hospitals Fund.

The change in the nature of the funding reduced the total cost of the project in the long term but required extensive negotiations during 2009–10 between the NBA, the Blood Service, jurisdictions, the likely developer and the Health and Hospitals Fund to develop alternative arrangements to meet the Blood Service's timetable and to obtain essential policy agreements. The funding agreements were executed on 11 March 2010.

The Principal site is being developed in a former industrial area of inner Melbourne. Construction is well under way with the initial emphasis on extensive land and building remediation work. The project is being monitored by the NBA relative to project and funding milestones and is tracking to schedule with practical completion expected in February 2012. When completed, the facility will be responsible for the manufacture of blood for both Victoria and Tasmania comprising 26 per cent of the nations blood supply.

EXTERNAL SOUTH-WEST CORNER, DEMOLITION STILL UNDERWAY, APRIL 2010

ATRIUM VIEW FROM LEVEL ONE LOOKING EAST, APRIL 2010

As part of the project there is provision in the 2010–11 National Supply Plan and Budget to construct a sample archive facility at the new principal site in Melbourne. The Therapeutic Goods Administration has a regulatory requirement to maintain an archive of samples at a temperature of –15°C for a minimum of 15 months. Sample archives are necessary to enable retesting of samples taken at the time of donation, in the event of a potential or disputed case of a possible transfusion-transmitted infection. The new facility will enable the Blood Service to comply with the Therapeutic Goods Administration's requirements while at the same time reducing capital costs by taking the opportunity to incorporate the sample archiving facility into the new manufacturing site.

National inventory framework

During 2009–10 the NBA and governments discussed with the Blood Service the need to develop a more detailed understanding of the most efficient and effective inventory level holdings for the sector. This was identified as a priority in light of the substantially higher levels of red cell stocks held during the year (Figure 3.19) and the impact this had on age of product when issued. Following concerns expressed by jurisdictions, the Blood Service quarantined all product over 21 days old. This decision was effective in reducing the average age over the year to 9.7 days, well within the performance parameters (see Figure 3.20).

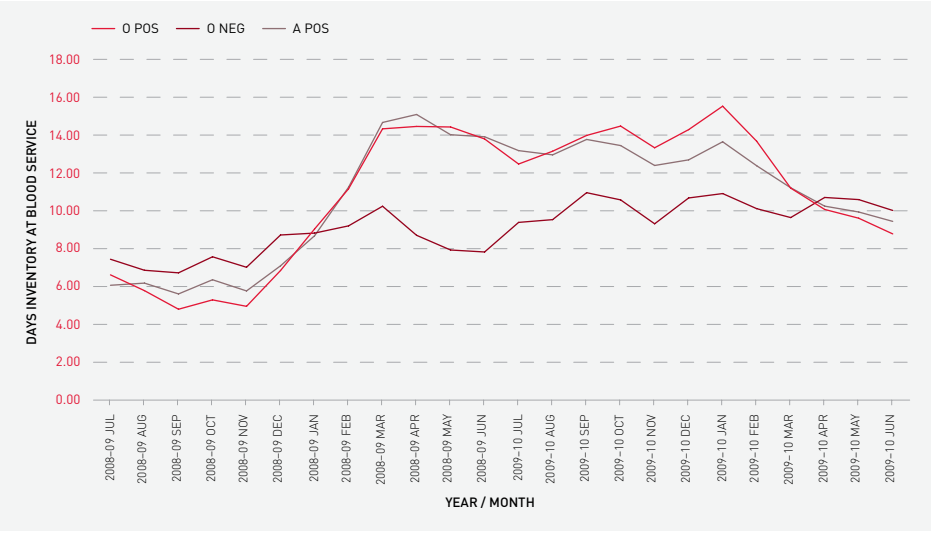


FIGURE 3.19 *Days of inventory at the Blood Service, of major blood type, by month, 2009–10*

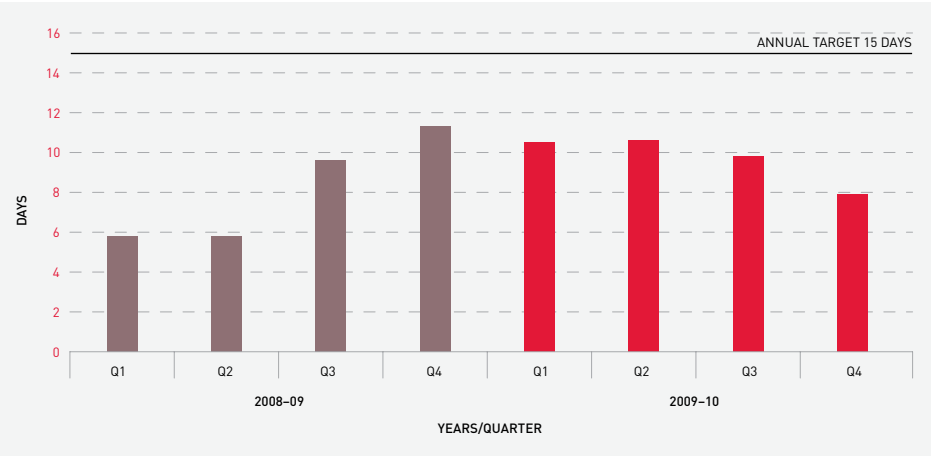


FIGURE 3.20 *Red cell age at issue by quarter 2008–09 to 2009–10*

As a result of these discussions, it was decided to develop a nationally consistent inventory framework for fresh blood components that defines normal operating inventory levels for the Blood Service and hospitals. The new framework will encompass stock holdings and stock movements across the whole of the blood sector, including at the local level. It will provide a focus on usage rather than on issues of product and contain minimum and maximum inventory bands to encourage approved health providers to hold the appropriate amount of stock.

National Managed Fund

The National Managed Fund is designed to cover future liability claims made against the Blood Service in relation to the supply of blood and blood related products in Australia. The Memorandum of Understanding for the management and administration of the National Managed Fund includes an expectation that interest would be earned on the funds held, to enable the real value of the annual contributions to the fund to be maintained over time, and reduce the level of contributions by the Australian, state and territory governments, and the Blood Service. During the year, the Minister for Finance and Deregulation delegated his powers under the *Financial Management and Accountability Act 1997* to the chief executive officer of the NBA, to manage future investments of National Managed Fund monies.

The National Indemnity Reference Group is a technical advisory subcommittee of the Jurisdictional Blood Committee on matters such as policy and review and monitoring of the Blood Service risk management strategy. The NBA provides secretariat support to the National Indemnity Reference Group, which meets twice a year.

In 2009–10 the reference group reviewed regular reports from companies contracted to manage claims and provide actuarial advice, and augmented its capacity to maintain a watching brief on risks to the National Managed Fund. In addition, planning commenced to undertake a claims-based simulation exercise during 2010, and the harmonisation of relevant legislation across all jurisdictions.

Draft indemnification guidelines are being prepared to assist the National Managed Fund manager, the National Indemnity Reference Group, and the Jurisdictional Blood Committee in aking decisions. These guidelines will be independently reviewed.

In late 2009–10 the NBA commenced a tender process to procure contractors to provide claims management and actuarial and other advice, as the current contracts with Marsh Pty Ltd and PricewaterhouseCoopers are due to expire in December 2010 and May 2011 respectively.

The National Indemnity Reference Group provides regular reports to the Jurisdictional Blood Committee. The 2009 Administrative Review of the national blood arrangements recommended that the National Indemnity Reference Group adopt a broader role in monitoring the risks around Australia's fresh blood product supply in the context of the health sector as a whole. In response, from 2010–11 the group will provide an Annual Liability Services Report to the Jurisdictional Blood Committee.

Australian Red Cross Blood Service Change Program funding

Seventeen projects costing $7 million in total have now been funded or committed under the Blood Service Change Program to help the organisation transition to a national operation, deliver cost savings or otherwise increase the efficiency of the production of goods and services under the current Deed of Agreement. No new commitments of funds will be made after 30 June 2010.

Table 3.7 summarises the nature of these projects and their status.

TABLE 3.7 Blood Service Change Program funding for projects 2006–07 to 2009–10

PROJECT	APPROVED BUDGET ($M)	STATUS
Product Costing and Forecasting Phase 2	0.55	Completed
Deed Transition Program Phases 2 and 3	0.53	Completed
Third Party Review Management	0.03	Completed
Deed Operations Initiative	0.13	Completed
Governance Standards	0.19	Completed
Handover Plan	0.10	In progress
Project Manager for Finance Portfolio's Deed Transition Management	0.10	Completed
National Asset Management System	0.70	In progress
Corporate information management and reporting—release 1	0.60	Completed
Automatic Budget Model	0.60	Completed
Donor Services Workforce Planning	1.64	In progress
Learning Management Project	0.72	In progress
Supplier Rationalisation and Online Catalogue	0.03	Completed
Hyperion 3 Yr Planning	0.28	In progress
National Inventory Framework	0.36	In progress
Process Improvement in the Consumable Supply Chain	0.33	In progress
Supply Chain Blood Component Efficiency	0.12	In progress

Management of plasma and recombinant product supply arrangements

The NBA is responsible for negotiating and managing contracts and standing offers with commercial suppliers of blood and blood related products. These contracts relate to the supply of:

- locally produced plasma-derived products
- imported plasma-derived and recombinant products
- diagnostic reagents.

Locally produced plasma-derived products: agreements with CSL Limited

In Australia, CSL Limited fractionates plasma at its facility in Broadmeadows, Victoria, from donations collected by the Blood Service. During 2009–10 plasma fractionation arrangements were governed by the five-year Plasma Products Agreement between the NBA and CSL Limited, which expired on 31 December 2009, and a new CSL Australian Fractionation Agreement which took effect on 1 January 2010. The agreements cover production, pricing, invoicing, supply planning and monitoring, risk management, and ordering and delivery.

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Continue and improve plasma fractionation and product distribution by concluding a new contract with CSL Limited	Met. New agreement signed on 23 December 2009 and took effect on 1 January 2010.

Table 3.8 shows that actual funding for CSL Limited increased from $158.1 million in 2008–09 to $182.4 million in 2009–10. This was an increase of 15.4 per cent compared to an average of 2.4 per cent from 2003–04 to 2008–09. This increase is primarily the result of volume changes contributing $17.3 million or 11 per cent (based on prices applying in 2008–09), and an additional contribution of $7 million or 4.4 per cent arising from price changes during 2009–10. Several related factors contributed to the volume changes:

- an increase of 15.8 per cent in the amount of plasma supplied to CSL Limited for fractionation (as opposed to 7.1 per cent and 10.7 per cent in 2007–08 and 2008–09 respectively)
- a 16.9 per cent increase in IVIg issued by CSL Limited as a result of increased plasma levels, giving a higher level of Australian self sufficiency for IVIg
- a strong demand for albumin resulting in 6.8 per cent growth in volume issued by CSL Limited.

TABLE 3.8 *CSL Limited annual funding commitments under the Plasma Products Agreement, 2003–04 to 31 December 2009, and the CSL Australian Fractionation Agreement from 1 January 2010*

YEAR	AMOUNT ($M)	% GROWTH
2003–04	$141.2	–
2004–05	$138.5	-1.9
2005–06	$133.0	-3.9
2006–07	$141.3	6.2
2007–08	$155.9	10.3
2008–09	$158.1	1.4
2009–10	$182.4	15.4
Total	**$1,050.4**	**4.6 (average)**

CSL Limited continued to perform well on all of the key performance indicators specified in the Plasma Products Agreement from July to December 2009 (see Table 3.9).

TABLE 3.9 *CSL Limited achievement against Plasma Products Agreement key performance indicators (July–December 2009)*

	QTR 1	QTR 2
Yield of group 1 products (Intragam P)	5.32 g/kg	5.39 g/kg
Loss of group 2 products	0.04% actual loss	0.03% actual loss
Delivery of products on time	99.2%	99.2%
Delivery of products in full	99.6%	99.8%

The finalisation of the new CSL Australian Fractionation Agreement was the culmination of a thorough development and negotiation process which commenced in 2008–09 with extensive consultation with stakeholders and expert workshops to inform the framing of negotiation terms and strategy. Negotiations in 2009–10 focused on pricing and related financial elements of the Agreement, defining the scope and details of the key performance indicator framework, consideration of CSL Limited proposals in relation to the term of the agreement and annual plasma volumes, and reaching decisions on the final drafting of the agreement.

NBA negotiation was conducted effectively by a small in-house negotiation team including both commercial managers and internal legal advisers. The General Manager's oversight of negotiations was supported by an internal steering group. Expert financial analysis was commissioned externally, and substantially supplemented from internal resources, to inform price negotiations. External legal advice was utilised for quality assurance and to confirm that legal and commercial risks for governments had been comprehensively addressed in the new agreement.

The NBA approach to negotiation on financial aspects of the new agreement was based heavily on complex analysis of financial performance of CSL Limited plasma fractionation operations in Australia against known financial performance data for other global fractionation companies. To support our analysis we also used other analyses of available sources of international price benchmarking information, intelligence of known models of cost allocation in the plasma fractionation industry, price comparison with the previous plasma fractionation contract with CSL Limited, and other relevant contracts where the NBA obtains prices for plasma products, as well as general economic indices and indicators. The NBA's continuous approach of intelligence gathering also provided specific information to support negotiations. This body of analysis will provide a guide to key pricing and value for money factors to be considered at the time of the contract review in 2014.

Jurisdictions were kept informed of progress throughout negotiations and were consulted on key emerging issues to confirm that negotiation outcomes remained within the policy requirements of all funding governments.

A number of elements of the CSL Australian Fractionation Agreement are subject to an agreed transition process, under which a number of plans to achieve minimum plasma, product and National CSL Limited reserve inventory levels are required to be developed and implemented. Most elements of the transition plan were complete or well advanced at 30 June 2010.

Quarterly contract management meetings, established under the new agreement, commenced in March 2010. The first biannual update and planning meeting between the Chief Executive Officers of the NBA and CSL Limited was also held in March.

The enhanced suite of key performance indicators in the new agreement is intended to highlight those areas of CSL Limited's performance which are of most significance to product recipients and funding governments. They cover:

- plasma stewardship—the amount of NBA funded starting plasma lost though the processes of manufacturing and distribution
- production yield—the annual average yield of IVIg production, with contractual incentives to achieve an annual average yield of 5.2 grams of IVIg per kilogram of starting plasma, or more
- management of required inventory levels—maintenance of the required minimum inventory levels of starting plasma, and of finished products held either in required CSL Limited inventory or NBA funded National Reserve
- fulfilment of orders—on time, in full and otherwise in accordance with the requirements of the agreement
- shelf life of national reserve products—maintenance of required minimum shelf life for products held in the NBA funded National Reserve.

The process of measuring and applying the key performance indicators provides incentive for high levels of performance by CSL Limited through balanced payment consequences, including a payment incentive for IVIg yield and structured rebates on other key performance indicators for performance below agreed tolerance thresholds.

THE NEW CSL AUSTRALIAN FRACTIONATION AGREEMENT

DR TURNER AND DR JEFF DAVIES SIGNING THE NEW AGREEMENT.

CSL BIOTHERAPIES PLASMA FRACTIONATION FACILITY, BROADMEADOWS, VICTORIA

The new CSL Australian Fractionation Agreement came into force on 1 January 2010 and, subject to government review in 2014, will continue until 31 December 2017. It provides for the continuation of arrangements for manufacture and supply of a comprehensive range of fractionated plasma products from Australian plasma provided by the Blood Service.

The new agreement is designed to bring improvements for governments in savings and value for money, and provides for improved performance requirements and security of supply, with no significant diminishment of the NBA's contractual position. The agreement also provides enhanced certainty for CSL Limited in planning future investment in its Australian operations.

The review in 2014 will consider CSL Limited performance against all required elements of the contract price and value for money, and any relevant changes in government policy.

The key benefits of the new agreement are:

- Minimal price rises (averaging 3.6 per cent nationally on commencement and annual indexation of CPI less 1 per cent going forward) and a pricing structure that provides increasing value for money for governments through lower average unit prices for IVIg as total supply volume increases year by year.
- Better designed key performance indicators to provide meaningful financial incentives for high performance by CSL Limited in key areas, including manufacturing yield, loss or wastage of plasma or of finished products, shelf-life on delivery, and fulfilment of orders—supported by improved reporting, monitoring and evaluation processes.
- Better security of product supply through increased requirements for inventory reserves held at CSL Limited cost to the point of supply, and supported by performance undertakings and guarantees and alternative supply arrangements which may be invoked in a serious risk scenario.
- An agreed improvement program, at CSL Limited cost, to increase shelf life and production and supply efficiency, targeted at certain products which historically have been prone to wastage through expiry in the supply chain.
- Removal of the ability of CSL Limited under the previous Plasma Products Agreement to seek additional payments for unavoidable fixed costs for changes in product demand.
- The duration of the new agreement will provide greater security of supply and long term continuity. It will also reduce costs associated with negotiation processes.

The new agreement provides for a level of additional payment to CSL Limited if annual plasma volume is less than a specified tonnage per annum. This figure is well within reasonable forward estimates of available plasma levels in any likely scenario, and the additional payment is applicable only in certain limited circumstances. No commitment has been given in the new agreement to exclusivity of access to Australian plasma, or access to any particular level of Australian plasma.

CSL Limited performed well against the revised key performance indicators specified in the new CSL Australian Fractionation Agreement from January to June 2010 (see Table 3.10).

TABLE 3.10 *CSL Australian Fractionation Agreement: key performance indicators 1 January—30 June 2010*

		RESULTS 2009–10	
DESCRIPTION OF PERFORMANCE MEASURE		Q3	Q4
KPI 1	Plasma stewardship	100% achieved	100% achieved
KPI 2	Production yield	5.26 gram/kilogram	
KPI 3	Management of required inventory levels	This KPI subject to transition arrangements.	
KPI 4	Fulfilment of orders	99% achieved	99% achieved
KPI 5	Shelf Life of National Reserve Products	100% achieved	99% achieved

In 2010 the NBA also conducted a review of the goods ordering and receipt verification procedures to ensure the continued currency of the testing procedures as they apply to the new agreement.

Imported intravenous immunoglobulin

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Review procurement options for the future supply of imported IVIg by May 2010.	Met. Following a review, the existing contract with Octapharma Australia Pty Ltd was extended for 12 months until December 2011. A procurement process will be undertaken in 2010–11 for supply from January 2012.

In 2009–10 the NBA continued importation of IVIg to fully meet domestic clinical demand. The cost of IVIg purchased from Octapharma Australia Pty Ltd under a fixed-price contract increased from $46.9 million in 2008–09 to $48.7 million in 2009–10 due to increased demand for this product.

During 2009–10 Octapharma Australia Pty Ltd performed well on all key performance indicators, as shown in Table 3.11.

TABLE 3.11 *Octapharma Australia Pty Ltd: performance against key performance indicators, 2009–10*

PERFORMANCE MEASURE	ACHIEVEMENT
In-Country Reserve	Fully achieved
Shelf-life on products delivered to Approved Recipients	Fully achieved
Delivery Performance	Fully achieved
Reporting	Fully achieved
Record Keeping	Fully achieved

The contract with Octapharma Australia Pty Ltd for the supply of Octagam was due to expire on 31 December 2010, with the NBA having an option to extend the contract by one year. To inform this decision, the NBA researched the market and sought advice from stakeholders. A stakeholder discussion paper was issued in February 2010 to obtain comments from users of IVIg, including patients, clinicians, nurses who administer the products, other

consumer and professional bodies, and those involved in the ordering and distribution of IVIg. In addition, a separate Request for Information was released to current and potential suppliers of imported IVIg, seeking information on products potentially available after December 2010, and on market capacity issues. The NBA received detailed and useful responses from seven interested suppliers and a range of other stakeholders. The NBA also undertook further active intelligence gathering of global market conditions.

After consideration of all available information, the NBA framed a series of recommendations to jurisdictions on the future supply arrangements which will best meet Australia's clinical and supply security needs and which will be most likely to represent best value for money in the short and longer term. With endorsement from the Jurisdictional Blood Committee, in May 2010 the NBA moved to exercise the option to extend the current contract with Octapharma Australia Pty Ltd, with improved value for money, for a further 12 months.

In 2011 the NBA will undertake a competitive tender process for the supply of imported IVIg from January 2012. The NBA expects that this tender process will increase the number and variety of imported IVIg products available under the national blood arrangements.

The NBA also supports purchases of IVIg by jurisdictions, outside the shared funding available through the national blood arrangements, using standing offer arrangements for Jurisdictional Direct Orders.

A contract with CSL Limited for the supply of Sandoglobulin NF (nanofiltration) Liquid under the Jurisdictional Direct Order arrangement expired at the end of December 2009. Following endorsement from jurisdictions, the NBA undertook a tender process and entered into a three-year contract with Lateral Grifols Pty Ltd for the supply of Flebogamma 5% DIF (dual inactivation plus nanofiltration) under Jurisdictional Direct Orders, which commenced on 1 January 2010.

Imported plasma-derived and recombinant blood products

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Continue the supply of imported plasma-derived and recombinant blood products by implementing extensions to supply contracts with Baxter Healthcare, Novo Nordisk and Wyeth.	Met. Contracts with Baxter Healthcare and Wyeth extended to June 2011, and contract with NovoNordisk extended to June 2012.

The NBA has established contracts with overseas suppliers for the importation of selected plasma-derived and recombinant blood products to augment domestic supply in cases where these are not produced in Australia or domestic production cannot meet demand.

Since 2006 the NBA has maintained contracts with three overseas companies: Baxter Healthcare Pty Ltd, Novo Nordisk Pharmaceuticals Pty Ltd and Wyeth Australia Pty Ltd. Contracts with Baxter Healthcare Pty Ltd and Wyeth Australia Pty Ltd have been extended until June 2011, and the contract with Novo Nordisk Pharmaceuticals Pty Ltd has been extended until June 2012.

In 2009–10 the NBA spent $166 million under these contracts for the supply of imported blood products (see Table 3.12).

TABLE 3.12 Annual expenditure on imported products (excluding intravenous immunoglobulin), by company, 2003–04 to 2009–10

YEAR	BAXTER		WYETH		NOVO NORDISK	
	AMOUNT ($M)	% GROWTH	AMOUNT ($M)	% GROWTH	AMOUNT ($M)	% GROWTH
2003–04	$32.2	---	$5.5	---	$14.6	---
2004–05	$54.5	69.3	$10.9	98.2	$18.8	28.8
2005–06	$69.9	28.3	$15.9	45.9	$23.4	24.5
2006–07	$71.5	2.3	$33.8	112.6	$26.9	15.0
2007–08	$80.1	12.0	$42.4	25.4	$17.4	-35.3
2008–09	$84.1	5.0	$48.6	14.6	$17.4	0.0
2009–10	$90.6	7.7	$48.9	0.7	$26.4	51.8
Total	**$482.9**	**20.8 (avg)**	**$206.0**	**49.6 (avg)**	**$144.9**	**14.1 (avg)**

Consistent with previous years, performance against contractual key performance indicators was again high in 2009–10 (see Table 3.13).

TABLE 3.13 Imported recombinant blood product contracts: key performance indicators, by supplier, 2009–10

PERFORMANCE MEASURE	BAXTER	WYETH	NOVO NORDISK
Delivery Performance	Fully achieved	Fully achieved	Fully achieved
In-Country Reserve	Substantially achieved*	Substantially achieved*	Fully achieved
Ordering	Fully achieved	Fully achieved	Fully achieved
Record Keeping	Fully achieved	Fully achieved	Fully achieved
Reporting	Fully achieved	Fully achieved	Fully achieved
Shelf-life on products delivered to Approved Recipients	Substantially achieved*	Substantially achieved*	Substantially achieved*

* In these instances, the performance of the relevant supplier departed from the contracted requirement at some periods during the year, but without a material effect on supply performance or supply security. Such instances are managed through specific prior approvals from the NBA, and increased discussion and scrutiny of supplier performance at regular contract management meetings.

During the year the NBA accepted a proposal from Wyeth Australia Pty Ltd to transition its recombinant Factor VIII product from the ReFacto brand name to the Xyntha brand name, following approval of the latter by the Therapeutic Goods Administration. Wyeth Australia Pty Ltd developed a transition process covering the provision of information materials to healthcare professionals and others. The company also managed stock transition processes to ensure appropriate levels of in-country stock were maintained and used in a way that avoided product wastage. The company had successfully completed the transition by May 2010.

Diagnostic reagent products

The NBA has contracts with four suppliers for the supply of blood testing diagnostic reagents to public laboratories: CSL Limited, Lateral Grifols Pty Ltd (previously called DiaMed Australian Pty Ltd), Abacus ALS Pty Ltd (previously called Australian Laboratory Services) and OCD (Ortho-Clinical Diagnostics—a Johnson and Johnson Company). The four contracts were due to expire on 31 October 2009 and, following consideration in 2008–09, were initially extended for one year. The NBA negotiated with suppliers to limit the weighted average price increase for the 2009–10 year to 3.76 per cent, based on 2009–10 expenditure.

Funding for diagnostic reagent supply is capped at $4.85 million per year. Figure 3.21 shows that the total market share of each supplier remains relatively stable.

Following the first extensions, in March and April 2010 the NBA consulted with jurisdictional representatives and public laboratories to ascertain whether there were any recent or potential changes to demand or requirements for relevant diagnostic reagents, or any shortcomings with the current contracts. The outcomes of the consultation were positive and the NBA, with jurisdictional endorsement, moved to further extend the current contracts for an additional eight months to June 2011. This will allow alignment of these contracts to the financial year. The NBA successfully negotiated a 2.1 per cent price increase for this period with all suppliers; this is lower than the CPI increases for the relevant period.

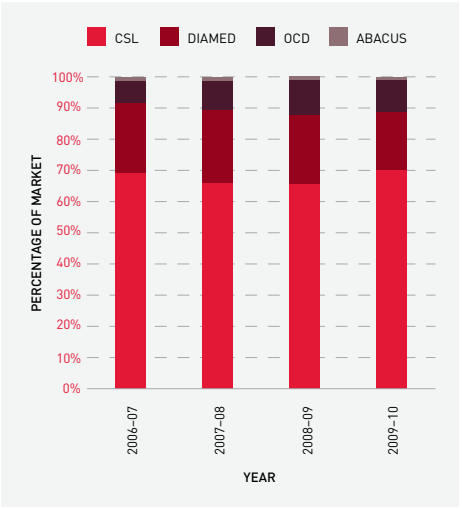


FIGURE 3.21 *Market share for suppliers of diagnostic products, 2006–07 to 2009–10*

Evaluation methodologies for change proposals

KEY PERFORMANCE INDICATOR	MEASURED BY
Management of the methodology and processes for adding products to the National Product Price List	The level of satisfaction of all funding jurisdictions with the NBA's management was 67 per cent, with strong recognition by jurisdictions of the quality of the methodology developed by the NBA. 33 per cent remained unsure. This relatively high unsure response reflects the work under way to integrate these processes with the wider Health Technology Assessment reforms.

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Improve the processes for adding products to the National Product Price List by researching and recommending a methodology for evaluating proposals.	Met. Jurisdictional Blood Committee endorsed the NBA's proposal for a methodology using a multi-criteria analysis framework.

Under the National Blood Agreement, interested parties can make proposals for changes to products or services on the National Product Price List. Schedule 4 of the agreement provides for evidence-based evaluation, information and advice to support decisions on these changes in the context of the primary and secondary objectives of the agreement (see Appendix 1).

In 2008–09 the NBA developed a comprehensive framework for assessing products which addressed relevant policy considerations and cost-effectiveness impacts of the proposals on the blood sector and, where relevant, the wider health sector. This multi-criteria analysis framework:

- quantifies consideration of each of the objectives of the National Blood Agreement
- provides consistent rigour for the assessment process
- uses an assessment methodology that incorporates principles similar to the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme.

Following detailed discussion by the Jurisdictional Blood Committee in February 2009, the National Blood Authority developed a third iteration of the multi-criteria analysis framework and published it on the NBA website seeking stakeholder comment.

A key issue raised by blood suppliers in the consultation process was the need for clarity on the circumstances under which a Schedule 4 proposal is required. In response the Jurisdictional Blood Committee recommended that the multi-criteria analysis framework be adopted as the basis for assessing all change proposals, irrespective of whether or not the product or service which is intended for change would be purchased through an existing contract. Requests may be classified as:

- *'Within category' proposals, or*
- *'Outside category' (Schedule 4) proposals.*

Within category proposals are defined as changes to products already approved by Health Ministers and which are already listed on the National Product Price List. Outside Category proposals are for:

- a new product/service not already on the approved National Product Price List; or
- a change to a product on the National Product Price List that has altered the nature of that product to take it outside the definition of the listed product.

Information on the multi-criteria analysis framework was released on the NBA website in April 2010, and a set of evaluation guidelines was developed.

The 2010–11 Budget provided the Department of Health and Ageing with $3.2 million over four years to develop and implement a process for assessing proposals for funding of new blood products, with a panel of independent experts considering the evidence of the need for, and cost effectiveness of, proposals. This panel will recommend to the Commonwealth whether products should be publicly funded and inform the Commonwealth's position on the proposals, in particular around matters of cost-effectiveness. The outcomes of this assessment process will be considered as part of the multi-criteria analysis framework for the evaluation of new proposals.

Conducting economic evaluation of blood sector proposals within established government review processes will ensure a consistent approach to the economic evaluation of new medical technologies in Australia and enable the methodology to be kept up to date and in line with global best practice. In addition, the NBA and the Jurisdictional Blood Committee are cognisant of the recommendation of the 2005 Productivity Commission Research Report, *Impacts of advances in medical technology in Australia*, which called for better coordinated and more systematic processes across all levels of government.

Further consideration of current Schedule 4 applications will be undertaken at the direction of the Jurisdictional Blood Committee.

NBA OFFICER, MS SANDRA RUSSELL WORKING ON THE MULTI-CRITERIA ANALYSIS

3.2 MANAGEMENT OF RISK AND SECTOR PERFORMANCE IMPROVEMENT

A second key strategic direction for the NBA in 2009–10 was to ensure effective risk management arrangements are in place to implement blood policy, and to continue to improve sector performance. The National Blood Supply Contingency Plan was not activated during the year due to strong inventory levels and good contractual compliance.

Risk management

The NBA continues to give high priority to our obligation to manage blood sector risks, especially those related to supply security. We do this by ensuring that responsibility and accountability lie with those best placed to manage risk. During 2009–10 this required the NBA to:

- continue scrutiny of compliance with risk management strategies contractually required of suppliers
- manage both real and potential risks to the supply plan during the year.

Contractual obligations

All supply contracts have a requirement for the suppliers to develop and provide risk management plans to the NBA. These plans detail the supplier's approach to ensuring that risks in relation to providing products and services are identified and avoided or mitigated as far as possible.

For example, in the negotiation of the new CSL Australian Fractionation Agreement, the NBA has enhanced supply security elements at CSL Limited's cost, and agreed other supporting measures.

During the European transport interruptions in April 2010 due to volcanic ash, the NBA liaised closely with suppliers to monitor possible impacts, and provided a public update on supply security via the NBA website. All of our suppliers were well-prepared and there were no material impacts on any supply arrangements for Australia.

The National Blood Supply Contingency Plan

KEY PERFORMANCE INDICATOR	MEASURED BY
Management of the National Blood Supply Contingency Plan.	The level of satisfaction of all funding jurisdictions with the NBA's management and implementation, when appropriate was rated at 89 per cent, with 11 per cent unsure. High stock levels were maintained throughout the Australian winter which mitigated any significant adverse impact on stock availability arising from the H1N1 influenza. In the absence of any other crises, the plan was not activated during 2009–10.

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Increase the scope of the National Blood Supply Contingency Plan by submitting the transfusion-transmitted infection annex for ministerial clearance by June 2010.	Partially met. The Jurisdictional Blood Committee considered a draft of the annex at its meeting in May 2010.

The National Blood Supply Contingency Plan was officially launched in November 2008. We were delighted to receive the 2009 Australian Government Comcover Award for Excellence in Risk Management in the Risk Initiative category, which was presented in November 2009.

The judges praised the NBA's risk-based methodology to engage stakeholders and identify the most appropriate means of achieving the objectives of governments, and highlighted the benefits of the plan in providing:

- an agreed framework for the sector against which to assess the nature of a crisis and determine appropriate actions in a nationally consistent manner, thereby ensuring a collaborative approach at state and Commonwealth level
- strategies for addressing stock levels and managing available products that are discussed and agreed nationally and that include engagement by state and territory ministers
- increased awareness of the importance of blood product supply in the health sector and the requirement for a coordinated response, hence ensuring the continued delivery of blood products at a national level.

The NBA also presented the keynote address at a national risk management workshop held in March 2010, detailing the development and evaluation of the plan.

THE COMCOVER TROPHY AND THE NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

To ensure that potential risks to the blood sector are addressed promptly, the NBA communicates regularly with the Blood Service on issues such as inventory and donor management trends, clinical demand for products, and impact on Blood Service staff and overall capabilities.

During the year the NBA closely monitored international impacts of the H1N1 Influenza 2009 on blood services during the northern hemisphere winter and reported these to the Jurisdictional Blood Committee for its consideration in wider health sector planning. For example, in the United Kingdom and Canada the emphasis was on increasing blood supply by revising donor criteria and shortening donor deferral periods in certain situations. United States blood centres have developed models with scenarios involving staff absenteeism of up to 40 per cent, and the US Food and Drug Administration recommended that donation by potential donors with suspected or confirmed H1N1 should be deferred until at least 24 hours after all symptoms had disappeared.

NBA STAFF TRIALLING THE INCIDENT ROOM SET UP

Other strategies adopted internationally included more aggressive promotion of vaccinations to health sector employees, more stringent infection control measures in hospitals, cross-training to enlarge the potential skill base in collection centres and chemistry laboratories, communication within and between organisations (and internationally), and sound planning.

A key requirement of the National Blood Supply Contingency Plan is the development of an annex covering the management of a transfusion-transmitted infection in the blood supply. An initial draft was considered by the Jurisdictional Blood Committee during 2009–10.

Early interception of any contaminated products and avoidance of the transmission of contaminants through the blood supply (where possible) is currently very effectively managed through the regulatory framework and quality assurance and/or testing procedures used by the Blood Service. These are enforced and overseen by the Therapeutic Good Administration. There are two parts to the current framework:

1. Blood donors are initially screened through questionnaires and interviews; these aim to mitigate the risk of a transfusion-transmitted infection in a donation.
2. Donated blood is tested for transfusion-transmitted infections (for example, HIV and Hepatitis C). These mandatory tests are listed in the *Code of Good Manufacturing Practice for Human Blood and Tissue 2000*.

The new annex does not include these procedures. Rather, it focuses on growing concerns about the need to detect and then deal with contaminations by previously unknown viruses, from bacterial contamination in a blood product, or from consumable products involved in the donation that emerge post donation. Although the residual risks are estimated as being low, nevertheless, they are real.

The annex provides a framework to guide the management of a potential or real incident of contamination within the Australian blood supply *outside the normal risk parameters*. The response would be initiated before the National Blood Supply Contingency Plan is formally activated. The latter would only be activated in the event that a transfusion-transmitted infection, or the public health response to an incident, impacts on the ability of the Blood Service to maintain normal supply levels for all fresh blood components.

The transfusion-transmitted infection annex defines:

- the distinction between the response to a potential or real public health issue as a result of a transfusion-transmitted infection in blood components, and a shortage in supply as a result of a transfusion-transmitted infection in blood components.

- the process for how significant contamination issues can be identified
- how communication and early notifications between the relevant organisations will operate
- the roles and responsibilities of each of the major organisations for each type of impact.

The annex will be consistent with the mechanisms and processes already operating between the Blood Service and the Therapeutic Goods Administration, and also with the roles and responsibilities of the Office of Health Protection under the national health emergency arrangements.

The NBA is seeking input on the annex from members of the Communicable Diseases Network Australia and the Public Health Laboratory Network at a state level, coordinated by members of the Jurisdictional Blood Committee. When these have been received, further consultations will be held with the Blood Service and national level organisations during 2010–11.

Sector improvement initiatives

The NBA has a number of projects designed to improve the overall efficiency of the sector as a key element in improving affordability and minimising risk. These projects require detailed investigation and are always implemented with input and guidance from stakeholders and experts in the field of inquiry. During 2009–10 these activities involved the NBA in:

- focusing on data capture and analysis projects, including enhancements to the Australian Bleeding Disorders Registry; this important aspect of the NBA's work is described in Part 4 of the report
- using our international networks to strengthen our knowledge and understanding of supply issues overseas, especially for plasma products
- reviewing distribution arrangements for plasma and recombinant blood products
- developing a statement to increase awareness of stewardship obligations by those receiving blood products to dispense to patients
- undertaking work as part of contract negotiations to benchmark performance of contracts with suppliers for price and quality and also provide reference points for sector performance improvement (see pages 53 to 60)
- monitoring progress by the Blood Service in implementing the recommendations of the Blood Service KMPG business study (as described on pages 47 and 48)
- negotiating with the Blood Service to develop an output based funding model to allow greater transparency and accountability at all levels of the blood sector as well as allow for appropriate international comparisons (for further details, see pages 47 to 49)
- revising policy and management arrangements for the provision of product to Australians temporarily overseas.

The collaboration of national plasma product supply planners

The second meeting of the collaboration of national plasma product supply planners was held in Rome in March 2010, with the NBA again providing the chair and secretariat support. The group consists of a number of national agencies that have oversight responsibility for plasma products. The aim of the group is to support participants to better meet patients' needs for a secure, cost effective supply of plasma for fractionation, plasma derivatives and their clinically substitutable recombinant products. It is the only international forum that shares data and experiences in the management of plasma products.

This year the members, from Canada, Finland, Italy, New Zealand and Australia, shared usage data, discussing the significant variations in usage rates of albumin internationally. Members identified the need for much better evidence underpinning albumin usage. Other issues discussed included:

- the uptake of sub-cutaneous immunoglobulin and the extent to which this has been influenced by funding arrangements
- the management of demand for product
- international trade in plasma and impediments to this trade
- the role of regulators in assessing potential viral loads in plasma products (on which it was agreed that there should be some international consensus between regulators based on a thorough and consistent risk assessment)
- procedures for evaluating new proposals in various countries
- price trends in plasma and IVIg markets.

The group agreed that the collaboration continues to be worthwhile. During 2010 further comparative data will be assembled and analysed, and the group will meet again early in 2011.

MEMBERS OF NPPSPA-KEITH BUCHANAN, DR GABRIELE CALIZZANI, DR PETER FLANAGAN, DR GIULIANO GRAZZINI AND DR TOM KRUSIUS, WITH DR TURNER AND MICHAEL STONE, AND PRESENTERS FROM BAXTER INTERNATIONAL AND UBS

Review of distribution arrangements for plasma and recombinant blood products

KEY PERFORMANCE INDICATOR	ASSESSMENT SUMMARY
Review of distribution arrangements for plasma and recombinant products completed to review timetable.	Met. Stage 2 is complete. Stage 3 has commenced, developing a feasibility study to trial the preferred option in one jurisdiction.

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Identify performance improvement opportunities for the blood sector by finalising the review of the distribution arrangements for plasma and recombinant products by June 2010.	Met. Stage 2 of the review recommended adoption of a manufacturer direct distribution model, based on analysis of possible improvement opportunities. Following consideration by the Jurisdictional Blood Committee, planning is under way to evaluate this model in one jurisdiction, as stage 3 of the review.

In 2007 governments endorsed a recommendation in the review of Australia's plasma fractionation arrangements that the NBA should review the distribution supply chain for plasma-derived and recombinant products (fresh blood and blood components were not considered in the review). The first stage of the work, undertaken in 2008–09, concluded that current arrangements were neither ideal nor optimal from cost and governance perspectives, and that there were significant opportunities for improving arrangements and moving towards more contemporary, risk-based supply chain practices, including the development and application of measures of performance.

Stage 2 of the study commenced in August 2009 and explored the potential costs and benefits of three options to effect the changes needed to achieve improvements, including the production of data that allows the extraction of performance metrics. A series of stakeholder consultations was held, and the Jurisdictional Blood Committee considered the recommendations arising from these at its meeting held in February 2010. At this stage the option to establish a centralised distributor was eliminated from further consideration.

The NBA then undertook further detailed analysis of costs, benefits and risks for the two remaining options; enhancement of existing arrangements, and adoption of a manufacturer direct distribution model. These options were assessed against the extent to which they would deliver the following success criteria that had been determined following stakeholder consultation:

1. Supply security delivered through inventory planning
2. Adequate information flow that enables appropriate management and quick response to emerging issues
3. Authorisation process ensures appropriate use of product
4. Inventory costs minimised by having no more steps in the supply chain than the level determined by inventory planning
5. Service delivery has wide geographic coverage and fulfils orders completely and on time
6. Minimal product wastage through damage and expiry of product at all levels of the supply chain, from supplier through distributor to approved recipients
7. Appropriate product storage throughout the supply chain to maintain product quality (this includes both storage and transportation)
8. Maximal product shelf life on issue to Approved Health Providers
9. Reduced AHP effort by having a system that requires entry once and provides seamless connection to all suppliers
10. Cost of delivery enables best value for money
11. Approved Health Providers supported when moving products to other providers, including capacity to get it moved.

In May 2010 the Jurisdictional Blood Committee endorsed the NBA's recommendation to develop a feasibility study of a manufacturer-direct distribution model. This model will be trialled in stages in order to minimise risk and allow full evaluation of the costs and benefits for governments and the sector.

CSL LIMITED DISTRIBUTION WAREHOUSE

Statement on National Stewardship Expectations for the supply of blood and blood products

Blood and blood products are a precious resource, supplied free of charge, and should be managed with care and respect. The Statement on National Stewardship Expectations for the supply of blood and blood products has been developed to address the lack of specific accountability obligations, other than general safety and quality issues mandated by other agencies, on health providers such as laboratories in hospitals and clinics and other institutions that receive blood and blood products for dispensing to patients. The statement contains a concise description of responsible, sustainable and appropriate use of blood and blood products relevant to handling, storage, administration, usage and capacity to report inventory. It was developed following stakeholder consultation and advice from the Jurisdictional Blood Committee, and will be considered by health ministers in 2010–11.

Overseas supply policy

In February 2010 the Jurisdictional Blood Committee agreed to the NBA's recommendation that, for the purposes of supply of blood products to Australian residents temporarily overseas, 'temporarily' should normally be taken to mean a maximum of 12 months; this could be extended for a further three months in exceptional circumstances, but only where there is continued clinical supervision.

This clarification is expected to better align the provision of blood products to Australians travelling overseas for a temporary period, with provisions in other areas of the health sector. The NBA website contains a Fact Sheet describing the arrangements.

3.3 APPROPRIATE PATIENT BLOOD MANAGEMENT AND SAFE USE OF BLOOD AND BLOOD PRODUCTS

Australian governments are committed to promoting safe, high-quality management and use of blood and blood related products and services in Australia. A key feature of the NBA's approach to meeting this commitment is consultation with key stakeholders, such as clinical specialists and practitioners, to develop and promulgate national standards and guidelines to better inform and influence appropriate blood usage.

This stakeholder engagement is an essential component of the NBA's knowledge network. Physicians, transfusion nurses and policy advisors in states and territories are valued members of a wide range of working groups and many other experts are involved in making submissions to committees of review, evaluating clinical evidence and preparing training material.

The NBA's program of activities in this area is ambitious and integrates with the appropriate use activities being undertaken by the states and territories.

In 2009–10 the NBA worked on:

- establishing a National Patient Blood Management Program
- making significant progress in developing the *Patient blood management guideline*
- implementing the 2010 review of the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia*
- developing the Australian National Haemovigilance Program
- developing a national indicator for blood use
- a red cell usage analysis methodology
- a national roll-out of state-initiated education projects.

Patient blood management

The Jurisdictional Blood Committee endorsed a National Patient Blood Management Program in 2009. During 2009–10 the NBA continued to develop governance arrangements for the program and to undertake initial research to identify priorities for consideration as part of the program's design phase.

A National Patient Blood Management Program Steering Committee, consisting of experts in haematology and transfusion medicine, pathology services, general practice, iron therapy, medical teaching and Indigenous, rural and remote health, was established; consumer views and perspectives are also represented.

NATIONAL PATIENT BLOOD MANAGEMENT PROGRAM STEERING COMMITTEE (NPBMP SC)	
Dr Simon Towler	Chief Medical Officer, Department of Health Western Australia (Chair)
Dr Lilon Bandler	General Practitioner and Senior Lecturer Indigenous Health Unit, University of Sydney
Dr Steve Flecknoe-Brown	Haematologist and Senior Consultant Physician, Broken Hill Health Service
Professor James Isbister	Emeritus Consultant Haematologist, Royal North Shore Hospital and Clinical Professor of Medicine, University of Sydney
Dr Beverly Rowbotham	Haematologist, Sullivan Nicolaides Pathology
Ms Karen Carey	Consumer Representative

Building on the initial ideas and concepts highlighted in discussions with jurisdictions, the committee has identified several policy opportunities to improve patient blood management that will support activities at local jurisdictional level—both public and private—including:

- establishment of national objectives and performance measures
- development of a patient blood management tool kit to support local programs to achieve national objectives
- establishment of a national approach to education, focusing on training health workers and administrators in how to implement and support patient blood management initiatives, increasing knowledge of all health care professionals wherever transfusion is commonly practised, and informing consumers about patient blood management, including alternatives to transfusion
- establishment of a working group to drive national focus on iron deficiency and anaemia management, especially in the peri-operative setting. Work on this activity has commenced, with the engagement of key stakeholders such as the National Prescribing Service, to assist in understanding, recognising and treating iron deficiency anaemia, and the Therapeutic Goods Administration, to improve access to a broader range of iron therapies

ANAEMIA MANAGEMENT WORKING GROUP (SUBGROUP OF NPBM SC)	
Dr Steve Flecknoe-Brown	Haematologist and Senior Consultant Physician, Broken Hill Health Service (Chair)
Dr Ian Prosser	Senior Medical Advisor, Office of Devices, Blood & Tissues, Therapeutic Goods Administration
Dr Kathryn Robinson	Independent Haematology Expert, Iron Deficiency Anaemia, Queen Elizabeth Hospital Adelaide

During 2009–10 the key elements of the program took shape. Proposed national outcome and performance measures will be presented to the Jurisdictional Blood Committee during 2010–11.

Review of *Clinical practice guidelines on the use of blood components*

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Provide clinicians with evidence-based information on safe and appropriate blood management by releasing two elements of the National Health and Medical Research Council Clinical practice guidelines for patient blood management by 30 June 2010.	Not met due to the need to transition to a second systematic reviewer and the volume and complexity of the evidence. A public consultation process was undertaken for the critical bleeding/massive transfusion module in April 2010, and a similar process will be initiated for the peri-operative module early in 2010–11.

The *Clinical practice guidelines on the use of blood components* were published in 2001. Some important areas of practice were omitted from that publication and, since the guidelines were published, new clinical and scientific data have emerged. The guidelines are being reviewed under the auspices of the National Health and Medical Research Council and Australian and New Zealand Society of Blood Transfusion, with funding from the Commonwealth and the jurisdictions, and project management and secretariat services provided by the NBA.

The review is addressing:

- variable compliance with the recommendations of the 2001 guidelines, indicated by a high degree of variation in transfusion practices
- failure of the 2001 guidelines to address a range of clinical settings where patient blood management is commonly required, including medical conditions, obstetrics, paediatrics, critical bleeding and massive transfusion
- increasing evidence of transfusion-related outcomes, leading to the emergence of new practices, including restrictive transfusion strategies and the increased use of alternatives to transfusion in the management of anaemia
- growing support nationally for a 'multi-modal' approach based on medical and surgical concepts for minimising patients' exposure to allogeneic transfusion, where transfusion needs are based on the individual patient's needs, taking into account patient-specific clinical and physiological factors and patient preferences.

In response to this situation, it was agreed by jurisdictions that a series of six phased, comprehensive, patient-focused, evidence-based modules would be developed that will, together, comprise a new patient blood management guideline.

In 2009–10 work concentrated on the peri-operative and critical bleeding/massive transfusion modules. The work has proved to be exceptionally complex, and of considerable volume. Delays were exacerbated by the need to replace the consultant undertaking the systematic reviews following the consultant's decision to withdraw from the contract, necessitating the development of transition arrangements. Nevertheless, the draft critical bleeding/massive transfusion module was released for public consultation in April 2010. Over 30 submissions were received, leading to some significant improvements. The final draft will be subject to external independent and peer review and then submitted to the National Health and Medical Research Council for approval by October 2010.

The production of the critical bleeding and peri-operative modules has required a significant and substantial commitment from the group of college and society representatives as detailed below, without whom it would not have been possible for the modules to be developed.

CLINICAL REFERENCE GROUP—CRITICAL BLEEDING / MASSIVE TRANSFUSION AND PERI-OPERATIVE	
Professor Zsolt Balogh	Royal Australasian College of Surgeons
Dr Craig French (co-Chair)	Australian and New Zealand Intensive Care Society
Associate Professor Russell Gruen	Royal Australasian College of Surgeons
Associate Professor Larry McNichol	Australian and New Zealand College of Anaesthetists
Dr Richard Seigne	Australasian and New Zealand Society of Blood Transfusion
Mr Darryl Teague	Australian Orthopaedic Association
Dr Amanda Thomson (co-Chair)	Australasian and New Zealand Society of Blood Transfusion
Dr Phillip Truskett	Royal Australasian College of Surgeons
Dr John Vinen	Australian College of Emergency Medicine
Mr Shannon Farmer	Independent Patient Advocate
Dr Chris Hogan	National Blood Authority

The draft peri-operative module will be released for public consultation in 2010–11. Work on the phase 2 modules (medical conditions and critical care) started late in 2009–10 and the commencement of phase 3 (obstetrics and neonatal and paediatric modules) is planned to commence early in 2011.

MEMBERS OF THE CLINICAL REFERENCE GROUP FOR THE CRITICAL BLEEDING AND PERI-OPERATIVE MODULES OF THE PATIENT BLOOD MANAGEMENT GUIDELINE

A VALUABLE MEMBER OF THE NBA'S KNOWLEDGE NETWORK

Associate Prof Sean Riminton MBChB(Dist), PhD, FRACP, FRCPA

The clinicians who invest their time to work with the NBA are experts in their discipline who maintain substantial clinical, education and research workloads in addition to their contribution to the NBA. The NBA acknowledges with gratitude the significant and valuable contribution that these individuals have made to developing and implementing better practices and evidence based guidelines to improve patient outcomes.

A/Prof Sean Riminton has been a major contributor to the NBA's development and achievements since its inception in 2003. In recognition of this significant contribution, he was acknowledged as NBA's first Fellow in 2006. He is a Senior Staff Specialist in Clinical Immunology and Immunopathology at Concord and Prince Alfred Hospitals in Sydney and a Clinical Associate Professor in Medicine at the University of Sydney. His keen interest in primary immunodeficiencies led to the establishment of the Australasian Society of Clinical Immunology and Allergy's Register of Primary Immunodeficiency Diseases (PID) for Australia and New Zealand. He also played an instrumental role in establishing the Immune Deficiency Foundation of Australia, the first national patient representative body for PID. He complements his clinical workload which specialises in treating patients with PID and HIV, with an extensive research program where his interests lie in immuno-mediated inflammatory disorders and neuro-immunological inflammatory suppression.

In 1999, A/Prof Riminton saw two patients on the same day; one was being treated with intravenous immunoglobulin (IVIg) despite not requiring this treatment; the other required IVIg but was denied access to it by the then guidelines. This prompted A/Prof Riminton to investigate the processes that that had led to this difference in treatment availability. This experience inspired him to invest his own time to investigate and work with the government to 'fix the system'. He obtained a copy of the AHMAC 2000 IVIg Guidelines. To his surprise, he had to request a copy in writing. He then conducted a clinical audit of IVIg use at two Sydney hospitals. The audit confirmed his hypothesis that there was wide variation in prescribing practices and confirmed the need to review and update the guidelines. A/Prof Riminton believes that while the bureaucratic hurdles have become easier to negotiate since the inception of the NBA work is still required to improve responsiveness. He acknowledges however, the improved linkage fostered by the NBA between the clinical and government sectors, has led to better, clinician-guided standardisation of IVIg therapy and policy.

A/Prof Riminton, continues to invest time in working with governments because his expertise informs decisions that impact health care for his patients and fellow clinicians. Knowing that he has influenced the positive reforms that have occurred in recent years afford him great satisfaction. For him, some major achievements have been contributing to the establishment of a contingent supply of IVIg, and the *Criteria for the clinical use of intravenous immunoglobulin in Australia* (the Criteria). He sees some of the benefits of the Criteria as providing a strong evidence base to guide clinical use of IVIg. He believes that the wide consultation and engagement of the clinical community which occurred during their development was also very positive in leading to improved consistency and awareness around treatment regimes.

While A/Prof Riminton can see the improvements that have occurred, as with all things there are many more improvements that can be made. He continues to work with the NBA to explore how we might provide better data on trends, usage, and demand for product to better meet the evolving needs of patients.

Review of the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia*

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Ensure the continued alignment of the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia* with new and emerging clinical outcome evidence by agreeing the methodology for a review of the criteria by December 2009.	Met.

The NBA has established a National IVIg Criteria Review Working Group to conduct a formal triennial review. The working group includes representatives from the intravenous immunoglobulin discipline subgroups (formed when the criteria were first developed), clinical representatives from specific colleges and societies, the Blood Service, the Commonwealth, NBA and the Jurisdictional Blood Committee. The working group is chaired by the Jurisdictional Blood Committee member for Western Australia, Ms Joan Bedford.

During 2009–10 the methodology for the review was developed. The review will be limited to proposals from the clinical community requesting reassignment between chapters, removal and modification of existing indications, and addition of new indications. The working group accessed clinical evidence on the requests that had become available since the original review, and sought specialist clinical expertise from relevant colleges and societies to ensure that any proposed amendments to the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia* continue to reflect best possible clinical practice. A systematic reviewer was engaged to support the review of the medical literature. The working group is also taking into account the need to maintain parity with international guidelines wherever possible.

As a result of a formal submission process conducted from December 2009 to February 2010, the working group received and considered 28 submissions. The working group also reviewed evidence statements and literature to determine how best to address the requests made in submissions.

As in other NBA programs, the tasks associated with the working group have required a significant and substantial commitment from a group of specialist college and society representatives without whom it would not be possible for the review to be completed.

NATIONAL IVIG CRITERIA REVIEW WORKING GROUP	
Ms Joan Bedford (Chair)	Jurisdictional Blood Committee, Western Australia (Chair)
Dr Marija Borosak	Australian Red Cross Blood Service representative
Dr Philip Crispin	Haematological Society of Australia and New Zealand representative
Ms Carolyn Duck	Jurisdictional Blood Committee representative ACT
Professor Henry Ekert	Department of Health and Ageing clinical representative
Associate Professor John Gibson	Independent expert—Haematology
Dr Chris Hogan	National Blood Authority Clinical representative
Dr Lynette Kiers	Australian and New Zealand Association of Neurology representative
Associate Professor Andrew Kornberg	Independent expert—Neurology
Dr Jane Peake	Australian Society of Clinical Immunology and Allergy representative
Associate Professor Sean Riminton	Independent expert—Clinical Immunology

MEMBERS OF THE NATIONAL IVIG CRITERIA REVIEW WORKING GROUP

During 2010–11 the NBA will undertake a public consultation process to seek comments on the proposed changes.

Australian National Haemovigilance Program

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Provide clinicians and stakeholders with information on the safe use of blood by publishing the second *National Haemovigilance* Report by June 2010.	The report was completed by 30 June 2010 and will be ready for uploading to the NBA website by 28 July 2010

The Haemovigilance Advisory Committee, recommended by the Haemovigilance Project Working Group and endorsed by the Jurisdictional Blood Committee, met for the first time in July 2009. Issues occupying the committee during 2009–10 included the data definitions for the national haemovigilance data set, stakeholder engagement strategies, governance and access to national haemovigilance data, proposals for new transfusion-related national indicators of safely and quality in health care, and the elements of jurisdictional haemovigilance systems.

THE NBA'S KNOWLEDGE NETWORK IN ACTION : THE HAEMOVIGILANCE ADVISORY COMMITTEE

MEMBERS OF THE HAEMOVIGILANCE ADVISORY COMMITTEE

The evolution of the NBA's haemovigilance program is an excellent example of the way in which we harness existing systems and local capabilities to develop national initiatives.

At the outset we consulted the states and territories and found significant interest and support from both clinical and government sectors to provide enhanced and nationally consistent reporting on blood related adverse events. To inform the design of the project we collaborated with South Australia and New South Wales to explore the capacity of existing hospital systems to provide blood related adverse events information, and determined that not only was this possible, but that with expert guidance and some system development, the data thus obtained would have a strong concordance with international datasets of adverse events and their definitions. To know we would be able to compare our transfusion safety performance with that of overseas countries gave us a great start.

A National Haemovigilance Project Working Group was established in 2007 to drive the work forward. The group, an important component of the NBA's knowledge network, provided multi-sectoral and multi-disciplinary perspectives and expertise to identify key principles, and inform the development of a national database and reporting framework. Its identification of a national minimum dataset of reportable adverse events, endorsed by the Jurisdictional Blood Committee, led to the publication of the *Initial Australian Haemovigilance Report* in February 2008.

In addition to data, the report contained a number of recommendations for further work. The most significant of these was to establish an enduring haemovigilance program in Australia. The Jurisdictional Blood Committee endorsed this proposal and approved funding. The enthusiasm and commitment of the working group was again demonstrated when the majority of the members agreed to become members of the ongoing Haemovigilance Advisory Committee, thus continuing to assist the NBA in the delivery of this valuable component of its mandate. The current membership as at 30 June 2010 is given below.

The Haemovigilance Advisory Committee has now auspiced the second report on haemovigilance in Australia which contains increased and expanded data from the previous report and has developed a detailed set of recommendations to progress the core improvements in processes and procedures that have been observed.

Through the work of this network of committed representatives on the Haemovigilance Advisory Committee and the dedication of individuals on the ground within hospitals, haemovigilance in Australia is now well established and will contribute to improved patient outcomes.

HAEMOVIGILANCE ADVISORY COMMITTEE	
Dr Chris Hogan (Chair)	National Blood Authority (Principal Medical Officer)
Mr Neville Board	Australian Council for Safety and Quality in Health Care
Dr Simon Brown	Queensland Health Blood Management Program
Ms Maria Burgess	ACT Health
Mr Ken Davis	Australian & New Zealand Society of Blood Transfusion
Dr David De Leacy	QML Pathology
Professor Henry Ekert	Australian Department of Health and Ageing
Professor Robert Flower	NBA Fellow and Australian Red Cross Blood Service
Ms Jenny Hargreaves	Australian Institute of Health and Welfare
Ms Bernie Harrison	Clinical Excellence Commission, NSW
Dr Anne Haughton	Australian Association of Pathology Practices
Dr Bevan Hokin	Australian Private Hospitals Association
Ms Sue Ireland	Jurisdictional Blood Committee
Ms Susan McGregor	Transfusion Nurse, Western Health
Professor John McNeil	Monash University School of Public Health and Preventive Medicine
Dr Ian Prosser	Therapeutic Goods Administration
Dr Erica Wood	Australian Red Cross Blood Service

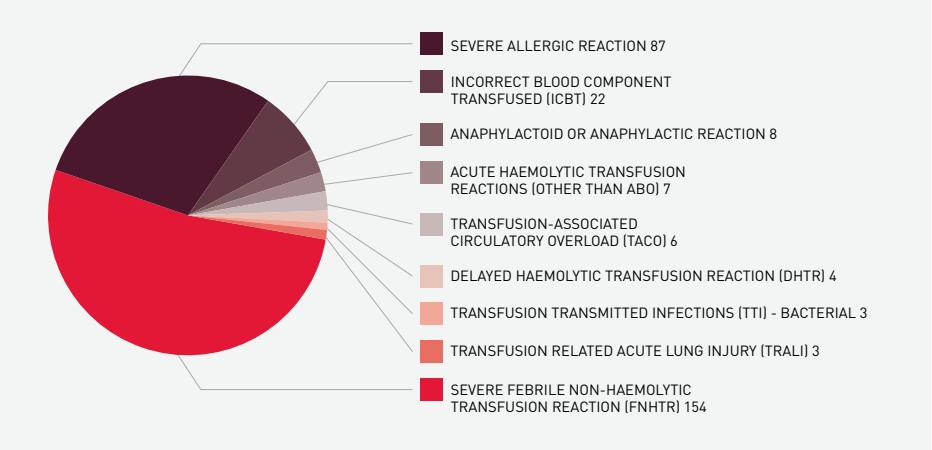


FIGURE 3.22 *Numbers of serious adverse events reported to the Australian National Haemovigilance Program 2008–09*

The NBA provided assistance to states and territories in collecting haemovigilance data by developing specifications to analyse haemovigilance data reporting capability. Jurisdictions overcame difficulties in preparing analyses and reports where data were not readily available, and grappled with issues of comparability and data custodianship. The *Australian Haemovigilance Report 2010* was completed by 30 June 2010 and will be available on the NBA website by 28 July 2010. Figure 3.22 identifies the numbers and types of events recorded.

The report delivers 12 key recommendations in the areas of:

- aligning prescribing practice better to patient blood management principles
- strategies to reduce procedural errors
- better integrating the haemovigilance activities to broader national quality and safety initiatives
- data quality and validation processes and consistency of reporting of defined events
- jurisdictional capacity to report haemovigilance data.

On the international front, Dr Chris Hogan, the NBA's Principal Medical Officer, represented the Australian program at the International Haemovigilance Network annual meeting in Dubrovnik, Croatia. Issues identified at this meeting are summarised in Part 5, on page 109.

Red cell usage analysis linkage project

QUALITATIVE DELIVERABLE	ASSESSMENT SUMMARY
Facilitate a more detailed analysis of red cell usage data by recommending methodology for a red cell usage linkage model to all jurisdictions by March 2010.	Partially met. In collaboration with the Australian Institute of Health and Welfare and jurisdictions, a minimum data set for recording red cell usage was agreed.

The purpose of the red cell utilisation project is to provide for more detailed analysis of red cell usage data through state- and territory-based data linkage projects. This will provide data on the appropriateness of the use of red cell products in Australia by:

- providing a nationally consistent data set of (and ultimately a national report on) red cell use in Australia
- making available data that could be used to drive and influence clinical practice via peer-based review.

The NBA is collaborating with the Australian Institute of Health and Welfare to develop a proposal for a nationally facilitated data linkage project. As part of this, the NBA organised for an expert on health care data linkage to conduct a workshop in December 2009 to provide guidance on the development of a strategic approach. The Department of Health in South Australia and the Clinical Excellence Commission in New South Wales are also contributing research and data to the project.

The challenge for the NBA is to devise a methodology that will allow the disparate data collection systems within each jurisdiction to provide information against the proposed minimum data set (summarised in Table 3.14). The development of the fate-of-product capability in the ordering and receipting blood system will be a major step forward for the capture of a significant proportion of this data and will influence the next steps on this project.

During 2009–10 the members of the red blood cell utilisation working group were:

NAME	
Ms Joan Bedford	Western Australia
Ms Karen Botting	Victoria
Ms Rachel Allden	South Australia
Ms Carolyn Der Vartanian	New South Wales
Dr Marija Borosak	Blood Service
Mr Ken Tallis	Australian Institute of Health and Welfare
Ms Kate Mallen	Australian Institute of Health and Welfare
Dr Phil Anderson	Australian Institute of Health and Welfare

TABLE 3.14 Proposed minimum data set for recording red cell usage

HOSPITAL SYSTEM	BLOOD BANK	PATHOLOGY
Hospital number Patient unit number Admission date/time Separation date/time Episode of care Nature of separation Source of referral Admission category Patient category Sex Gender Date of birth Age grouping—standard Age grouping—with obstetrics separately identified Statistical local area Postcode State flag Length of stay in hours Hours in intensive care unit Diagnosis related group (DRG) Major diagnostic category (MDC) ICD (International Classification of Diseases) codes (all diagnoses, procedures, external cause, activity and place of occurrence) Service related group (SRG) code Enhanced Service related group (eSRG) code Surgical/medical/other Overnight Emergency Transfusion	Hospital code Patient medical record number Date/time of issue Type of blood product Donation bar code (if available) Date of return (blank if product was not returned)	Hospital code Patient medical record number Admission haemoglobin test date/time Admission haemoglobin test result Pre-transfusion haemoglobin test date/time Pre-transfusion haemoglobin test result Post-transfusion haemoglobin test date/time Post-transfusion haemoglobin test result Separation haemoglobin test date/time

Education initiatives

The two projects described below are examples of how significant and useful programs initiated by individual states and territories have been helped by the NBA to become nationally available.

The BloodSafe e-Learning Project

In 2006 the South Australian Department of Health funded the development of an online education package for clinical staff involved in the transfusion chain, including medical officers, nurses, midwives and courier or porter staff, who transport blood products. The Bloodsafe e-Learning tool has been very successful throughout Australia and in 2008–09 the Jurisdictional Blood Committee agreed to provide national support for three years.

The website continues to be popular, with new registrations averaging around 2,500 per month; in June 2010 it reached a significant milestone when the user registration number hit 50,000. The project is highly regarded; in 2009 the program received two South Australian awards and was a finalist for the South Australian Premier's Award.

During 2009–10, governance arrangements for the project were established with the creation of a National e-Learning Transfusion Advisory Committee. Additional material was added to the website, including promotional print documents, a promotional DVD and reporting functionality, and discussions commenced with the database developers on changes needed for additional content. The committee agreed that the program for the next 12 months would focus on:

- review of existing content and update as needed to conform to current practice and policy (using the new patient blood management guideline if available)
- completion of the post-partum haemorrhage module
- expansion of the existing assessment database and formats
- development of an anaemia management module with an initial emphasis on iron deficiency anaemia
- development of a blood/cold chain management/inventory module (particularly for hospitals with no on-site pathology laboratory).

Graduate Certificate in Transfusion Practice

In February 2009, the Jurisdictional Blood Committee agreed to provide funds additional to those already committed by the Victorian Department of Human Services to support the redevelopment of the Graduate Certificate in Transfusion Practice course material for delivery through the University of Melbourne in the 2010 academic year. This is the only formal transfusion-specific tertiary qualification in Australia especially intended for transfusion improvement practitioners. The NBA administers the funds approved for this purpose by the Jurisdictional Blood Committee.

The redeveloped course includes modules on transfusion patient safety, clinical transfusion practice and quality requirements. It has also provided an opportunity to incorporate national input into the curriculum's content, in consultation with the Australian and New Zealand Society of Blood Transfusion, the Blood Service, the Royal College of Nursing and the University of Melbourne.

During the latter half of 2009 and in 2010 the course material for both semesters was reviewed and updated using authors from across Australia, and was evaluated by a small expert panel. Topics were developed or altered to align with national direction, and there is a particular focus on patient blood management.

The first student intake of the redeveloped course is proceeding well, with the initial informal evaluation positive for content, delivery and support. Semester 2 topics are in preparation for the latter half of 2010.

PART FOUR
SECTOR INFORMATION MANAGEMENT INITIATIVE

SAMPLE HOLDER AT THE BLOOD SERVICE

› USED TO TEST SAMPLES OF DONOR BLOOD

› EVERY DONATION IS SCREENED FOR HEPATITIS B AND C, HIV, HTLV AND SYPHILIS

PART FOUR PROVIDES INFORMATION ABOUT THE NATIONAL BLOOD AUTHORITY'S NATIONAL INFORMATION MANAGEMENT AND REPORTING STRATEGIES FOR THE BLOOD SECTOR—MAJOR PROJECTS THAT ARE IMPACTING ON ALL ACTIVITIES OF THE ORGANISATION.

4

4.1 INTRODUCTION

Since its establishment in 2003, the NBA's work has ensured that Australian patients have access to a secure supply of high-quality blood products. To achieve this, we have implemented rigorous and well-designed processes and strong and innovative risk mitigation and management strategies. The NBA has actively engaged with the clinical sector to address the appropriateness of the use of product.

In 2009–10, while these activities proceeded as 'business as usual', we implemented a range of new strategies to drive enhanced performance of the sector through the provision of systems and data. The scheduling of the development of the NBA's capabilities is depicted in figure 4.1 below.

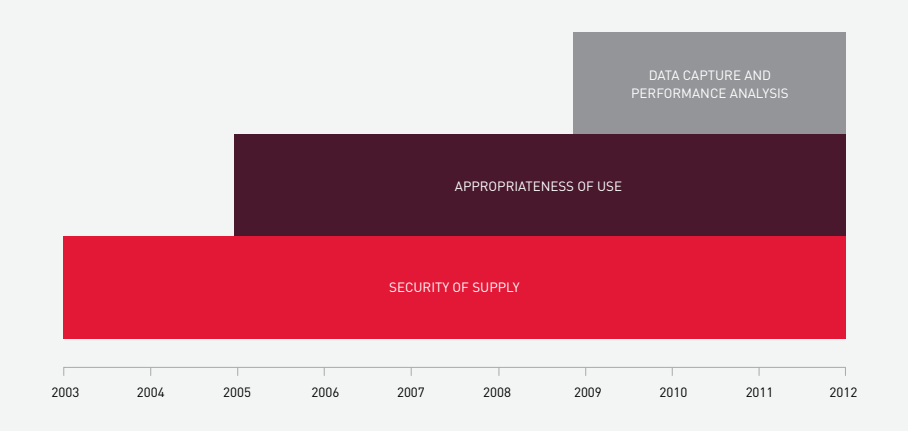


FIGURE 4.1 *Evolution of the NBA's priorities*

The work on data delivers against the NBA's roles as defined in the National Blood Agreement at clause 25(o), 'to undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply', and clause 35(f), 'to facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector'.

The NBA's roles also reflect the 2001 Stephen Review recommendation that 'the National Blood Authority should develop a national information management and reporting plan for the Australian blood sector. This should include development of a range of indicators for monitoring performance'.

4.2 INFORMATION AND DATA ACTIVITIES, 2003 TO 2009

The NBA and the Jurisdictional Blood Committee have undertaken a range of activities to progress the objectives outlined in the National Blood Agreement and the recommendations of the Stephen Review.

There have been a number of decisions and reports on this matter, including the Crawford Report and the Jurisdictional Blood Committee's 2007 decision on data principles for sector data developments. The process culminated in the adoption of the Sector Information Management and Data Strategy (the strategy) by the Jurisdictional Blood Committee in August 2008.

The primary objectives of the strategy are to provide a framework to support the development of information management systems and the generation of data on blood and blood products that contributes, in a cost-effective way, to:

- improved clinical outcomes
- improved cost-effectiveness and utilisation of products
- a secure supply.

The strategy built on an earlier analysis of the information flows within the sector which identified that information and data within the blood sector falls within four broad domains:

- supply: this data covers the physical manufacture and distribution of product
- clinical: data generated in this domain contributes to improving health outcomes. This can be at an individual patient level (for example, data on an individual's clinical usage of product and the outcomes) or in broader clinical groups (for example, to influence guideline development)
- blood sector management and policy: functions that lie within this domain include managing and optimising supply, predicting demand, contingency planning and organising supply and logistics
- health sector policy: in terms of scope, content and definition the data should align with broader health sector policies and procedures.

TABLE 4.1 Information/data needed in the supply, clinical, sector management and health sector policy domains

SUPPLY	CLINICAL	BLOOD SECTOR MANAGEMENT	HEALTH SECTOR POLICY
Production levels	Product administered	Production levels	Standards
Importation levels	Indication	Importation levels	Regulations
Orders received	Patient outcome	Orders received	Data dictionaries
Inventory levels	Haemovigilance events	Product issued	Data definitions
Production information (batch #, expiry date etc)		Product received	Performance measures
Registered Approved Health Providers		Product fate (including wastage)	
Product issued		Forecast	
Supply forecasts		Demand drivers	
		Consumption versus forecast	
		Registered Approved Health Providers	
		Cost and payment information	

The nature of the information required by different users within each domain or for each management purpose (summarised in Table 4.1) will also be driven by a number of aspects including:

- the value of the product used and other cost pressures
- whether the product is, or could be, in short supply
- where accountability lies
- whether the information can contribute towards improving clinical care
- the type of product and its use.

In addition, in the absence of any national control or consistency, suppliers have developed purpose-specific systems to manage and track their products. As a result, existing information and data collection systems in the blood sector have generally been built incrementally from a product-based approach. On that basis, the strategy recommended inter alia that:

> *The development of systems that generate data for use in the Blood Sector should have a product focus, but seek opportunities for incorporation within broader systems which cover classes of blood products and/or pharmaceuticals.*

Following endorsement of the strategy by the Jurisdictional Blood Committee, two major activities were undertaken:

- the NBA was tasked by the Jurisdictional Blood Committee to develop systems to capture details on high-cost and rapid-growth blood products
  - this led to the redevelopment of the Australian Blood Disorders Registry and the development of specifications for a national IVIg management system
- the NBA developed internal capacities—particularly the Integrated Data Management System.

At the same time, the Queensland Department of Health commenced development of an ordering and receipting blood system to aid in the verification of Queensland's use and expenditure.

4.3 FROM SYSTEMS TO INTEGRATION, 2009 ONWARDS

Following a review in early 2009, the NBA was restructured in July 2009 and the NBA's inaugural Chief Information Officer was appointed, with a remit to implement the strategy and to collect, analyse and disseminate performance data relating to the Australian blood sector.

The restructure included the establishment of a dedicated ICT team in the NBA with the objective of progressing our role from the provision of system-specific capacity, to understanding the scope for and designing the framework to allow the effective integration of these systems. During 2009–10 this team has undertaken a range of activities detailed below.

Enhancement of existing systems and capabilities

The analysis of the existing system and capabilities of the sector revealed that there is an excellent potential to capture much of the data required to effectively identify and monitor the performance of the sector and its individual components (such as in the areas of inventory management, product orders and issues, age of product, use of product). This data can be measured on an ongoing and comparable basis.

Developments proposed for a number of the systems described below are designed to consolidate the availability of this data for access by government in a timely manner.

Australian Bleeding Disorders Registry

The redeveloped Australian Bleeding Disorders Registry was launched in December 2008 and was deployed to users in all haemophilia treatment centres and clinics across the nation. The system is designed to produce data which fulfils the needs of clinicians, patient representative groups and governments within a highly controlled governance framework.

The registry contains an electronic summary care record for all patients with haemophilia and other bleeding disorders within Australia which can be created, accessed and updated by authorised clinical users within the patients' respective haemophilia treatment centres. The system promotes an enhanced quality of care for these patients, particularly for those that may require treatment at more than one Haemophilia Treatment Centre.

2009 saw the delivery of the capacity of the NBA to access the three patient de-identified reports that provide the NBA and jurisdictions with data relating to product demand, product use and patient demographics. These reports enable the NBA to undertake more reliable supply planning and forecasting. In addition, the data is used to enable the high-cost patient pool to be calculated and monitored.

The NBA worked through the Australian Bleeding Disorders Registry Steering Committee and the Australian Haemophilia Centres Directors Organisation to assist data managers employed in Haemophilia Treatment Centres to improve both the completeness and quality of data in the system. We hope that the improvements in the quality and volume of data now available in this system will enable the NBA, in consultation with the Australian Bleeding Disorders Registry Steering Committee, to produce an annual report before January 2011.

KEY PERFORMANCE INDICATOR	MEASURED BY
The Australian Bleeding Disorder Registry meets stakeholder expectations	Level of satisfaction of stakeholders with ABDR management and functionality. 68% of users satisfied with management support. 57% agreed that functionality had improved over the year with between 50% and 80% of users satisfied with core elements of system functionality However, 79 % stated that the functionality did not yet meet their expectations reflecting the continued delay in the delivery of the reporting module.

Extensive work was also undertaken in conjunction with the vendor of the system to resolve outstanding functionality requirements and a large number of ongoing technical issues that made the system significantly more 'user friendly'. The key functionality delivered during the year was an advanced search module to enable users to query the system and readily export data for further manipulation and analysis.

National Blood Authority business intelligence system

Launched in January 2010, the NBA's new business intelligence system provides a single repository for the secure storage, manipulation, integration and analysis of data drawn from other NBA systems. Many of the tables and figures in this report are drawn from this system.

Data sets incorporated into the system during 2009–10 relate to product, purchases, inventory, issues and specialised data sets relating to clotting factor products. When further populated, the system will allow us to provide consistent and timely updating to jurisdictions and other stakeholders.

Integrated Data Management System

The Integrated Data Management System is used by the NBA to manage the budgeting and forecasting of supply and demand for blood and blood related products, inventory management and contract administration. One of the key functions performed by the system is the validation of supplier invoices for blood and blood products before payment.

A significant program of work was undertaken in 2009–10 to deliver a series of enhancements to consolidate the functionality and useability of the system. A comprehensive user training program was undertaken along with continued work on cleansing of data migrated from the previous systems.

National IVIg Management System

The National IVIg Management System was envisaged as a system to capture information on the use of intravenous immunoglobulin (IVIg) in order to support and align with the *Criteria for clinical use of IVIg in Australia*. As reported in the NBA Annual Report 2008–09, the technical specifications for the system were developed following an extensive consultation process with all stakeholders.

No development work on the system was undertaken in 2009–10 while the team focused on the other systems already in existence and determined the best way to proceed. This work has now been completed and future development work for the National IVIg Management System will focus on supporting any future strategies for improving the management of IVIg.

Ordering and Receipting Blood System

Developed by Queensland Health as a state-wide system for the ordering and receipting of blood and blood products, the Ordering and Receipting Blood System replaces previous manual systems for ordering products from the Blood Service with an automated, user-friendly and secure system that also provides product receipting, inventory holding collection, feedback mechanisms and electronic delivery of product issue notes.

Most significantly, this data is available to all users, enabling them to track usage and ordering patterns. The data also gives information to users about the status of their inventory holdings—for example, so that they know the age of product at receipt. One of the great benefits of the system for the Blood Service is that it can obtain direct and automated feedback on the quality of its distribution services.

In recognition of the fundamental requirement of this capability to support the introduction of the output based funding model for fresh blood products, a National Proof of Concept trial of the Ordering and Receipting Blood System commenced in December 2009, with the NBA and Queensland Health working with South Australia and Tasmania to deploy the system in those jurisdictions. The system was deployed in three hospitals in South Australia (two public and one private facility) and across all hospitals (both public and private) in Tasmania. Two further states have expressed a strong interest in the system and a number of hospitals in Victoria are due to start using the system in late July 2010. Feedback to date on the trial has been highly positive from both hospitals and the Blood Service. A full evaluation of the trial will be completed and presented to the Jurisdictional Blood Committee by the end of 2010.

During the year, significant additional development work on the Ordering and Receipting Blood System was undertaken by Queensland Health and the NBA. The system now delivers the enhanced functionality required for the system to be deployed nationally, for example:

- the system is now able to operate across multiple jurisdictions and time zones
- the transmission of orders to the Blood Service can now be performed by encrypted email rather than through the facsimile system
- the security of the system has been enhanced
- a fate-of-product module was scoped so that hospitals will be able to record how product is used. This will enable monitoring of the appropriateness of use and level of wastage of blood and blood products.

In addition during 2009–10, the NBA commenced work closely with a number of jurisdictions to define the work required to interface the Ordering and Receipting Blood System into existing hospital laboratory information management systems, thereby enabling the automated transfer of issue note, inventory and fate-of-product data between the two systems.

Development work to expand the Ordering and Receipting Blood System so that the system can order and receipt blood products from suppliers other than the Blood Service, is currently scheduled for late 2010, should the Jurisdictional Blood Committee agree to its national deployment.

ORBS SCREEN SHOT

Assessing the international experience

During 2009–10 a detailed analysis was undertaken of blood sector systems in place in a number of countries comparable to Australia, with the aim of integrating best practices and/or systems from these countries into the Australian blood sector.

In summary, many excellent methodologies and individual performance metrics were identified, as were a number of systems, at least some of which could be easily implemented in Australia in the near future. These methodologies will be further analysed during 2010–11 for their capacity and applicability for replication in Australia.

Performance measures for the Australian blood sector

One of the key drivers behind recent work to implement the Sector Information Management and Data Strategy has been the need to develop a framework that supports performance measures to improve clinical outcomes, demonstrate cost-effectiveness and the degree of effective utilisation of products, and monitor security of supply.

In 2009–10 the NBA developed a draft set of performance measures for the Australian blood sector aligned to the existing national health performance matrix:

- effectiveness
- appropriateness
- efficiency
- responsiveness
- accessibility
- safety
- continuity
- capability
- sustainability.

It is intended that the measures will be reported at a national level and also:

- at the clinical level (that is, at the hospital/patient level) to capture clinical outcomes, cost-effectiveness and how products are used
- at the supplier level, to capture efficiency and adequacy of supply arrangements
- at the government level, to capture effectiveness of management of the sector.

A discussion paper on the performance measures, to be released publicly by the NBA in 2010–11, will seek the views of all stakeholders on the proposed measures and frameworks before a decision is made by the Jurisdictional Blood Committee.

Governance arrangements

Detailed governance arrangements are in place for a number of the individual systems within the blood sector, such as the Australian Bleeding Disorders Registry Steering Committee. During the course of the year, the NBA considerably strengthened the information protection arrangements in place for all systems.

The NBA commenced work on a detailed information and data governance framework to guide the use and access to data that will be generated from the implementation of the strategy.

MEMBERS OF THE AUSTRALIAN BLEEDING DISORDERS REGISTRY STEERING COMMITTEE DR JOHN ROWELL, DR MEGAN SARON, SHARON CARIS, DR CHRIS BARNES AND GEOFF SIMONS, WITH NBA STAFF

Proposed implementation of the Sector Information Management and Data Strategy

The outcomes of the work and analysis described above were presented to the Jurisdictional Blood Committee at its meeting held in May 2010, together with a high-level implementation plan. A detailed implementation plan will be considered by the Jurisdictional Blood Committee in December 2010. The NBA's aim is to implement the strategy in full by June 2012.

The system enhancements will enable the NBA to provide data on performance measures for the Australian blood sector. At the same time, they will reduce reliance on some systems that suppliers currently have in place, so that the NBA will not need to rely on suppliers to provide many of the data sets that are critical to assessing performance measures.

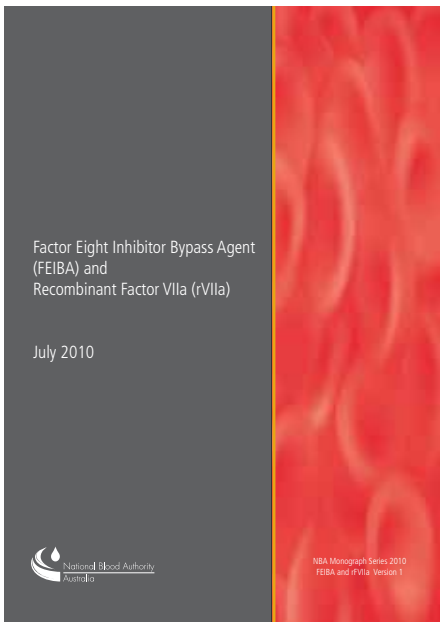
4.4 DISSEMINATION OF INFORMATION

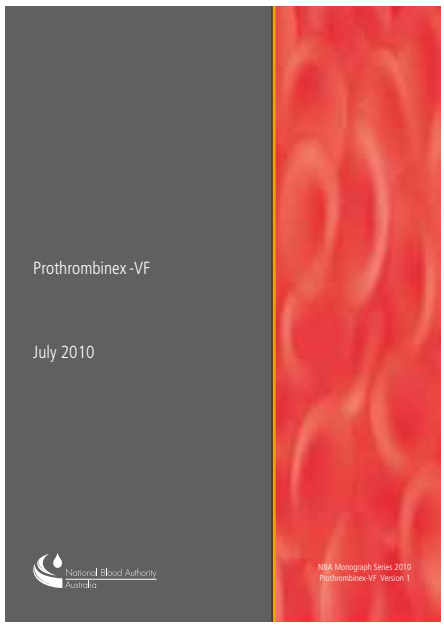
The NBA is committed to providing accurate data and information to inform the blood sector and to ensure supply. As part of this commitment, in 2009–10 the NBA began producing a series of product monographs.

The purpose of the monograph series is to provide a single, comprehensive source of information that can be used to gain accurate and thorough information about the products. The monographs provide critical information, including:

- product descriptions
- product indications
- historical information on policy and practice changes since the start of the NBA
- current management requirements
- a brief description of the demand for the product and the issue and expenditure trends over time.

The monographs aim to provide a useful resource for states and territories and NBA staff. In 2009–10, drafts of the first monographs, covering FEIBA, recombinant Factor VIIa and Factor IX, were sent to states and territories for comment and was finalised by July 2010.





NBA MONOGRAPHS

4.5 DATA STANDARDS AND INDICATORS

Regardless of how comprehensive and efficient an information management system is, it depends for its robustness and usefulness on the accuracy and consistency of the data it contains. In addition to the work the NBA undertook in 2009–10 on the Sector Information Management and Data Strategy, steps were also taken to develop nationally agreed data standards that will enable consistent reporting using comparable data when blood and blood related products are referenced.

In developing these standards the NBA was involved in extensive consultation with stakeholders and collaboration with other agencies in the broader health sector.

National indicators project

Suitable clinical coding is vital to data collection projects because it unifies relevant data on blood and blood related activities in hospital systems' central patient records. However, currently, ICD-10-AM codes and AR-DRG codes are not specific enough to directly capture blood-specific data and treatments involving blood data, although we note that work in this area has recently been initiated.

An NBA proposal for a national indicator on transfusion complications was included in a report from the Australian Institute of Health and Welfare to the Australian Commission on Safety and Quality in Health Care. The proposal recommended indicators for national reporting on safety and quality. The commission will forward its recommendations to the Australian Health Ministers Advisory Council.

In 2009–10 the Haemovigilance Advisory Committee also agreed to work with the National Centre for Classification in Health to explore the possibility of defining new clinical coding standards for transfusion-related adverse events in the ICD-10-AM codes. However, the committee is mindful that there is no consensus on issues such as mandatory reporting.

National clinical coding would align blood sector standards with those applying in the health sector more generally, and would help to ensure that our data collection methodology is consistent with current best practice.

Standard measures for the use of fresh blood components in Australia

The consultative draft *Guide to the set of standard measures for the use of fresh blood components in Australia* was released on the NBA website at the end of June 2009, and was published early in 2009-10. The draft guide has been publicised, including at international conferences.

The period of review of the draft guide concluded at the end of June 2010. In the coming year, the NBA will review the comments received and, in consultation with stakeholders, prepare an initial version of the guide.

Barcoding

In 2007 the Jurisdictional Blood Committee mandated standards for the barcoding of blood and blood related products, to be implemented from July 2011. During 2009–10 a barcode translation device was developed as a technical solution to allow hospitals to deal with barcodes. However, the NBA identified several complex technological issues that the blood sector must address before the barcoding policy can be implemented. In May 2010, therefore, the Jurisdictional Blood Committee endorsed the NBA's proposal to delay the implementation of the barcoding policy so that it can align with the implementation of blood ordering and receipting technology.

In 2010–11 the NBA will work with the sector to determine the details to be captured on barcodes and the technology to be used, and will develop an implementation plan.

PART FIVE
HORIZON SCANNING

› SEPARATED AND FROZEN WITHIN 18 HOURS OF COLLECTION CONTAINS ALL OF THE COAGULATION FACTORS

PART FIVE DESCRIBES EXTERNAL INFLUENCES THAT COULD AFFECT THE WAY THE NBA DOES BUSINESS IN THE FUTURE. IT PROVIDES A SUMMARY OF THE CORE DEVELOPMENTS THAT WE HAVE MONITORED DURING 2009–10, INCLUDING FACTORS THAT MAY AFFECT GLOBAL SUPPLY, DEMAND AND PRICING, INCLUDING SAFETY ISSUES AND INTERNATIONAL REGULATORY TRENDS.

5

5.1 INTRODUCTION

The NBA monitors international developments that may influence the management of blood and blood related products in Australia. The horizon scanning program, which forms an integral part of our knowledge network, allows the NBA to be well informed and provide the best possible advice to governments and stakeholders.

Our ongoing focus is on:

- information that may have an impact on global supply, demand and pricing—for example, changes in company structure, capacity, organisation and ownership
- diseases or pandemics that may have an impact on supply
- new product developments and applications
- global regulatory and blood practice trends
- emerging risks that could potentially put financial or other pressures on the Australian sector.

This Part gives a summary of the core developments that have come to our attention during the year. They are not presented in any order of priority. However, the detail and the breadth of the coverage have been influenced by the very positive feedback we received last year from this chapter in our annual report. In particular, given that we explained in that report the implications on our business of each aspect of the external environment that we survey, this year we have focused on providing more examples of the developments in research and product development.

5.2 FRESH BLOOD

Transmissible diseases

Transmissible diseases, whether endemic to Australia, emerging in Australia or potentially arriving from overseas, are monitored by the NBA as part of our horizon scanning program. This activity is vital for two reasons:

- It is essential that the blood supply is safe and the community remains confident that the national blood supply is free of the risk of infection.
- Any upsurge in community infection—bacterial, viral or parasitic—has the capacity to lead to increased deferrals of blood donors and hence a potential shortage of blood and blood-derived products. The impact of these diseases may be regional (as in the case of the dengue outbreak in northern Queensland in 2009–10) or national.

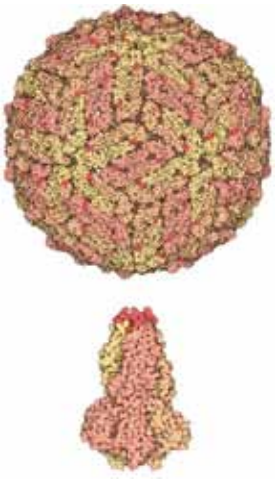
In its *Annual Report, 2008–09*, the NBA discussed a range of diseases of concern, including:

- mosquito-borne diseases—specifically, dengue, chikungunya, and malaria
- influenza, both seasonal and pandemic.

The focus on understanding changes in the nature or spread of these diseases continued throughout the year. A brief update on issues related to these diseases is given below, along with information about a range of other diseases of potential concern.

Dengue

Dengue remains a disease of concern in all parts of the world. In Australia, the presence of this virus again resulted in the need to restrict blood collections in northern Queensland in the summer of 2009–10.



DENGUE VIRUS STRUCTURE. ATTRIBUTION: DAVID S. GOODSELL (DOI: 10.2210/RCSB_PDB/MOM_2008_7)]

Those infected with the virus can exhibit symptoms ranging from flu-like illness to dengue hemorrhagic fever/dengue shock syndrome, which can cause a capillary leak syndrome, disseminated intravascular coagulation and life-threatening shock.

Tetravalent vaccine is now considered by some researchers to be essential because dengue can be caused by any one of four related virus serotypes of the genus *Flavivirus*. Research by the La Jolla Institute in the United States supports the hypothesis that subneutralising levels of dengue virus antibodies may exacerbate the disease. Accordingly, the challenge in developing any vaccine is to ensure that recipients develop antibodies to all dengue serotypes.

A number of vaccines are in development or undergoing clinical trials. Sanofi is continuing to test its tetravalent vaccine and hopes to market it in 2015.

There were several other promising developments during the year:

- The University of Queensland received a $US100,000 grant from the Bill and Melinda Gates Foundation to explore options to fight dengue, malaria and other mosquito-borne diseases, with the main focus being on producing an affordable vaccine.
- Inovio Biomedical Corporation announced that the company's first SynCon dengue virus vaccine induced neutralising antibody responses against all four distinct serotypes of dengue virus.
- A vaccine created at GenPhar's headquarters in South Carolina has proved effective in protecting primates against all four strains of dengue fever. The Naval Medical Research Center is conducting human clinical trials.
- Arbovax is testing its proprietary dengue fever vaccine platform on primates in 2010. The platform is designed to create cost-effective vaccines targeting other arthropod-borne diseases as well—for example, Japanese encephalitis, West Nile virus, chikungunya and yellow fever.

Chikungunya

Chikungunya is a mosquito-borne disease that can cause fever, headache, fatigue, nausea, vomiting, muscle pain, rash and joint pain. Symptoms typically last a few weeks, although some patients have reported joint pain lasting for months. The disease can be fatal and there is no vaccine. Recently, the US National Institute of Allergy and Infectious Diseases has tested a chikungunya vaccine successfully on monkeys.

As with dengue, the geographic range of chikungunya has increased considerably.

There were several developments during 2009–10:

- Dr James Diaz of the Louisiana University Health Sciences Center (USA) has warned that chikungunya is a potentially serious threat to the US and Europe. Since 2005, the virus has reached Italy and France. Efforts are under way in southern Europe to eliminate the Asian tiger mosquito.
- A research paper on emerging infectious diseases, published by the US Centers for Disease Control and Prevention, has indicated that the strain of chikungunya that caused the 2006 epidemic in India is a new strain belonging to the novel Central/East African genotype, and it appears to have replaced the relatively uncomplicated Asian genotype. Several unusual clinical features were noted during that epidemic, including meningo-encephalitis, severe hepatitis and mother–child transmission.
- A significant outbreak of chikungunya affected Thailand, particularly the southern region, including tourist destinations such as Phuket.

In Australia, no cases of local transmission of chikungunya have been reported, although known competent mosquito vectors for chikungunya are to be found here—for example, *Aedes aegypti* occurs in northern Australia and *Aedes albopictus* is found on the Cocos, Christmas and Torres Strait islands.

Malaria

Malaria continues to pose significant health problems for a large part of the world's population.

Resistance is developing to one of the main malaria drugs now in use, just as we saw resistance to chloroquine develop 50 years ago. Two studies have highlighted the growing problem of resistance to artemisinins in *Plasmodium falciparum* malaria in Southeast Asia.

However, Australian researchers have discovered how the malaria parasite resists chloroquine. As a result of a belief that an earlier breakthrough implicated a particular gene in this process, biochemist Dr Rowena Martin and her team at the Australian National University have now shown how this gene affects resistance, and this allows the gene to be circumvented when developing new drugs.

Efforts to develop vaccines continued this year. Recent research carried out during the year included:

- Dutch biotechnology firm Crucell has gained funding to accelerate the development of a malaria vaccine. It has entered into a collaboration with two US-based organisations—the PATH Malaria Vaccine Initiative and the US Agency for International Development Malaria Vaccine Development Program. The company is already involved in Phase 1 trials of its malaria vaccine with the National Institutes of Health in the US.
- Researchers targeting malaria have:
  - detailed the structure and function of an enzyme crucial to the malaria parasite which could be a highly effective drug target
  - discovered how the malaria parasite is able to invade human cells, which again offers hope for a new range of anti-malarial drugs
  - identified some of the genes mosquitoes use to hunt down their blood meal, offering scope for improving mosquito repellents
  - capitalised on the ability of mosquitoes to transmit pathogens by co-opting them to deliver vaccines instead. Researchers from the Jichi Medical University in Japan have genetically engineered the *Anopheles stephensi* strain of mosquitoes—most infamous for their role in spreading malaria—modifying their salivary gland to deliver a vaccine protecting against the parasite *Leishmania*.

West Nile virus

West Nile virus has proved a significant problem for the US blood supply. A US study has revealed that the infection rate for West Nile virus in its population is very much higher than was previously thought. It is now known that people infected with West Nile virus may have persistent virus in their kidneys for years, potentially leading to kidney problems. No vaccine currently exists for West Nile virus. There are continuing concerns about the rate of spread of this disease, with newly-colonised areas appearing in central Switzerland and Italy.

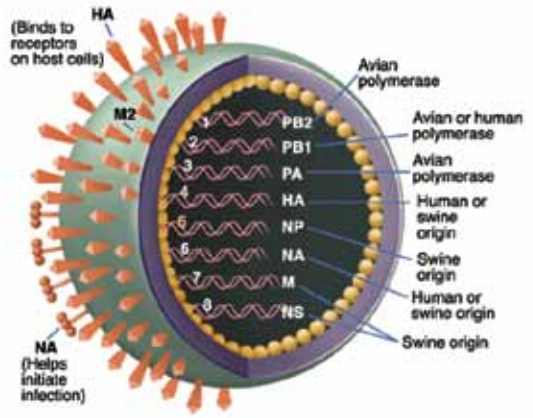
Influenza

The H1N1 2009 influenza virus (swine flu), declared pandemic by the World Health Organization in 2009, has caused serious illness and death.

In Australia, a vaccine for both adults and children became available towards the end of 2009 and was provided free of charge by the Australian Government. Meanwhile, the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) were being used around the world to ameliorate influenza symptoms. Various countries have reported an oseltamivir-resistant strain of influenza, but this has not yet become a widespread issue.

Around the world, the H1N1 pandemic was seen as a 'test run' for the feared pandemic of Avian flu (A(H5N1)). A number of forums have discussed the lessons learned from the world's response to this pandemic. They have provided better understanding of, and planning for, the impact of a pandemic on the blood sector and should further enhance our ability to manage pandemic events in the future.

One of the concerns about the fast-spreading H1N1 virus was that there might be a genetic re-assortment with the more deadly Avian flu virus (H5N1) and that H1N1 might be the vehicle through which H5N1 achieved human-to-human transmission. Avian flu is not of immediate concern at the moment in Australia, but it continues to claim lives in a number of countries, including Indonesia, Vietnam and Egypt.



SCHEMATIC IMAGE OF H1N1 VIRUS

The H1N1 influenza 2009 also focused attention on research that may be of use in fighting future influenza pandemics. These include:

- a vaccine that works by selectively silencing targeted genes in the viral genome
- a monoclonal antibody intended to protect against multiple strains of influenza
- a vaccine that strings together peptides from target amino acids
- use of antibodies from people who have recovered from the virus to cure those in intensive care
- a vaccine that inserts key proteins into *Escherichia coli* bacteria, prompting the bacteria to produce the fusion protein.

In the intensive care unit of a Melbourne hospital during the H1N1 outbreak last year, it was confirmed that, the sicker patients were, the lower their IgG2 levels were. This observation offered a potential guide to successful treatment. The World Health Organization was alerted at the time, and a paper detailing the research was published in the journal *Clinical Infectious Diseases*. This development may result in higher demand for immunoglobulin (IVIg) products in the future.

The NBA monitored the H1N1 pandemic closely for its potential impact on the blood supply in Australia and observed how blood services around the world responded to the outbreak (see page 64).

Other diseases

HIV/AIDS

Scientists at the Scripps Research Institute in the US have isolated two antibodies that can prevent patients with human immunodeficiency virus (HIV) from developing acquired immunodeficiency syndrome (AIDS). The discovery is a potential breakthrough in the 20-year search for an AIDS vaccine and may eventually help to produce a treatment for HIV-positive patients who develop AIDS.

According to a report in the journal *Science*, the antibodies are able to neutralise many strains of the HIV virus and they target a more or less stable portion of the virus that researchers had previously overlooked. This target does not experience the mutations that have previously made it difficult to develop an AIDS vaccine.

Companies developing an AIDS vaccine include GeoVax, Bionor Immuno, PhotoImmune Biotechnology, and Mymetics Corporation. A six-year Phase 3 trial with 16,000 adult volunteers in Thailand has demonstrated that a vaccine combining Sanofi Pasteur's ALVAC vaccine and AIDSVAX, developed by VaxGen and now owned by the Global Solutions for Infectious Diseases, was 'safe and modestly effective' in preventing HIV infection.

Hepatitis B

The number of people in Australia with chronic hepatitis B infection is predicted to increase markedly over the next decade, according to a new report released by the Australian Centre for Economic Research on Health at The Australian National University.

In order to better meet the potential increased risk to the blood supply, the Blood Service will replace its current semi-automatic nucleic acid testing (NAT) system and duplex assay (for HIV and hepatitis C only) with a fully-automated system and a new triplex, highly sensitive TIGRIS/Ultrio assay for the simultaneous detection of HIV, hepatitis C and hepatitis B. The new system will enable single donations to be tested for hepatitis B DNA and provide for more efficient process control and greater sensitivity for hepatitis B detection.

Table 5.1 shows the change in the infectious window period (WP), the percentage of WP closure and the residual risk estimates for hepatitis B following the implementation of hepatitis B NAT. The WP closure of 37.6 per cent for hepatitis B will reduce the residual risk of transfusion-transmitted hepatitis B from one in 739,000 to one in 1.1 million, which is significantly lower than comparable international blood services.

TABLE 5.1 *Comparison of residual risk estimates following introduction of hepatitis B NAT testing*

VIRUS	ASSAY	NAT POOL SIZE	INFECTIOUS WP (DAYS)	% WP CLOSURE	ESTIMATE OF RESIDUAL RISK (PER UNIT)
Hepatitis B	HBsAg	No NAT	38		1 in 739,000
	ULTRIO	1	24	37.6%	1 in 1.1 million

Cytomegalovirus

Cytomegalovirus is a common infection in the general community, and antibodies are carried by a significant proportion of the population. It is an important cause of post-transplant infection. In that setting, where the patients are highly immunocompromised, the disease can lead to serious sequaelae. For mothers who suffer primary infection during pregnancy, there is a risk to the foetus. The NBA contracts with CSL Limited to produce cytomegalovirus immunoglobulin and issued just over 50 million international units in 2009–10.

US company Vical is trialling a therapeutic cytomegalovirus vaccine for transplant recipients and developing a prophylactic vaccine for women so that they can be vaccinated against the disease prior to pregnancy. If the trials are successful, there could be significant changes in how these patient groups are treated (noting however, that all vaccines require approval by the Therapeutic Goods Administration before they are used in Australia).

Sickle cell disease

As populations move around the world, so too does the nature and profile of diseases more prevalent within those populations. One of these diseases is sickle cell anaemia. Sickle cell anaemia is concentrated particularly in populations of sub-Saharan African descent and affects millions of people worldwide.

The abnormal haemoglobin in patients with sickle cell disease causes red blood cells to adopt an abnormal shape. This impedes the passage of those red cells through vessels and can cause severe pain syndromes and other serious complications. Regular transfusions are used as part of the treatment in sickle cell disease and to prevent complications.

Given recent immigration trends, this disease may become more prevalent in Australia. This could lead to an increase in demand for related transfusion therapy for these patients.

Research to assist patients with this disease include the following:

- GlycoMimetics Inc is completing two mid-stage clinical trials on its drug for sickle cell patients, with results from the first phase showing no serious side effects.
- Sickle cell disease was reversed in 9 out of 10 patients given bone marrow transplants using a new technique. Recipients were free of sickle cells 30 months later.

Donor selection and deferral

Donor selection and deferral is the initial point of screening that maintains the safety of the blood supply. The Therapeutic Goods Administration and the Blood Service regularly review the frameworks around donor selection and deferral, as these must be flexible in order to respond to rapidly emerging threats.

For example, in 2009–10 (following a decision by the Canadian Blood Services, and approved by the Therapeutic Goods Administration in Australia) the Blood Service deferred donations from chronic fatigue syndrome sufferers, as it had been linked in one study to xenotropic murine leukaemia virus related virus infection.

Other issues that impacted on donor selection decision-making during the year include:

- local transmission of dengue virus infection occurring as far south as Townsville
- new guidance for managing human immunodeficiency virus type 1 (HIV-1) group O infection
- the decision to defer recipients of yellow fever vaccine from blood product donation for two weeks because of the theoretical risk of transmission from a viraemic donor.

Product safety

Debate continues on the nature and timing of testing required to maintain the optimal level of safety for the blood supply, as companies develop an increasing range of testing capabilities and/or specificity. In the coming years, clear criteria will need to be developed against which any further changes to the testing regime measured, especially given the very sound status of, and minimal risks to the blood supply posed by, the system currently in place. Examples of developments in testing and screening technology that emerged during the year include:

- Using the EP–vCJD blood-screening assay, Amorfix Life Sciences Ltd has tested 19,000 blood donations in France for variant Creutzfeldt-Jakob disease.
- The US Food and Drug Administration has issued guidance for industry on nucleic acid testing (NAT) to reduce the possible risk of parvovirus B19 transmission by plasma-derived products.
- The US Food and Drug Administration approved a further use for Roche's licensed NAT, for screening source plasma in pools comprising up to 96 individual donations.
- The Canadian Blood Services will begin testing the blood supply for Chagas disease.
- Ortho Clinical Diagnostics announced US Food and Drug Administration approval of a diagnostic assay for the detection of antibodies to HIV types 1 and 2 (Anti-HIV-1+2) for use on a single testing platform.
- Abbott received approval from the US Food and Drug Administration for its ABBOTT PRISM HIV O Plus test—the first fully automated test to screen blood for HIV-1 and HIV-2.
- Lateral Grifols Pty Ltd will use a Melbourne facility to build 'lateral flow' blood-typing machines based on a Swiss invention—a hand-held card that can test blood types in a fraction of the time of older technology. The factory was established with a grant from the Victorian Government and an equity investment from Grifols.

Pathogen inactivation

Progress in the testing and uptake of pathogen inactivation technology has been strong over the last year. The market continues to be dominated by two companies—Cerus Corporation and CaridianBCT. There are several examples of the significant progress made by these companies:

- Cerus Corporation has now sold its system for both platelets and plasma in Europe, Russia, the Middle East and selected countries in other regions around the world. In November 2009 the US Food and Drug Administration Blood Products Advisory Committee delivered a positive opinion on the proposed haemostatic efficacy and safety endpoints for a potential US Phase 3 clinical trial of the Cerus INTERCEPT Blood System for platelets.
- Cerus Corporation is developing the INTERCEPT Blood System to inactivate pathogens in red blood cells for transfusion. The Phase 1 trial of red blood cells treated with the INTERCEPT Blood System met its primary endpoint, meeting the criteria recommended by the US Food and Drug Administration.
- CaridianBCT's Mirasol Pathogen Reduction Technology received a CE Mark (European approval) for treating platelets suspended in plasma in 2007. It received a CE Mark for fresh frozen plasma and platelets suspended in platelet additive solutions in 2008. The system is currently in routine use in nine countries in Europe, the Middle East and Africa.
- CaridianBCT continues to seek further endorsement of its system through research and testing. For example, in March 2010 CaridianBCT announced that a panel of experts had endorsed the effectiveness of the Mirasol Pathogen Reduction Technology System for replacing gamma irradiation—the current standard of care for preventing transfusion-related graft versus host disease in platelet recipients. The company received a $US5.6 million grant from the US Department of Defence Deployment Related Medical Research Program to allow for the next phase of development for the Mirasol Pathogen Reduction Technology System, designed to improve the safety of whole blood for transfusions in trauma cases.

A relative newcomer to the field, Aphios Corporation, announced in August 2009 that it had been awarded a Phase 1 Small Business Innovative Research Grant from the National Heart Lung and Blood Institute, US National Institutes of Health, to develop critical fluid inactivation as a generally-applicable virus and pathogen inactivation technology for human plasma, plasma products and biologics. Aphios argues that current approaches, such as heating or pasteurisation, solvent detergent technique, ultraviolet irradiation, chemical inactivation and filtration, are not always effective against a wide spectrum of human and animal viruses, are sometimes encumbered by process-specific deficiencies and often result in denaturation of the biologics that they are designed to protect.

Determining an appropriate testing regime for blood supplies is a complex and challenging task and any recommendation to change testing requirements must be based on a thorough analysis of the risks to be managed and the costs associated with the changes.

Prion filtration

In the United Kingdom, the Advisory Committee on the Safety of Blood, Tissues and Organs—an independent committee that advises the UK Department of Health—recommended the adoption of the P-Capt prion reduction filter to pretreat red blood cells destined for children born after 1 January 1996. A cost–benefit analysis is now routinely carried out on all new measures to assist the committee in its decision-making, and it is one of several factors the committee will consider. Implementation of prion filtration was considered not to be cost-effective under the majority of scenarios modelled for risk. Estimates from the UK National Blood and Transplant Authority say the cost to the National Health Scheme of producing one unit of blood would double—from £50 to around £100 using the filter—so introducing the filter could cost about £100 million.

However, increasingly, governments around the world will need to make difficult choices involving weighing overall risk against the cost of any change. The consensus conference planned for October in 2010, organised by the Canadian Blood Services, will generate a useful framework against which these risks can be assessed.

There are two major companies working in this field:

- ProMetic Life Sciences has agreed to collaborate with Abraxis BioScience to develop and commercialise applications of ProMetic's prion capture technology platform. ProMetic already has arrangements MacoPharma SA for the commercialisation of the P-Capt prion capture filter and with Octapharma for OctaplasLG, the only commercially-available prion-reduced plasma for transfusion.
- Pall Corporation launched a blood filter that simultaneously reduces prions and leukocytes. The Leukotrap Affinity Plus Prion and Leukocyte Reduction Filter System has received a CE Mark.

Other transfusion safety issues

Blood is a biological product and, despite the rigour and discipline in screening and testing, adverse events do arise from transfusions. In 2009–10 the NBA completed the second *Australian Haemovigilance Report*, which summarises what is known about transfusion-related adverse events in Australia (see page 77). In addition to this, and the NBA's Patient Blood Management Program, there were notable developments in research and approaches to transfusion safety in 2009–10:

- The prevalence of human leucocyte antigen (HLA) antibodies in blood donors, and whether their presence is related to previous transfusion or pregnancy, has been examined.

Researchers concluded that HLA Class I and Class II antibodies are detectable at low prevalence in male donors regardless of whether or not they have had a transfusion, and in female donors without known immunising events. It has been observed that, in women, the prevalence of HLA antibodies continues to increase significantly with the number of pregnancies the woman has had. As a result, the Canadian Blood Services has deferred female plasma donors who have been pregnant even once, because their donations may, by the presence of such antibodies, trigger transfusion-related acute lung injury in the transfusion recipients.

- The US Centers for Disease Control and Prevention launched a national surveillance system to monitor adverse transfusion events.

As a supplement to our ongoing horizon-scanning program in this area, the NBA's Principal Medical Officer attends the annual International Haemovigilance Network seminar to remain up to date on the latest studies and developments in transfusion safety.

At the 2010 meeting, contemporary and emerging themes in haemovigilance internationally included: haemovigilance as a component of overall "biovigilance"; the need for eventual consideration of blood donor vigilance data to be included with national transfusion vigilance data; and the value of confidential sharing of haemovigilance data and experience internationally—to help develop better benchmarking and in particular to generate early warnings and alerts of new threats to the blood supply (for example, an emerging viral epidemic). An international haemovigilance database has been created. Australia will now have the opportunity to collaborate with this project through the International Haemovigilance Network, which the USA has now joined.

Blood storage and shelf life

A study reported in the journal *Critical Care* in September 2009 again raised questions about the shelf life of blood. The study found that the risk of death was almost doubled in trauma patients given a transfusion of blood stored for more than a month. While an accepted world standard in blood use says blood may be stored for up to 42 days, this research suggested that blood stored for a shorter time carries an increased risk. Commenting on the study, the Blood Service said it already has a 'last in, first out' policy for blood use in the nation's hospitals.

Research continued on this issue during the year and it will be monitored closely for its potential impact on inventory management within Australia. Developments in this area include the following:

- Researchers at the medical school at the University of Pittsburgh and Wake Forest University School of Medicine will participate in a four-year study of the changes in blood characteristics with storage. They will focus on why the quality degrades over time and how the problem can be resolved.
- The US Food and Drug Administration approved an additive to allow more efficient storage of blood platelets for up to five days. Currently, platelets are stored in a solution that still includes a moderate quantity of blood plasma. InterSol, which is derived from salt, will free up some of the donor plasma for other purposes.

Patient blood management

The NBA has continued to make good progress on the development of guidelines for the use of fresh blood components in critical bleeding circumstances and in the peri-operative setting (see pages 72 and 73). Two core elements of this approach are improvement of anaemia management and control of blood loss (both of which reduce the need for blood transfusion).

Improving anaemia management

A key element of the new peri-operative module in the patient management guideline will be a focus on effective management of anaemia, with the objective of reducing the need for transfusion. This is in response to growing evidence that a considerable proportion of the population—particularly the elderly and young women—is anaemic. Our understanding of the significance of this is increasing and solid research in many facets of this discipline continues. For example:

- Researchers at the Queensland Institute of Medical Research have identified a new variant of a gene that helps to regulate iron and haemoglobin levels. The findings improve understanding of iron metabolism and may have implications for the management of iron overload and hereditary anaemia.
- In the US later this year Akebia Therapeutics plans to start Phase 1 clinical trials on an oral medication designed to create new red blood cells in anaemia patients.
- Also in the US, Acceleron Pharma Inc and Celgene Corporation have announced the initiation of a second Phase 2 clinical study of ACE-011 to evaluate its potential to treat chemotherapy-induced anaemia in patients with metastatic breast cancer.

Controlling blood loss

A range of new products emerged on the market during the year to assist in controlling blood loss, potentially leading to a reduction in need for blood transfusions:

- Recothrom (Zymogenetics' synthetic enzyme used to control bleeding during surgery) is approved for use in the US. However, the application to European regulators was withdrawn after the Committee for Medicinal Products for Human Use said the submission did not meet the necessary standards. A further study will be required to gain approval. It is not approved in Australia.
- Researchers at the Carnegie Mellon University in the US are currently working on a new method of stopping excessive blood loss when it occurs during surgery. They expect their hydrosurgery system to be particularly useful in brain and heart surgery.
- ADS Biotechnology is working to commercialise a product that treats capillary leak syndrome—a condition that endangers patients with accident or battlefield injuries, including traumatic brain injury and significant burns.

Platelets

Recent studies have demonstrated that there is limited evidence of benefit in providing prophylactic platelets to prevent bleeding compared to providing platelets at the time of bleeding. However, in the UK, 60 per cent of platelets are provided for prophylactic transfusions.

A Cochrane review published in 2009 concluded that there is uncertainty about the practice of rophylactic transfusion therapy in light of concerns that blood products, including platelets, could become an increasingly scarce and costly resource for which adequate alternatives do not exist. Consideration should be given to developing trials to compare

prophylaxis with therapeutic platelet transfusion that have enough patient episodes enrolled so that small, but statistically significant, differences in clinical outcome can be demonstrated.

Given that the volume of platelets issued in Australia has increased significantly over the last five years, it is essential that we are confident that platelets are being used appropriately. Research around the world is highlighting a number of factors that governments in Australia may wish to take into account when determining the platelet supply plan over time:

- A study has found that a lower dose of platelets than is commonly used is safe for chemotherapy and bone marrow transplant patients who require transfusions. More frequent transfusions were required for the low-dose group, but fewer platelets were used in the long run.
- A multi-centre, randomised trial has shown that, for patients with hypoproliferative thrombocytopenia, the dose of platelets in a prophylactic transfusion had no effect on the rate of bleeding. The lowest dose—about half the typical dose used in clinical practice—decreased the overall number of platelets used but also increased the number of transfusions needed. Patients in the low-dose group required an average of five platelet transfusions compared with three transfusions in the medium- and high-dose groups.
- A team from the University of Utah in the US has conducted research on the ability of platelets to divide in the circulatory system and has found that platelets used for transfusion are even capable of division when they are stored in bags for five days. This suggests that platelet numbers may be increased after they are removed from the body—a finding that could have a significant impact on transfusion medicine.

Synthetic blood related products and oxygen carriers

Interest in synthetic blood related products and oxygen carriers, and an expectation that they can be commercially produced, continues. The major attractions of artificial blood are that it does not need to be refrigerated, there is no need to test for blood type and it is free of transmissible diseases, so it can be given to patients with life-threatening blood loss who need immediate blood transfusion. Despite many different approaches to producing synthetic products, it appears that it will be some time before these products become available.

Some examples of developments in the area and the issues identified during the year include the following:

- In South Africa, the Medicines Control Council has approved the use of Hemopure—a blood substitute manufactured through the extraction of red blood cells from cattle. The appeals committee of the Medicines Control Council said 'Hemopure is a blood substitute that can be used in emergencies where blood is not available. It is administered to enhance oxygen delivery to tissues and organs'. However, a planned clinical trial of Hemopure by the Naval Medical Research Center in the US was not approved by the US Food and Drug Administration.

- Oxygen Biotherapeutics received approval for its Phase 2 dose escalation clinical trial in Switzerland for use of Oxycyte(R)in traumatic brain injury. Oxycyte is the company's perfluorocarbon therapeutic oxygen carrier.
- Researchers have gained new insights into how to control a severe side effect of haemoglobin-based oxygen carriers (HBOCs) (see *Anesthesiology*, March 2010). HBOCs have a tendency to scavenge nitric oxide, so blood vessels constrict and blood clotting is activated. Researchers used an HBOC of reduced molecular weight to decrease nitric oxide scavenging. They found that animals with cardiovascular disease are much more sensitive to the adverse effects of HBOCs but that, if they were allowed to breathe nitric oxide before being given the HBOCs, they did not experience either vasoconstriction or other cardiac-related side effects. These results may explain the higher mortality and increased frequency of heart attacks and strokes seen in some HBOC recipients.

Other research has focused on developing products to decrease bleeding rather than replace blood loss. For example, the US Food and Drug Administration has approved the surgical sealant TachoSil, which was developed by Baxter International Inc and Nycomed. Tachosil is used to control blood loss and is manufactured and patented by Nycomed—a privately-held Swiss drug company. Tachosil is currently available in more than 50 markets outside the US.

5.3 PLASMA AND RECOMBINANT PRODUCTS

Plasma

Supply of fresh frozen plasma in Australia has increased by an average of 2.7 per cent per annum over the last five years. A commentary in the *Canadian Medical Association Journal* reported that a large amount of frozen plasma is being used inappropriately. The most common inappropriate use is in patients with no bleeding but whose laboratory coagulation test results are abnormal. The authors conclude that measures should be introduced to improve practice, including by promoting the use of available alternatives and, prospectively, screening orders of frozen plasma for transfusion where use is against practice guidelines.

Immunoglobulin

Potential use of immunoglobulin in Alzheimer's disease

Currently, research is under way focusing on whether IVIg therapy may have a role in the treatment of Alzheimer's disease. With a major Phase 3 study in progress to determine the efficacy of IVIg in Alzheimer's disease, there is concern that a successful outcome could have major implications for sufficiency of supply and price for IVIg. The NBA is therefore monitoring these developments closely. Since the current trial has not yet produced its complete findings, there has been uncertainty in the market. Towards the end of 2009–10 there were some predictions of a softening in the IVIg market, at least in the short term. We note the following:

- The Phase 3 clinical trial of Baxter's Gammagard is expected to report in July 2011. Current results show remarkable improvements in some patients but not in others. If the study is successful, Baxter is expected to make a submission to the US Food and Drug Administration within two or three years.
- A study at the Mount Sinai School of Medicine in New York has found that people who received IVIg for other conditions had a 42 per cent lower risk of developing Alzheimer's disease over four years compared with those who did not receive IVIg. Only 2.8 per cent of those treated with IVIg developed Alzheimer's disease compared with 4.8 per cent of those not treated.
- In February 2010, Octapharma started Phase 2 clinical trials for Octagam 10 per cent in patients with mild to moderate cases of Alzheimer's disease.

Other immunoglobulin and hyperimmunes developments

- The US Food and Drug Administration approved CSL Limited's Hizentra—a weekly immune replacement therapy for people with genetic disorders who require frequent injections. Hizentra (IgPro20) is the first 20 per cent subcutaneous immunoglobulin that allows patients to treat themselves at home. The product is not yet approved in Australia.
- The US Food and Drug Administration has approved a one-year extension for the shelf life of CSL Limited's (Behring) Privigen—its 10 per cent liquid immunoglobulin. The change allows the product to be stored at room temperature for three years.
- Octapharma has initiated Phase 3 studies for its new 10 per cent Octagam, investigating its safety and efficacy in the treatment of primary immune deficiency. Octapharma AG has submitted its Biological License Application for Octagam 10 per cent for the treatment of idiopathic thrombocytopenic purpura to the US Food and Drug Administration, and has also submitted an investigational new drug application for a next generation IVIg product for the treatment of chronic inflammatory demyelinating polyneuropathy.

- Talecris Biotherapeutics Inc announced the publication of the health-related quality of life results from the largest clinical trial ever conducted in patients with chronic inflammatory demyelinating polyneuropathy in neurology. The data demonstrate that long-term treatment with Gamunex (Immune Globulin Intravenous 10 per cent) improves and maintains quality of life.
- Virdante Pharmaceuticals Inc of Massachusetts in the US has developed what it calls Sialic Switch technology and is applying it to developing plasma-derived IVIg. Company founder Jeffrey Ravetch, a professor at Rockefeller University, found that sialic acid is a key molecule for the anti-inflammatory activity of IVIg. By adding the sialic acid sugar molecule to its IVIg product, Virdante hopes to increase the drug's anti-inflammatory potency and reduce its delivery time in therapy.
- There has been some experience around the world (for example, in Western Australia, the UK and Sweden) of conserving IVIg by using adjusted body weight dosing.
- GlaxoSmithKline's Revolade has been recommended for approval in Europe. The drug helps stimulate bone marrow into producing blood platelets in patients with chronic idiopathic thrombocytopenic purpura.

In Australia, anti-Rh(D) immunoglobulin therapy is available to all Rh(D) negative women who may be carrying an Rh(D) positive baby, to reduce the risk of Rh(D) haemolytic disease of the newborn. Recent research now offers the possibility of testing foetal DNA in maternal blood samples early in the pregnancy, to identify whether or not the baby of the current pregnancy is Rh(D) positive. Thus this option may over time potentially reduce the demand for anti-Rh(D) immunoglobulin. There has been relevant research on this subject in 2009–10:

- The Blood Service reported that a non-invasive technique to collect foetal DNA from the maternal circulation could eliminate the need for amniocentesis in Rh(D)-negative women where there is a risk to the baby of Rh(D) haemolytic anaemia.
- Sequenom announced its new SensiGene test—a non-invasive assay that detects circulating cell-free foetal DNA in maternal blood.
- Cangene Corporation will cease marketing WinRho SDF (Rho (D) Immune Globulin) in European Union (EU) countries where marketing authorisations had already been obtained. The reason cited was the cost of obtaining regulatory approval in the remaining 16 EU countries.

Coagulation (clotting) factors

Plasma-derived clotting factors

Haemophilias are bleeding disorders caused by low levels of particular blood coagulation factors which are essential for blood clotting. For example, in haemophilia A there is a deficiency of clotting Factor VIII. Haemophilia patients often need transfusion with clotting factor concentrates. Just under 16.3 per cent of the budget for the national supply plan is used to purchase these products with an average rate of growth of around 11 per cent per year. Important research findings and developments in 2009–10 include the following:

- Octapharma has received orphan drug exclusivity approval from the US Food and Drug Administration for the use of Wilate for the treatment of spontaneous or trauma-induced bleeding episodes in patients with severe von Willebrand disease (vWD) as well as in patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated.

- Scientists have discovered a molecular mechanism that is a key step in the regulation of blood clotting. The Harvard team identified an area on the vWF blood-clotting protein that contains a molecular sensor to regulate the overall size of the protein; this is important for it to work effectively. The team says that the work will improve understanding of how the body regulates the formation of blood clots and could also give some insight into how bleeding disorders such as vWF disrupt this regulation system, potentially leading to new avenues for treatment and diagnosis.

Recombinant clotting factors: factors VIIa, VIII and IX

Around 10 novel molecules are in the recombinant Factor VIII pipeline, four of them already in clinical phases. In the recombinant Factor IX pipeline there are 15 developments, with three in clinical phases. In the recombinant Factor VIIa pipeline, most developments are modifications such as longer-acting drugs, with four projects in clinical trials. There have been some notable developments this year:

- The Recombinant Proteins Feeder Facility opened at Monash University in Melbourne. It will be available for use by Australian scientists who use recombinant proteins for drug discovery and preclinical research. The funding for the facility was provided by CSIRO ($4.6 million), the National Collaborative Research Infrastructure Strategy ($2.8 million), the Victorian Government ($2.8 million) and Monash University ($1 million). The centre will be used for the production of recombinant proteins under non-GMP (Good Manufacturing Practice) conditions for preclinical trials.
- Bayer has stopped a Phase 2 clinical trial for its long-acting recombinant Factor VIII drug, BAY79-4980, after the drug proved less effective than hoped. Bayer has alternative candidates in development.
- Biovitrum has begun a Phase 1/2a study of its long-acting recombinant Factor VIII Fc. Biovitrum also plans to trial recombinant Factor IX Fc in 2010.
- PTC Therapeutics is expanding the development of ataluren to a third indication, with the initiation of a Phase 2a clinical trial in nonsense mutation haemophilia (nmHA and nmHB). Nonsense mutations account for 10 to 30 per cent of all haemophilia cases.
- Baxter International and Flamel Technologies have agreed to formulate longer-acting applications of blood-clotting factor replacement therapies using Flamel's Medusa Technology, which uses biodegradable polymers to adsorb therapeutic large molecules through hydrophobic interaction, with no loss of bioactivity, for controlled release applications.
- PROLOR Biotech has developed technology to extend the half-life and biological activity of major therapeutic proteins including erythropoietin, Factor VII and Factor IX.
- Octapharma sponsored two symposia during the International Society on Thrombosis and Haemostasis Biennial Congress in Boston:
  - *Prevention and Eradication of FVIII Inhibitors: Bridging Lab and Field Research* introduced data supporting the use of vWF/FVIII concentrates for immune tolerance induction in haemophilia A patients with poor prognosis for a successful immune tolerance induction outcome.
  - *From Humans to Humans—Introducing the First Recombinant FVIII Produced from a Human Cell Line* outlined potential benefits of using a human cell-based protein; preclinical characterisations and some of the functional properties of the first recombinant Factor VIII from a human cell-line; and the planned global clinical development program with the new recombinant Factor VIII derived from human cells.

The NBA monitors these developments closely, as they provide excellent scope for increasing competition to meet the demand in Australia for recombinant products.

Other plasma products

- The US Federal Trade Commission released a report entitled *Follow-on Biologic Drug Competition*, which examines whether the price of products manufactured using living tissues and microorganisms could be reduced by competition from so-called 'follow-on biologics'. Follow-on biologics are like generic drugs but with significant differences. No pathway currently exists for follow-on biologics to enter the market and compete with their pioneer counterparts. The Federal Trade Commission report concludes that providing the US Food and Drug Administration with the authority to approve follow-on biologics would be an efficient way to bring these lower-priced drugs to market.
- The US Federal Trade Commission has approved CSL Limited's Berinert—a protein product derived from human plasma—as the first treatment for the rare genetic disease hereditary angiodema. Patients with this condition may suffer attacks of acute abdominal pain, facial swelling and even death.

Industry structure and market conditions

LATERAL GRIFOLS PRODUCTION LINE

Demand and price

During the year there was some evidence that the growth in the global market for plasma has slowed and even that demand was decreasing. It appeared that fewer new plasma collection centres were opened internationally and some existing centres were reducing donor payments and/or closing at weekends.

In the IVIg market, there were reports of price decreases in Europe, and it appeared that companies were keener to lock in longer-term contracts than previously. Those companies that saw a downturn expected pricing pressure to last for one to two years. Others denied any downward pressure. Albumin markets were in equilibrium, with prices holding.

Market capacity

Australia's interest in the international plasma product market lies largely in Europe and North America. We stay abreast of their demand, supply, price, research and development and regulatory occurrences to inform our own management of the blood sector. Activities to build stronger relations are detailed in the report of the National Plasma Products Supply Planners meeting (page 66). As with all markets, there was variable performance:

- Investment in new capacity continued, with Talecris expanding its North Carolina plant.
- Italian fractionator Kedrion was awarded a contract to upgrade and expand a bulk plasma fractionation factory in Hungary, due for completion in the first quarter of 2011.
- Galiot Capital Corporation received delisting warnings from NASDAQ due to its failure to maintain a minimum market capitalisation.
- CSL Limited has formed a strategic alliance with GlaxoSmithKline to enter the Russian Federation and the company is generating double-digit growth from a push into China. It is also moving into Brazil, Mexico and the Middle East.
- China has a very substantial plasma products industry, producing for both domestic and overseas markets. China Biologic Products Inc concluded an agreement with the Institute of Blood Transfusion to strengthen its research and development and manufacturing capabilities. Under the terms of the agreement, China Biologic Products Inc has priority purchase rights to commercialise any new technologies or products that result from the collaboration.

- The European Patent Office has granted a patent to Héma-Québec for a new method for fractioning intravenous immunoglobulins from human plasma. Obtaining a European patent is seen as especially beneficial because several human plasma fractionation companies and laboratories are located in Europe.

Market concentration

The plasma industry has a relatively small number of players and is characterised by intense competition for markets. There were several specific actions during the year that have the potential to fundamentally change the face of the sector and, through this, the range and price of products available:

- CSL Limited has withdrawn its takeover offer of $US3.1 billion for US plasma fractionator Talecris Biotherapeutics after opposition from the US Federal Trade Commission, which was concerned about decreased industry competition.
- CSL Limited said that it was satisfied that, over the next three to five years, it will continue to have excellent opportunities to expand the use of its specialty plasma products, particularly from its Marburg plant. CSL Limited has been active in registering products in the US and is running a number of Phase 3 clinical trials to support label enhancements and new indications. Therapies Hizentra and Privigen are among a group of new products likely to boost earnings over the next decade.
- Therapure Biopharma and LFB Biomedicaments, a wholly-owned subsidiary of LFB SA, have announced the signing of a toll manufacturing agreement.
- Inspiration Pharmaceuticals and Ipsen are merging their haemophilia portfolios.
- The Plasma Protein Therapeutics Association announced that Kedrion is the sixth company to be certified through its international Quality Standards of Excellence, Assurance, and Leadership Program. The program evaluates manufacturers of plasma protein therapies. Kedrion joins Baxter BioScience, CSL Limited (Behring), Biotest AG, Grifols and Talecris Biotherapeutics.

5.4 INQUIRIES AND LEGAL ACTIONS

CSL Limited and Baxter International are the subject of a US-based class action facing allegations that they were involved in a conspiracy to fix the prices of plasma products. The class action was launched by a public hospital in Missouri. Lawyers for Pemiscot Memorial Hospital claimed CSL Limited and Baxter entered into a conspiracy as far back as 2004 to coordinate their production of blood plasma and thereby push prices higher than they should have been under normal market conditions. The action is continuing.

Other interesting activities included:

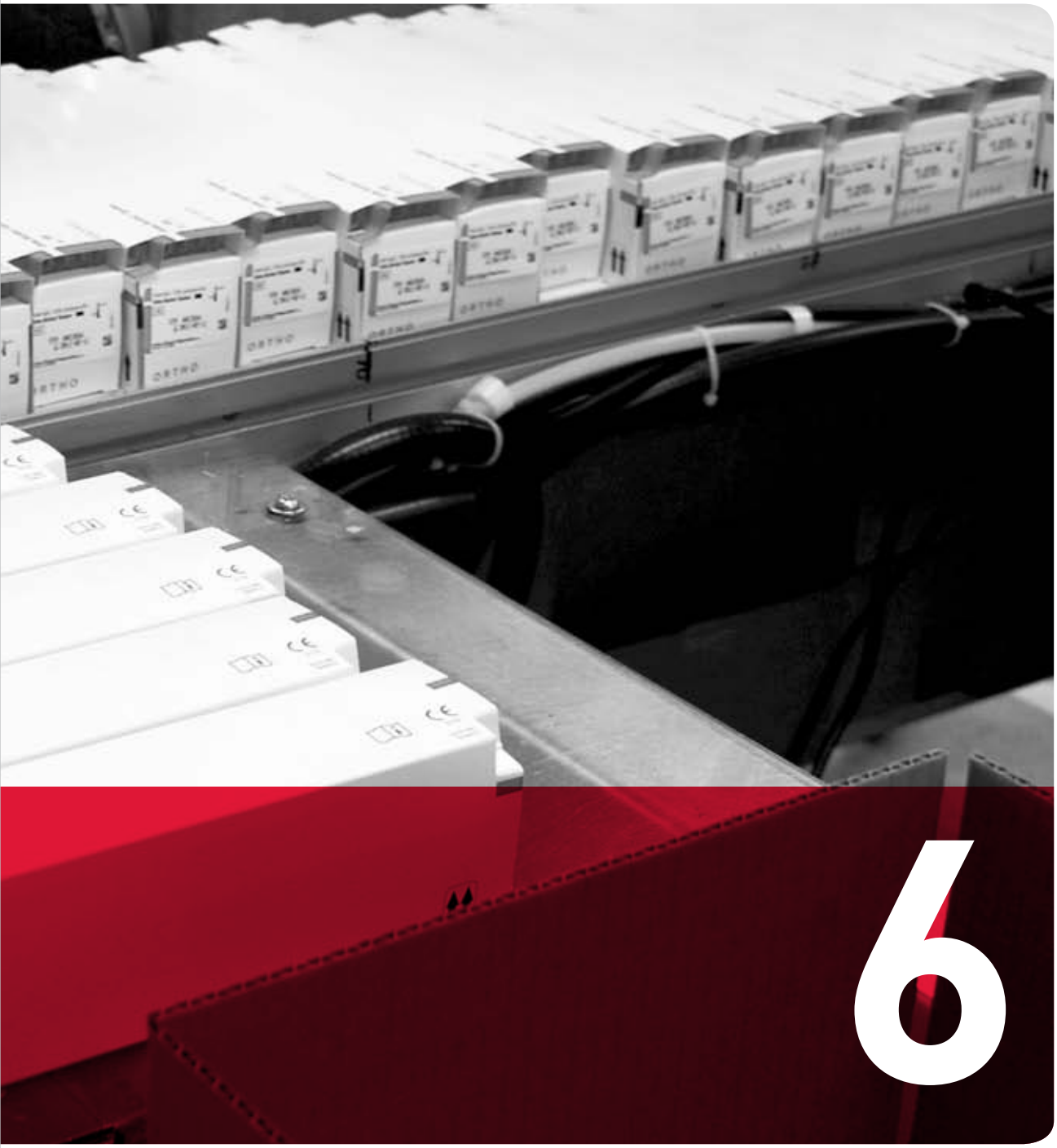
- A homosexual man in Canada sued the country's blood services for barring him from donating blood. He admitted in court that he had lied about his sexual history. Tests revealed that his blood was infected with syphilis. Syphilis may be sexually-transmitted. He was sued by Canadian Blood Services for negligent misrepresentation, but he countersued, claiming that the ban is scientifically unjustified and unconstitutional.
- Three people in south China suffering from haemophilia who claim they contracted the HIV virus from a blood product have launched a compensation battle in three separate lawsuits. The patients said they were infected with the HIV virus after using Factor VIII made by the state-owned Shanghai Institute of Biological Products. Chancheng District People's Court in Foshan City, Guangdong Province, accepted the lawsuits. The institute stopped producing Factor VIII in 1995 due to health fears, but they did not stop selling the product until 1996.

PART SIX
OUR MANAGEMENT ARRANGEMENTS

DIAGNOSTIC REAGENTS READY FOR DISPATCH

- ORTHO-CLINICAL DIAGNOSTICS INC IS ONE OF FOUR SUPPLIERS OF DIAGNOSTIC REAGENTS TO THE NBA
- REAGENTS ARE USED IN BLOOD TYPING AND CROSS MATCHING

PART SIX DESCRIBES VARIOUS ASPECTS OF HOW WE MANAGE OUR AFFAIRS. IT INCLUDES INFORMATION ON CORPORATE GOVERNANCE, PLANNING AND SERVICE DELIVERY, AND PEOPLE MANAGEMENT. IT ALSO DESCRIBES OUR AUDIT ARRANGEMENTS AND HOW WE MANAGE RISK AND FRAUD. FINALLY, INFORMATION IS PROVIDED ON OUR BUDGET AND FINANCIAL MANAGEMENT ARRANGEMENTS.



6

6.1 CORPORATE GOVERNANCE

At 30 June 2010 the National Blood Authority senior executive management team comprised the following staff:

- General Manager and Chief Executive Officer, Dr Alison Turner
- Principal Medical Officer, Dr Chris Hogan.
- Deputy General Manager, Sector Coordination, Systems and Corporate, Ms Stephanie Gunn
- Deputy General Manager, Fresh Blood and Clinical Development, Mr Andrew Mead
- General Counsel and Deputy General Manager, Commercial Contracts, Mr Michael Stone

Figure 6.1 shows the NBA's organisational structure.

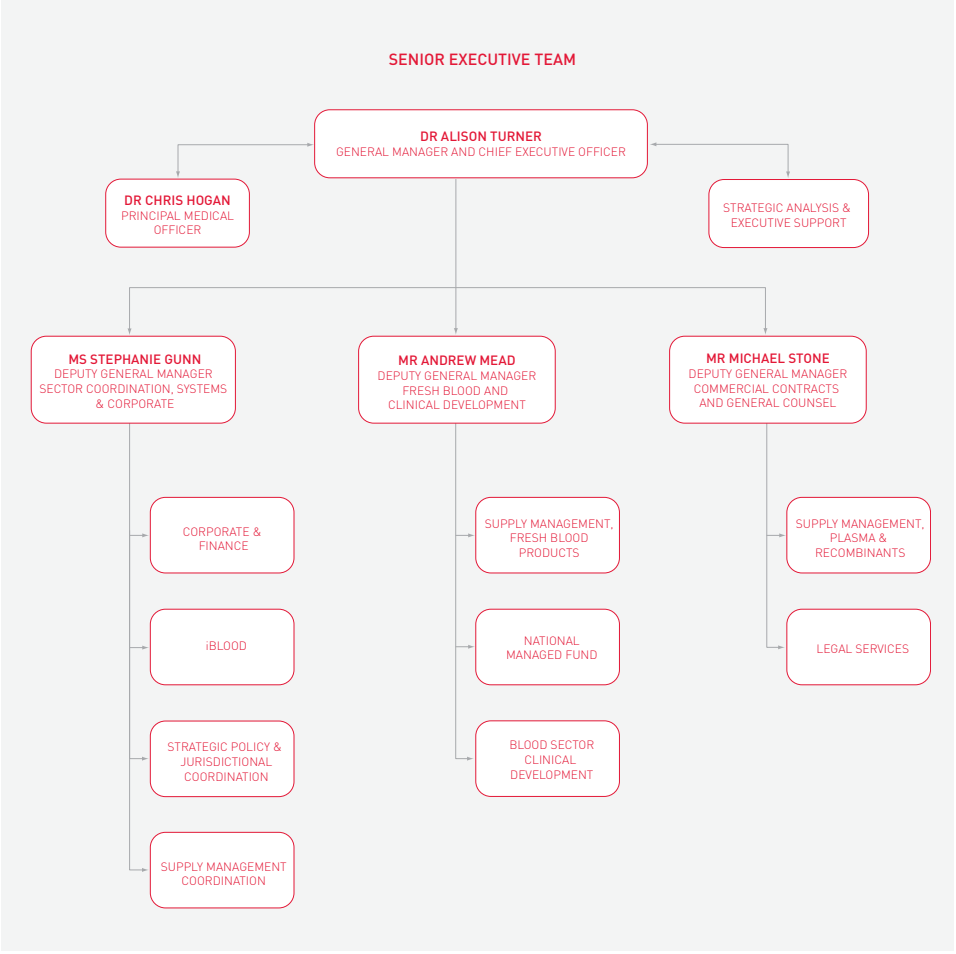


FIGURE 6.1 *National Blood Authority organisational structure*

Senior Executive Service

Mr Michael Stone is the NBA's senior manager responsible for the establishment and management of commercial product supply contracts, associated supply planning and management, and relationship management with the NBA's commercial suppliers. He is also the NBA's General Counsel and has worked on all major blood supply tendering and contracting processes conducted by the NBA since its establishment in 2003.

Mr Stone has extensive experience in providing legal advice and services for a wide range of Australian Government agencies in the fields of commercial and public law, agency governance and accountability, and the development and implementation of legislation and administrative schemes. He has previously had substantial legal experience with the Australian Government Solicitor, and worked on the development of the National Blood Agreement and establishment of the NBA in the Legal Services Branch of the Australian Government Department of Health and Ageing.

Mr Stone has worked with the NBA since its inception in 2003.

Ms Stephanie Gunn is the NBA's Sector Coordination, Systems and Corporate Deputy General Manager. She has qualifications in economics and extensive experience in program and project management associated with the analysis of regional and industry development. Ms Gunn joined the Department of Health and Ageing in 1996, working in the Minister's office. She then moved to senior management roles in Ageing and Community Care and Corporate Management, focusing on corporate governance, procurement and planning.

Ms Gunn joined the NBA in November 2003.

Mr Andrew Mead is the NBA's Deputy General Manager for Supply Management (Fresh Blood) and Blood Sector Clinical Development. He has qualifications in health services management and nursing.

Before joining the NBA, he was responsible for risk management and audit at the Australian National University. He has also held positions as General Manager of Griffith Base Hospital and Albury Base Hospital. Over the past 27 years, Andrew has worked in various administrative and clinical roles in the acute health care setting, including in tertiary referral and regional and rural hospitals. He has also held academic appointments at Charles Stuart University in health management and paediatrics. He has been involved in the delivery of health service management development programs in Indonesia.

Mr Mead joined the NBA in July 2008.

Ms Jill Divorty was responsible for the management of commercial contracts and supply planning for plasma-derived and recombinant blood products during the period July 2009 to January 2010. She was the Relationship Manager for commercial suppliers

Ms Divorty joined the Australian Public Service in 1996 and came to the NBA from Defence Housing Australia. She had senior management experience in finance and accounting, planning, procurement, and project and program management. She is a certified practising accountant and holds an MBA.

Ms Divorty joined the NBA in August 2008. She resigned in January 2010.

Governance structure

Three formal governance committees—the Senior Executive Managers Committee, the Executive Managers Committee and the Audit Committee—help the NBA executive plan for and manage core strategic projects and stakeholder concerns.

The committees are actively involved in activities such as:

- maintaining our rigour in reporting and measuring performance against our Operational Plan
- improving our focus on internal and external performance indicators
- providing for more informal discussion of strategies, concepts and ideas for continual improvement.

In July 2009 the NBA also established two new formal cross-team functional committees to provide opportunities for staff to discuss strategies, issues, and processes, and share experiences on issues of common relevance. The functional committees are a key element in our internal knowledge network, helping us to cover demand forecasting and supply coordination and data and systems development.

To enhance communication within its new governance structure, the NBA also redeveloped the charters of existing governance committees to define their roles and relationship to the new committees.

Senior Executive Managers Committee

The Senior Executive Managers Committee is the NBA's primary policy and process decision-making body, and it supports the General Manager in matters relating to risk, compliance, stakeholder management, ethics and governance of the NBA. Members of the committee are the General Manager and Chief Executive Officer, deputy general managers, General Counsel and Principal Medical Officer.

The committee is responsible for:

- identifying, considering and agreeing on strategic directions for key emerging policy issues to ensure that understanding, approach and communication on these issues are consistent
- maintaining an overview of the progress and development of the NBA and the environment in which it operates, and translating this into NBA programs, projects and policies
- applying their collective experience and skills to the development of policies where more complex elements are involved—for example, where policies affect more than one≈program element—thus enhancing quality and commitment
- regularly considering key strategic planning, documentation and relationships.

The committee meets three times a month.

Executive Managers Committee

The Executive Managers Committee consists of all NBA officers at director level and above. It focuses on monitoring and improving performance and identifying and managing operational risks. It is also a forum in which major projects can be discussed and synergies and dependencies identified.

The committee is responsible for:

- identifying NBA performance issues that arise as a result of changes, for example to processes or resourcing
- monitoring the effectiveness of performance measures and identifying improvements.

The committee meets once a month.

Audit Committee

The Audit Committee advises the General Manager on strategies to enhance the organisation's control framework, improve the objectivity and reliability of externally published financial information and comply with legislative requirements and obligations. Its membership is as follows:

- Ms Jennifer Morison (Chair)
- Mr Ken Barker
- Mr Mick Roche
- Mr Andrew Mead.

Mr Mead, NBA Deputy General Manager Supply Management (Fresh Blood) and Blood Sector Clinical Development, was appointed in August 2009. Representatives from the Australian National Audit Office and NBA internal auditors also attend meetings as observers for most matters.

Ms Jennifer Morison FCA, FCPA, FAIM, the Chair of the Audit Committee, is a chartered accountant with 28 years of broad experience in the profession and in commerce. Her career has included audit, taxation, management consulting, corporate advisory work, and consulting to government. She is a leading consultant in the area of public sector financial management reform in Australia and is an independent member and chair of Australian and ACT government audit and risk committees. Ms Morison was appointed Chair of the NBA's Audit Committee in 2007, having been a member of the committee since 2004.

The Senior Executive Managers Committee considers the Audit Committee minutes and any findings from internal and other audits to confirm priorities and resourcing for any recommended changes or improvements.

During 2009–10 the Audit Committee explored the adequacy of mechanisms to ensure compliance with relevant legislation and regulatory requirements. Presentations on our internal monitoring and assessment processes were provided to the Audit Committee. The committee gave valuable advice on the adequacy of the NBA's insurance arrangements and oversaw the NBA's internal audit program.

The Audit Committee's work program progressed well during 2009–10. Activities included:

- review and recommendation to the Chief Executive for the 2008–09 Annual Financial Statements
- review and recommendation to the Chief Executive for the 2008–09 Certificate of Compliance
- review and advice on the financial management risk plan
- provision of advice on financial management, risk management, the Fraud Control Plan and accountability issues.

The committee met six times in 2009–10.

Internal audit

The NBA's internal audit program, guided by the Audit Committee, plays a key part in making sure that risk is managed appropriately.

The Audit Committee accepted that the proposed 2009–12 Internal Audit Plan should be delayed to allow for the appointment of new internal audit services through a tender process. The tender resulted in the appointment of Walterturnbull Pty Ltd as internal auditor for three years.

The internal auditor commenced work in late 2009 and during the year has undertaken a review of the NBA's control framework, analysed options to improve contract management procedures and undertaken a review of the NBA's policies and procedures for the verification of goods ordering and receipting.

Risk management

The NBA's governance framework integrates risk management considerations into all planning activities and ensures:

- development of an annual Strategic Risk Management Plan—assessed against Corporate Plan objectives and specific annual priorities
- a six-monthly review of the Strategic Risk Management Plan by the Executive Management Committee
- development of detailed actions within the annual Operational Plan to address core risks
- monthly reporting to the Executive Management Committee against the Operational Plan and on status of core risks
- regular reporting to the NBA Board on the Operational Plan and the status of core risks.

The NBA participated in the 2010 Comcover Risk Management Benchmarking Program and received a benchmarking score of 7.1 out of a possible 10 in 2010. This benchmarking score places the NBA in a 'structured' maturity level. The NBA will strive for further improvement by renewing its focus on disaster recovery, risk profiling and resourcing.

Fraud Control Plan

The Commonwealth Fraud Control Guidelines require agencies to develop a fraud control plan every two years. The current NBA Fraud Control Plan, which will expire in late 2010, is based on the findings of a fraud risk assessment carried out in 2008.

The findings of the 2008 fraud risk assessment were that the overall fraud risk of the NBA was low, with a universally strong control environment in operation. No significant gaps were identified in the NBA's fraud controls.

Under its current Fraud Control Plan, the NBA continually monitors accountability and control frameworks to meet the specific needs of the agency, and ensures that it complies with the Commonwealth Fraud Control Guidelines.

During 2010, the NBA has procured a new supplier to undertake fraud risk assessment, a Fraud Control Plan and training.

Relationship with external auditors

The NBA acknowledges the assistance provided by its external auditors, the Australian National Audit Office, in 2009–10. This assistance enabled the NBA to ensure compliance and appropriate accountability and to identify scope for continual improvement in our activities.

External scrutiny

Australian National Audit Office

In 2009–10, the Australian National Audit Office (ANAO) commenced a performance audit of NBA activities. The objective of the audit is to 'assess whether the NBA's governance and contractual arrangements are effective in ensuring sufficient blood supply and services'. The ANAO has undertaken field work to 'examine whether the NBA demonstrates:

- sound governance and administrative systems to support blood and blood product supply, including arrangements to assess and consider value for money
- accountable and responsive contract management of the ARCS Deed of Agreement to meet legislative requirement, government policy and improve national supply and
- sound performance information, including links to higher level outcomes, to assess the effectiveness of contractual arrangements in meeting national blood supply needs.'

The audit is expected to be tabled in early 2011.

FILES READY FOR THE ANAO PERFORMANCE AUDIT

Other external scrutiny

There were no judicial decisions or decisions of administrative tribunals that impacted on the operations of the NBA during 2009–10. There were no reports of the agency by a Parliamentary committee or the Commonwealth Ombudsman.

6.2 PLANNING AND SERVICE DELIVERY

Performance against the 2009–10 Operational Plan

In 2009–10 the NBA delivered 91 per cent of activities against the planned outcomes. Table 6.1 demonstrates the overall trend in the NBA's delivery against our operational plans over the past four years.

TABLE 6.1 NBA performance in achieving objectives of its Operational Plans, 2006–7 to 2009–10

YEAR	2006–07	2007–08	2008–09	2009–10
Performance (%)	85%	81%	95%	91%

Good progress was made on the six outstanding uncompleted items, although our original timeframes were not met. Three items relate to internal processes. They are now scheduled for completion in 2010–11. The other three items relate to the development of clinical guidelines and obtaining and analysing data on red blood cell usage. Even though these activities were not completed during 2009–10, the NBA is delighted with the clinical participation in these areas and will continue to foster clinical partnerships into 2010–11.

The 2010–11 Operational Plan

Through its 2010–11 Operational Plan the NBA will continue to focus on supply planning, professional contract negotiation and management, and strategies to increase the appropriateness of product use while increasing our effort on sector systems and data capture and analysis.

Key challenges for the coming year include ensuring continuing quality, security of supply and value for money in negotiating new arrangements with the Blood Service and suppliers of imported plasma, recombinant blood products and diagnostic reagents, and on implementation and review of the output based funding model for the Blood Service. In the area of clinical development, priority areas will be the production of modules of the Patient Blood Management guideline, publication of the outcomes of the review of the *Criteria for the clinical use of intravenous immunoglobulin in Australia*, and development of the national patient blood management program. Continued expansion and enhancement of our capacity to collect and analyse data will be essential to inform all of the activities of the organisation.

Corporate

Jurisdictional Blood Committee secretariat

During 2009–10 the NBA provided secretariat services for five face-to-face meetings and three teleconferences of the Jurisdictional Blood Committee. The NBA set performance indicators relating to the quality and timeliness of support provided. Table 6.2 shows how the NBA performed against these indicators.

TABLE 6.2 NBA performance indicators for Jurisdictional Blood Committee support, 2009–10

PERCENTAGE OF PAPERS PREPARED BY THE NBA PROVIDED TO THE JBC (SEVEN DAYS BEFORE THE MEETING)	PERCENTAGE OF RECOMMENDATIONS IN NBA PAPERS AGREED BY THE JBC
98.75	85.70

Secretariat services were also provided to the NBA Board, which met five times during 2009–10. Three of those meetings were held in Canberra and two were held by teleconference.

Information communication and technology

The Jurisdictional Blood Committee portal was established in 2009 and has been used extensively this year. The portal gives committee members access to all meeting papers and minutes (including historical papers) in an electronically searchable and secure environment at any time. A portal for the NBA Board was established during the year and historical papers are being progressively uploaded. Details on other ICT developments are provided in Part 4 of this report.

Customer Service Charter

The NBA is committed to providing a professional, high-quality, efficient service to clients, stakeholders and the general public, in accordance with the *Public Service Act 1999*. Our roles and responsibilities in dealing with external clients, and their rights in dealing with us, are described in the NBA Customer Service Charter.

During the reporting year the NBA received two feedback responses, both commenting positively on NBA initiatives.

The Customer Service Charter is available on the NBA website at www.nba.gov.au/feedback.html.

6.3 PEOPLE MANAGEMENT

Our values

The NBA recognises the important role that blood and blood products play in the treatment and clinical management of Australian patients.

We are committed to:

- meeting patient needs for the provision of a safe, secure, adequate and affordable supply of blood and blood products
- working collaboratively with stakeholders to develop, monitor and improve national networks and systems for improved clinical awareness and practices in the use of blood and blood and blood products
- strengthening our civil and private networks to inform policy and program development
- developing the professional and technical competence of our staff
- delivering our mission in an efficient, professional, inclusive, responsive and innovative manner.

TABLE 6.3 *Number of NBA staff at 30 June 2010*

SUBSTANTIVE ROLE CLASSIFICATION	FEMALE (FULL TIME)	FEMALE (PART TIME)	MALE (FULL TIME)	MALE (PART TIME)	TOTAL
Statutory office holder	1	-	-	-	**1**
Senior Executive Service	1	-	2	-	**3**
Health Economist	-	1	-	-	**1**
Principal Medical Officer	-	-	-	1	**1**
EL 2	4*	-	5	-	**9***
EL1 Legal	-	-	-	-	**0**
APS 6 Legal	-	-	-	-	**0**
EL 1	10**	2	7	-	**19****
APS 6	7**	-	1	-	**8****
APS 5	1	2	-	-	**3**
APS 4	2	-	-	-	**2**
APS 3	-	1	-	-	**1**
Total	**26**	**6**	**15**	**1**	**48**

* One employee on extended Long Service Leave

** One position filled by an agency employee

Staffing profile

The total number of staff employed in the NBA rose from 44 in 2008–09 to 48 at the end of June 2010. During the restructure of the NBA in July 2009, most roles were reviewed. Affected staff were given the opportunity to move to new roles, with some joining different teams. Initially, there was a higher than normal turnover, which resulted in an increase in recruiting activity. This has now settled to a level consistent with previous years. During peak periods, short-term, non-ongoing staff are used to meet staffing requirements. Table 6.3 shows NBA staff numbers, by classification, at 30 June 2010.

Workforce planning, staff turnover and retention

Staff turnover in 2009–10 increased significantly from 16 per cent to 25 per cent. This was mainly a result of the restructure, as mentioned above. The capability strategy developed in 2007 had been designed to minimise the impact of staff turnover and so the effect of the restructure was minimal.

The average length of service for NBA staff is now approximately three years. Nearly 30 per cent of staff have now been with the NBA for more than four years. We are fortunate that our staff profile contains a diverse range of skills, experience and backgrounds.

During 2008–09 the NBA conducted two surveys—one to assess current staff skills and capabilities and the other to gauge staff satisfaction. The NBA will conduct similar surveys in 2010–11, to provide a direct measure against earlier surveys. New criteria will be drawn from other valuable sources, such as the *State of the service report 2010–11*, to maximise our ability to benchmark against other agencies.

Skills and professional development

The skill survey conducted in late 2008 showed that both our generic skills and knowledge and our contextual knowledge of the blood sector are strong. It also revealed an interest on the part of staff to improve skills relating to the broader public sector context—for example, broadening their knowledge of parliamentary processes and accountability arrangements and undertaking training in project management, cause-and-effect analysis, targeted research and demand analysis.

An important vehicle for professional development at the NBA is the individual Personal Development Plan. Personal Development Plans help the organisation meet the objectives of its Operational Plan by focusing on what individual staff members must deliver in order to meet goals outlined in the plan. Each staff member has an individual meeting with his or her manager on a quarterly basis. At the beginning of each quarter, a clear agreement is reached between the staff member and manager on the support and skills needed by the staff member if they are to achieve these goals. At the end of each quarter, the staff member and manager discuss progress in obtaining the required skills and the relevance and value of the training provided.

The regular NBA Knowledge Management Forums also provided staff with the opportunity to increase their knowledge and understanding on a wide range of subjects (see page 132 for a list of forums in 2009–10).

Staff satisfaction

The results of the 2008–09 staff satisfaction survey showed progress against core concerns but highlighted the need to continue to focus on our communication processes.

The Staff Participation Forum is one mechanism to address this concern. It consists of members who represent all staff, and it plays an important role in identifying issues, shaping policies and keeping the Executive Team informed of staff concerns. During 2009–10 the Staff Participation Forum played an important role in initiating the enterprise bargaining process for a new agreement. Other issues raised during 2009–10 included issues arising from the introduction of the *Fair Work Act 2009*, occupational health and safety, development of the NBA's health and wellbeing program, review of the Knowledge Forum program, and the activities of the social club.

One of the important goals of the restructure in July 2009 was to improve communication across NBA teams. This was facilitated by the establishment of the cross-team functional committees.

Features of employment tools

Employment tools

Table 6.4 shows numbers of NBA employees covered by the NBA Collective Agreement 2007–10, common law agreements, section 24 determinations, and Australian Workplace Agreements, at 30 June 2010.

TABLE 6.4 *Numbers of NBA staff on types of employment agreements*

STAFF	COLLECTIVE	AUSTRALIAN WORKPLACE	COMMON LAW OR SECT. 24
SES	Nil	Nil	3
Non–SES	32	9	3

Collective Agreement salary rates

The second NBA Collective Agreement was signed in October 2007, and staff received a second salary increase of 4.1 per cent on the first full pay period following 1 July 2009. No further increases are due under the Collective Agreement. Table 6.5 shows salary levels at 30 June 2010.

TABLE 6.5 *NBA Collective Agreement: 30 June 2010 salary levels*

CLASSIFICATION	MINIMUM	MAXIMUM
Executive Level 2	99,668	112,338
Executive Level 1	83,537	95,293
EL1 Legal	83,540	101,145
APS 6 Legal	66,844	74,723
APS Level 6	67,979	76,689
APS Level 5	61,622	65,038
APS Level 4	56,655	59,864
APS Level 3	50,005	55,429

Enterprise Agreement-Making

As the current Collective Agreement expires on 1 October 2010, the NBA Management Team has entered negotiations with employees for a new enterprise agreement.

Non-salary benefits

The Collective Agreement and other employment arrangements provide a range of non-salary benefits in addition to those consistent with national employment standards and the *Fair Work Act 2009*. The benefits provided are similar to those provided by many other agencies. They are detailed in the NBA Collective Agreement, available on the NBA website. A summary is shown in Table 6.6.

TABLE 6.6 Non-salary benefits

NON-SENIOR EXECUTIVE SERVICE STAFF
– access to the Employee Assistance Program
– maternity and adoption leave
– parental leave
– leave for compassionate purposes
– access to leave accruals at half pay
– flex-time (not all officers)
– flexible working arrangements with time off in lieu where appropriate, including recognition of travel time
– access to laptop computers, dial-in facilities, and mobile phones (not all officers)
– support for professional and personal development
– provision of eyesight testing and reimbursement of prescribed eyewear costs specifically for use with screen-based equipment
– influenza vaccinations for staff and families
– annual close-down

SENIOR EXECUTIVE SERVICE STAFF AND OTHERS ON AUSTRALIAN WORKPLACE AGREEMENTS, COMMON LAW AGREEMENTS OR S.24 DETERMINATIONS
– all the forgoing benefits except flex-time
– car parking (not all officers)
– airport lounge membership (not all officers)
– vehicle leasing arrangements made available for office duties during work hours or salary in lieu (not all officers)

Remuneration and Performance pay

Total remuneration for senior executive officers is determined through negotiation between individual officers and the General Manager, taking into account Australian Public Service benchmark data. Performance pay is not applicable.

Professional and personal development

Eighty-one per cent of NBA staff met our internally determined training target of 30 points, which represents about seven days of training and development during a year. The NBA offers a wide range of training programs to staff so they can extend their knowledge and skills.

The NBA attaches high priority to ensuring staff develop their skills—either through sourced internal training or our knowledge management forums, or through external training—conferences, seminars, accredited training organisations and learning institutions. Performance against training targets is measured internally and reported to the NBA Board.

The list of topics covered by our knowledge forums has grown over the years, and we now have the delightful 'problem' of fitting all suggestions and offers for presentations into the year. Highlights of this year's knowledge forum program focusing on blood issues included the following:

- Dr Garry Jen Cowitz and Dr Karl Lozier, Novo Nordisk, provided an update on product development
- Dr Elizabeth Campbell, CSL Limited, presented on the use of Cohn and chromatography equipment
- Dr Robert Flower, Australian Red Cross Blood Service and NBA Fellow, talked to staff about risks to the blood supply
- Ms Jennifer Williams, Dr Joanne Pink and Dr Pip Hetzel, Australian Red Cross Blood Service, presented the 2008–09 Supply trend analysis report
- Mr Andrew Dalton, Australian Institute of Health and Welfare, gave us an understanding of economic evaluations in health care
- Dr David Irving, Australian Red Cross Blood Service, presented the Blood Service annual research and development report
- Dr Dominique Pifat, Talecris Inc, gave staff insight into differences in IVIg manufacturing
- Mr David Mitchell, Baxter Healthcare Pty Ltd, gave an update on current and upcoming clinical trials
- Ms Trish Garrett, Therapeutics Goods Administration, provided an overview of the regulatory environment for the blood sector in Australia

DR DOMINIQUE PIFAT, TALECRIS, PRESENTING AT AN NBA KNOWLEDGE FORUM

In addition, our Principal Medical Officer, Dr Chris Hogan, made a number of presentations to staff: on the current status of infectious hazards of transfusion; thrombocytopenia; transfusion in settings of massive blood loss; bone marrow transplantation; transfusion issues in neonates; and leukaemia.

Dr Turner also briefed staff on the development of the Dublin consensus statement on encouraging ethical behaviours in suppliers of blood products. Other staff who travelled to participate in conferences provided detailed written or oral briefings to staff on key emerging issues.

As in other years, the knowledge forums continued to provide opportunities to ensure that all staff attend a selected range of mandated training sessions. In 2009–10 topics included:

- procurement of non-blood products, and probity
- government financial management frameworks
- change management
- the NBA's business intelligence capability—Big Red
- the Australian Public Service Code of Conduct
- records management
- security
- an overview of contracts
- an update of chief executive instructions and the *Financial Management and Accountability Act 1997*.

The effectiveness of all training is assessed as part of discussions between staff and managers in the quarterly Personal Development Plan meetings described above.

Staff contributions and activities

The NBA Staff Wellbeing Program continued in 2009–10. Staff were offered the opportunity to participate in a range of small, targeted activities throughout the year, including fitness and contributions to a range of community causes. Highlights included:

- participation in the Australian Bureau of Statistics (ABS) fun run for charity
- lunchtime yoga classes
- donation of blood to the Blood Service, resulting in the NBA moving from sixth place in 2008–09 to fifth place in 2009–10, by ratio, for government agencies in Canberra
- participation in training on occupational health and safety and stress management which are seen as key contributors to a healthier workplace.

NBA STAFF ABOUT TO START IN THE ABS ANNUAL FUN RUN

6.4 BUDGET AND FINANCIAL MANAGEMENT

This section provides an overview of the NBA's financial management and outcome in 2009–10. See Appendix 2 for details of overall NBA resourcing.

Funding

The functions of the NBA are outlined in the *National Blood Authority Act 2003* and the National Blood Agreement. As a material statutory agency, the NBA has a range of corporate and compliance responsibilities under the National Blood Authority Act, the *Financial Management and Accountability Act 1997*, the *Australian Public Service Act 1999*, along with a responsibility to meet ministerial, parliamentary and financial reporting requirements.

Under the National Blood Agreement between the Commonwealth, the states and the territories, 63 per cent of NBA funding is provided by the Australian Government and the remaining 37 per cent is provided by the state and territory governments. The funding covers both the national blood supply and the operations of the NBA.

Special accounts

The NBA operates wholly through two special accounts—the National Blood Account and the National Managed Fund (Blood and Blood Products) Special Account.

Special accounts are held in the Consolidated Revenue Fund and are used for setting aside and recording amounts to be used for specified purposes. Funding received from the Commonwealth, states and territories is held within the special accounts and expended as required on the supply of blood, blood products and services and on the operation of the NBA.

Funding for the supply of blood and blood products and the operation of the NBA is included in the National Blood Account, established under section 40 of the National Blood Authority Act.

The National Managed Fund (Blood and Blood Products) Special Account was established under section 20 of the Financial Management and Accountability Act. This special account accumulates funds required to meet liabilities arising from potential product liability claims against the Australian Red Cross Blood Service. Contributions to the account are made by all governments and the Blood Service. In addition, interest is received on special account balances.

For budgeting and accounting purposes, the NBA's financial transactions are classified as either departmental or administered revenues or expenses.

Assets, liabilities, revenues and expenses controlled by the agency in its own right—that is, for the operations of the NBA—are classified as departmental revenues and expenses.

Activities and expenses controlled or incurred by Australian governments—mainly procurement of the products and services that make up the blood supply—that are managed through contracts or projects by the NBA on behalf of governments, are classified as administered revenues and expenses.

Transactions in the National Blood Account are separated into departmental and administered components. All balances in the National Managed Fund (Blood and Blood Products) Special Account are administered funds.

Table 6.7 summarises the NBA's revenue and expenditure for 2009–10. The NBA's agency resource statement and total resources for outcome tables are included as Appendix 2.

TABLE 6.7 *Overall funding and expenditure for the NBA in 2009–10: a summary*

	FUNDING INCL. APPROPRIATIONS ($M)	EXPENDITURE ($M)
Departmental—NBA operations	9.524	9.475
Administered—national blood and blood product supply	872.549	859.152

Overview of financial performance in 2009–10

This section provides a summary of the NBA's financial performance for 2009–10. Details of departmental and administered results are shown in the audited financial statements, and this summary should be read in conjunction with those statements.

Audit report

The NBA received an unqualified audit report for 2009–10.

Departmental finances

The NBA's departmental finances cover the NBA's operations.

Funding for the NBA since 2005–06 was provided to build capacity—particularly for risk management, appropriate patient blood management and the safe use of blood and blood products. Although all planned initiatives in these areas are well under way, several factors have caused delays in implementation. As a result, funds provided for those initiatives have not yet been fully spent.

These unspent funds will be drawn on to meet the staffing and other costs of completing these initiatives in 2010–11 and 2011–12, so operating deficits will occur in those financial years. These deficits have been approved by the Minister for Finance and Deregulation. As the initiatives will be fully implemented by 2012–13, staffing and other costs will be managed down to match the level of funding provided at that time.

Operating result

The NBA's income statement reports a 2009–10 operating surplus of $0.049 million, compared with an operating surplus of $0.105 million in 2008–09. Table 6.8 shows the NBA's key results for 2008–09 and 2009–10.

TABLE 6.8 Key results in financial performance, 2009–10, 2008–09 and 2007–08

REVENUE AND EXPENSES	2009–10 ($'000)	2008–09 ($'000)	2007–08 ($'000)
Contributions from the Australian Government	5 712	5 865	5 993
Contributions from states and territories and other revenue	3 812	3 989	4 408
Total revenue	**9 524**	**9 854**	**10 401**
Employee expenses	5 636	6 162	5 826
Supplier expenses	2 677	2 709	2 621
Other expenses	1 162	878	574
Total expenses	**9 475**	**9 749**	**9 021**
Operating result	**49**	**105**	**1 380**

Income statement

Revenue

Total departmental revenue received in 2009–10 amounted to $9.524 million: $5.712 million in funding from the Commonwealth Government; $3.732 million in contributions received from the states and territories and other revenue; and $0.08 million for resources received free of charge. This represents a reduction of $0.33 million (3.3 per cent) on revenue received in 2008–09.

('Other revenue' refers to contributions arising from officers transferring from other agencies and the use of funds provided in earlier years for specific projects.)

Expenses

The NBA's expenses for 2009–10 amounted to $9.475 million—3 per cent lower than in 2008–09. Measures to control departmental employee expenses and supplier costs, as well as favourable movements in the valuations of assets and employee entitlements,

have resulted in a reduction in expenses over the previous year.

Balance sheet

Details of the NBA's assets and liabilities are presented in the audited financial statements in this report.

Financial assets

The NBA held cash of $0.21 million at 30 June 2010. Funds received from all jurisdictions are transferred to the Official Public Account held by the Department of Finance and Deregulation until required for expenditure. In the NBA's financial statements these funds are classified as a receivable. The funds represent amounts intended to be used for implementing key information technology projects and for consultancies on the quality and appropriate use of blood products in Australia, as well as being surpluses from prior years, which will be accessed in 2009–10 and beyond to maintain the level of services.

Non-financial assets

The reduction in the carrying amount of non-financial assets largely results from the depreciation of infrastructure, plant and equipment—particularly information technology equipment and furniture and fittings.

Payables

Payables to suppliers and other payables decreased by $0.20 million, down from $2.7 million in 2008–09.

Provisions

Employee provisions, which cover annual and long service leave entitlements, remained constant at $1.2 million.

Administered finances

On behalf of the Australian Government, the NBA manages and coordinates the Australian blood supply in accordance with the National Blood Agreement between the Commonwealth, state and territory governments. This includes negotiating and managing national contracts with suppliers of blood and blood related products on behalf of all governments.

The NBA-administered finances include contributions from all states and territories and the Australian Government for the supply of blood and blood related products. Each year the Australian Health Ministers Council approves an annual National Supply Plan and Budget, which is formulated by the NBA from demand estimates provided by the states and territories.

Revenue

Total estimated revenue for 2009–10 is presented in Table 6.9. Because funding is provided to meet the cost of supplying blood and blood products, the increase of $43.4 million in funding (5 per cent) for the current financial year reflects the increasing demand for products, and contractually agreed increases in prices.

TABLE 6.9 *Administered revenue, 2009–10, 2008–09 and 2007–08*

ADMINISTERED REVENUE	2009–10 ($000)	2008–09 ($000)	2007–08 ($000)
Funding for supply of blood and blood products	871 195	827 640	699 596
Total administered revenues	**872 549**	**829 190**	**699 596**

Expenses

Table 6.10 shows the NBA's administered expenses in 2009–10, 2008–09 and 2007–08.

TABLE 6.10 Key results of administered expenses, 2009–10, 2008–09 and 2007–08

ADMINISTERED EXPENSE	2009–10 ($000)	2008–09 ($000)	2007–08 ($000)
Grants to the private sector—non-profit organisation	456 881	433 385	385 029
Rendering of goods and services—external entities	402 143	356 568	340 749
Other	128	3 103	–
Total administered expenses	**859 152**	**793 056**	**725 778**

Administered expenses for 2009–10 increased by 8 per cent over those for 2008–09. Total payments to commercial suppliers increased by 13 per cent; payments to the Blood Service increased by 5 per cent.

Administered assets and liabilities

Administered assets comprise the following:

- blood and blood product inventory held for distribution, including the national reserve of blood products
- financial assets and liabilities associated with funds for GST receipts from the Australian Taxation Office and payment to suppliers for products.

Administered assets and liabilities increased marginally in 2009–10.

Unspent funds received from jurisdictions are transferred to the Official Public Account and are not classified as administered assets.

PART SEVEN
OUR ACCOUNTABILITY

CHROMATOGRAPH COLUMN AT CSL LIMITED

- SEPARATES THE VARIOUS PLASMA PROTEINS IN HUMAN PLASMA
- USED IN THE MANUFACTURE OF PLASMA-DERIVED PRODUCTS
- WITH OTHER PROCESSES, USED TO ELIMINATE VIRUSES

PART SEVEN SPECIFIES HOW THE NATIONAL BLOOD AUTHORITY COMPLIES WITH A RANGE OF EXTERNAL POLICIES. AMONG THE SUBJECTS COVERED ARE PURCHASING, ASSET MANAGEMENT, PERFORMANCE UNDER THE COMMONWEALTH DISABILITY STRATEGY, OCCUPATIONAL HEALTH AND SAFETY, PRODUCTIVITY GAINS, ECOLOGICALLY SUSTAINABLE DEVELOPMENT AND FREEDOM OF INFORMATION.

7

7.1 PURCHASING

The National Blood Authority adheres to the Commonwealth Procurement Guidelines and Best Practice Guidance when undertaking procurements. The guidelines are applied to the NBA's activities through chief executive instructions management instructions and key business processes.

The NBA has developed business processes to ensure that the knowledge and best practices developed within the agency for our key purchasing activities are captured and made available to new staff, and that relevant procedures and processes are documented and followed.

Over recent years the internal auditor completed several audit programs that tested these processes to ensure that they meet government policy and better practice. The audit findings were consistently favourable in relation to complying with mandatory processes and offered the NBA improvement opportunities to deliver an optimal process for the future. The findings have been implemented. The key business processes will be constantly reviewed and refined as part of the NBA's own requirement for continual improvement in the management of its core business functions.

The NBA used extension provisions to extend several current contracts following a value-for-money assessment, and completed several small open source procurements, including:

- internal audit services
- systematic review services
- printing services.

The NBA has outsourced all air travel bookings. Government policy requires the NBA to obtain the 'lowest practical fare' for domestic travel and the 'best fare of the day' for international travel for NBA employees. From 1 July 2010, the NBA will be included in Commonwealth Government whole-of-government air travel arrangements.

The NBA did not administer any discretionary grants during 2009–10. However, following consideration and approval by the Jurisdictional Blood Committee, three funding agreements have been entered into with jurisdictions using interest monies from administered funds. Information on these is available on the NBA website, www.nba.gov.au.

Exempt contracts

The Chief Executive Officer did not issue any exemptions from the required publication of any contract or standing offer in the *Purchasing and disposal gazette* during 2009–10.

Competitive tendering and contracting

There were no contracts of $100,000 or more (inclusive of GST) let in 2009–10 that did not provide for the Auditor-General's access to the contractor's premises.

Advertising and market research

Section 311A of the *Commonwealth Electoral Act 1918* requires particulars of all amounts greater than $10,300 paid during a financial year to:

- advertising agencies
- market research organisations
- polling organisations
- direct mail organisations
- media advertising organisations.

The NBA made no payments of this kind in 2009–10.

Consultants

In 2009–10, three new consultancy contracts were entered into, involving total actual expenditure of $149,289 (GST inclusive). In addition, six ongoing consultancy contracts were active during the year, involving actual expenditure of $342,744 (GST inclusive). Total expenditure on consultancies in 2009–10 was $ 492,033.

Annual reports contain information about actual expenditure on contracts for consultancies. Information on the value of contracts and consultancies is available on the AusTender website, www.tenders.gov.au.

The policies and procedures for selecting consultants and approving the required expenditure are set out in chief executive and management instructions and key business processes. These processes adhere to the principles of the Commonwealth Procurement Guidelines and Best Practice Guidance.

Standard form contracts are used. Where necessary, these documents are adapted to suit individual circumstances.

Table 7.1 shows total expenditure on all consultancy services from 2007–08 to 2009–10, covering both new contracts let in the applicable year and ongoing contracts let in previous years.

TABLE 7.1 *Expenditure on consultancy services, 2007–08 to 2009–10*

2007–08		2008–09		2009–10	
No. let	**Total expenditure on new and existing consultancies ($)**	**No. let**	**Total expenditure on new and existing consultancies ($)**	**No. let**	**Total expenditure on new and existing consultancies ($)**
9	1 624 081	14	997 076	3	492 033

Table 7.2 provides details of consultancy contracts by the NBA in 2009–10 and the value of the contract over its entire life. Contracts with a value of less than $10,000 have not been included, in line with the annual reporting requirements of the Joint Committee of Public Accounts and Audit.

TABLE 7.2 *Consultancy services of $10,000 or more, 2009–10*

CONSULTANT NAME	DESCRIPTION	CONTRACT PRICE (GST INCL.)	SELECTION PROCESS	JUSTIFICATION
Australian Healthcare Associates Pty Ltd	Provision of Business Analysis of Haemovigilance	36,258	Direct Source	B
Biotext Pty Ltd	Systematic Reviewer for the 2010 review of the IVIg Criteria for Use	150,000	Open Tender	A
Gaudin Consultancy Limited	Provision of professional services to provide independent advice for Output Based Funding Model	60,000	Direct Source	B
Health Technology Analysts Pty Limited	Procurement of a Systematic Reviewer and Technical Writer Services	1,200,000	Open Tender	A
IMS Australia Pty Ltd	Procurement of Systematic Reviewer	304,175	Open Tender	A
Ken Barker Consulting Pty Ltd	Consultancy services for an independent member of the National Blood Authority's Audit Committee	22,000	Direct Source	B
Logistics Bureau Pty Ltd	Procurement of Services—Review of Distribution of Blood Products	551,756	Open Tender	A
Morison Consulting Pty Ltd	Consultancy services for an independent member of the National Blood Authority's Audit Committee	48,400	Direct Source	B
The Loch Group Pty Limited	Consultancy services for an independent member of the National Blood Authority's Audit Committee	41,800	Direct Source	B

Notes:

'open tender'—a procurement procedure in which a request for tender is published inviting all businesses that satisfy the conditions for participation to submit tenders.

'select tender'—a procurement procedure in which the procuring agency selects which potential suppliers are invited to submit tenders in accordance with the mandatory procurement procedures.

'direct sourcing—a procurement procedure, available only in defined circumstances, in which an agency may contact a single potential supplier or suppliers of its choice and for which conditions for direct sourcing apply under the mandatory procurement procedures.

Justification for decision to use consultancy: A—requirement for specialist expertise not available within the NBA; B—requirement for independence considered essential.

7.2 THE COMMONWEALTH DISABILITY STRATEGY

The NBA's recruitment and employment practices are consistent with the principles of the Commonwealth Disability Strategy. During early 2010, following consultation with staff, a three year Disability Action Plan was developed. The plan seeks to further develop an inclusive work environment within the NBA that enables people with a disability to access secure and sustainable employment opportunities commensurate with their skills, capabilities and interests, and the operational requirements of the NBA.

The plan documents the NBA's commitment to promoting the Australian Public Services values and addresses the overarching Commonwealth Disability Strategy principles and objectives through a range of strategies. Activities undertaken during the year against these core objectives are summarised below.

- *A culture that values diversity and actively promotes the employment of people with disability*

The NBA commenced the design of a formal staff survey (to be implemented in early 2011) to encourage staff to voluntarily disclose any impairment or disability, and facilitate and encourage attendance at disability-focused seminars and training courses where needed.

- *Designing internal policies and procedures that reflect the expectations of the Commonwealth Disability Strategy*

A review of internal policies and procedures commenced, to ensure that the needs of employees and stakeholders with disabilities are considered.

- *Undertaking our core business in a manner consistent with the principles of the Commonwealth Disability Strategy*

In conducting our procurement and contract management functions explicit consideration was given to options to improve the lives of people with disabilities. This is particularly relevant when designing choice of product and accessibility options such as home delivery arrangements for products.

- *Providing information in flexible and 'user friendly' formats*

The NBA commenced a review of the material and presentation of our website to gauge its overall readability and useability against agreed standards. Where we, or people with disability, identify the need for information in formats other than those normally provided, we are endeavouring to meet these needs in a timely manner.

- *Ensuring adequate access to our facilities*

During 2009–10 designs were prepared to allow hearing aid loop technology in our main meeting room.

- *Complaints mechanisms*

The NBA Service Charter and feedback register on the website provides a ready avenue for complaints or comments on services and information provided by the NBA. This charter will be reviewed during the life of the plan to ensure its continued appropriateness.

7.3 ASSET MANAGEMENT

Physical assets are not a significant aspect of the NBA's strategic management. The NBA has developed an asset replacement strategy to ensure that it has adequate funding for the replacement of assets as these come to the end of their useful life.

7.4 OCCUPATIONAL HEALTH AND SAFETY

Comcare determined that the NBA was compliant with Section 16(2) (d) of the *Occupational Health and Safety Act 1991*, following a desktop audit of the NBA as part of its National Proactive Campaign on Health and Safety Management Arrangements (HSMA) for Commonwealth Agencies.

No reportable incidents were required to be logged with Comcare during the year.

Other initiatives that were undertaken by the NBA during the year to maintain our ongoing commitment to a safe and secure workplace included:

- reports on Occupational Health and Safety issues and wider HSMA issues were reported to our Staff Participation Forum on a regular basis
- the NBA's Health and Safety Representative completed necessary training
- workstation assessments were conducted for all new and temporary staff, and for ongoing staff on request
- office lighting was connected to the office alarm, ensuring adequate lighting while the office was attended after hours
- Material Safety Data Sheets were updated and made available to all staff
- software was installed for those staff requesting assistance in managing keyboard requirements
- testing and tagging for electrical items in the entire office was implemented; one faulty item was replaced.

Several minor improvements to the safety of the office area were identified and assessment of the most suitable solutions is expected to be completed by August 2010.

In addition, the NBA supported a number of health programs, including stress management, yoga, participation in the Australian Bureau of Statistics fun run, the provision of allowances for screen based spectacles, hand hygiene promotion (including the provision of hand sanitiser equipment upon entry to our premises), flu vaccination and additional swine flu vaccination.

7.5 PRODUCTIVITY GAINS

In 2009–10 the NBA has experienced a period of consolidation following our restructure, during which staff turnover increased for a period of time. However, this restructure has enabled the NBA to deploy existing resources to commence new functions, specifically in the area of systems development and data analysis and reporting. Achievements in this area are detailed at Part 4.

The NBA has also scoped the business requirements and developed a project plan for an electronic records and document management system which will be implemented later in 2010. This is expected to result in considerable savings in staff time and resources relating to ecords management and the efficiency of our internal knowledge transfer.

7.6 ECOLOGICALLY SUSTAINABLE DEVELOPMENT AND ENVIRONMENTAL REPORTING

Ecologically sustainable development

The ability of the NBA to promote ecologically sustainable principles outlined in Section 3A of the *Environment Protection and Biodiversity Conservation Act 1999* are limited but we remain mindful of the potential to ensure that:

- our decision-making processes effectively integrate both long-term and short-term economic, environmental, social and equitable considerations (the 'integration principle')
- the principle of inter-generational equity—that the present generation should ensure that the health, diversity and productivity of the environment is maintained or enhanced for the benefit of future generations (the 'intergenerational principle')
- improved valuation, pricing and incentive mechanisms should be promoted (the 'valuation principle').

These principles are most relevant to our purchasing activities. During 2009–10 we pursued these principles by investigating options to improve our performance in ecologically sustainable development within our blood product supply contracts. Some areas for potential improvement were identified and are being considered in the context of forthcoming tendering processes and also in the review of product distribution arrangements. The main areas identified to date are:

- potential for cold chain product packaging to be reduced, or support for increased reuse or recycling of such material
- more efficient distribution arrangements and delivery systems
- availability of products that are suitable for room temperature storage, thereby reducing energy costs of refrigeration and transport costs of cold chain management
- the ecologically sustainable development footprint of suppliers' own global manufacturing and distribution operations.

Environmental Performance

During 2009–10, the NBA focused on four major areas of activities aimed at improving our environmental performance outcomes, including

Purchasing

- increased purchasing of recycled products such as photocopy paper and pens
- sole sourcing of renewable energy for the office
- reduction in energy consumption through the implementation of automated light switches linked to motion sensors
- continued focus on reducing domestic air travel through the increased use of teleconference facilities.

Measurement

- The NBA has adopted, where practical and cost effective, the Australian Government Information Management Office Green ICT Quick Wins strategy. During 2009–10 we calculated our IT specific carbon emissions for the first time. The results will provide the benchmark for future bi-annual calculations and reporting.
- Measurement of photocopy output continued in an endeavour to achieve further savings over the previous year.

Recycling

Staff continued the strong commitment to recycling with the result that:

- all toner cartridges were recycled as were several old phones
- office recycling was expanded and the frequency of the service increased

Awareness raising

The NBA has formally trained Green ICT personnel to monitor progress and raise awareness levels within the organisation. As an example, Earth Hour was again publicised within the NBA; the office was fully compliant and all staff were encouraged to participate.

In summary, the tables below provide information on the impact our activities have on the natural environment and measures taken and planned to further reduce these impacts.

TABLE 7.3 *NBA performance in addressing environmental themes, 2009–10*

ENVIRONMENTAL PERFORMANCE REPORTING THEME	STEPS TAKEN TO REDUCE EFFECT	MEASURES TO REVIEW AND IMPROVE REDUCING THE EFFECT
Energy efficiency	100% of energy sourced from renewable energy sources Energy efficient lights installed and connected to movement sensors Computers automatically switch off after idle time is exceeded The ratio of desktop computers to desktop printers has been reduced.	Benchmark data for energy use on information and communication technology activities will be monitored
Waste	Introduced more regular recycling bin service Signs placed in kitchen and amenities room to advise on recyclable materials	Benchmark data on printing and photocopying per head of staff will be monitored
Water	Signs placed in the kitchen and bathrooms reminding staff about water consumption Timers were placed in the showers reminding staff to limit showers to less than 3 minutes New dishwasher purchased with increased water and energy efficiencies	Benchmark water usage data

TABLE 7.4 *NBA Environmental performance indicators*

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11
Energy efficiency	Total consumption of energy—this includes all energy consumed when undertaking the functions of the agency, such as energy consumed for office buildings and transportation	Amount of electricity purchased/ consumed ($/kWh)	139701 KWh	139701 KWh
		Amount of gas purchased/ consumed ($/MJ)	0 MJ	0 MJ
		Amount of other fuels purchased/ consumed ($/kWh/MJ/L)	2356 L	2356 L
		Air travel distances (km)	543 492 Km	543 492 Km
	Total consumption of green energy—this includes the purchase of energy from sustainable resources	Amount of green energy purchased/consumed ($/kWh) during the reporting period	139701KWh	139701KWh
	Greenhouse gas emissions	Amount of greenhouse gases produced(tonnes)	169.3 tonnes	169.3 tonnes
	Relative energy uses—this includes the green energy use relative to non-renewable energy use and energy use per employee	Amount of green energy purchased/consumed divided by the amount of electricity/gas/ other fuels purchased/consumed	100%	100%
		amount of total energy purchased/ consumed ($/kWh) per employee	2910kWh	2910kWh

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11
Waste[1]	Total waste production—this includes the green energy waste (i.e.unwanted byproducts) produced undertaking the functions of the agency	Amount of waste produced (tonnes)	Monitoring will be introduced for all waste	
	Un-recyclable waste production—this includes all wastes that are not re-used or recycled	Amount of waste going to landfills (tonnes)		
	Recyclable waste production (excluding office paper	Amount of waste going to recycling facilities (tonnes)		
	Paper waste production	Amount of waste paper going to recycling facilities (tonnes) Amount of paper sourced from recyclable sources (tonnes) Percentage of paper sourced from recyclable sources (per cent)		
	Use of renewable/recyclable products	Amount of products sourced from renewable/recyclable sources (tonnes)		
	Relative waste production	Amount of the total waste (tonnes) per employee		
Water	Total consumption of water—this includes all water consumed when undertaking the functions of the agency	Amount of water purchased/ consumed ($/L)	680 000 L	680 000 L
	Grey water capture and use—this includes all waste water capture and re-use/recycling	Amount of grey water captured (L) Amount of grey water recycled (L) Amount of grey water re-used(L)	0 L 0 L 0 L	0 L 0 L 0 L
	Rainwater capture and use—this includes all rain water captured and used onsite	Amount of rainwater captured (L) Amount of captured rainwater used (L)	0 L 0 L	0 L 0 L
	Relative consumption/use of water—this includes the use of water per employee	Amount of total water use (L) per employee	14 000 L	14 000 L

INDICATORS

[1]No formal measures were recorded in previous years. Work will continue during the year to improve our measurement capabilities.

[2]The NBA leases an old B class building where grey water and rain water capture would require significant remedial work.

NATIONAL BLOOD AUTHORITY ICT SUSTAINABILITY PLAN 2010

The NBA has demonstrated a strong commitment to benchmarking of ICT sustainability across specific measures and has successfully implemented a number of changes over the past two years. As a result of this uptake a number of benchmarks have already been met and the benchmark of 'reams of paper per annum' has been exceeded.

The NBA was represented on the inaugural Australian Government Information Management Office Green ICT Quick Wins.

Summary of Measures:

MEASURE	GOVERNMENT BASELINE	ACTUAL 2010	GOVERNMENT MEASURE
SUSTAINABLE PROCUREMENT (SECTION 2.1)			
Relevant ICT equipment meets ISO14024 or ISO14021 standards at a level of EPEAT Silver or equivalent as a minimum standard	n/a	100%	100% by 2015
ICT equipment complies with current ENERGY STAR version	n/a	100%	100% by 2015
Product take-back and appropriate resource recovery or reuse for mobiles, toner cartridges; and ICT equipment covered by the national e-waste recycling scheme under the NWP	n/a	100%	100% by 2015
General use office copy paper (post consumer recycled content)	50% by 2011	61%	100% by 2015
Suppliers participate in *National Packaging Covenant* (NPC) (JULY 2011) or comply with the Used Packaging Materials NEPM	n/a	100%	100% by 2015
Suppliers EMS aligned to ISO14001	n/a	Commenced	%100 by 2015
MANAGING RESOURCE CONSUMPTION AND DEMAND (SECTION 2.2)			
Internal copy per end user (reams per annum)	18.6	16.8	9 by 2015
Desktop computers to printer ratio	8:01	8:01	20:1 by 2015
Desktop devices (inc. laptops) per end user[a]	1.6:1	1.8:1	1.2:1 by 2015
MANAGING RESOURCE CONSUMPTION AND DEMAND (SECTION 2.2)			
e-waste reused or recycled	75%	100%	75% by 2015
ICT packaging recycled (targets as per NPC timeframes)	48%	100%	65% by 2010
MANAGING ENERGY CONSUMPTION (SECTION 3.5)			
Desktop energy per end user (kWh per annum and averaged across agency)	630	Commenced	250 by 2015
Power useage effectiveness (PUE) in data centres and server rooms	2.5	Commenced	1.9 by 2015
Desktop computers off after hours	n/a	100%	90% by 2010

[a] this includes desktops required for incident management

7.7 FREEDOM OF INFORMATION

Section 8 of the *Freedom of Information Act 1982* requires that Australian Government agencies publish in their annual report information about:

- functions and decision-making powers that affect the public
- arrangements for public participation in the formulation of policy
- the categories of documents that are held by the agency
- how these documents can be accessed by the public.

In 2009–10 the NBA did not receive any requests for access to documents, or any requests for internal review, under the Act. The NBA was not involved in any Administrative Appeals Tribunal matters in respect of the Act.

National Blood Authority functions and powers

Information on the NBA's structure and functions is included in this publication (at page 122).

Ministers and the NBA's General Manager exercise decision-making powers under the *National Blood Authority Act 2003*. The National Blood Authority operates as an Australian Government agency in which staff exercise functions and powers under Acts such as the *Financial Management and Accountability Act 1997* and the *Public Service Act 1999*. Many decisions are given effect through NBA-administered contracts with suppliers.

Arrangements for public participation

Under the National Blood Agreement, the primary responsibility for policy in the national blood sector rests with the Australian Health Ministers Conference, supported by the Jurisdictional Blood Committee.

In the performance of its functions, the NBA has established consultative forums, among them a Professional and Community Forum and a Suppliers Forum. The NBA now regularly issues public consultation papers on elements of its work, including before most major blood procurement activities. The NBA also consults with a range of other expert bodies and interested parties in relation to specific projects.

Categories of documents

The NBA maintains records pertaining to the performance of its functions. Records are retained for varying periods, depending on their administrative and historical value, and are disposed of in accordance with the standards and practices approved by the National Archives of Australia under the *Archives Act 1983*. Table 7.5 shows the categories of documents held by the NBA.

TABLE 7.5 Categories of documents held by the National Blood Authority

CATEGORY	DESCRIPTION
Program documents	The NBA holds documents relating to contracts and tendering processes; dealings with Australian Government and state and territory ministers, committees and other government agencies under the National Blood Agreement; and the performance of its functions under the *National Blood Authority Act 2003*.
Working files	The NBA holds working files including correspondence, analysis and advice by NBA staff, documents received from third parties, and drafts of these and other documents.
Internal administration records	The NBA holds personnel records, organisational and staffing records, financial and expenditure records and internal operating documentation such as office procedures, instructions and indexes.
Documents open to public access subject to a fee or other charge	The NBA holds no documents in this category.
Documents available for access or purchase subject to a fee or other charge	The NBA holds no documents in this category.
Documents customarily available free of charge on request	Annual reports and other selected documents relating to the NBA are available on the internet at www.nba.gov.au.

Procedures and contact details

A request for access to documents under the *Freedom of Information Act 1982* must be in writing. Applicants must enclose the $30 application fee and provide an address in Australia to which notices can be sent. In certain circumstances the fee is not required or can be remitted by the NBA.

To enable a prompt response and to help the NBA meet its obligations under the *Freedom of Information Act 1982*, applicants should provide as much information as possible about the document(s) sought. We also ask that the applicant include a telephone number or an electronic mail address to allow NBA staff handling a request to seek clarification if necessary. Applicants might be liable to pay charges at rates prescribed by the Freedom of Information (Fees and Charges) Regulations.

Inquiries about making a formal request under the Act should be made in writing to the NBA's Freedom of Information Coordinator.

Facilities for access

Physical access to documents at the NBA's premises can be arranged. Inquiries should be directed to the Freedom of Information Coordinator:

Freedom of Information Coordinator
National Blood Authority
Locked Bag 8430
CANBERRA ACT 2601

PART EIGHT
FINANCIAL STATEMENTS

A SCIENTIST AT WORK

› THE TECAN GENESIS WORKSTATION 150 IS A ROBOTIC SYSTEM USED FOR CONDUCTING ELISA AND OTHER KINETIC TYPE ASSAYS

› SYSTEMS SUCH AS THESE RESULT IN MORE REPRODUCIBLE AND TIMELY DATA

PHOTO KINDLY PROVIDED BY WYETH AUSTRALIAN PTY LTD

PART EIGHT PROVIDES THE NATIONAL BLOOD AUTHORITY'S AUDITED FINANCIAL STATEMENTS FOR THE YEAR ENDING 30 JUNE 2010.

8

Australian National
Audit Office

INDEPENDENT AUDITOR'S REPORT

To the Minister for Health and Ageing

Scope

I have audited the accompanying financial statements of the National Blood Authority for the year ended 30 June 2010, which comprise: a Statement by the Chief Executive and Chief Finance Officer; Statement of Comprehensive Income; Balance Sheet; Statement of Changes in Equity; Cash Flow Statement; Schedule of Commitments and Contingencies; Schedule of Asset Additions; Schedule of Administered Items and Notes to and Forming Part of the Financial Statements, including a Summary of Significant Accounting Policies.

The Responsibility of the Chief Executive for the Financial Statements

The National Blood Authority's Chief Executive is responsible for the preparation and fair presentation of the financial statements in accordance with the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997*, including the Australian Accounting Standards (which include the Australian Accounting Interpretations). This responsibility includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

My responsibility is to express an opinion on the financial statements based on my audit. I have conducted my audit in accordance with the Australian National Audit Office Auditing Standards, which incorporate the Australian Auditing Standards. These auditing standards require that I comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor

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19 National Circuit BARTON ACT 2600
Phone (02) 6203 7300 Fax (02) 6203 7777

considers internal control relevant to the National Blood Authority's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the National Blood Authority's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the National Blood Authority's Chief Executive, as well as evaluating the overall presentation of the financial statements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

Independence

In conducting the audit, I have followed the independence requirements of the Australian National Audit Office, which incorporate the requirements of the Australian accounting profession.

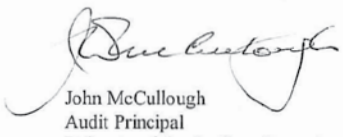
Auditor's Opinion

In my opinion, the financial statements of the National Blood Authority:

(a) have been prepared in accordance with the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997*, including the Australian Accounting Standards; and

(b) give a true and fair view of the matters required by the Finance Minister's Orders including the National Blood Authority's financial position as at 30 June 2010 and its financial performance and cash flows for the year then ended.

Australian National Audit Office



John McCullough
Audit Principal
Delegate of the Auditor-General

Canberra
9 August 2010

National Blood Authority
Financial Statements
For the year ended 30 June 2010

Statement by the Chief Executive and Chief Finance Officer

In our opinion, the attached financial statements for the year ended 30 June 2010 are based on properly maintained financial records and give a true and fair view of the matters required by the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997*, as amended.

A J Turner
Chief Executive Officer

9 August 2010

Peter Hade
Chief Finance Officer

9 August 2010

NATIONAL BLOOD AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME
for the year ended 30 June 2010

	Notes	**2010** **$'000**	2009 $'000
EXPENSES			
Employee benefits	3A	**5 636**	6 019
Supplier expenses	3B	**2 677**	2 852
Depreciation and amortisation	3C	**973**	867
Write-down and impairment of assets	3D	**188**	-
Losses from asset sales	3E	**1**	11
Total expenses		**9 475**	9 749
LESS:			
OWN-SOURCE INCOME			
Own-source revenue			
Sale of goods and rendering of services	4A	**193**	432
Funding from State and Terrritory governments	4B	**3 539**	3 445
Total own-source revenue		**3 732**	3 877
Gains			
Other gains	4C	**80**	112
Total gains		**80**	112
Total own source income		**3 812**	3 989
Net cost of services		**5 663**	5 760
Revenue from Government	4D	**5 712**	5 865
Surplus attributable to the Australian Government		**49**	105
OTHER COMPREHENSIVE INCOME			
Changes in asset revaluation reserves		**191**	-
Total other comprehensive income		**191**	-
Total comprehensive income		**240**	105
Total comprehensive income attributable to the Australian Government		**240**	105

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
BALANCE SHEET
as at 30 June 2010

	Notes	**2010 $'000**	2009 $'000
ASSETS			
Financial Assets			
Cash and cash equivalents	5A, 9	**210**	22
Trade and other receivables	5B	**8 622**	8 536
Total financial assets		**8 832**	8 558
Non-Financial Assets			
Leasehold improvements	6A, 6C	**141**	96
Property, plant and equipment	6B, 6C	**254**	483
Intangibles	6D, 6E	**1 610**	1 647
Other	6F	**57**	77
Total non-financial assets		**2 062**	2 303
Total Assets		**10 894**	10 861
LIABILITIES			
Payables			
Suppliers	7A	**644**	381
Other	7B	**1 823**	2 286
Total payables		**2 467**	2 667
Provisions			
Employee provisions	8	**1 194**	1 201
Total provisions		**1 194**	1 201
Total Liabilities		**3 661**	3 868
Net Assets		**7 233**	6 993
EQUITY			
Contributed equity		**812**	812
Reserves		**206**	15
Retained surplus		**6 215**	6 166
Total Equity		**7 233**	6 993

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
STATEMENT OF CHANGES IN EQUITY
for the year ended 30 June 2010

Item	Retained Earnings		Asset Revaluation Reserve		Contributed Equity/Capital		Total Equity	
	2010 $'000	2009 $'000	**2010 $'000**	2009 $'000	**2010 $'000**	2009 $'000	**2010 $'000**	2009 $'000
Opening balance								
Balance carried forward from previous period	**6 166**	6 061	**15**	15	**812**	812	**6 993**	6 888
Adjusted opening balance	**6 166**	6 061	**15**	15	**812**	812	**6 993**	6 888
Comprehensive Income								
Other comprehensive income	**-**	-	**191**	-	**-**	-	**191**	-
Surplus (Deficit) for the period	**49**	105	**-**	-	**-**	-	**49**	105
Total comprehensive income	**49**	105	**191**	-	**-**	-	**240**	105
of which:								
attributable to Australian Government	**49**	105	**191**	-	**-**	-	**240**	105
Closing balance as at 30 June	**6 215**	6 166	**206**	15	**812**	812	**7 233**	6 993
Closing balance attributable to the Australian Government	**6 215**	6 166	**206**	15	**812**	**812**	**7 233**	6 993

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
CASH FLOW STATMENT
for the year ended 30 June 2010

	Notes	**2010** **$'000**	2009 $'000
OPERATING ACTIVITIES			
Cash received			
Goods and services		**3 415**	3 709
Appropriations		**5 523**	5 447
Net GST received		**263**	401
Total cash received		**9 201**	9 557
Cash used			
Employees		**5 441**	5 551
Suppliers		**2 867**	3 904
Total cash used		**8 308**	9 455
Net cash flows from operating activities	9	**893**	102
INVESTING ACTIVITIES			
Cash used			
Purchase of property, plant and equipment		**32**	121
Purchase of intangibles		**652**	423
Total cash used		**684**	544
Net cash flows used by investing activities		**(684)**	(544)
Net increase (decrease) in cash held		**209**	(442)
Cash and cash equivalents at the beginning of the reporting period		**22**	63
Cash transferred to (from) the Official Public Account		**(21)**	401
Cash and cash equivalents at the end of the reporting period	5A	**210**	22

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF COMMITMENTS AND CONTINGENCIES
as at 30 June 2010

SCHEDULE OF COMMITMENTS	2010 $'000	2009 $'000
BY TYPE		
Commitments receivable		
GST recoverable on commitments	**145**	161
Total commitments receivable	**145**	161
Commitments payable		
Capital commitments		
Infrastructure, plant and equipment		-
Intangibles	**209**	373
Other capital commitments		-
Total capital commitments	**209**	373
Other commitments		
Operating leases [1]	**671**	1 029
Other commitments	**716**	364
Total other commitments	**1 387**	1 393
Net commitments by type	**1 451**	1 605
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**118**	82
From one to five years	**27**	79
Total other commitments receivable	**145**	161
Commitments payable		
Capital commitments		
One year or less	**209**	263
From one to five years	**-**	110
Total capital commitments	**209**	373
Operating lease commitments		
One year or less	**503**	449
From one to five years	**168**	580
Total operating lease commitments	**671**	1 029
Other commitments		
One year or less	**584**	191
From one to five years	**132**	173
Total other commitments	**716**	364
Net commitments by maturity	**1 451**	1 605

NB: Commitments are GST inclusive where relevant.
[1] Operating leases included are effectively non cancellable and comprise:

Nature of lease	*General description of leasing arrangement*
Lease for Canberra office accommodation	The current lease for office accommodation has been extended until 31 October 2011.
Lease for Melbourne office accommodation	The current lease for office accommodation has been extended until 31 October 2011.

SCHEDULE OF CONTINGENCIES

Quantifiable Contingencies
None

Unquantifiable but material contingencies are disclosed in **Note 10: Contingent Liabilities and Assets**

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ASSET ADDITIONS
for the year ended 30 June 2010

The following non-financial non-current assets were added in 2009-10: (Refer to Notes 6C and 6E)

Item	Leasehold improvements $'000	Other Property, Plant and equipment $'000	Intangibles $'000	Total $'000
By purchase - appropriation ordinary annual services	-	20	452	472
By purchase - other	-	12	266	278
Total additions	-	32	718	750

The following non-financial non-current assets were added in 2008-09: (Refer to Notes 6C and 6E)

Item	Leasehold improvements $'000	Other Property, Plant and equipment $'000	Intangibles $'000	Total $'000
By purchase - appropriation ordinary annual services	14	71	1 172	**1 257**
By purchase - other	8	41	689	**738**
Total additions	**22**	**112**	**1 861**	**1 995**

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS
for the year ended 30 June 2010

Income administered on behalf of Government *for the year ended 30 June 2010*	**Notes**	**2010** **$'000**	2009 $'000
Revenue			
Non-taxation revenue			
Funding from governments	14A	**871 195**	827 640
Other	14B	**1 354**	1 550
Total income administered on behalf of Government		**872 549**	829 190
Expenses administered on behalf of Government *for the year ended 30 June 2010*			
Grants	15A	**456 881**	433 385
Suppliers	15B	**402 143**	356 568
Amortisation	15C	**128**	66
Write-down and impairment of assets	15D	**-**	3 037
Total expenses administered on behalf of Government		**859 152**	793 056

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Assets administered on behalf of Government *as at 30 June 2010*	**Notes**	**2010** **$'000**	2009 $'000
Financial assets			
Cash and cash equivalents	16A	**389**	-
Receivables	16B	**10 210**	9 969
Total financial assets		**10 599**	9 969
Non-financial assets			
Inventories	16C	**67 212**	65 462
Intangibles	16D	**445**	498
Other	16E	**12**	12
Total non-financial assets		**67 669**	65 972
Total assets administered on behalf of Government		**78 268**	75 941
Liabilities administered on behalf of Government *as at 30 June 2010*			
Payables			
Suppliers	17A	**39 496**	36 908
Total payables		**39 496**	36 908
Total liabilities administered on behalf of Government		**39 496**	36 908

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

	Notes	2010 $'000	2009 $'000
Administered Cash Flows			
for the year ended 30 June 2010			
OPERATING ACTIVITIES			
Cash received			
Commonwealth contributions		**548 057**	523 807
State and territory contributions		**323 138**	303 833
Net GST received		**85 464**	79 139
Other		**410**	1 420
Total cash received		**957 069**	908 199
Cash used			
Grant payments		**501 150**	477 058
Suppliers		**441 797**	395 302
Total cash used		**942 947**	872 360
Net cash flows from (used by) operating activities		**14 122**	35 839
INVESTING ACTIVITIES			
Cash used			
Purchase of intangibles		**75**	267
Total cash used		**75**	267
Net cash flows (used by) investing activities		**(75)**	(267)
Net increase (decrease) in Cash Held		**14 047**	35 572
Cash and cash equivalents at the beginning of the reporting period		**-**	-
Cash from Official Public Account for:			
- Appropriations		**7 707**	10 893
- Special accounts		**943 037**	872 627
		950 744	883 520
Cash to Official Public Account for:			
- Special accounts		**964 402**	919 092
		964 402	919 092
Cash and cash equivalents at the end of the reporting period		**389**	-

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Administered Commitments *as at 30 June 2010*	**2010** **$'000**	2009 $'000
BY TYPE		
Commitments receivable		
GST recoverable on commitments	**287 342**	81 619
Total commitments receivable	**287 342**	81 619
Commitments payable		
Capital commitments		
Intangibles [1]	**157**	372
Total capital commitments	**157**	372
Other commitments		
Other commitments [2]	**3 160 602**	897 433
Total other commitments	**3 160 602**	897 433
Net commitments by type	**2 873 417**	816 186
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**94 201**	64 137
From one to five years	**107 651**	17 482
Over five years	**85 490**	-
Total other commitments receivable	**287 342**	81 619
Commitments payable		
Capital commitments		
One year or less	**127**	165
From one to five years	**30**	207
Total capital commitments [1]	**157**	372
Other commitments		
One year or less	**1 036 079**	705 346
From one to five years	**1 184 133**	192 087
Over five years	**940 390**	-
Total other commitments [2]	**3 160 602**	897 433
Net commitments by maturity	**2 873 417**	816 186

NB: All commitments are GST inclusive where relevant.

[1] Capital commitments relate to amounts payable under agreements or contracts for the development and maintenance of internally generated software in respect of which the supplier has yet to provide goods or services.

[2] Other commitments relate to amounts payable under agreements or contracts in respect of which the grantee or supplier has yet to provide goods or services for blood or blood related products required under the agreement or contract to meet demand under the National Supply Plan and Budget. During 2009-10 the NBA entered into a new agreement with CSL Limited for the fractionation of plasma into blood products until 31 December 2017.

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Administered Contingencies
as at 30 June 2010

There were no quantifiable administered contingent liabilities as at 30 June 2010.

Unquantifiable but material contingencies are disclosed in **Note 19: Administered Contingent Liabilities and Assets**

Statement of Activities Administered on Behalf of Government

The major activities of the National Blood Authority are directed towards managing national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood products and services.

The NBA manages and coordinates Australia's blood supply in accordance with the National Blood Agreement agreed by the Commonwealth, States and Territories. Under this agreement, the Commonwealth contributes 63 per cent of blood supply funding and the States and Territories provide 37 per cent. The funding for blood and blood products is funded from a special account established under the National Blood Authority Act 2003.

Details of planned activities for the year can be found in the Agency Portfolio Budget Statements for 2009 - 10 which have been tabled in Parliament.

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

The following non-financial non-current assets were added in 2009-10: (Refer to Note 16D)

Item	Intangibles $'000	Total $'000
By purchase - other	75	75
Total additions	**75**	**75**

The following non-financial non-current assets were added in 2008-09: (Refer to Note 16D)

Item	Intangibles $'000	Total $'000
By purchase - other	564	564
Total additions	**564**	**564**

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the period ended 30 June 2010

INDEX TO THE NOTES OF THE FINANCIAL STATEMENTS

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 1 Summary of Significant Accounting Policies

1.1 Objectives of the National Blood Authority

The National Blood Authority (NBA) is an Australian Government statutory authority which was established on 1 July 2003 with the principal role of managing national blood arrangements, ensuring sufficient supply and providing a new focus on the quality and appropriateness of blood products.

The NBA manages and coordinates Australia's blood supply in accordance with the National Blood Agreement agreed by the Australian Government, States and Territories. Under this agreement, the Australian Government contributes 63 per cent of blood supply funding and the States and Territories provide 37 per cent. The NBA operates under a special account – the National Blood Account. Revenues and expenses associated with the funding and supply of blood and blood products, as well as the operations of the NBA are recorded in this special account.

The NBA also operates a special account – the National Managed Fund (Blood and Blood Products) Special Account which is intended to meet potential blood and blood products liability claims against the Australian Red Cross Blood Service.

The NBA contributes to the Department of Health and Ageing Portfolio Outcome 13 - Acute Care, under the following outcome and output group:

Outcome	Output Group
Australia's blood supply is secure and well managed.	*Output Group 1* – Meet product demand through effective planning and the management of supply arrangements.

NBA activities contributing to this outcome are classified as either departmental or administered. Departmental activities involve the use of assets, liabilities, income and expenses controlled or incurred by the NBA in its own right. Administered activities involve the management or oversight by the NBA, on behalf of the Government, of items controlled or incurred by the Government.

The continued existence of the NBA in its present form, and with its present programs, is dependent on Government policy, the enabling legislation *National Blood Authority Act 2003*, and on continuing appropriations by Parliament and contributions from States and Territories for the NBA's administration and programs.

1.2 Basis of Preparation of the Financial Report

The financial statements are required by Section 49 of the *Financial Management and Accountability Act 1997* and are general purpose financial statements.

The financial statements and notes have been prepared in accordance with:

- Finance Minister's Orders (FMOs) for reporting periods ending on or after 1 July 2009; and
- Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that apply for the reporting period.

The financial statements have been prepared on an accrual basis and in accordance with the historical cost convention, except for certain assets and liabilities at fair value. Except where stated, no allowance is made for the effect of changing prices on the results or the financial position.

The financial report is presented in Australian dollars and values are rounded to the nearest thousand dollars unless otherwise specified.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.2 Basis of Preparation of the Financial Report (cont..)

Unless an alternative treatment is specifically required by an accounting standard or the FMOs, assets and liabilities are recognised in the balance sheet when and only when it is probable that future economic benefits will flow to the NBA or a future sacrifice of economic benefits will be required and the amounts of the assets or liabilities can be reliably measured. However, assets and liabilities arising under Agreements Equally Proportionately Unperformed are not recognised unless required by an accounting standard. Liabilities and assets that are unrecognised are reported in the schedule of commitments and the schedule of contingencies.

Unless alternative treatment is specifically required by an accounting standard, income and expenses are recognised in the statement of comprehensive income when and only when the flow, consumption or loss of economic benefits has occurred and can be reliably measured.

The NBA is a single reporting entity.

Administered revenues, expenses, assets and liabilities and cash flows reported in the Schedule of Administered Items and related notes are accounted for on the same basis and using the same policies as for departmental items, except where otherwise stated at Note 1.18.

1.3 Significant Accounting Judgments and Estimates

No accounting assumptions or estimates have been identified that have a significant risk of causing a material adjustment to carrying amounts of assets and liabilities within the next accounting period.

1.4 Changes in Australian Accounting Standards

Adoption of New Australian Accounting Standard Requirements

No accounting standard has been adopted earlier than the application date as stated in the standard.

The following new standards (including reissued standards) were issued prior to the signing of the statement by the Chief Executive and Chief Finance Officer, were applicable to the current reporting period and had a disclosure impact on the NBA:

- AASB 101 Presentation of Financial Statements

Other new standards, revised standards, interpretations and amending standards that were issued prior to the signing of the statement by the Chief Executive and Chief Finance Officer and are applicable to the current reporting period did not have a financial impact, and are not expected to have a future financial impact on the NBA.

Future Australian Accounting Standard Requirements

No new standards, revised standards, interpretations and amending standards were issued by the Australian Accounting Standards Board prior to the signing of the statement by the Chief Executive and Chief Finance Officer, which are expected to have a financial impact on the NBA for future reporting periods:

Other new standards, revised standards, interpretations and amending standards that were issued prior to the signing of the statement by the Chief Executive and Chief Finance Officer and are applicable to the future reporting period are not expected to have a future financial impact on the NBA.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.5 Revenue

Revenue from Government

Amounts appropriated for departmental outputs for the year (adjusted for any formal additions and reductions) are recognised as revenue when the NBA gains control of the appropriation, except for certain amounts that relate to activities that are reciprocal in nature, in which case, revenue is recognised only when it has been earned.

Appropriations receivable are recognised at their nominal amounts.

Other Types of Revenue

Revenue from the sale of goods is recognised when:

- the risks and rewards of ownership have been transferred to the buyer;
- the seller retains no managerial involvement or effective control over the goods;
- the revenue and transaction costs incurred can be reliably measured; and
- it is probable that the economic benefits associated with the transaction will flow to the NBA.

Revenue from rendering of services is recognised by reference to the stage of completion of contracts at the reporting date. The revenue is recognised when:

- the amount of revenue, stage of completion and transaction costs incurred can be reliably measured; and
- the probable economic benefits with the transaction will flow to the NBA.

Funding from State and Territory governments is recognised by reference to the stage of completion of contracts at the reporting date. The revenue is recognised when:

- the amount of revenue, stage of completion and transaction costs incurred can be reliably measured; and
- the probable economic benefits with the transaction will flow to the NBA.

The stage of completion of contracts at the reporting date is determined by reference to:

- services performed to date as a percentage of total services to be performed.

Receivables for goods and services, which have 30 day terms, are recognised at the nominal amounts due less any impairment allowance. Collectability of debts is reviewed at balance date. Allowances are made when collectability of the debt is no longer probable.

1.6 Gains

Other Resources Received Free of Charge

Resources received free of charge are recognised as gains when and only when a fair value can be reliably determined and the services would have been purchased if they had not been donated. Use of those resources is recognised as an expense.

Resources received free of charge are recorded as either revenue or gains depending on their nature.

Contributions of assets at no cost of acquisition or for nominal consideration are recognised as gains at their fair value when the asset qualifies for recognition, unless received from another Government agency or authority as a consequence of a restructuring of administrative arrangements. (Refer to Note 1.7)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.6 Gains (cont..)

Sale of Assets

Gains from the disposal of assets are recognised when control of the asset has passed to the buyer.

1.7 Transactions with the Government as Owner

Equity Injections

Amounts appropriated which are designated as 'equity injections' for a year (less any formal reductions) are recognised directly in contributed equity in that year.

Restructuring of Administrative Arrangements

Net assets received from or relinquished to another Australian Government agency or authority under a restructuring of administrative arrangements are adjusted at their book value directly against contributed equity.

1.8 Employee Benefits

Liabilities for 'short term employee benefits' (as defined in AASB 119 *Employee Benefits*) and termination benefits due within twelve months of balance date are measured at their nominal amounts.

The nominal amount is calculated with regard to the rates expected to be paid on settlement of the liability.

All other employee benefit liabilities are measured at the present value of the estimated future cash outflows to be made in respect of services provided by employees up to the reporting date.

Leave

The liability for employee entitlements includes provision for annual leave and long service leave. No provision has been made for sick leave as all sick leave is non-vesting and the average sick leave taken in future years by employees of the NBA is estimated to be less than the annual entitlement for sick leave.

The leave liabilities are calculated on the basis of employees' remuneration at the estimated salary rates that will apply at the time the leave is taken, including the NBA's employer superannuation contribution rates to the extent that the leave is likely to be taken during service rather than paid out on termination.

The liability for long service leave has been determined by reference to the work of an actuary as at 30 June 2010. The estimate of the present value of the liability takes into account expected attrition rates and pay increases through promotion and inflation.

Superannuation

Staff of the NBA are members of the Commonwealth Superannuation Scheme (CSS), the Public Sector Superannuation Scheme (PSS), the PSS Accumulation Plan (PSSap), the Australian Government Employee Superannuation Trust (AGEST) or other non-government superannuation funds.

The CSS and PSS are defined benefit schemes for the Australian Government. The PSSap, AGEST and the non-government superannuation funds are defined contribution schemes.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.8 Employee Benefits (cont..)

The liability for defined benefits is recognised in the financial statements of the Australian Government and is settled by the Australian Government in due course. This liability is reported by the Department of Finance and Deregulation as an administered item.

The NBA makes employer contributions to the employee superannuation scheme at rates determined by an actuary to be sufficient to meet the current cost to the Government of the superannuation entitlements of the NBA's employees. The NBA accounts for the contributions as if they were contributions to defined contribution plans.

The liability for superannuation recognised as at 30 June represents outstanding contributions for the final fortnight of the year.

1.9 Leases

A distinction is made between finance leases and operating leases. Finance leases effectively transfer from the lessor to the lessee substantially all the risks and rewards incidental to ownership of leased assets. An operating lease is a lease that is not a finance lease. In operating leases, the lessor effectively retains substantially all such risks and benefits.

Operating lease payments are expensed on a straight line basis which is representative of the pattern of benefits derived from the leased assets.

1.10 Cash and Cash Equivalents

Cash and cash equivalents includes cash on hand, cash held with outsiders, demand deposits in bank accounts with an original maturity of 3 months or less that are readily convertible to known amounts of cash and subject to insignificant risk of changes in value. Cash is recognised at its nominal amount.

1.11 Financial Assets

The NBA classifies its financial assets as loans and receivables.

The classification depends on the nature and purpose of the financial assets and is determined at the time of initial recognition.

Financial assets are recognised and derecognised upon trade date.

Effective Interest Method

The effective interest method is a method of calculating the amortised cost of a financial asset and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset, or, where appropriate, a shorter period.

Income is recognised on an effective interest rate basis.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.11 Financial Assets (cont..)

Loans and Receivables

Trade receivables, loans and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'loans and receivables'. Loans and receivables are measured at amortised cost using the effective interest method less impairment. Interest is recognised by applying the effective interest rate.

Impairment of Financial Assets

Financial assets are assessed for impairment at each balance date.

- *Financial assets held at amortised cost* - if there is objective evidence that an impairment loss has been incurred for loans and receivables held at amortised cost, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the asset's original effective interest rate. The carrying amount is reduced by way of an allowance account. The loss is recognised in the statement of comprehensive income.

1.12 Financial Liabilities

Financial liabilities are classified as other financial liabilities.

Financial liabilities are recognised and derecognised upon 'trade date'.

Other Financial Liabilities

Supplier and other payables are recognised at amortised cost. Liabilities are recognised to the extent that the goods or services have been received (and irrespective of having been invoiced).

1.13 Contingent Liabilities and Contingent Assets

Contingent liabilities and contingent assets are not recognised in the balance sheet but are reported in the relevant schedules and notes. They may arise from uncertainty as to the existence of a liability or asset or represent an asset or liability in respect of which the amount cannot be reliably measured. Contingent assets are disclosed when settlement is probable but not virtually certain and contingent liabilities are disclosed when settlement is greater than remote.

1.14 Acquisition of Assets

Assets are recorded at cost on acquisition except as stated below. The cost of acquisition includes the fair value of assets transferred in exchange and liabilities undertaken. Financial assets are initially measured at their fair value plus transaction costs where appropriate.

Assets acquired at no cost, or for nominal consideration, are initially recognised as assets and income at their fair value at the date of acquisition, unless acquired as a consequence of restructuring of administrative arrangements. In the latter case, assets are initially recognised as contributions by owners at the amounts at which they were recognised in the transferor agency's accounts immediately prior to the restructuring.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.15 Property, Plant and Equipment

Asset Recognition Threshold
Purchases of property, plant and equipment are recognised initially at cost in the balance sheet, except for purchases costing less than the thresholds listed below for each class of asset, which are expensed in the year of acquisition.

Asset class	***Recognition Threshold***
Infrastructure, Plant and Equipment	$2,000
Purchased Software	$5,000
Leasehold improvements	$10,000
Internally Developed Software	$50,000

The initial cost of an asset includes an estimate of the cost of dismantling and removing the item and restoring the site on which it is located. This is particularly relevant to 'make good' provisions in property leases taken up by the NBA where there exists an obligation to restore the property to its original condition. These costs are included in the value of the NBA's leasehold improvements with a corresponding provision for the 'make good' recognised.

Revaluations
All valuations are conducted by an independent qualified valuer and are undertaken by the Australian Valuation Office.

Fair values for each class of asset are determined as shown below.

Asset class	***Fair value measured at:***
Leasehold improvements	Depreciated replacement cost
Infrastructure, plant & equipment	Market selling price

Following initial recognition at cost, property, plant and equipment are carried at fair value less subsequent accumulated depreciation and accumulated impairment losses. Valuations are conducted with sufficient frequency to ensure that the carrying amounts of assets do not differ materially from the assets' fair values as at the reporting date. The regularity of independent valuations depends upon the volatility of movements in market values for the relevant assets.

Revaluation adjustments are made on a class basis. Any revaluation increment is credited to equity under the heading of asset revaluation reserve except to the extent that it reverses a previous revaluation decrement of the same asset class that was previously recognised in the surplus/deficit. Revaluation decrements for a class of assets are recognised directly in the surplus/deficit except to the extent that they reverse a previous revaluation increment for that class.

Any accumulated depreciation as at the revaluation date is eliminated against the gross carrying amount of the asset and the asset restated to the revalued amount.

Depreciation
Depreciable property, plant and equipment assets are written-off to their estimated residual values over their estimated useful lives to the NBA using, in all cases, the straight-line method of depreciation.

Depreciation rates (useful lives), residual values and methods are reviewed at each reporting date and necessary adjustments are recognised in the current, or current and future reporting periods, as appropriate.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.15 Property, Plant and Equipment (cont..)

Depreciation rates applying to each class of depreciable asset are based on the following useful lives:

Asset class	**2009 - 10**	2008 - 09
Infrastructure, Plant and Equipment	**3 to 7 years**	3 to 7 years
Leasehold improvements	**Lease term**	Lease term

The aggregate amount of depreciation allocated for each class of asset during the reporting period is disclosed in Note 3C.

Impairment
All assets were assessed for impairment at 30 June 2010. Where indications of impairment exist, the asset's recoverable amount is estimated and an impairment adjustment made if the asset's recoverable amount is less than its carrying amount.

The recoverable amount of an asset is the higher of its fair value less costs to sell and its value in use. Value in use is the present value of the future cash flows expected to be derived from the asset. Where the future economic benefit of an asset is not primarily dependent on the asset's ability to generate future cash flows, and the asset would be replaced if the NBA were deprived of the asset, its value in use is taken to be its depreciated replacement cost.

Derecognition
An item of property, plant and equipment is derecognised upon disposal or when no further economic benefits are expected from its use or disposal.

1.16 Intangibles

The NBA's intangibles comprise internally developed software and purchased software for internal use. These assets are carried at cost less accumulated amortisation and accumulated impairment losses.

Software is amortised on a straight-line basis over its anticipated useful life. The useful lives of the NBA's software are:

Type	**2009 - 10**	2008 - 09
Purchased software	**3 years**	3 years
Internally developed software	**5 years**	5 years

All software assets were assessed for indications of impairment at 30 June 2010.

1.17 Taxation

The NBA is exempt from all forms of taxation except Fringe Benefits Tax (FBT) and the Goods and Services Tax (GST).

Revenues, expenses, liabilities and assets are recognised net of GST except:

- where the amount of the GST incurred is not recoverable from the Australian Taxation Office; and
- for receivables and payables.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.18 Reporting of Administered Activities

Administered revenues, expenses, assets, liabilities and cash flows are disclosed in the schedule of administered items and related notes.

Except where otherwise stated below, administered items are accounted for on the same basis and using the same policies as for departmental items, including the application of Australian Accounting Standards.

Administered Cash Transfers to and from the Official Public Account

Revenue collected by the NBA for use by the Government rather than the NBA is administered revenue. Collections are transferred to the Official Public Account (OPA) maintained by the Department of Finance and Deregulation. Conversely, cash is drawn from the OPA to make payments under Parliamentary appropriation on behalf of Government. These transfers to and from the OPA are adjustments to the administered cash held by the NBA on behalf of the Government and reported as such in the statement of cash flows in the schedule of administered items and in the administered reconciliation table in Note 18.

Revenue

All administered revenues are revenues relating to the course of ordinary activities performed by the NBA on behalf of the Australian Government.

Collectability of debts is reviewed at balance date. Allowances are made when collection of the debt is judged to be less rather than more likely.

Amounts appropriated during the year for administered interest are recognised in the balance sheet.

Grants

The NBA administers a number of grant schemes on behalf of the Government. Grant liabilities are recognised to the extent that (i) the services required to be performed by the grantee have been performed or (ii) the grant eligibility criteria have been satisfied, but payments due have not been made. A commitment is recorded when the Government enters into an agreement to make these grants but services have not been performed or criteria satisfied.

Inventories of Blood and Blood Related Products

The NBA negotiated and implemented a new contract with CSL Limited (CSL) effective from 1 January 2010. The contract stipulates that CSL must establish and hold the National CSL Reserve (the Reserve) as a separately identified and managed inventory of products. The Australian Government, through the NBA, controls the Reserve and there are two significant input costs to the Reserve:

- Collection costs of raw plasma product provided by the Australian Red Cross Blood Service (ARCBS); and
- Purchase costs paid to CSL Limited (CSL) for the fractionated product.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

1.18 Reporting of Administered Activities (cont..)

Since the establishment of the NBA, processes have been put in place that allow for the collection of data to enable measurement of these costs. A costing methodology has been agreed and is reviewed annually to ensure reliability and appropriateness.

The NBA negotiated and implemented new arrangements with the ARCBS in August 2006. These arrangements formalised the control of the inventory held by ARCBS on behalf of the NBA for distribution to approved recipients.

The Australian Government, through the NBA, controls such inventory held by the ARCBS and it is disclosed in the financial statements of the NBA. There are three significant input costs to ARCBS Inventory:

- Collection costs of raw plasma product provided by the ARCBS;
- Purchase costs paid to CSL Ltd for the plasma product; and
- Purchase costs paid to other suppliers for blood related products.

Inventories are valued at the lower of cost and replacement cost per the requirements of Accounting Standard AASB 102. A costing methodology has been agreed and is reviewed annually to ensure reliability and appropriateness.

Movements in the Reserve and inventory held by ARCBS on behalf of the NBA are funded by the Commonwealth and State and Territory governments as per the National Blood Agreement.

National Managed Fund

The National Managed Fund was established to manage the liability risks of the ARCBS in relation to the provision of blood and blood products. The National Managed Fund was reported in 2003-04 by the Department of Health and Ageing under "Services for Other Governments and Non-Departmental Bodies Special Account". The NBA now manages this fund on behalf of the Australian Government and States and Territories. To facilitate the transfer of the fund to the NBA a special account under Section 20 of the *Financial Management and Accountability (FMA) Act 1997* was established, and this fund was transferred to the NBA for reporting.

The Fund came into effect on 1 July 2000 and to date, no claims have been made against the fund. The balance of the fund as at 30 June 2010 is $74,448,609 (30 June 2009: $63,597,682). Refer to Note 22.

Indemnities

The maximum amounts payable under the indemnities given is disclosed in the schedule of administered items – contingencies. At the time of completion of the financial statements, there was no reason to believe that the indemnities would be called upon, and no recognition of any liability was therefore required.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 2 Events after the Reporting Period

There were no significant events occurring after 30 June 2010.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $'000	2009 $'000
NOTE 3 Expenses		
Note 3A - Employee Benefits		
Wages and salaries	**3 822**	4 010
Superannuation:		
Defined contribution plans	**267**	299
Defined benefit plans	**410**	465
Leave and other entitlements	**898**	1 043
Separation and redundancies	**50**	-
Other employee expenses	**189**	202
Total employee benefits	**5 636**	6 019
Note 3B - Suppliers		
Goods and services		
Consultants	**317**	311
Contractors	**202**	143
Stationery	**17**	33
Travel	**294**	396
Committees, board and conferences	**40**	153
Audit and legal	**221**	228
IT and communications	**699**	666
Property expenses	**123**	116
Other expenses	**241**	354
Total goods and services	**2 154**	2 400
Goods and services are made up of:		
Provision of goods - external parties	**193**	218
Rendering of services - related entities	**503**	241
Rendering of services - external parties	**1 458**	1 941
Total goods and services	**2 154**	2 400
Other supplier expenses		
Operating lease rentals - external parties:		
Minimum lease payments	**465**	390
Workers compensation expenses	**58**	62
Total other supplier expenses	**523**	452
Total supplier expenses	**2 677**	2 852
Note 3C - Depreciation and Amortisation		
Depreciation:		
Property, plant and equipment	**321**	331
Leasehold improvements	**63**	70
Total depreciation	**384**	401
Intangibles:		
Computer Software	**589**	466
Total amortisation	**589**	466
Total depreciation and amortisation	**973**	867
Note 3D - Write-Down and Impairment of Assets		
Asset write-downs and impairments from:		
Impairment on intangible assets	**166**	-
Revaluation decrements:		
Property, plant and equipment	**22**	-
Total write-down and impairment of assets	**188**	-
Note 3E - Losses from Asset Sales		
Property, plant and equipment		
Proceeds from sale - trade in value	**-**	(13)
Carrying value of assets sold	**1**	24
Total losses from asset sales	**1**	11

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $'000	2009 $'000
NOTE 4 Income		
Revenue		
Note 4A - Sale of Goods and Rendering of Services		
Rendering of services - related entities	**160**	409
Rendering of services - external parties	**33**	23
Total sale of goods and rendering of services	**193**	432
Note 4B - Funding from State and Territory Governments		
Funding from State and Terrritory governments	**3 539**	3 445
Total funding from State and Territory govenments	**3 539**	3 445

Funding from State and Territory governments includes $111,000 revenue (2009: $245,448) which had been previously received and recognised as unearned revenue (Refer Note 7B).

Gains		
Note 4C - Other Gains		
Resources received free of charge	**80**	112
Total other gains	**80**	112
Revenue From Government		
Note 4D - Revenue from Government		
Appropriations:		
Departmental outputs	**5 712**	5 865
Total revenue from Government	**5 712**	5 865

Departmental outputs includes $189,000 revenue (2009: $417,925) which had been previously received and recognised as unearned revenue (Refer Note 7B).

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 **$'000**	2009 $'000
NOTE 5 Financial Assets		
Note 5A - Cash and Cash Equivalents		
Cash on hand or on deposit	**210**	22
Total cash and cash equivalents	**210**	22
Note 5B - Trade and Other Receivables		
Goods and Services:		
Goods and services - related entities	**31**	-
Total receivables for goods and services	**31**	-
Other receivables:		
GST receivable from the Australian Taxation Office	**85**	51
Special Account - cash held in the OPA	**8 506**	8 485
Total other receivables	**8 591**	8 536
Total trade and other receivables (gross)	**8 622**	8 536
Total trade and other receivables (net)	**8 622**	8 536
Receivables are expected to be recovered in:		
Less than 12 months	**8 622**	8 536
Total trade and other receivables (net)	**8 622**	8 536
Receivables are aged as follows:		
Not overdue	**8 622**	8 485
Overdue by:		
Less than 30 days	**-**	51
Total receivables (gross)	**8 622**	8 536

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010	2009
	$'000	$'000
NOTE 6 Non-Financial Assets		
Note 6A - Leasehold improvements		
Fair value	**157**	265
Accumulated depreciation	**(16)**	(169)
Total leasehold improvements	**141**	96

No indicators of impairment were found for leasehold improvements.
No leasehold improvements are expected to be sold or disposed of within the next 12 months.

Note 6B - Property, Plant and Equipment		
Fair Value	**293**	1 135
Accumulated depreciation	**(39)**	(652)
Total property, plant and equipment	**254**	483

All revaluations were conducted in accordance with the revaluation policy stated at Note 1. On 30/06/10, an independent valuer, the Australian Valuation Office, conducted the revaluations.

Revaluation increments of $108,005 for leasehold improvements (2009: $nil) and increments of $83,668 for plant and equipment (2009: $nil) were credited to the asset revaluation reserve by asset class and included in the equity section of the balance sheet. Decrements of $21,540 were expensed (2009: $nil)

No indicators of impairment were found for property, plant and equipment.

No property, plant or equipment is expected to be sold or disposed of within the next 12 months.

Note 6C - Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2009-10)

Item	Leasehold improvements	Infrastructure plant and equipment	Total Property, Plant and Equipment
	$'000	$'000	$'000
As at 1 July 2009			
Gross book value	265	1 135	1 400
Accumulated depreciation and impairment	(169)	(652)	(821)
Net book value 1 July 2009	**96**	**483**	**579**
Additions:			
By purchase	-	32	32
Revaluations and impairments recognised in other comprehensive income	108	83	191
Revaluations recognised in the operating result	-	(22)	(22)
Depreciation expense	(63)	(321)	(384)
Disposals:			
Other disposals	-	(1)	(1)
Net book value 30 June 2010	**141**	**254**	**395**

Net book value as of 30 June 2010 represented by:			
Gross book value	157	293	450
Accumulated depreciation and impairment	(16)	(39)	(55)
	141	**254**	**395**

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 6 Non-Financial Assets (cont..)

Note 6C (cont..) - Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2008-09)

Item	Leasehold improvements	Infrastructure plant and equipment	Total Property, Plant and Equipment
	$'000	$'000	$'000
As at 1 July 2008			
Gross book value	243	1 061	1 304
Accumulated depreciation and impairment	(99)	(335)	(434)
Net book value 1 July 2008	**144**	**726**	**870**
Additions:			
By purchase/internally developed	22	112	134
Depreciation expense	(70)	(331)	(401)
Disposals:			
Other disposals	-	(24)	(24)
Net book value 30 June 2009	**96**	**483**	**579**

Net book value as of 30 June 2009 represented by:			
Gross book value	265	1 135	1 400
Accumulated depreciation and impairment	(169)	(652)	(821)
	96	**483**	**579**

	2010	2009
	$'000	$'000
Note 6D - Intangibles		
Computer software		
Internally developed - in use	**2 453**	1 839
Purchased	**660**	555
Total computer software (gross)	**3 113**	2 394
Accumulated amortisation	**(1 503)**	(747)
Total computer software (net)	**1 610**	1 647
Total intangibles	**1 610**	1 647

Apart from the matter referred to in Note 3D, no indicators of impairment were found for intangible assets.

No intangibles are expected to be sold or disposed of within the next 12 months.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 6 Non-Financial Assets (cont..)

Note 6E - Reconciliation of the Opening and Closing Balances of Intangibles (2009-10)

Item	Computer software internally developed	Computer software purchased	Total
	$'000	$'000	$'000
As at 1 July 2009			
Gross book value	1 839	555	2 394
Accumulated amortisation and impairment	(337)	(410)	(747)
Net book value 1 July 2009	**1 502**	**145**	**1 647**
Additions:			
By purchase	-	105	105
Internally developed	613	-	613
Amortisation	(467)	(122)	(589)
Impairments recognised in the operating result	(166)		(166)
Disposals:			
Other disposals			-
Net book value 30 June 2010	**1 482**	**128**	**1 610**

Net book value as of 30 June 2010 represented by:			
Gross book value	2 453	660	3 113
Accumulated amortisation and impairment	(971)	(532)	(1 503)
	1 482	**128**	**1 610**

Note 6E (Cont..) - Reconciliation of the Opening and Closing Balances of Intangibles (2008-09)

Item	Computer software internally developed	Computer software purchased	Total
	$'000	$'000	$'000
As at 1 July 2008			
Gross book value	39	533	572
Accumulated amortisation and impairment	(39)	(281)	(320)
Net book value 1 July 2008	**-**	**252**	**252**
Additions:			
By purchase		22	22
Internally developed	1 839		1 839
Amortisation	(337)	(129)	(466)
Impairments recognised in the operating result			
Disposals:			
Other disposals	-	-	-
Net book value 30 June 2009	**1 502**	**145**	**1 647**

Net book value as of 30 June 2009 represented by:			
Gross book value	1 839	555	2 394
Accumulated amortisation and impairment	(337)	(410)	(747)
	1 502	**145**	**1 647**

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $'000	2009 $'000
NOTE 6 Non-Financial Assets (cont..)		
Note 6F - Other Non-Financial Assets		
Prepayments	**57**	77
Total other non-financial assets	**57**	77
No indicators of impairment were found for other non-financial assets.		
Total other non-financial assets are expected to be recovered in :		
No more than 12 months	**57**	77
More than 12 months	**-**	-
Total other non-financial assets	**57**	77
NOTE 7 Payables		
Note 7A - Suppliers		
Trade creditors and accruals	**644**	381
Total supplier payables	**644**	381
Supplier payables expected to be settled within 12 months:		
Related entities	**23**	19
External parties	**621**	362
Total supplier payables	**644**	381
Settlement is usually made within 30 days.		
Note 7B - Other Payables		
Salaries and wages	**98**	82
Unearned revenue from States and Territories	**638**	928
Unearned revenue from outputs	**1 087**	1 276
Total other payables	**1 823**	2 286
Total other payables are expected to be settled in:		
No more than 12 months	**1 823**	2 286
Total other payables	**1 823**	2 286
NOTE 8 Provisions		
Note 8 - Employee Provisions		
Leave	**1 194**	1 201
Total employee provisions	**1 194**	1 201
Employee provisions are expected to be settled in:		
No more than 12 months	**559**	875
More than 12 months	**635**	326
Total employee provisions	**1 194**	1 201

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 **$'000**	2009 $'000
NOTE 9 Cash Flow Reconciliation		
Reconciliation of cash and cash equivalents as per Balance Sheet to Cash Flow Statement		
Cash and cash equivalents as per:		
Cash flow statement	**210**	22
Balance sheet	**210**	22
Difference	**-**	-
Reconciliation of net cost of services to net cash operating activities:		
Net cost of services	**(5 663)**	(5 760)
Add revenue from Government	**5 712**	5 865
Adjustments for non-cash items		
Depreciation / amortisation	**973**	867
Net write-down of non-financial assets	**188**	-
Loss on disposal of assets	**1**	11
Changes in assets and liabilities:		
(Increase) / decrease in net receivables	**(65)**	314
(Increase) / decrease in non-financial assets	**18**	(10)
Increase / (decrease) in employee provisions	**10**	244
Increase / (decrease) in supplier payables	**195**	(618)
Increase / (decrease) in other payables	**(476)**	(811)
Net cash from (used by) operating activities	**893**	102

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 10 Contingent Liabilities and Assets

Quantifiable Contingencies
There were no quantifiable contingent assets or liabilities in this reporting period.

Unquantifiable Contingencies
There were no unquantifiable contingent assets or liabilities in this reporting period.

Significant Remote Contingencies
The Australian Government has indemnified the lessor of the National Blood Authority's premises for negligent acts committed by the National Blood Authority up to the value of $1,000,000.

NOTE 11 Senior Executive Remuneration

Note 11A - Actual Remuneration Paid to Senior Executives

Executive Remuneration

The number of senior executives who received or were due:	**2010**	2009
less than $145,000 *	**-**	-
$175 000 to $189 999	**-**	1
$190 000 to $204 999	**1**	-
$205 000 to $219 999	**1**	2
$235 000 to $249 999	**1**	-
$250 000 to $264 999	**-**	1
$325 000 to $339 999	**-**	1
$340 000 to $354 999	**1**	-
Total	**4**	5

* Excluding acting arrangements and part year service.

Total expense recognised in relation to Senior Executive employment

	$	$
Salary (including annual leave taken)	**693 180**	768 922
Changes in annual leave provisions	**4 287**	35 386
Performance bonus	**34 819**	30 910
Other [1]	**101 288**	80 171
Total Short-term employee benefits	**833 574**	915 389
Superannuation (post employment benefits)	**128 066**	173 525
Other long-term benefits	**36 346**	94 810
Total	**997 986**	1 183 724

During the year the NBA paid no termination benefits to senior executives (2009: $nil)

Notes
[1] "Other" includes motor vehicle allowances and other allowances

NATIONAL BLOOD AUTHORITY
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for the year ended 30 June 2010

Note 11B: Salary Packages for Senior Executives as at 30 June

Average annualised remuneration packages for substantive Senior Executives as at 30 June

	As at 30 June 2010			As at 30 June 2009		
	No. SES	Base salary (including annual leave)	Total remuneration package[1]	No. SES	Base salary (including annual leave)	Total remuneration package[1]
Total remuneration*:						
$160 000 to 174 999	-			1	125 946	163 956
$175 000 to $189 999	1	138 633	186 037	-		
$190 000 to $204 999	-			1	149 800	198 176
$205 000 to $219 999	-			2	329 538	422 065
$220 000 to $234 999	1	155 942	221 302	-		
$265 000 to $279 999	1	193 846	271 566	-		
$280 000 to $294 999	1	227 980	285 590	1	209 856	280 456
Total	4			5		

* Excluding acting arrangements and part-year service.

Notes
[1] Non-Salary elements available to Senior Executives include:
(a) Performance Bonus
(b) Motor vehicle allowance
(c) Superannuation

NOTE 12 Remuneration of Auditors	**2010 $'000**	2009 $'000
Financial statement audit services were provided free of charge to the NBA.		
The fair value of the services provided was	**80**	112
	80	112

No other services were provided by the Auditor-General.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010	2009
	$'000	$'000
NOTE 13 Financial Instruments		
NOTE 13A Categories of Financial Instruments		
Financial Assets		
Cash on hand or on deposit	**210**	22
Loans and receivables:		
Trade and other receivables	**31**	-
Carrying amount of financial assets	**241**	22
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**644**	381
Carrying amount of financial liabilities	**644**	381

Note 13B Fair Value of Financial Instruments

Financial assets

The fair values of all monetary financial assets approximate their carrying amounts.

Financial liabilities

The fair values of all monetary financial liabilities approximate their carrying amounts.
All financial liabilities are current, therefore a maturity analysis is not required.

Note 13C Credit Risk

The NBA is exposed to minimal credit risk as loans and receivables are cash and trade receivables. The maximum exposure to credit risk at reporting date in relation to each class of recognised financial assets is the carrying amount of those assets as indicated in the Balance Sheet

The NBA has no significant exposures to any concentrations of credit risk.

Note 13D Liquidity Risk

The NBA's financial liabilities are trade and other creditors. The exposure to liquidity risk is based on the notion that the NBA will encounter difficulty in meeting its obligations associated with financial liabilities. This is highly unlikely due to appropriation funding and mechanisms available to the NBA (e.g. Advance to the Finance Minister) and internal policies and procedures put in place to ensure there are appropriate resources to meet its financial obligations.

Note 13E Market Risk

The NBA holds basic financial instruments that do not expose it to certain market risks. The NBA is not exposed to 'interest rate risk', 'currency risk' or 'other price risk'.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTES TO THE SCHEDULE OF ADMINISTERED ITEMS

NOTE 14 Income Administered on Behalf of Government	**2010 $'000**	2009 $'000
Revenue		
Non-Taxation Revenue		
Note 14A: Funding from Governments		
Commonwealth contributions	**548 057**	523 807
State & Territory contributions	**323 138**	303 833
Total funding from governments	**871 195**	827 640
Note 14B: Other Revenue		
Other contributions	**1 354**	1 550
Total other revenue	**1 354**	1 550

NOTE 15 Expenses Administered on Behalf of Government		
Expenses		
Note 15A: Grants		
Private sector:		
Non-profit organisations	**456 881**	433 385
Total grants	**456 881**	433 385
The nature of the grants is Deeds for the provision of services relating to blood and blood related products and bleeding disorders and related activities.		
Note 15B: Suppliers		
Purchases of blood products	**400 508**	355 462
Consultants	**1 039**	750
Other goods and services	**596**	356
Total goods and services	**402 143**	356 568
Goods and services are made up of:		
Provision of goods - external parties	**400 536**	355 462
Rendering of services - external parties	**1 607**	1 106
Total suppliers expenses	**402 143**	356 568
Note 15C: Amortisation		
Intangibles		
Computer software	**128**	66
Total amortisation	**128**	66
Note 15D: Write-Down and Impairment of Assets		
Asset write-downs and impairments from:		
Impairment on financial instruments	**-**	3 037
Total write-down and impairment of assets	**-**	3 037

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 16 Assets Administered on Behalf of Government	2010 $'000	2009 $'000
Financial Assets		
Note 16A - Cash and cash equivalents		
Cash on hand or on deposit	**389**	-
Total cash and cash equivalents	**389**	-
Note 16B - Receivables		
Goods and services receivable - external parties	**3 037**	3 270
Other receivables:		
GST receivable from Australian Taxation Office	**10 210**	9 736
Total receivables (gross)	**13 247**	13 006
Less impairment allowance account:		
Goods and services	**(3 037)**	(3 037)
Total receivables (net)	**10 210**	9 969
Receivables are expected to be recovered in:		
No more than 12 months	10 210	9 969
Total trade and other receivables (net)	**10 210**	9 969
Receivables were aged as follows:		
Not overdue	**10 210**	9 969
Overdue by:		
More than 90 days	**3 037**	3 037
Total receivables (gross)	**13 247**	13 006
The impairment allowance account is aged as follows:		
Overdue by:		
More than 90 days	**(3 037)**	(3 037)
Total impairment allowance account	**(3 037)**	(3 037)
Credit terms are within 30 days from date of invoice (2009: 30 days).		
Reconciliation of the Impairment Allowance Account		
Movements in relation to 2010		
Other Receivables		
Opening balance	**(3 037)**	-
Increase / decrease recognised in net surplus	**-**	(3 037)
Closing balance	**(3 037)**	(3 037)
Non-Financial Assets		
Note 16C - Inventories		
National Reserve inventory held for distribution	**40 143**	37 539
Other inventory held for distribution	**27 069**	27 923
Total inventories	**67 212**	65 462
During 2009-10, $1,247,277 of inventory held for distribution related to a net write-off of damaged and expired stock and was recognised as an expense (2009: $1,015,214)		
No items of inventory were recognised at fair value less cost to sell.		
All inventory is expected to be distributed in the next 12 months.		
Note 16D - Intangibles		
Computer software		
Internally developed - in use	**638**	564
Total computer software (gross)	**638**	564
Accumulated amortisation	**(193)**	(66)
Computer software (net)	**445**	498
Total intangibles (non-current)	**445**	498

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 16 Assets Administered on Behalf of Government (cont…)

Note 16D - Intangibles (cont..)

Table B - Reconciliation of the opening and closing balances of intangibles (2009-10)

Item	Computer software internally developed
	$'000
As at 1 July 2009	
Gross book value	564
Accumulated amortisation and impairment	(66)
Net book value 1 July 2009	**498**
Additions:	
By purchase or internally developed	75
Amortisation	(128)
Net book value 30 June 2010	**445**

Net book value as of 30 June 2010 represented by:	
Gross book value	638
Accumulated amortisation and impairment	(193)
	445

Table B (cont..) - Reconciliation of the opening and closing balances of intangibles (2008-09)

Item	Computer software internally developed
	$'000
As at 1 July 2008	
Gross book value	-
Accumulated amortisation and impairment	-
Net book value 1 July 2008	**-**
Additions:	
By purchase/internally developed	564
Amortisation	(66)
Net book value 30 June 2009	**498**

Net book value as of 30 June 2009 represented by:	
Gross book value	564
Accumulated amortisation and impairment	(66)
	498

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 16 Assets Administered on Behalf of Government (cont…)	2010 $'000	2009 $'000
Note 16E - Other Non-Financial Assets		
Prepayments	**12**	12
Total other non-financial assets	**12**	12
NOTE 17 Liabilities Administered on Behalf of Government		
Payables		
Note 17A - Suppliers		
Trade creditors and accruals	**39 496**	36 908
Total suppliers	**39 496**	36 908
Supplier payables expected to be settled within 12 months:		
Related entities	**26 615**	-
External parties	**12 881**	36 908
Total suppliers	**39 496**	36 908
Settlement is usually made within 30 days		
Total liabilities administered on behalf of Government	**39 496**	36 908
NOTE 18 Administered Reconciliation Table		
Opening administered assets less administered liabilities as at 1 July	**39 033**	38 471
Plus: Administered income	**872 549**	829 190
Less: Administered expenses (non CAC)	**(859 152)**	(793 056)
Administered transfers to/from Australian Government:		
Appropriation transfers from OPA:		
Annual appropriations for administered expenses (non CAC)	**7 707**	10 893
Special account:		
Transfers from OPA	**943 037**	872 627
Transfers to OPA	**(964 402)**	(919 092)
Closing administered assets less administered liabilities as at 30 June	**38 772**	39 033

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 19 Administered Contingent Liabilities and Assets

Unquantifiable Administered Contingencies

Under certain conditions the Australian Government and the States/Territories jointly provide indemnity for the the Australian Red Cross Blood Service (the Blood Service) through a cost sharing arrangement for claims, both current and potential, regarding personal injury and loss of damage suffered by a recipient of certain blood products. The Australian Government's share of any liability is limited to sixty three percent of any agreed net cost.

The Deed of Agreement between the Australian Red Cross Society (the Red Cross) and the NBA in relation to the operation of the Blood Service includes certain indemnities and a limit of liability in favour of the Red Cross. These cover a defined set of potential business, product and employee risks and liabilities arising from the operations of the Blood Service. The indemnities and limitation of liability only operate in the event of the expiry and non-renewal, or the earlier termination, of the Deed of Agreement, and only within a defined scope. They are also subject to appropriate limitations and conditions including in relation to mitigation, contributory fault, and the process of handling relevant claims.

The Deed of Indemnity between the Red Cross and the NBA indemnifies the Red Cross in relation to the NSW and ACT Principal Sites (NAPS) and Victoria and Tasmania Principal Site (VTPS) development funding arrangements. If the NAPS or VTPS funding arrangements cease in respect of a NAPS or VTPS contract for any reason, the NBA indemnifies the Red Cross in respect of the liability of the Red Cross to make payments of a Funded Obligation, to the extent that the payments become due and payable under the terms of the NAPS or VTPS contract after the date when the Red Cross no longer has sufficient NAPS or VTPS funding to meet the funded obligations as a result of the cessation of the NAPS or VTPS funding.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $'000	2009 $'000
NOTE 20 Administered Financial Instruments		
NOTE 20A Categories of Financial Instruments		
Financial Assets		
Cash on hand or on deposit	**389**	-
Loans and receivables:		
Trade and other receivables	**-**	233
Carrying amount of financial assets	**389**	233
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**39 496**	36 908
Carrying amount of financial liabilities	**39 496**	36 908

Note 20B Fair Value of Financial Instruments

Financial assets

The fair values of all monetary financial assets approximate their carrying amounts.

Financial liabilities

The fair values of all monetary financial liabilities approximate their carrying amounts.

Note 20C Credit Risk

The NBA is exposed to minimal credit risk as loans and receivables are cash and trade receivables. The maximum exposure to credit risk at reporting date in relation to each class of recognised financial assets is the carrying amount of those assets as indicated in the Balance Sheet

The NBA has no significant exposures to any concentrations of credit risk.

Note 20D Liquidity Risk

The NBA's financial liabilities are trade and other creditors. The exposure to liquidity risk is based on the notion that the NBA will encounter difficulty in meeting its obligations associated with financial liabilities. This is highly unlikely due to special account funding and internal policies and procedures put in place to ensure there are appropriate resources to meet its financial obligations.

Note 20E Market Risk

The NBA holds basic financial instruments that do not expose it to certain market risks. The NBA is not exposed to 'interest rate risk', 'currency risk' or 'other price risk'.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

Note 21 Appropriations

Table A1 - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Ordinary Annual Services Appropriations

Particulars	Administered Expenses *Outcome 1*		Departmental Outputs		Total	
	2010	2009	**2010**	2009	**2010**	2009
	$	$	**$**	$	**$**	$
Balance brought forward from previous period *(Appropriation Acts)*					**-**	-
Appropriation Act:						
Appropriation Act (No. 1, 3 & 5) 2009-2010 as passed	**7 707 000**	10 893 000	**5 523 000**	5 447 000	**13 230 000**	16 340 000
Relevant agency receipts (*FMA Act* s 31)			**162 382**	532 119	**162 382**	532 119
Total appropriation available for payments	**7 707 000**	10 893 000	**5 685 382**	5 979 119	**13 392 382**	16 872 119
Cash payments made during the year (GST inclusive)					**-**	-
Appropriations credited to special accounts (GST exclusive)	**7 707 000**	10 893 000	**5 685 382**	5 979 119	**13 392 382**	16 872 119
Total as at 30 June	**-**	-	**-**	-	**-**	-

[1] The amounts in this line item are calculated on an accrual basis to the extent that an expense may have been incurred that includes GST but has not been paid by year end.

Table A2 - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Ordinary Annual Services Appropriations (Reduction in Administered Items)

Table A2 is blank for financial years 2009 and 2010

Table B1 - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Other than Ordinary Annual Services Appropriations

Table B1 is blank for financial years 2009 and 2010

Table B2 - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Other than Ordinary Annual Services Appropriations (Reduction in Administered Items)

Table B2 is blank for financial years 2009 and 2010

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $	2009 $

NOTE 22 Special Accounts (cont..)

NATIONAL MANAGED FUND (BLOOD AND BLOOD PRODUCTS)
Legal Authority: Financial Management and Accountability Act 1997 section 20
Appropriation: Financial Management and Accountability Act 1997 section 20

Purpose: For the receipt of monies and payment of all expenditure related to the management of blood and blood products liability claims against the Australian Red Cross Society (ARCS) in relation to the activities undertaken by the operating division of the ARCS known as the Australian Red Cross Blood Service.

National Managed Fund (Blood and Blood Products) - Administered

Balance brought forward from previous period	**63 597 682**	51 817 761
Appropriation for reporting period	**2 961 000**	3 915 000
Appropriations to take account of recoverable GST (*FMA Act* section 30A)	**-**	(237)
Other receipts - Commonwealth contributions	**4 936 113**	4 936 113
Other receipts - State and Territory contributions	**2 898 987**	2 898 987
Other receipts - External parties	**159 900**	175 890
Total increase	**74 553 682**	63 743 514
Payments made to suppliers	**105 073**	145 832
Total decrease	**105 073**	145 832
Balance carried to next period and represented by:	**74 448 609**	63 597 682
Cash - held in the Official Public Account	**74 448 609**	63 597 682
Total balance carried to the next period	**74 448 609**	63 597 682

The NBA has an "Other Trust Moneys - National Blood Authority Special Account". This account was established under section 20 of the *Financial Management and Accountability Act 1997 (FMA Act).* For the years ended 30 June 2009 and 2010, the account had a nil balance and there were no transactions debited or credited to it. The purpose of the Other Trust Moneys - National Blood Authority Special Account is for the expenditure of monies temporarily held on trust for the benefit of a person other than the Commonwealth.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

	2010 $	2009 $
NOTE 22 Special Accounts (cont..)		

NATIONAL MANAGED FUND (BLOOD AND BLOOD PRODUCTS)
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Appropriation: Financial Management and Accountability Act 1997 section 20

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NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

NOTE 23 Compensation and Debt Relief

Administered
No 'Act of Grace' expenses were incurred during the reporting period. (2009: no expenses)

No waivers of amounts owing to the Australian Government were made pursuant to subsection 34 (1) of the *Financial Management and Accountability Act 1997*. (2009: no waivers)

No ex gratia payments were provided during the reporting period. (2009: no payments)

Departmental
No payments were made under the Defective Administration Scheme during the reporting period. (2009: no payments)

No payments were made under section 73 of the *Public Service Act 1999* during the reporting period. (2009: no payments)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

Note 24 Reporting of Outcomes

Note 24A - Net Cost of Outcome Delivery

Particulars	Outcome 1	
	2010 $'000	2009 $'000
Expenses		
Administered	**859 152**	793 056
Departmental	**9 475**	9 749
Total expenses	**868 627**	802 805
Income from non-government sector		
Administered		
Activities subject to cost recovery	**-**	-
Other	**324 492**	305 383
Total administered	**324 492**	305 383
Departmental		
Activities subject to cost recovery	**-**	-
Other	**3 812**	3 989
Total departmental	**3 812**	3 989
Total	**328 304**	309 372
Other own-source income		
Administered	**-**	-
Departmental	**-**	-
Total	**-**	-
Net cost / (contribution) of outcome delivery	**540 323**	493 433

The National Blood Authority operates under one outcome and one output. Transactions reported under this output are reported in the Statement of Comprehensive Income and the Balance Sheet.
Outcome 1 is described in Note 1.1. Net costs shown include intra-government costs that are eliminated in calculating the actual Budget Outcome. Refer to Outcome 1 Resourcing Table in this Annual Report.
Costs recovered include contributions from State and Territory governments.

Note 24B - Major Classes of Departmental Expense, Income, Assets and Liabilities by Outcomes

Particulars	Outcome 1	
	2010 $'000	2009 $'000
Departmental Expenses		
Employees	**5 636**	6 019
Suppliers	**2 677**	2 852
Depreciation and amortisation	**973**	867
Other expenses	**189**	11
Total	**9 475**	9 749
Departmental Income		
Income from government	**5 712**	5 865
Sales of goods and services	**3 732**	3 877
Other non-taxation revenue	**80**	112
Total	**9 524**	9 854
Departmental Assets		
Cash and cash equivalents	**210**	22
Trade and other receivables	**8 622**	8 536
Leasehold Improvements	**141**	96
Infrastructure, plant and equipment	**254**	483
Intangibles	**1 610**	1 647
Other non-financial assets	**57**	77
Total	**10 894**	10 861
Departmental Liabilities		
Suppliers	**644**	381
Other payables	**1 823**	2 286
Employee provisions	**1 194**	1 201
Total	**3 661**	3 868

Outcome 1 is described in Note 1.1. Net costs shown include intra-government costs that are eliminated in calculating the actual Budget Outcome.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2010

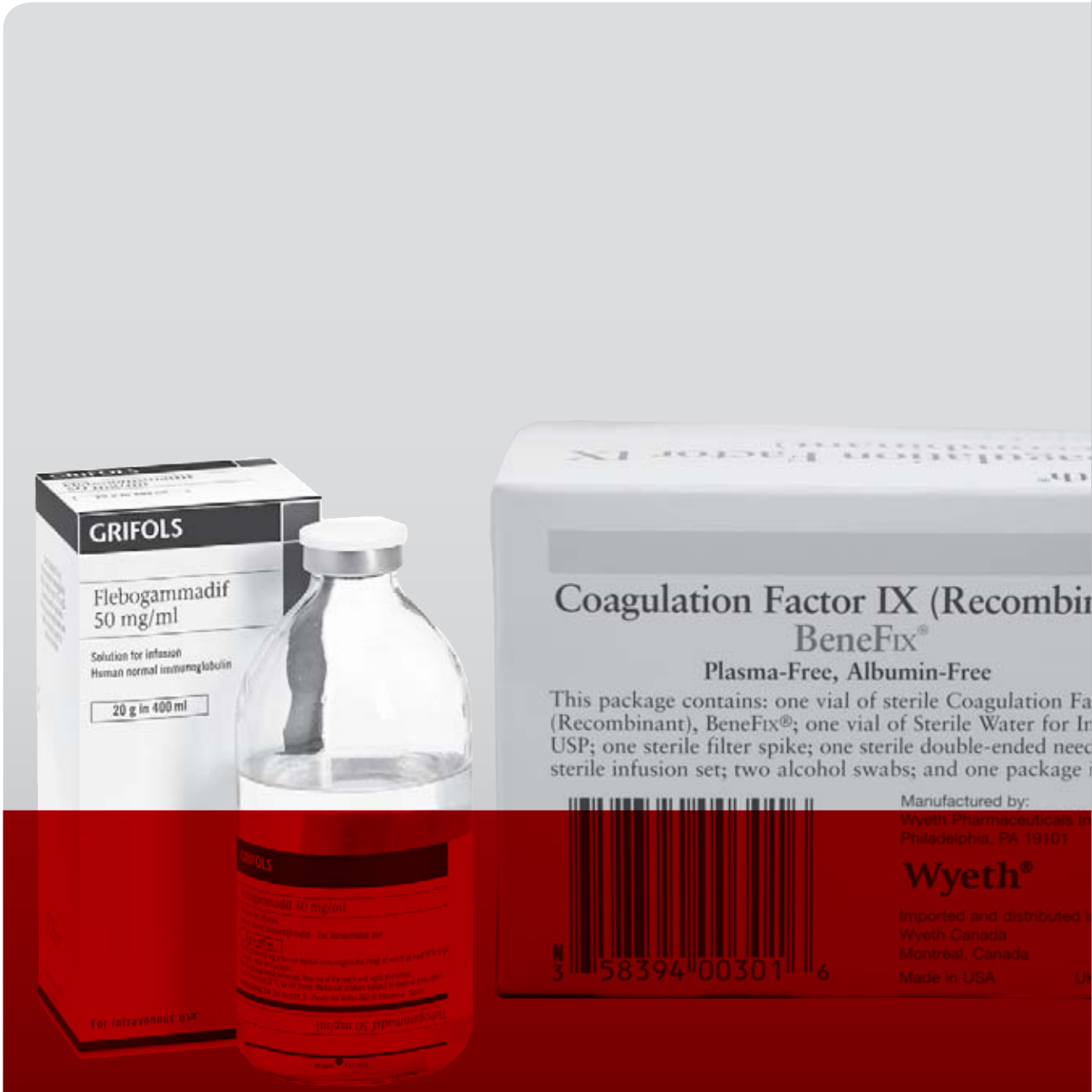
Note 24 Reporting of Outcomes (cont…)

Note 24C - Major Classes of Administered Expenses, Income, Assets and Liabilities by Outcomes

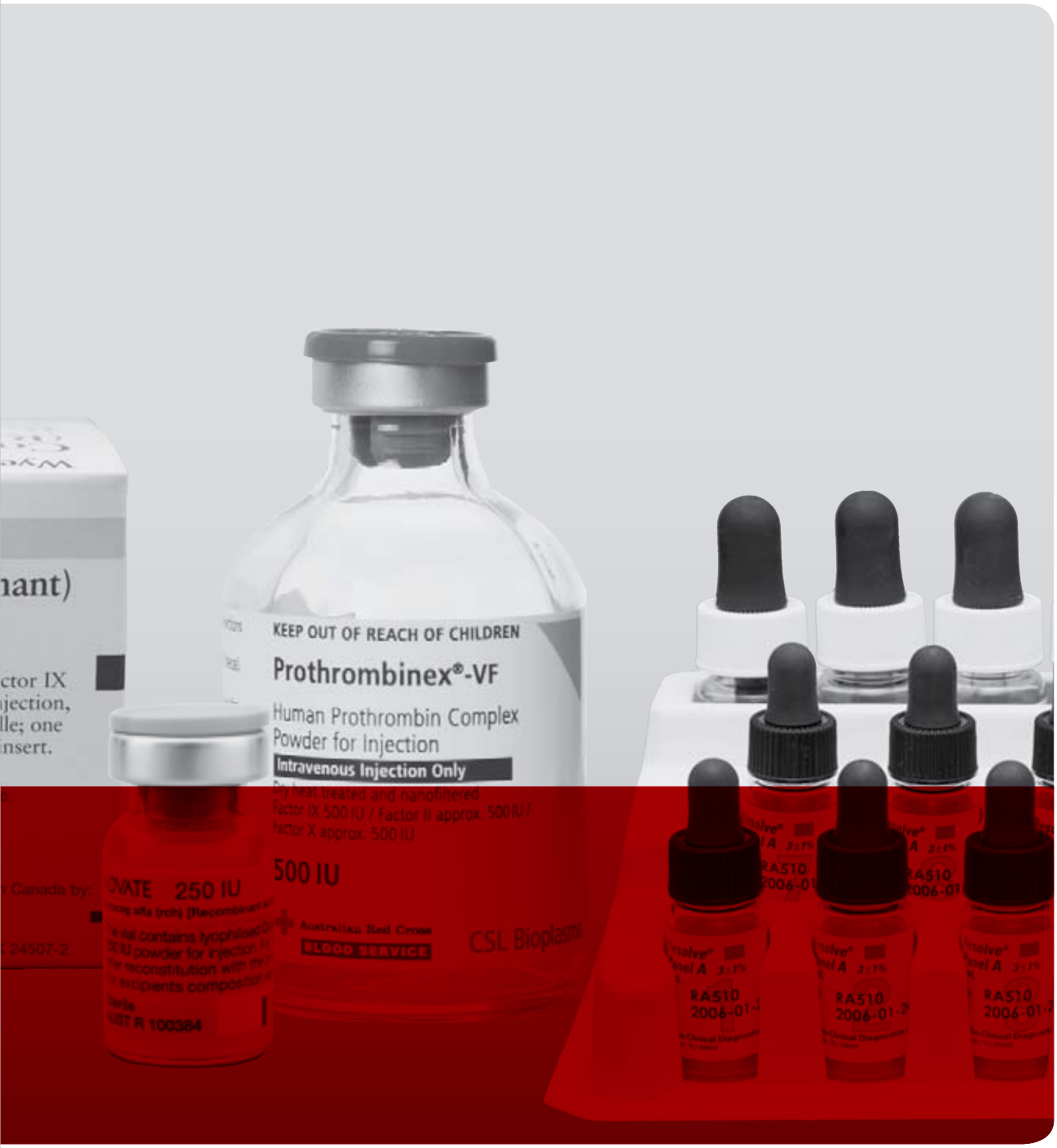
Particulars	Outcome 1	
	2010	2009
	$'000	$'000
Administered expenses		
Grants	**456 881**	433 385
Suppliers	**402 143**	356 568
Amortisation	**128**	66
Write-down and impairment of assets	**-**	3 037
Total	**859 152**	793 056
Administered income		
Provision of goods - related entities	**548 057**	523 807
Provision of goods - external parties	**323 138**	303 833
Other	**1 354**	1 550
Total	**872 549**	829 190
Administered assets		
Cash and cash equivalents	**389**	-
Receivables	**10 210**	9 969
Inventories	**67 212**	65 462
Intangibles	**445**	498
Other non-financial assets	**12**	12
Total	**78 268**	75 941
Administered liabilities		
Suppliers	**39 496**	36 908
Other payables	**-**	-
Total	**39 496**	36 908

Outcome 1 is described in Note 1.1.

APPENDICES



PLASMA-DERIVED AND RECOMBINANT PRODUCTS PURCHASED BY NBA



APPENDIX 1. THE NATIONAL BLOOD AGREEMENT: OBJECTIVES OF GOVERNMENTS

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
   (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 sectors
   (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
   (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.

APPENDIX 2. NATIONAL BLOOD AUTHORITY: AGENCY RESOURCE STATEMENT

The Agency Resource Statement provides details of the funding sources that the NBA drew upon in 2009–10. In addition it provides information about special accounts balances to be carried over to 2010–11.

	Actual Available Appropriations for 2009–10 ($'000)	Payments Made 2009–10 ($'000)	Balance Remaining 2009–10 ($'000)
Ordinary Annual Services			
Departmental appropriation			
Departmental appropriation	5 523	5 523	–
Total	**5 523**	**5 523**	**–**
Administered expenses			
Outcome 1:	7 707	7 707	
Total	**7 707**	**7 707**	
Total ordinary annual services	**13 230**	**13 230**	
Special Accounts			
Opening balance	231 375		
Appropriation receipts	13 230		
Non-appropriation receipts	960 747		
Payments made		952 014	
Closing Balance			253 338
Total Resourcing and Payments	1 205 352	952 014	

Resources for Outcomes

This table is intended to provide details of the total funding for each Outcome. In 2009–10 the NBA operated under a single outcome.

Outcome 1—Australia's blood supply is secure and well managed

	Budget 2009–10 ($'000)	Actual Expenses 2009–10 ($'000)	Variation 2009–10 ($'000)
Output Group 1			
Special Accounts			
Administered Items	891 015	859 152	31 863
Departmental Outputs	11 124	9 475	1 649
Total for Outcome 1	**902 139**	**868 627**	**33 512**
Average Staffing level (number)		**44**	

APPENDIX 3. FRESH BLOOD COMPONENTS LISTED IN THE NATIONAL SUPPLY PLAN 2009–10

PRODUCT NUMBER	PRODUCT NAME
1a	Whole Blood
1b	Whole Blood—Leucodepleted
2a	Whole Blood Red Cell
2b	Whole Blood Red Cell—Leucodepleted
2c	Whole Blood Red Cell—Buffy Coat Poor
2d	Whole Blood Paediatric Red Cell—Leucodepleted (Set of 4)
2e	Whole Blood Washed Red Cell
2f	Whole Blood Washed Red Cell—Leucodepleted
2g	Apheresis Red Cell—Leucodepleted
3a	Whole Blood Platelet
3b	Whole Blood Platelet—Leucodepleted (Pool of 4)
3c	Whole Blood Platelet—Buffy Coat Poor (Pool of 4)
3d	Apheresis Platelet—Leucodepleted
3e	Paediatric Apheresis Platelet—Leucodepleted (Set of 4)
4b	Whole Blood Clinical FFP
4c	Paediatric Whole Blood Clinical FFP (Set of 4)
4d	Apheresis Clinical FFP
5a	Whole Blood Cryoprecipitate
5b	Apheresis Cryoprecipitate
6a	Whole Blood Cryo-depleted Plasma
6b	Apheresis Cryo-depleted Plasma
7a	Autologous from Blood Donors
7b	Directed donations complying with AHMAC Guidelines
7c	Therapeutic Venesections for Whole Blood for Discard
7d	Serum Eye Drops—Single Collection Unit
7e	Granulocytes

APPENDIX 4. PLASMA AND RECOMBINANT PRODUCTS SUPPLIED UNDER CONTRACT IN 2009–10

List of products supplied under the Plasma Products Agreement

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS
CSL Limited	**Albumin**	
	Albumex 4	Used to treat hypovolaemia arising from shock, surgery or multiple organ failure
	Albumex 20	Used to treat patients suffering extensive burns or shock due to blood loss, or kidney or liver disease
	Immunoglobulins	
	Hyperimmune globulins	Used to prevent a specific infection such as tetanus, hepatitis B, Zoster or cytomegalovirus
	Intragam P	Used to reduce susceptibility to infections and manage many immune system disorders
	Rh (D) Immunoglobulin	Used in the prevention of haemolytic disease of the newborn (HDNB), a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers
	Clotting factors	
	Biostate	Used in the treatment of bleeding episodes in patients with FVIII deficiency due to haemophilia A. Biostate is also used in the treatment of bleeding episodes in patients with von Willebrand disease.
	MonoFIX-VF	Used in the treatment of bleeding episodes in patients with Factor IX deficiency, known as haemophilia B or Christmas disease
	Prothrombinex-VF	Used to manage patients who need warfarin reversal for urgent surgery and treatment of some bleeding episodes in patients who have factor deficiency II, IX and X when a more purified factor concentrate is not available.
	Thrombotrol-VF	Used to manage an inherited condition wherein a patient's blood clots too quickly

List of imported IVIg products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
CSL Limited	Sandoglobulin	Used to reduce susceptibility to infections and manage many immune system disorders (available for Jurisdictional Direct Orders)
Octapharma Australia Pty Ltd	Octagam	Used to reduce susceptibility to infections and manage many immune system disorders

List of imported IVIg products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
Lateral Grifols	Flebogamma	Used to reduce susceptibility to infections and manage many immune system disorders (available for Jurisdictional Direct Orders)

List of imported rare bleeding and blood disorder plasma products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS
Baxter Healthcare Pty Ltd	Anti Inhibitor Coagulant Complex Concentrates/ FEIBA	Used in the treatment of bleeding episodes including surgical interventions in haemophilia A and B patients with inhibitors
Baxter Healthcare Pty Ltd	Protein C/Ceprotin	Used in the treatment of haemorrhagic conditions associated with congenital Protein C deficiency
Baxter Healthcare Pty Ltd	FVII concentrate	Used in the treatment of bleeding episodes in people with Factor VII deficiency
Baxter Healthcare Pty Ltd	WinRho	Used in the prevention of a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers
CSL Limited	FXI/BPL Factor XI	Used in the treatment of bleeding episodes in people with Factor XI deficiency (sometimes called haemophilia C)
CSL Limited	FXIII/Fibrogammin P	Used in the treatment of bleeding episodes in people with Factor XIII deficiency

List of imported rare bleeding and blood disorder recombinant products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS
Novo Nordisk Pharmaceuticals Pty Ltd	rFVIIa/NovoSeven	Used in the treatment of bleeding episodes including surgical intervention in haemophilia A or B patients with inhibitors to Factor VIII or Factor IX.
Baxter Healthcare Pty Ltd	rFVIII/Recombinate	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients.
Baxter Healthcare Pty Ltd	rFVIII/Advate	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients.
Wyeth Australia Pty Ltd	rFVIII/Refacto/Xyntha	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients.
Wyeth Australia Pty Ltd	rFIX/BeneFIX	Used in the prevention and control of haemorrhagic episodes in haemophilia B or Christmas disease(Factor IX deficiency) patients.

APPENDIX 5. UNITS OF RED CELLS, PLATELETS AND IVIG ISSUED PER 1000 HEAD OF POPULATION BY STATE AND TERRITORY, 2006–07 TO 2009–10

FIGURE A5.1 Units of red cells issued per 1000 head of population by state and territory, 2006–07 to 2009–10

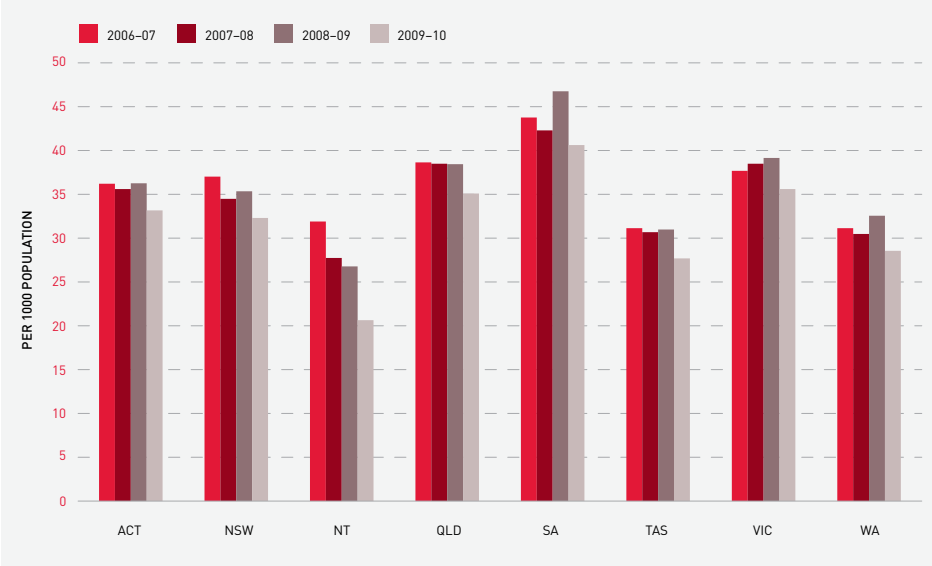


FIGURE A5.2 Units of platelets issued per 1000 head of population by state and territory, 2006–07 to 2009–10

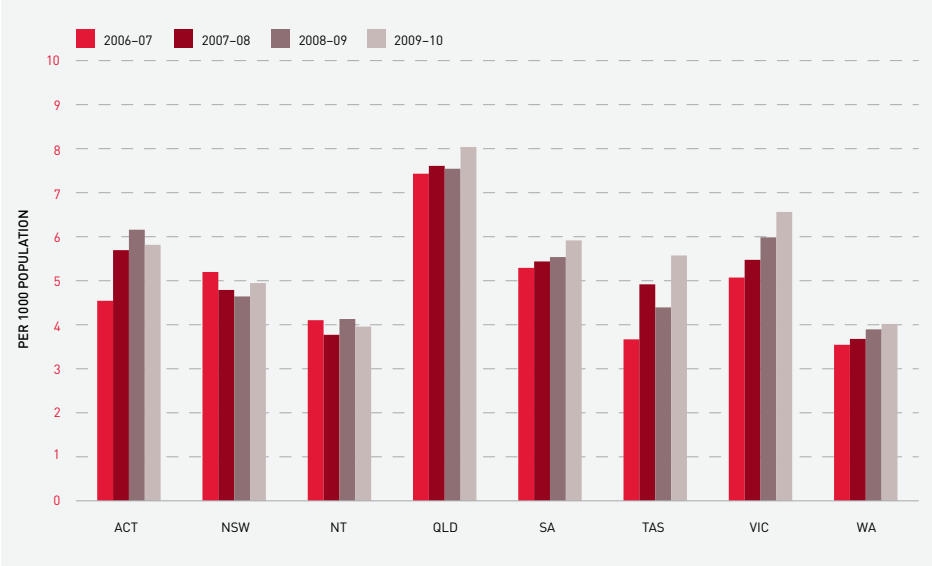
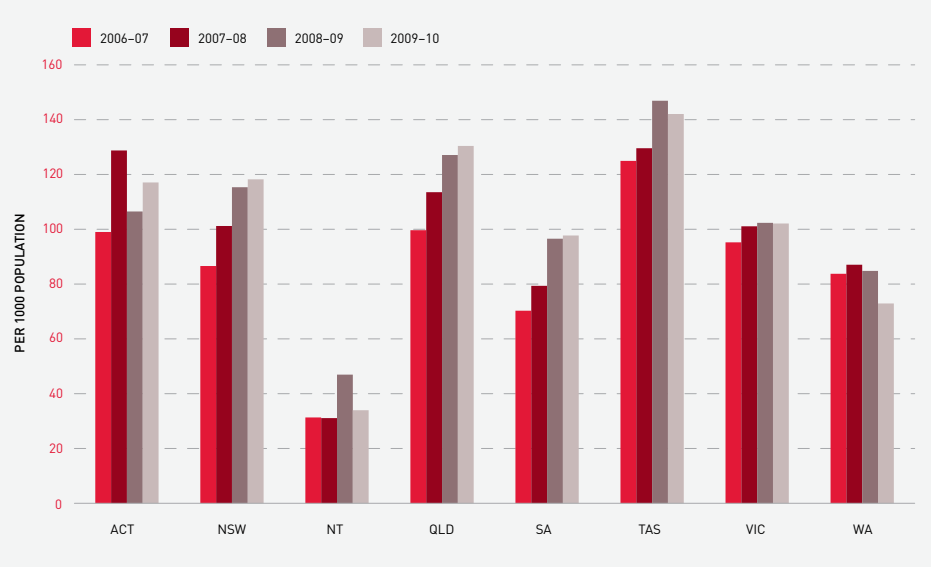


FIGURE A5.3 *Units of IVIg issued per 1000 head of population by state and territory, 2006–07 to 2009–10*



APPENDIX 6. ERRATUM

Table 2.11 (page 49) of the National Blood Authority Annual Report 2008–09 contained errors in calculating percentage figures for growth of expenditure by suppliers of imported products. The amounts themselves were accurate. The equivalent table in this 2009–10 Annual Report (Table 3.13) contains corrected percentage figures.

APPENDIX 7. GLOSSARY OF TERMS AND ACRONYMS

Acronyms

ABDR	Australian Bleeding Disorders Registry
ABS	Australian Bureau of Statistics
ANAO	Australian National Audit Office
AWA	Australian Workplace Agreement
CSL Limited	Now the name of a private company; the name derives from its earlier existence as the Commonwealth Serum Laboratories
DIF	dual inactivation and nanofiltration
EMS	Environment Management System
EU	European Union
FEIBA	Factor Eight Inhibitor Bypass Agent
GST	goods and services tax
HBOC	haemoglobin-based oxygen carrier
HMSA	Health and Safety Management Arrangements
HIV	human immunodeficiency virus
HLA	human leucocyte antigen
ICT	information and communication technologies
IVIg	Intravenous immunoglobulin
ITP	Idiopathic thrombocytopenic purpura
IU	International unit
JBC	Jurisdictional Blood Committee
KPI	key performance indicator
kWh	kilowatt hour
NBA	National Blood Authority
NAT	nucleic acid test
NPBM SC	National Patient Blood Management Steering Committee
NF	nanofiltration
NPC	National Packaging Convention
NWP	National Waste Policy
OHS	Occupational Health and Safety
ORBS	Ordering and Receipting Blood System
PID	primary immunodeficiency disease

rFVIIa	recombinant Factor seven (A)
rFVIII	recombinant Factor eight (clotting factor)
rFIX	Recombinant Factor nine (clotting factor)
SES	Senior Executive Service
SNOWMED-CT	Systemised nomenclature of medicine—clinical terms
vWD	von Willebrand disease

Glossary of terms

Acquired hypogammaglobulinaemia	See http://www.nba.gov.au/ivig/pdf/criteria.pdf.
Acquired immunodeficiency syndrome	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
Albumin	The main protein in human blood and the key to the regulation of the osmotic pressure of plasma. It is extracted from blood and manufactured into an intravenously administered product
allogeneic transfusion	A transfusion of product taken from different individuals of the same species
amino acids	One of the 21 building blocks of protein
anaemia	A medical condition in which the haemoglobin is less than normal. For men, anaemia is typically defined as haemoglobin level of less than 13.5 gram/100ml and in women less than 12.0 gram/100ml
anti-Rh(D) immunoglobulin therapy	The provision of product containing Anti-Rh(D) immunoglobulin, to prevent Rhesus sensitisation in Rh(D) negative females at or below child-bearing age
apheresis	A procedure in which blood is cycled out into a machine, one or more components are selectively removed, and the remainder of the blood is reinfused back into the donor
assay	An analysis undertaken to determine the presence of a substance and the amount of that substance
bleeding disorders	Diseases that cause abnormal or exaggerated bleeding and poor blood clotting
blood products	Products manufactured from donated blood
Blood Service	The Australian Red Cross Blood Service
capillary leak syndrome	A rare medical condition where the number and size of the pores in the capillaries are increased which leads to a leakage of fluid from the blood to the interstitial fluid, resulting in low blood pressure, oedema and multiple organ failure due to limited perfusion

Chagas disease	An infection caused by a protozoan parasite (Trypanosoma cruzi) that can result in acute inflammatory skin changes
Chikungunya	A disease resembling dengue fever, seen mainly in Africa, the Indian subcontinent, and Southeast Asia, caused by an arbovirus transmitted by Aedes mosquitoes
Chloroquine	A drug used to treat patients with malaria
Chronic fatigue syndrome	A complex disorder characterized by profound fatigue that is not improved by bed rest and that may be worsened by physical or mental activity
Chronic inflammatory demyelinating polyneuropathy	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
critical bleeding	Major haemorrhage that is life threatening and is likely to result in the need for massive transfusion and/or haemorrhage of a smaller volume in a critical area or organ (e.g. intracranial, intraspinal or intraocular), resulting in patient morbidity or mortality
Cytomegalovirus	A member of the herpesvirus group
Dengue	A disease caused by a family of viruses that are transmitted by mosquitoes. It is an acute illness of sudden onset that usually follows a benign course with symptoms such as headache, fever, exhaustion, severe muscle and joint pain
Desmopressin	A drug used to treat mild von Willebrand's disease
diagnostic reagent products	Products used in blood typing and cross matching
Erythropoietin	A substance produced by the kidney that leads to the formation of red blood cells in the bone marrow
follow-on biologics	A term used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product
fractionation	Blood plasma fractionation refers to the general processes of separating the various components of blood plasma
fresh whole blood	Fresh blood contains red blood cells, white cells and platelets suspended in a straw-coloured liquid known as plasma
Genome	The entire genetic complement, all of the hereditary material possessed by an organism
Guillian-Barré syndrome	See http://www.nba.gov.au/ivig/pdf/criteria.pdf

Haemoglobin	A molecule in red blood cells that transports molecular oxygen
haemoglobin-based oxygen carriers	A type of blood substitute
Haemophilia A	Classic haemophilia: an inherited blood coagulation disorder that results from a quantitative deficiency of Factor VIII, a blood clotting protein necessary for normal coagulation
Haemophilia B	An inherited blood coagulation disorder similar to haemophilia A but caused by a quantitative deficiency of Factor IX
haemostasis	The cessation of bleeding through clot formation, platelet plug formation and vasoconstriction
haemovigilance	A set of surveillance procedures covering the transfusion chain, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.
Hereditary angiodema	A rare genetic disorder caused by a deficiency in a blood protein, that can cause rapid swelling of the face and other parts of the body
human leucocyte antigen	The human leucocyte antigen system (HLA) is the name of the major histocompatibility complex (MHC) in humans
Hyperimmunes	Products used to provide rapid passive immunity in the post exposure period
Hypoproliferative thrombocytopenia	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
Idiopathic thrombocytopenic purpura	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
IgG2 levels	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immune replacement therapy	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immune tolerance induction	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immunodeficiency diseases	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
in-country reserve	A contractual requirement for blood product suppliers to the NBA for maintenance of a specified volume of product in Australia
infectious window period	The time between first infection and when a test can reliably detect that infection. In antibody-based testing, the window period is dependent on the time taken for sero-conversion
intravenous immunoglobulin	A product provided under the national blood arrangements to reduce susceptibility to infections and manage many immune system disorders

iron deficiency	A common disorder, sometimes nutritional, which results in anaemia as iron is necessary to make haemoglobin
issues/issuage	The volume of a particular product provided to Approved Health Providers in a jurisdiction under the National Blood Arrangements
jurisdiction	A signatory to the National Blood Agreement. This includes the Australian Government and all state and territory governments
Jurisdictional Direct Orders	Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg for the treatment of conditions not satisfying the Criteria
leucodepletion	The removal of white cells from a blood product
leucocytes/leukocytes	White cells in the blood
Malaria	An infectious disease transmitted by the bite of an infected Anopheles mosquito
massive transfusion	In adults, 'massive transfusion' may be defined as a transfusion of half of one blood volume in 4 hours, or more than one blood volume in 24 hours (adult blood volume is approximately 70 mL/kg). In children, 'massive transfusion' may be defined as a transfusion of more than 40 mL blood/kg.
mg	Milligram
monoclonal antibody	Monospecific antibodies that are all identical, arising from a single lymphocyte cell clone
National Blood Agreement	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the blood sector
National Blood Supply Contingency Plan	A plan approved by ministers to coordinate an appropriate response to a shortage of blood or blood products
National Product Price List	The price of all products supplied under the national blood arrangements approved by ministers
national reserve products	Products held in the national reserve managed by CSL to mitigate against an interruption to supply
National Supply Plan and Budget	The agreed volume of products to be supplied under the national blood arrangements approved by ministers
nitric oxide scavenging	An adverse impact of blood substitutes

nonsense mutation	A nonsense mutation is a change in the DNA sequence resulting in either the production of mRNA (the 'instructions' from the gene) that does not then produce (code for) a peptide, or causes the premature signal to stop mRNA production
nucleic acid testing	A biochemical technique used to detect a virus or a bacterium
output-based finding model	A funding arrangement whereby the supplier is paid for product receipted, rather than on a grant basis
Parvovirus B19	A virus infection characterised by low-grade fever, fatigue, a 'slapped cheeks rash' and a rash over the whole body. Parvovirus B19 can temporarily decrease or halt the body's production of red blood cells, causing anaemia
pathogen inactivation technology	Pathogen inactivation is a method for treating blood products that inactivates existing or unknown pathogens that may be present in blood components
patient blood management	The process of improving the status of the patient's own blood using non-transfusion methods with the consequence that transfusions and the associated risks of transfusion are avoided.
Peptides	A molecule consisting of two or more amino acids
peri-operative settings	The period of time extending from when the patient goes into hospital, clinic, or doctor's office for surgery or a procedure, until the time the patient is discharged
pharmacokinetic dosing indicators	Dosing levels indicated by evidence from pharmacokinetic studies
plasma	The liquid part of the blood and lymphatic fluid, which makes up approximately half of its volume. Blood plasma contains antibodies and other proteins. It is taken from donors and made into products for a variety of blood related conditions
platelets	An irregular, disc-shaped element in the blood that assists in blood clotting. During normal blood clotting, the platelets clump together (aggregate)
prion	An infectious agent composed primarily of protein
prion filtration	The removal of prions from blood
prophylaxis	A treatment designed and used to prevent an episode or worsening of disease from occurring
R	The prefix 'r' means recombinant
recombinant products	Synthetic or manufactured blood products (as opposed to products derived from plasma)

red blood cells	The blood cell that carries oxygen. Red cells contain haemoglobin and it is the haemoglobin which permits them to transport oxygen (and carbon dioxide)
Rh(D) haemolytic anaemia	Anaemia due to haemolysis, the abnormal breakdown of red blood cells either in the blood vessels or elsewhere in the body
Rh(D) haemolytic disease	An alloimmune condition that develops in a foetus, when the IgG molecules (one of the five main types of antibodies) produced by the mother pass through the placenta
sequaelae	A pathological condition resulting from a prior disease, injury, or attack
Sickle cell disease	A type of anaemia associated with the presence of haemoglobin S
Specific Antibody Deficiency	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
Thrombosis	The formation or presence of a thrombus (a clot of coagulated blood) in a blood vessel or cardiac chamber
tolerisation	Some patients with haemophilia have antibodies (inhibitors) to transfused clotting factors (e.g. Factor VIII). Tolerisation is a treatment regimen aiming to reduce or eliminate those inhibitors
toll manufacturing agreements	Arrangements in which a firm with specialised equipment processes raw materials or semi manufactured goods for another company. In the blood sector these arrangements are used to process plasma from specific countries into products for that country
transfusion-transmitted infection	An infection that can be transmitted via transfusion
variant Creutzfeldt-Jakob disease	A rare, degenerative, fatal brain disorder in humans
vasoconstriction	Narrowing of the blood vessels resulting from contracting of the muscular wall of the vessels
von Willebrand disease	An inherited bleeding disorder in which a clotting protein called von Willebrand factor is deficient or defective
West Nile virus	The mosquito-borne virus that causes West Nile fever
Xenotropic murine leukaemia virus	A virus from the Retroviridae family and the genus gammaretrovirus. It has a single-stranded RNA genome that replicates through a DNA intermediate
Yellow fever	An acute systemic illness caused by a virus from the Flavivirus genus

APPENDIX 8. COMPLIANCE INDEX

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
		Letter of transmittal	Mandatory	iii
		Table of contents	Mandatory	iv, v
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Appendix 7		Glossary of terms and acronyms	Mandatory	216
		Contact officer(s)	Mandatory	Inside front cover
		Internet home page address and Internet address for report	Mandatory	Inside front cover
1.1	Review by Secretary	General Manager's Overview	Mandatory	2–6
1.1		Summary of significant issues and developments	Suggested	2–3
1.1		Overview of department's performance and financial results	Suggested	4
1.1		Outlook for 2010–11	Suggested	5
		Significant issues and developments—portfolio	Suggested	Not applicable
1.5	Departmental Overview	Overview description of department	Mandatory	20
1.4		Role and functions	Mandatory	19
6.1		Organisational structure	Mandatory	120
2		Outcome and program structure	Mandatory	28
		Where outcome and program structures differ from PB Statements/PAES or other portfolio statements accompanying any other additional appropriation bills (other portfolio statements), details of variation and reasons for change	Mandatory	Not applicable
1.4		Portfolio structure: part of Health and Ageing portfolio	Mandatory	19
2, 3, 4	Report on Performance	Review of performance during the year in relation to programs and contribution to outcomes	Mandatory	28, 32, 86
2, 3		Actual performance in relation to deliverables and KPIs set out in PB Statements/PAES or other portfolio statements	Mandatory	28 , 29, 31, 32, 54, 57, 61, 63, 67, 90, 29, 31

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
3		Performance of purchaser/ provider arrangements	Suggested	46, 47, 53, 57
		Where performance targets differ from the PBS/ PAES,	Mandatory	Not applicable
details of both former and new targets, and reasons for the change	Mandatory	Not applicable	Mandatory	
1.1, 2, 3, 4		Narrative discussion and analysis of performance	Mandatory	2, 28, 32–83, 86
3.1,		Trend information	Mandatory	32
4		Significant changes in nature of principal functions/ services	Suggested	86
1.1, 3.2, 4, 5		Factors, events or trends influencing departmental performance	Suggested	2, 63, 86, 101
1.1, 3.2, 6.1		Contribution of risk management in achieving objectives	Suggested	2, 63,120
6.3,		Social justice and equity impacts	Suggested	128
6.2		Performance against service charter customer service standards, complaints data, and the department's response to complaints	If applicable, mandatory	126
6.4, 8		Discussion and analysis of the department's financial performance	Mandatory	134–138, 156
		Discussion of any significant changes from the prior year or from budget.	Suggested	Not applicable
Appendix 2		Agency resource statement and summary resource tables by outcomes	Mandatory	209
		Developments since the end of the financial year that have affected or may significantly affect the department's operations or financial results in future	If applicable, mandatory	Not applicable
	Management Accountability			
	Corporate Governance			

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
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6.1		Senior management committees and their roles	Suggested	122
6.2		Corporate and operational planning and associated performance reporting and review	Suggested	126
6.1		Approach adopted to identifying areas of significant financial or operational risk	Suggested	124
6.1	Letter of transmittal	Agency heads are required to certify that their agency comply with the Commonwealth Fraud Control Guidelines.	Mandatory	Letter of transmittal
6.3		Policy and practices on the establishment and maintenance of appropriate ethical standards	Suggested	128, 133
6.3		How nature and amount of remuneration for SES officers is determined	Suggested	130
6.1	External Scrutiny	Significant developments in external scrutiny	Mandatory	120
6.1		Judicial decisions and decisions of administrative tribunals	Mandatory	120
6.1		Reports by the Auditor-General, a Parliamentary Committee or the Commonwealth Ombudsman	Mandatory	120
6.3	Management of Human Resources	Assessment of effectiveness in managing and developing human resources to achieve departmental objectives	Mandatory	128–130
6.3		Workforce planning, staff turnover and retention	Suggested	129
6.3		Impact and features of enterprise or collective agreements, determinations, common law contracts and AWAs	Suggested	130
6.3		Training and development undertaken and its impact	Suggested	132
7.4		Occupational health and safety performance	Suggested	146
7.5		Productivity gains	Suggested	147

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
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6.3		Enterprise or collective agreements, determinations, common law contracts and AWAs	Mandatory	130
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7.1	Australian National Audit Office Access Clauses	Absence of provisions in contracts allowing access by the Auditor-General	Mandatory	142
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APPENDIX 9. INDEX

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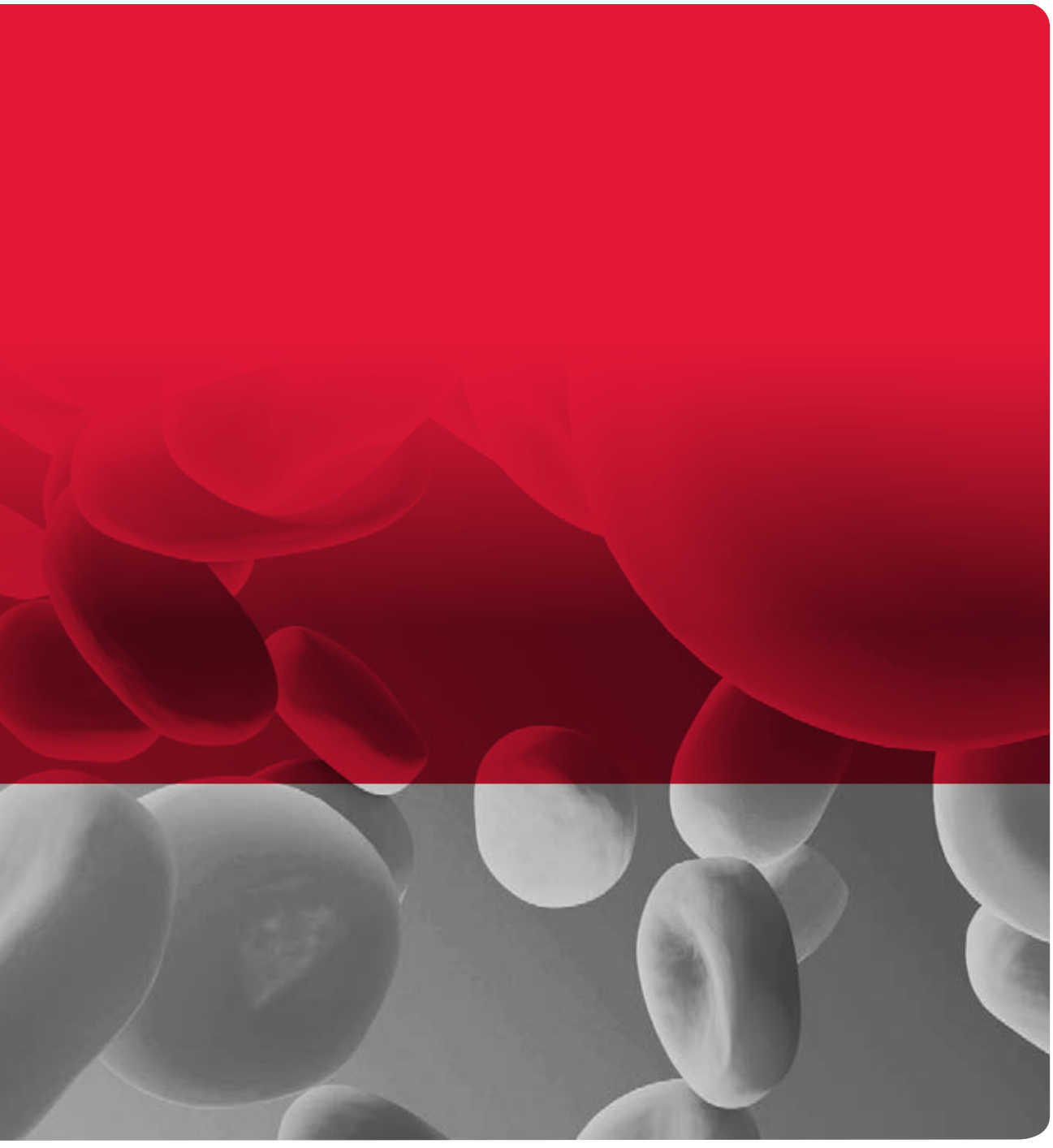
› AT REST, EACH MINUTE THE HEART PUMPS ABOUT 5 LITRES OF BLOOD OUT INTO THE CIRCULATION, DELIVERING ABOUT 1000 ML OF OXYGEN TO THE TISSUES

› AT REST, EACH MINUTE THE TISSUES USE ABOUT 250 ML OF THAT DELIVERED OXYGEN



NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT 2009–2010

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