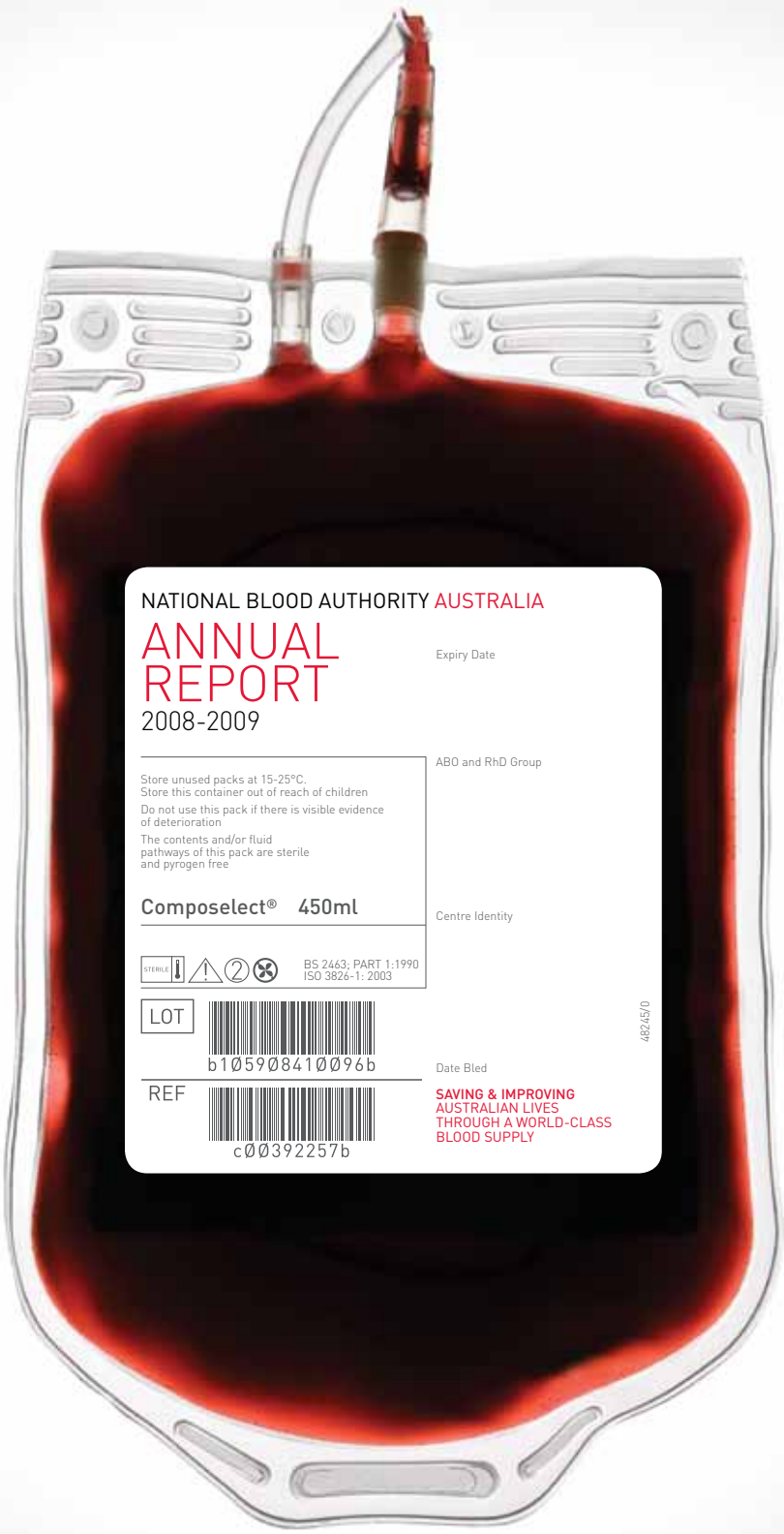
NATIONAL BLOOD AUTHORITY AUSTRALIA
ANNUAL REPORT
2008-2009
Expiry Date
ABO and RhD Group
Store unused packs at 15-25°C.
Store this container out of reach of children
Do not use this pack if there is visible evidence of deterioration
The contents and/or fluid pathways of this pack are sterile and pyrogen free
Composelect® 450ml
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STERILE
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ISO 3826-1: 2003
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SAVING & IMPROVING AUSTRALIAN LIVES THROUGH A WORLD-CLASS BLOOD SUPPLY
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Contact officer Stephanie Gunn Deputy General Manager
Locked Bag 8430
Canberra ACT 2601
Telephone 02 6211 8300
Facsimile 02 6211 8330
Email nba@nba.gov.au

Website www.nba.gov.au


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

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

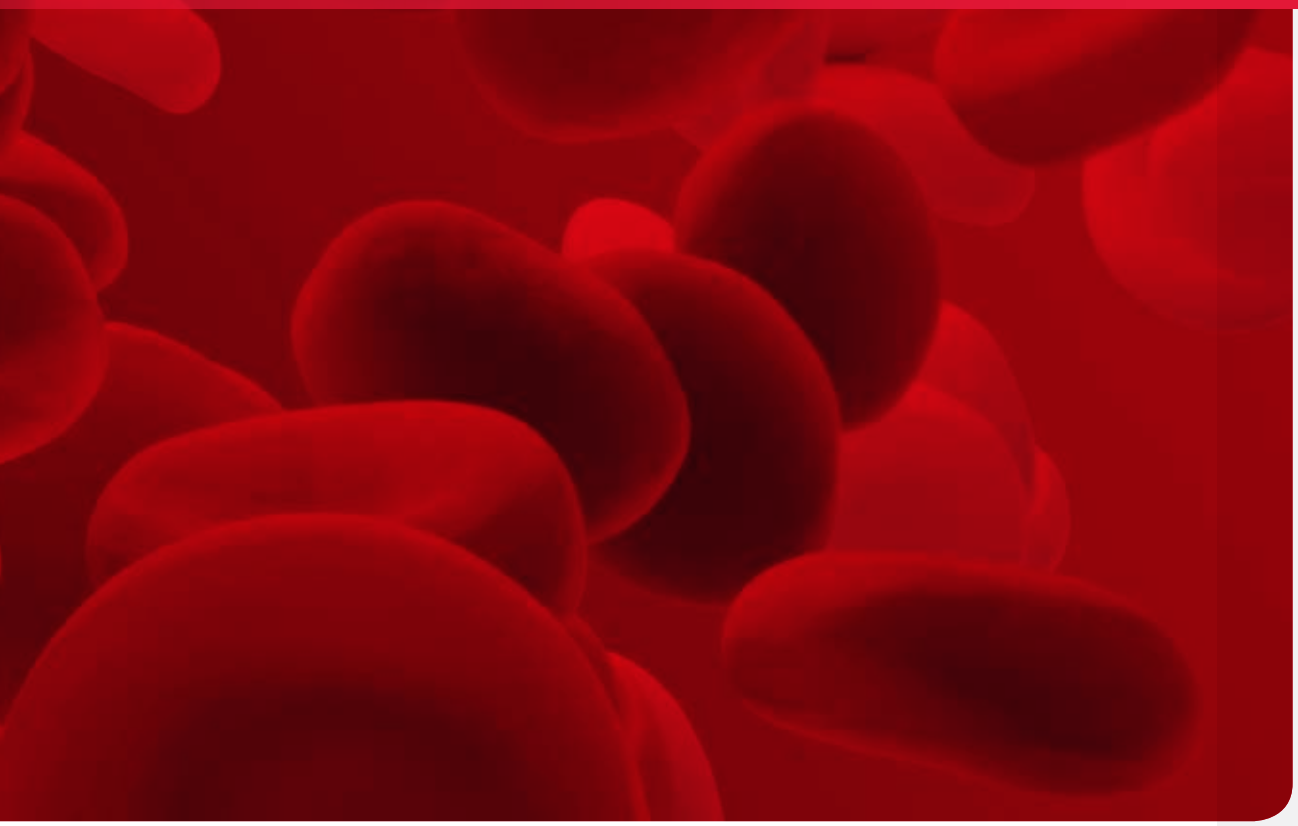
Our vision is saving and improving Australian lives through a world-class blood supply.

OUR ROLE

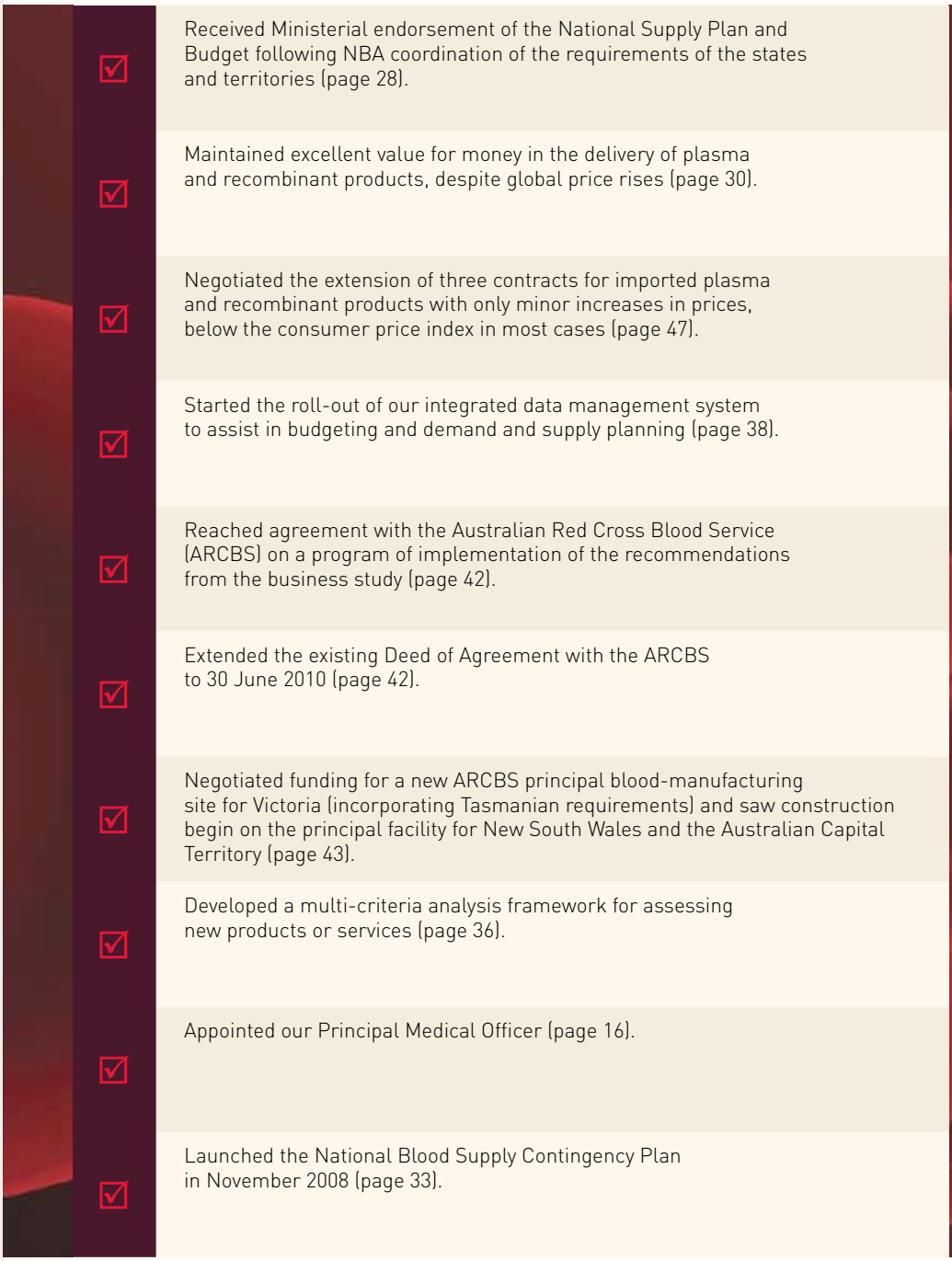
Our role is to coordinate national blood supply and demand planning, to purchase blood and blood products to meet clinical needs on behalf of all Australian governments, and to develop and implement national strategies to encourage better use of blood and blood-related products.

OUR EXPENDITURE

The NBA employed around 50 staff in Canberra. Our Principal Medical Officer works from Melbourne. The NBA's combined administered and departmental budget for the year was $806.8 million.



MAJOR ACHIEVEMENTS 2008-09



- ☑ Received Ministerial endorsement of the National Supply Plan and Budget following NBA coordination of the requirements of the states and territories (page 28).
- ☑ Maintained excellent value for money in the delivery of plasma and recombinant products, despite global price rises (page 30).
- ☑ Negotiated the extension of three contracts for imported plasma and recombinant products with only minor increases in prices, below the consumer price index in most cases (page 47).
- ☑ Started the roll-out of our integrated data management system to assist in budgeting and demand and supply planning (page 38).
- ☑ Reached agreement with the Australian Red Cross Blood Service (ARCBS) on a program of implementation of the recommendations from the business study (page 42).
- ☑ Extended the existing Deed of Agreement with the ARCBS to 30 June 2010 (page 42).
- ☑ Negotiated funding for a new ARCBS principal blood-manufacturing site for Victoria (incorporating Tasmanian requirements) and saw construction begin on the principal facility for New South Wales and the Australian Capital Territory (page 43).
- ☑ Developed a multi-criteria analysis framework for assessing new products or services (page 36).
- ☑ Appointed our Principal Medical Officer (page 16).
- ☑ Launched the National Blood Supply Contingency Plan in November 2008 (page 33).

- ☑ Worked with governments and suppliers to avoid supply problems during the Victorian bushfires, the Ashmore Reef incident and the pandemic (H1N1) 2009 outbreak (page 35).
- ☑ Completed the first phase of the review of distribution arrangements for blood (page 37).
- ☑ Organised the highly successful National Blood Sector Conference in November 2008 (page 56).
- ☑ Launched the redeveloped Australian Bleeding Disorders Registry in December 2008 (page 38).
- ☑ Launched the *Blood Measures Guide* on the NBA website in June 2009 (page 62).
- ☑ Arranged and chaired the inaugural meeting of national plasma products supply planners with New Zealand, Canada, Italy and Finland (page 79).
- ☑ Established the ongoing the Australian National Haemovigilance Program with Jurisdictional Blood Committee endorsement (page 53).
- ☑ Established a program to update the 2001 NHMRC/ASBT *Clinical Practice Guidelines on the use of blood components* (page 58).
- ☑ Established a national framework for continuing the development of the South Australian e-learning project (page 60).
- ☑ Significantly reduced staff turnover down to 16 per cent during the year (page 94).
- ☑ Received a silver medal for the *Annual Report 2007–08* in the Australasian Reporting Awards.

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 2009, 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 Output Groups of the *Health and Ageing Portfolio Budget Statements 2008–09*.

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 am satisfied that the National Blood Authority has prepared fraud risk assessments and fraud 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
National Blood Authority

10 October 2009

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TABLES

GRAPHS AND FIGURES

USER GUIDE

About this report

This annual report outlines the National Blood Authority's performance and achievements in the financial year ending 30 June 2009. It also incorporates 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 the Prime Minister and Cabinet's requirements for annual reports and was written to inform stakeholders, including government and the community, of the ways in which the roles and responsibilities of the NBA have been implemented.

The report is divided into seven parts:

Part One: Overview

Part One provides a summary explanation of the NBA's key activities and outlines our major achievements as well as issues and challenges faced during 2008–09. 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 new Principal Medical Officer, and an overview of the Australian blood sector.

Part Two: Our performance

Part Two reports on performance against the NBA's Operational Plan 2008–09. It provides an analysis of the NBA's performance against the Agency Outcomes and Output Groups within the *Health and Ageing Portfolio Budget Statements 2008–09* and describes the NBA's achievements during the year.

Part Three: Future trends

Part Three describes external influences that could affect the way that the NBA does business in the future. It describes 2008–09 changes to our external environment, identifies factors that may affect global supply, demand and pricing, and notes a range of international trends in regulatory and blood-related clinical practice.

Part Four: Our management arrangements

Part Four 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. Information is also provided on our budget and financial management arrangements.

Part Five: Our accountability

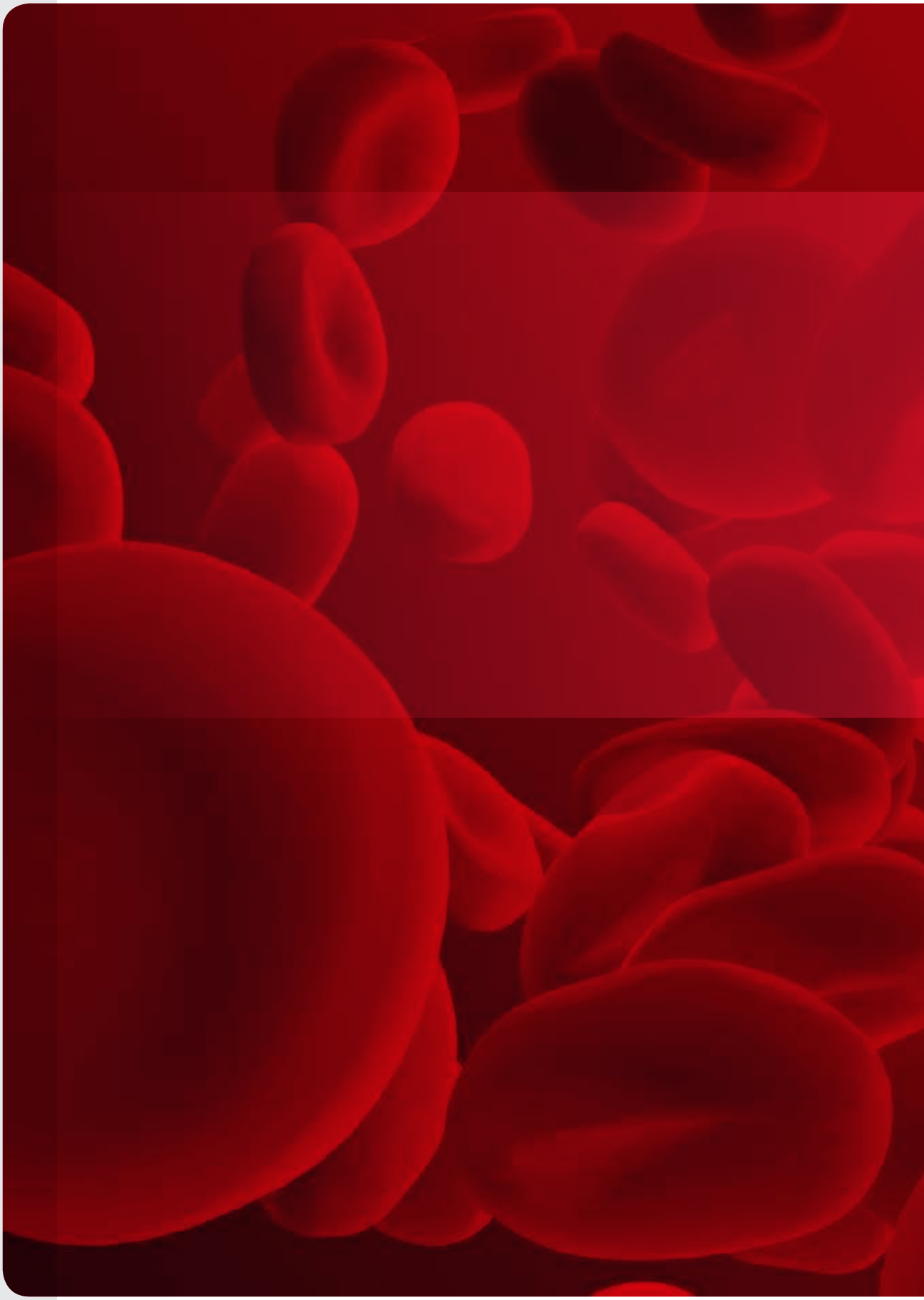
Part Five specifies how the NBA complies with a range of external policies. Among the subjects covered are disability, occupational health and safety, productivity gains, ecologically sustainable development, and freedom of information.

Part Six: Financial statements

Part Six presents the NBA's financial statements for the year ending 30 June 2009.

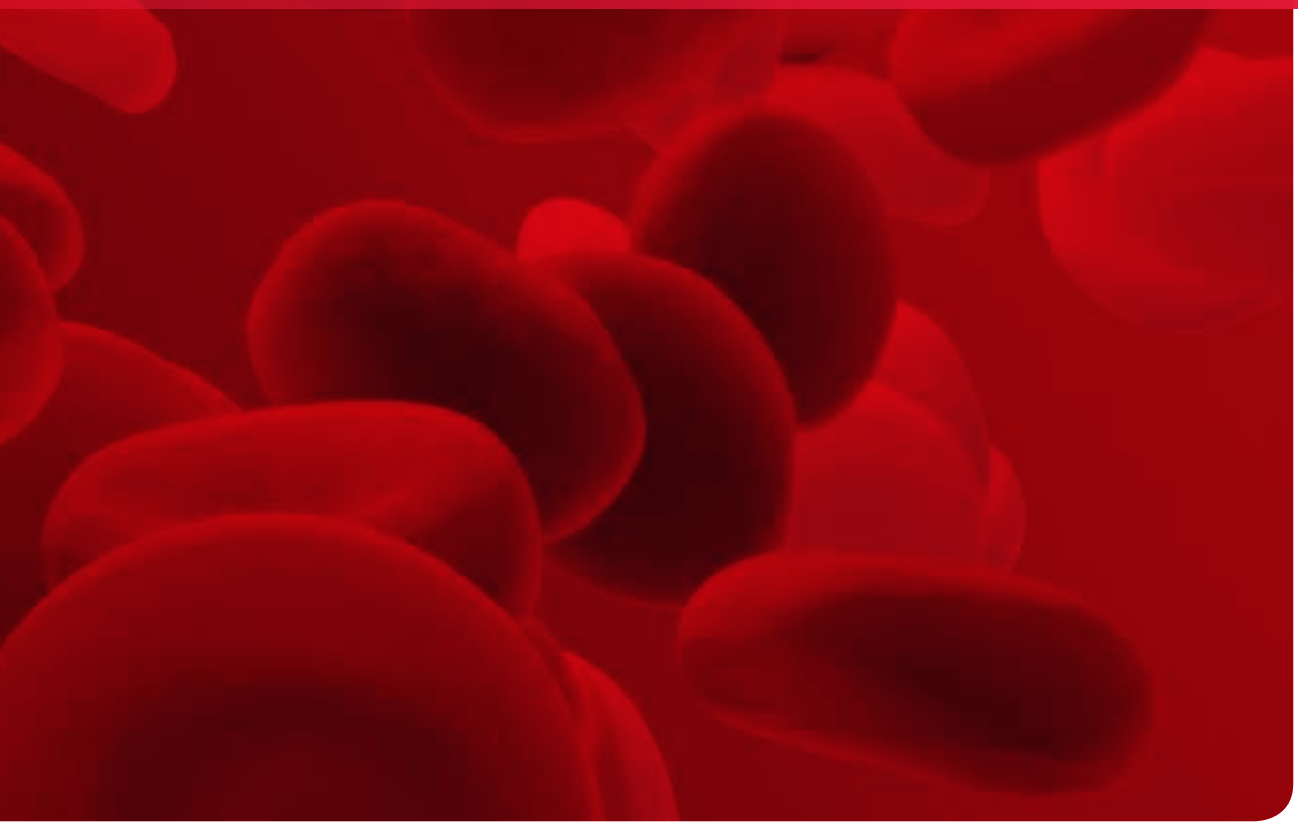
Appendices

The appendices contain the objectives of governments detailed in the National Blood Agreement, 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, a list of acronyms and an index.



PART ONE. OVERVIEW

PART ONE PROVIDES A SUMMARY EXPLANATION OF THE NBA'S KEY ACTIVITIES AND OUTLINES OUR MAJOR ACHIEVEMENTS AS WELL AS ISSUES AND CHALLENGES FACED DURING 2008–09. 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 NEW PRINCIPAL MEDICAL OFFICER, AND AN OVERVIEW OF THE AUSTRALIAN BLOOD SECTOR.



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

Our key focus this year was to continue to undertake our core business at an excellent standard, so that the community is able to access safe and effective blood and blood products.

We also took the opportunity to build organisational and sector capability that will allow the NBA to better meet the needs of stakeholders into the future—particularly in relation to the provision of information to improve planning, policy making, and the delivery of blood and blood products.

This capability building centred on the development of data, information and intelligence systems, blood sector contingency planning, and standards and guidance for the clinical sector. The NBA is fortunate to have the assistance of a range of people from the health sector who share our vision for saving and improving lives through a world-class blood supply.

Highlights of 2008–09

Management and implementation of planning, funding and risk-management activities

As for every year, the NBA's principal goal in 2008–09 was to make sure that blood and blood products are available when and where they are needed. The report describes the multitude of planning and risk-management activities that contribute to this goal and will do so in the future. A particular focus of our planning and risk management is to continue to improve the value for money that can be achieved by sector and process reform. There are four major activities relevant to this area: the National Supply Plan and Budget; sector risk planning and coordination; enhanced data capture and analysis; and sector improvement projects.

The National Supply Plan and Budget (NSPB)

Development of the NSPB brings together the best understanding of current and future demand and supply trends. Endorsement by commonwealth, state and territory health ministers of the 2008–09 NSPB ensured the continued supply of a range of products required to meet clinical need. Expenditure on the blood supply was $789.9 million, which was 2.3 per cent less than the Commonwealth Budget estimate of $808.7 million. Most importantly, the NBA was able to ensure that products were available at all times to meet clinical need.

Sector risk planning and coordination

Major achievements during 2008–09 included the following:

- The then Parliamentary Secretary, Senator the Hon Jan McLucas, launched the National Blood Supply Contingency Plan in November 2008. This plan establishes a clear decision-making framework for managing the blood supply in cases of supply shortage or demand surges and integrates with broader health emergency management arrangements. The plan was successfully activated from 22 August to 23 October during a shortage of red cells. Actions taken under the plan resulted in clinical practice not being compromised during this period.
- Three other incidents—the Victorian bushfires, the Ashmore Reef incident and the pandemic (H1N1) 2009 outbreak— had the potential to result in inadequate supply. While none of these incidents required activation of the National Blood Supply Contingency Plan, the NBA worked with governments and suppliers to closely monitor the supply situation.
- Understanding future risks—as well as opportunities—is a core activity within the NBA. Our horizon scanning program continues to deliver, for us and our stakeholders, early warning of possible future pressures and opportunities. In 2008–09 the NBA upgraded its reporting in the area; a comprehensive overview is provided in Part 3 of this report.
- Established a meeting of international colleagues under the banner of the collaboration of National Plasma Products Supply Planners to exchange information and data on planning and risk-management activities.

Enhanced data capture and analysis

Improvement in the blood sector, in both supply chain management and clinical practice, is hampered by a lack of data and analysis. Along with jurisdictions and suppliers, the NBA is taking steps to redress this shortfall.

In 2008–09 the NBA, on behalf of all governments, launched the redeveloped Australian Bleeding Disorders Registry to provide to stakeholders information about patients with haemophilia and other bleeding disorders. The registry also allows for more reliable supply forecasting and planning. Our internal data warehouse capability also improved greatly with the roll-out of our Integrated Data Management System, which will assist in the further development of the National Supply Plan and Budget and the transition to multi-year budgeting and demand and supply planning.

The release of the first *Blood Measures Guide* is a world first in establishing a nationally accepted set of measures on the use and effectiveness of fresh blood components. It is hoped that over time greater consistency in measurement will enable meaningful comparison of research results and lead to a better understanding of the use of fresh blood components.

Sector improvement projects

Progress on a number of projects continues to identify opportunities to improve the sector, especially in relation to value for money. In 2008–09 this included the following:

- development of a multi-criteria analysis framework for assessing new products or services (Schedule 4 of the National Blood Agreement) that aligns blood sector assessment methodology with that used in the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme and quantifies consideration of each of the objectives of the National Blood Agreement

- completion of the first phase of the review of distribution arrangements for plasma and recombinant blood products
- organisation of the National Blood Sector Conference on 6 and 7 November 2008. The successful conference focused on the identification of barriers to wider adoption of best practice in blood management and alternative therapies.

Supply of blood and blood products

The NBA continues to place a high emphasis on being knowledgeable about the international blood sector, so that we can take a highly informed approach to development of the best-value contracts to deliver the blood products Australia needs. In 2008–09 our contract-management and negotiation activities made a key contribution to minimising increases in the overall cost and affordability of the blood supply for governments. Among the highlights were:

- Prices for plasma and recombinant products were effectively restrained. Our analyses demonstrate that during the past six years the collective effect of our activities is that there have been no increases in prices, despite global price rises.
- Three contracts for imported plasma and recombinant products were successfully negotiated, with savings.
- All ministerial recommendations of the Australian Red Cross Blood Service business study progressed according to the agreed timetable, 32 per cent being fully implemented. This includes agreement to move towards a three-year rolling planning cycle and establishment of an output-based funding model.
- New contractual arrangements are in place with the Australian Red Cross Blood Service from 1 July 2009.
- The NBA progressed approvals through governments for the ARCBS's new principal blood manufacturing sites in accordance with the time frames necessitated by the ARCBS's project plans. This included managing the independent assessment of the Victoria and Tasmania principal site for the Australian Health Ministers Conference.

Monitoring and implementing the appropriate and safe use of products

Improving product and patient safety is a crucial element of the National Blood Agreement, and good progress in this regard was achieved in a number of projects during 2008–09. Highlights included:

- Information on adverse effects from blood transfusions has been increased through the establishment of the ongoing Australian National Haemovigilance Program. Among other things, this involved finalising the definitions of the national minimum haemovigilance data sets and developing a methodology for assessing the capability of jurisdictions to provide the required data.
- The revised National Health and Medical Research Council's guidelines for fresh blood will provide the most contemporary evidence-based information on when and how to use fresh blood components. In 2008–09, under the guidance of an expert working group of 27 clinicians, we began an extensive review of international research into blood-related guidelines. Evidence reports and associated recommendations for critical bleeding and peri-operative guidelines are due early 2010.
- The availability and quality of education on blood administration have been improved through the establishment of a national framework for the continued development of the South Australian e-learning project.
- Information on where red cells are used has been improved as a result of the development of a draft minimum data set to guide further red cell use data-linkage activities.

ACKNOWLEDGEMENTS

Our achievements are the result of NBA's hardworking staff members and all of our stakeholders. I would like to offer my sincere thanks to everyone for their efforts, dedication and commitment to our work and trust that our coming year will, while challenging, be rewarding. A list of those members of the clinical community who have provided their expert advice during 2008–09, is below.

Associate Professor Zsolt Balogh	Ms Janine Learmont
Associate Professor Donald Bowden	Dr Robert Lindeman
Dr Simon Brown	Dr Andrew Martin
Dr Stewart Bryant	Dr Peter McCall
Dr Heather Buchan	Professor John McNeil
Dr Matt Chacko	Associate Professor Larry McNicol
Dr Matthew Cook	Dr Zoe McQuilten
Dr Philip Crispin	Ms Leonie Mudge
Dr James Daly	Professor John Olynyk
Mr Ken Davis	Dr Santa Pasricha
Associate Professor Mark Dean	Associate Professor Michael Permezel
Dr David DeLeacy	Associate Professor Chris Reid
Mr Scott Dunkley	Associate Professor Sean Riminton
Professor Henry Ekert	Dr John Rowell
Ms Julia Ekert	Dr Helen Savoia
Dr Bernd Froessler	Dr Richard Seigne
Dr Craig French	Dr Ferenc Szabo
Ms Madeleine Gallagher-Swann	Ms Helen Starosta
Associate Professor John Gibson	Mr Matthew Stewart
Dr George Grigoriadis	Mr Daryl Teague
Associate Professor Russell Gruen	Dr Amanda Thomson
Dr Anne Haughton	Dr Philip Truskett
Ms Sharon Hawkins	Ms Kathryn van Diemen
Associate Professor Bob Heddle	Dr John Vinen
Dr Bevan Hokin	Ms Megan Walsh
Dr Anthony Holley	Dr Michael Wren
Professor James Isbister	Associate Professor John Zeigler
Associate Professor Andrew Kornberg	

Financial results

The NBA continues to perform within our budgetary allocation, and our end-of-year result was a surplus of $0.105 million. We have agreement from governments to carry forward prior years' operating surpluses, which will allow us to maintain close to current activity levels and staffing for the coming two years.

Corporate matters

During 2008–09 progress on implementing our capabilities strategy was excellent, and good results were achieved in core areas. In particular, our staff turnover was reduced to 16 per cent for the year and 81 per cent of our staff reached their training point targets. Staff participation in community events was admirable given our workload.

The second NBA skills and knowledge survey was designed and conducted in December 2008, and our second staff satisfaction survey was conducted in April 2009. The results of these surveys helped inform a comprehensive restructure that was implemented with effect from 6 July 2009. The restructure is designed to improve our ability to meet the expectations of stakeholders into the future.

On other fronts, we were pleased to receive a silver medal for our 2007–08 annual report from the Australasian Reporting Awards Committee.

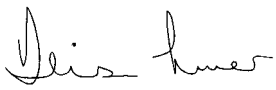
Finally, I was delighted to appoint Dr Chris Hogan as our first Principal Medical Officer. He adds immense strength to our clinical knowledge base and understanding of the clinical environment.

Outlook for 2009–10

The year to come promises to be another busy time, but our new structure will give us the capability to deliver improved information to support government policy deliberations—especially in the areas of data capture and analysis, demand forecasting, and research into blood sector trends. These activities will provide the basis for our continuing efforts to better integrate the blood sector with wider health sector priorities for patients and reforms in data evaluation and performance measurement.

Other priorities for 2009–10 are finalisation of the ARCBS output-based funding model and contractual arrangements with the Service after 30 June 2010. We also expect to release the first set of new guidelines on patient blood management.

The NBA needs to finalise a financial strategy for its future operations, noting that the revenue forward estimates reduce to $9.1 million in 2012–13. The nature of this strategy is likely to be influenced by the outcomes of the review of the implementation of the National Blood Arrangements, as required under the National Blood Agreement. This review, to be coordinated for governments by the Department of Health and Ageing, will produce its first report in November 2009.



Dr Alison Turner
General Manager and CEO
National Blood Authority

1.2 NATIONAL BLOOD AUTHORITY 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, Federal, private and not-for-profit sectors. At present, in addition to being Chair of the NBA 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).

This is my second report as Board Chair, and I am pleased to note that the NBA has made excellent progress on all activities that were the focus of the Board's attention this year.

The NBA Board was established under the Act 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 and appointed by the Australian Government Minister for Health and Ageing to serve a period not exceeding four years. The Board is required under section 44(2) of the *National Blood Authority Act 2003* to report on its activities on an annual basis.

2008–09 priorities

The Board held four face-to-face meetings and two teleconferences during 2008–09. The Board has continued to work with the General Manager to encourage continuing performance improvement and productivity achievements. I note that the executive of the NBA takes this responsibility very seriously and has put much effort into developing the NBA's capacity to respond to the changing expectations of its stakeholders into the future. I look forward to working with the executive to monitor and evaluate the effectiveness of these changes through the regular reporting provided to the Board on core operational performance.

As foreshadowed in my report last year, the Board identified five areas where the General Manager could be expected to seek the Board's advice.

Development of a methodology for assessment of proposals for products to be added to the Supply Plan

Maintaining a consistent approach to the assessment of new products and technologies for consideration in the National Products and Services List has proved a challenging task for JBC and the NBA in the past couple of years. Good progress was, however, achieved in 2008–09. The Board is mindful of the responsibility placed on the NBA by the National Blood Agreement to arrange for the evidence-based evaluation of new products before they are recommended for inclusion on the National Products and Services List. The Board has provided advice on the new model, which was developed during the reporting year. This has evolved into a multi-criteria analysis framework that, in the view of the Board, pays appropriate attention to the multi-faceted expectations and objectives of the Agreement—including safety, clinical benefit and cost-effectiveness. Importantly, the new framework also recognises that blood must be considered as part of the broader health sector. It incorporates elements of the existing technical and economic imperatives of the Pharmaceutical Benefits Scheme and Medical Benefits Scheme frameworks. The final version has now benefited from public consultation and will be presented to governments for endorsement in 2009–10.

Australian Red Cross Blood Service relationship building

In July 2008 health ministers accepted the recommendations of the business study that looked at the efficiency and effectiveness of the ARCBS. The Minister for Health and Ageing provided to the ARCBS a detailed statement of government expectations in October 2008. These two developments provided a strong background against which the NBA Board has been able to forge a relationship with the ARCBS Board. This relationship will improve the ARCBS's understanding of its accountability to government, as well as improve government's understanding of the pressures on the ARCBS. I am delighted to report that our Board met with the ARCBS Board in Adelaide in October 2008 and the General Manager and I met with the ARCBS Board in March 2009. Matters raised at these meetings will be further addressed when the ARCBS Chief Executive and a Board representative attend the July meeting of the NBA Board in Canberra. This ongoing series of meetings will form the basis of a new governance exchange between the two Boards that will promote more rapid responses to government expectations of accountability and transparency. The engagement will also support the development of agreed clear, longer term strategic priorities to be planned and progressed efficiently.

Central to this accountability and overall improved governance will be agreement by the ARCBS and the NBA to an output-based funding model. The NBA Board will continue to oversee the progress of this project and help to secure the engagement of the ARCBS Board to deliver on this expectation of governments.

The NBA Board also provided advice to the General Manager in relation to the next ARCBS Deed of Agreement. The Board was supportive of the decision to extend the current Deed, which has proved an effective vehicle for ARCBS–NBA engagement. Extension of the Deed will allow both parties to progress and finalise all the new elements that will be central to a new Deed, rather than attempting to negotiate a Deed that will need to be revised shortly after its commencement.

CSL Ltd Domestic Fractionation Agreement

Negotiations for the new plasma products agreement with CSL Ltd are on track, and the Board is confident they will provide a good outcome for the sector. The new agreement is expected to be in place by 1 January 2010. The Board has contributed advice and strategic guidance to the NBA General Manager in ensuring that the financial implications for governments are fully explored, and the Board has used its broad sector knowledge to provide insight into the negotiation phase.

Development of a patient blood management strategy

The National Blood Agreement recognises that blood is a scarce resource and should be used wisely. Significant opportunities exist to achieve better use of blood and improve patient outcomes at the same time. To this end the Board has monitored the development of a national patient blood management strategy that is designed to take account of the influence particular policies have on blood use. A key element of the strategy is to facilitate participation by other authorities and organisations in order to address broader health concerns that affect the appropriate use of fresh blood components.

Review of the operation of the arrangements for the National Blood Agreement

The review of the operation of the arrangements for the National Blood Agreement, which is required under the Agreement, is to evaluate the implementation of the Agreement and is scheduled for completion by June 2010. The Board has considered the NBA's own assessment, which has identified where good progress has been made and where further opportunities lie. The delay in progressing the review has limited the NBA's ability to finalise a suitable three-year corporate plan and has created a degree of uncertainty in determining the priorities and overall funding and purpose of the NBA in the future. As a consequence, the Board recommended that the current corporate plan be extended until the review is complete. The Australian Health Ministers Advisory Council accepted this. The current corporate plan is available at www://nba.gov.au/pubs/pdf/corp-06-09.pdf

Stakeholder engagement

During 2008–09 the Board continued with its program of stakeholder engagement. In August 2008 it invited Canberra-based senior health officials to a discussion of major issues in the blood sector. This provided an opportunity to discuss broad sector matters, particularly in relation to blood, and to obtain sector input into the role the NBA might have in driving, or supporting, a sustainable future, potential challenges it might face, and areas for reform.

The Board also met with the then Parliamentary Secretary, Senator the Hon Jan McLucas, in February 2008. This meeting afforded an excellent opportunity to discuss some major factors that might well affect future government policy in relation to blood.

Other core areas of activity

Through its meetings and individual member contributions, the Board also provided input to a number of other core NBA activities, including:

Distribution arrangements for plasma and recombinant products

The review of distribution arrangements for plasma and recombinant products, foreshadowed in my last report, has been progressing well and is expected to be completed on time. The Board has noted the findings of Phase 1 and was supportive of the exploration of options to identify possible efficiencies in a Phase 2 study.

Sector data

The Board has strongly supported the work of the NBA in developing reliable data sources to inform its own activities and those of the sector more broadly. The success in bringing online two projects that should redress some of this information shortfall should not be dismissed lightly.

The Australian Bleeding Disorders Registry, which came on-line in December 2008, will provide an improved understanding of the nature of product demand and use as well as greater fidelity in supply forecasting and planning. There is no comparable register internationally, and the Board has strongly supported this development. Ultimately, the Registry should position Australia to be a leader in research into, and understanding of, trends in clotting factor use.

Another major project, the Integrated Data Management System, has been implemented in order to facilitate the supply and management of blood and blood-related products across core operational areas of the NBA. This includes budgeting and forecasting of supply and demand for blood and blood products, inventory and supply chain management, contract administration, and management of *Financial Management and Accountability Act 1997* reporting obligations. The implementation is in its infancy, but early indications are that the system will provide crucial data that will deliver real and increasing benefits for the sector in the future.

Improved IT integration and data capability across the blood sector offers real potential to contribute towards sector reform. Developments undertaken by the Queensland Government for its Ordering and Receipting Blood System (ORBS) offer some of these opportunities. The potential for developing the National Intravenous Immunoglobulin (IVIg) Management System within the ORBS and/or the Australian Bleeding Disorders Registry framework, and further sector IT integration, was the subject of more detailed advice to the NBA by Board member Dr Peter Lewis-Hughes. The Board is now keen to explore options for a more integrated, IT-supported, innovative and broad approach to the overall management framework of blood products in Australia, including intravenous immunoglobulin.

NBA performance

A major focus for the Board is discharging our obligation to provide to the General Manager advice about the performance of the NBA. To assist in this, the Board receives regular and detailed reporting and operational feedback. I am pleased to report that the NBA has been able to continue to perform at a high level, delivering some 95 per cent of all planned activities within the operational plan, an increase of 14 per cent on the 2007–08 plan. The feedback reports demonstrate the extent of the activities undertaken by the NBA, progress with these activities, and the professionalism of staff in their dealings with stakeholders.

2009–10 priorities

Looking to the new financial year, the Board is mindful of the challenges the NBA will face in the future. It is important that the capability and expertise that the NBA has built since 2003 is maintained. The Board believes that the NBA's increased focus on data and understanding of demand drivers presents many opportunities for the organisation to continue to increase the value it provides to governments.

For 2009–10 the Board will specifically focus on:

- the development of the output-based funding model with the ARCBS and progress in the negotiation of the new Deed of Agreement
- value for money in the contracts and overall relationships with CSL and other commercial suppliers and the ARCBS
- innovation in the development and implementation of tools for the clinical community, to encourage greater appropriateness of use
- progress in the sector informatics strategy
- development of the NBA's new capabilities.

Mr Garry Richardson
Chair
National Blood Authority Board

1.3 MEMBERS OF THE NATIONAL BLOOD AUTHORITY BOARD

MR KEN BARKER

Financial Expert

Mr Ken Barker is currently Chief Financial Officer with New South Wales Health and is 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 has worked for New South Wales Health for 24 years and has 41 years of experience in the New South Wales Government. In relation to Australia's blood service, he 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 ARCBS.

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 and four years as National President, Vice President of Haemophilia Foundation South Australia and Board member since 1994, a member of the Coagulation User and Advisory Group with the Australian Red Cross South Australia and member since 1995, and Vice-President Finance of the World Federation of Hemophilia, Montreal, Canada, since 2004.

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 twelve 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.

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

ASSOCIATE PROFESSOR DAVID COOPER

Public Health Expert

Associate Professor David Cooper was recently appointed 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.

Operationally, Associate Professor Cooper's experience includes the health response to both of the Bali bombings, the tsunami disaster and the Yogyakarta earthquake, where he led the first AusAID disaster medical team. He also has substantial experience in planning for mass gatherings such as the Sydney 2000 Olympics, the Rugby World Cup in 2007, and World Youth Day in 2008.

His interest in the blood sector relates 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 on the NBA Board in May 2007.

DR PETER LEWIS-HUGHES

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.

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
(from March 2009)

Ms Mary Murnane is currently Deputy Secretary in the Australian 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, and 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 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.

MR DAVID KALISCH

Australian Government Representative
(until March 09)

Mr David Kalisch was appointed Deputy Secretary of the Department of Health and Ageing in June 2006, with responsibility for the Portfolio Strategies Division, the Acute Care Division, the Mental Health and Workforce Division, and the South Australian and Western Australian state offices of the department.

Mr Kalisch is an economist who has worked in a range of social policy areas of government since the early 1980s. This has included policy advising and program management in such diverse areas such as labour markets and employment policy, retirement incomes, family assistance, children's services, welfare reform and, more recently, health services.

In addition to these appointments, Mr Kalisch was principal adviser to a former Minister for Social Security and has worked at the OECD in Paris, in its Employment Programs Division (1990) and Social Policy Division (1997–98), and at the Australian Delegation to the OECD (1998–99). Apart from his social policy and program management experience, he has an interest in enhancing organisational capability.

Mr Kalisch served as Australian Government Representative on the NBA Board from November 2006 until March 2009.

1.4 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 is both an exciting and a challenging time to be working in the blood sector. The clinical and resource environment is complex and rapidly changing. Demand for specialised blood products such as intravenous immunoglobulin is increasing. The need for strong relationships between production, supply and the patient interface is even greater nowadays because of the increased sophistication of disease treatment programs, important niche areas of expert sub-specialist practice, and the climate of finite resources.

Together with these clinical demands, the need for systematic and critical practice review through usage audits and registry data is now a standard. Data gathering and management and data warehousing are themes running through the NBA's approach to meeting these challenges as we go forward. Properly balancing the management of clinical safety, efficacy and sufficiency of the supply of blood and blood products requires major data and data management resources.

During 2008–09 the NBA progressed a major project to revise the National Health and Medical Research Council's *Clinical Practice Guidelines on the use of blood components*. Peri-operative, critical bleeding, paediatric and neonatal, medical and obstetric guidelines will be produced as part of a suite of clinical, scenario-based product use and practice standards and recommendations.

The NBA's development of the National Blood Supply Contingency Plan, now endorsed by health ministers, was a significant step forward. There is now related activity on the part of the states and territories, hospitals and pathology providers to flesh out the more local details of the plan and response. This work has been relevant in the context of the emergence of the pandemic (H1N1) 2009 and the potential threat this poses for our health system, our volunteer blood donor base, and the blood supply. The rise in the incidence of dengue fever in Queensland and internationally, the outbreak of chikungunya virus infection in northern Italy, and increasing concerns about West Nile virus and variant Creutzfeldt–Jacob disease all serve to heighten the need to maintain vigilance about new and emerging threats to our blood supply and to develop strategic and robust plans to manage such circumstances, together with our colleagues in the Australian Red Cross Blood Service and other parts of the health sector.

The NBA has now set up an enduring national haemovigilance structure, the Haemovigilance Advisory Committee. This structure will enable the development of a national haemovigilance data set and contribute to blood and transfusion safety reviews and initiatives. In part the committee builds on foundation work achieved through jurisdictional initiatives such as Blood Matters, Blood Safe and Blood Watch. Australia will soon be in a position to share its national haemovigilance data with the newly founded International Haemovigilance Network.

The new *Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia* were released in March 2008 and the NBA is in the process of reviewing patterns of IVIg issue and use against the criteria. This will in turn support clinical practice review and supply and demand planning. It is interesting to note that international data on IVIg use patterns in Human Development Index countries similar to Australia show significant variation in per capita IVIg annual use and I look forward to researching this further.

I particularly thank Dr Turner and all the NBA team for the support they gave me as I took up my new role and for their commitment and hard work this year in a demanding and increasingly complex blood sector. I sincerely thank my clinical colleagues in the health sector who have demonstrated their commitment to and interest in working with me and other NBA staff on a number of important initiatives during the reporting year.

Dr Chris Hogan
Principal Medical Officer
National Blood Authority

1.5 AGENCY OVERVIEW

The National Blood Authority, an Australian government agency within the Health and Ageing portfolio, is responsible for 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 which includes:

- working with jurisdictions to determine the clinical requirements for blood and blood products to meet national needs—including the development of an annual supply plan and budget
- negotiating and managing national contracts with suppliers of blood and blood products to obtain the products needed
- blood supply risk assessment and contingency planning – both for risks arising in the sector and for those that impact on the sector (e.g. pandemic (H1N1) 2009)
- supporting the work of the jurisdictions to improve how blood products are used. This includes facilitating and developing strategies and programs that will improve the safety, quality and effectiveness of blood usage, particularly around national standards, guidelines and data provision
- providing expert advice to support government policy development, including the identification of emerging risks, developments, trends and new opportunities
- managing the evaluation of proposals for blood sector improvements – including for new products, technologies and system change
- providing secretariat services to the Jurisdictional Blood Committee.

The cake celebrating the NBA's 5th anniversary

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 business. This results in the NBA being a highly informed purchaser and policy advisor. In addition, the NBA has built up an extensive network of clinical and blood sector experts and information flows; this allows the agency to maintain awareness of the clinical and business environment and how it will or might 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 explicit in the National Blood Agreement are summarised in the extract set out in Appendix 1.

To understand how these functions are implemented, Section 1.6 contains a brief description of the blood sector and the overall governance framework for management and determination of priorities for action in the sector.

1.6 THE BLOOD SUPPLY CHAIN

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 2008–09 governments provided $806.8 million for the purpose of procuring and managing Australia's blood supply (see Table 1.1).

Since the establishment of the NBA, governments have spent $3740.4 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 2008–09

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
Total	**3740.4**	**11.9 (average)**

TABLE 1.2 Government funding for the operation of the NBA, 2003–04 to 2008–09

YEAR	AMOUNT ($M)	CHANGE (%)
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

The NBA manages the national planning and purchasing of blood and blood-related products in close cooperation with a number of stakeholders. The following pages outline the roles and responsibilities of the key stakeholders in the Australian blood sector.

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

Suppliers of blood and blood-related products

The NBA contracts with a number of suppliers of blood and blood-related components and products, including:

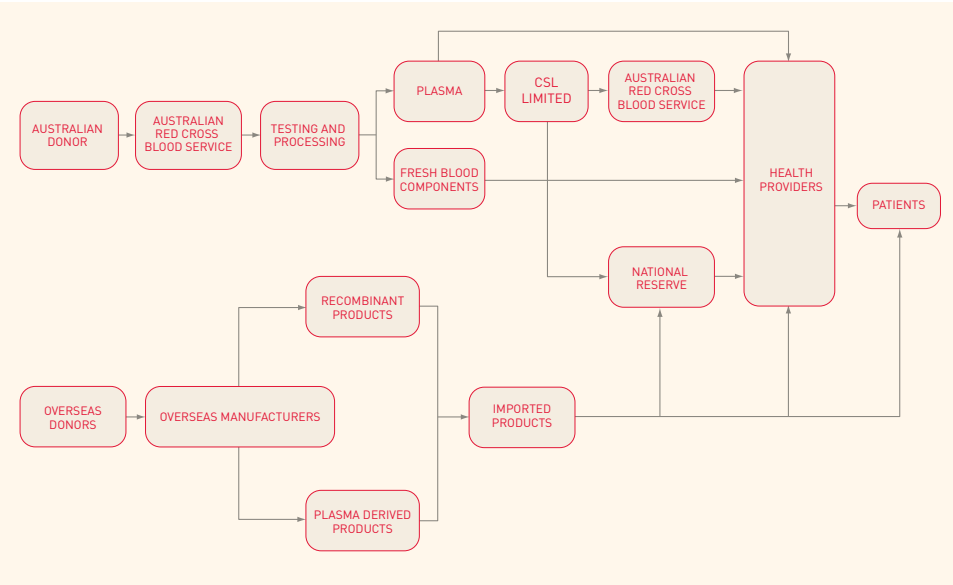
- the Australian Red Cross Blood Service, for the collection of red cells, platelets and plasma from donors; production, testing and distribution of fresh and some manufactured products; and the provision of donated plasma to CSL Ltd
- CSL Ltd, for fractionating plasma supplied by the ARCBS and supplying a range of plasma products
- other bio-pharmaceutical companies that are responsible for the supply and some distribution of a range of imported blood products (in cases where the product is not produced in Australia or domestic production capacity cannot meet demand).

Contracts with suppliers for the provision of blood and blood-related products under standing offer arrangements include:

- CSL Ltd, DiaMed Australia Pty Ltd, Ortho-Clinical Diagnostics Inc (USA) and Australian Laboratory Services Pty Ltd, for the supply of diagnostic reagents
- CSL Ltd and Octapharma Australia Pty Ltd for the provision of overseas-sourced intravenous immunoglobulin
- Baxter Healthcare Pty Ltd, Wyeth Australia Pty Ltd and Novo Nordisk Pharmaceuticals Pty Ltd, for the provision of a range of defined blood products.

Figure 1.1 shows the location of these stakeholders in the blood supply chain.

FIGURE 1.1 *The Australian blood supply chain*



External governance arrangements

The key governing bodies in the Australian blood sector, their roles and relationships with each other are set out in the National Blood Agreement and the *National Blood Authority Act 2003*. Figure 1.2 shows the governance structure of the sector.

Australian Health Ministers Conference

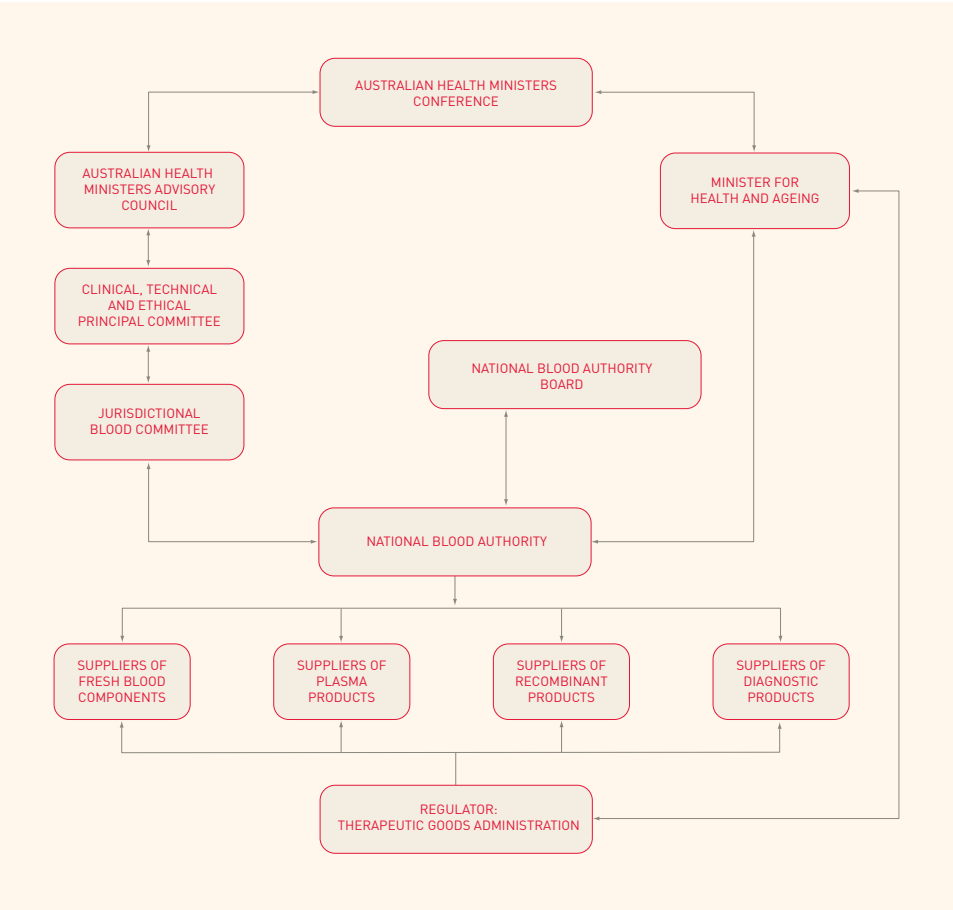
The Australian Health Ministers Conference is responsible for overseeing and managing the blood sector in conjunction with the Australian Government. It sets the governance, policy and financial frameworks under which the NBA operates. In 2008–09 key decisions made by ministers included:

- approval of the 2009–10 National Supply Plan and Budget
- funding for the ARCBS's Victorian and Tasmanian principal site
- the response to and implementation strategy for the recommendations of the report on the ARCBS business study.

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 with which the NBA must comply in performing its functions, for 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.

FIGURE 1.2 *Governance structure of the Australian blood sector*



Senator the Hon Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing, was responsible for oversight of the NBA until she retired from ministerial responsibilities. The Hon Mark Butler MP was appointed as Parliamentary Secretary on 9 June 2009.

Australian Health Ministers Advisory Council

The Australian Health Ministers Advisory Council provides support to the Australian Health Ministers Conference. It advises 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 consider and 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; 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; and the impact of such developments outside the health care sector.

Jurisdictional Blood Committee

All Australian 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.

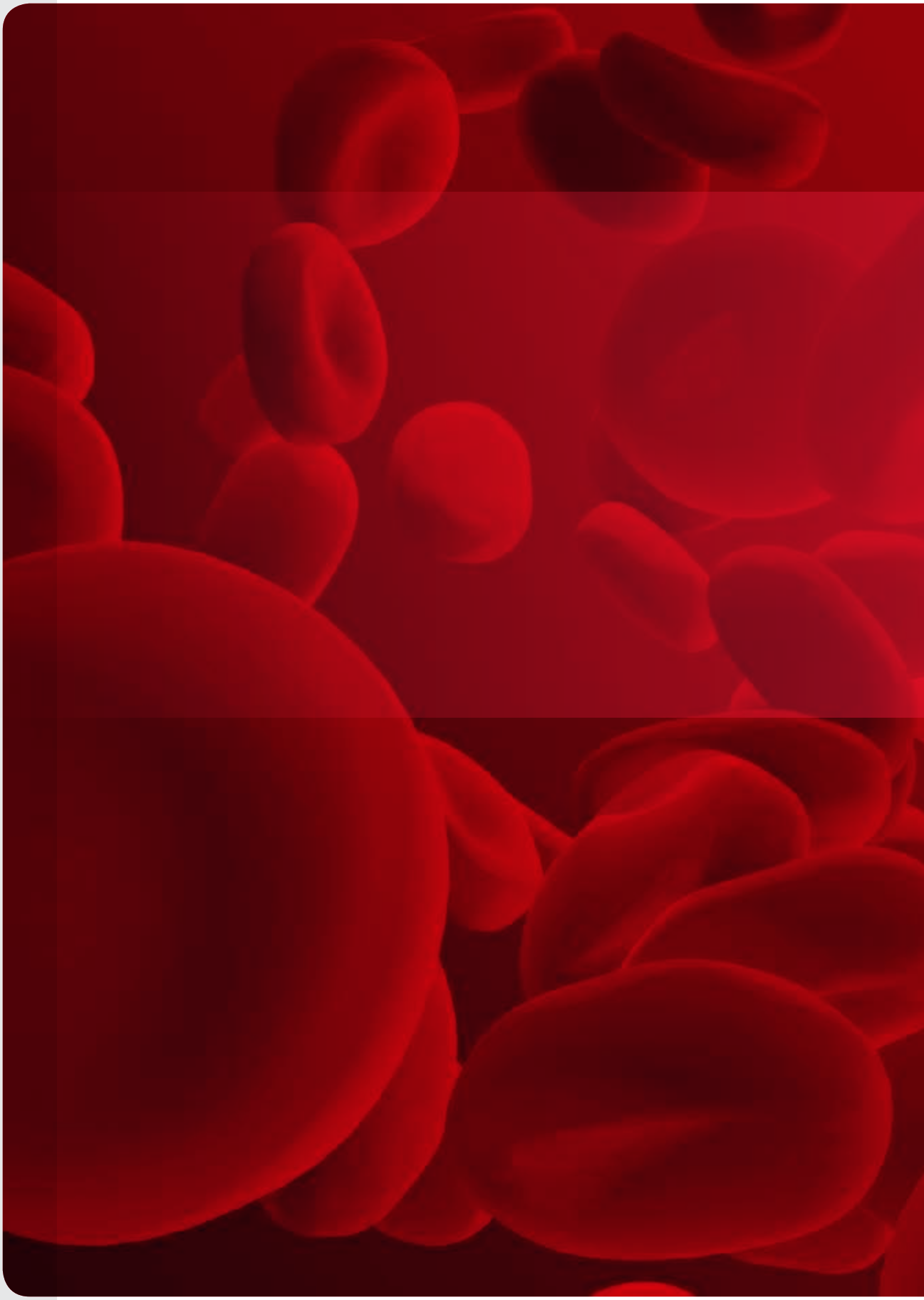
JBC member Joan Bedford in discussion with CTEPC Member Simon Towler (centre) and JBC Proxy member Ashley Eccles at the NBA Blood Sector Conference.

National Blood Authority Board

The NBA Board is responsible for providing to the General Manager advice about the performance of the NBA. It also liaises with governments, suppliers and other stakeholders on matters relating to the NBA's functions. The NBA Board is an advisory body: it has no capacity to engage personnel or to enter into dealings with other parties, nor does it have a governance role.

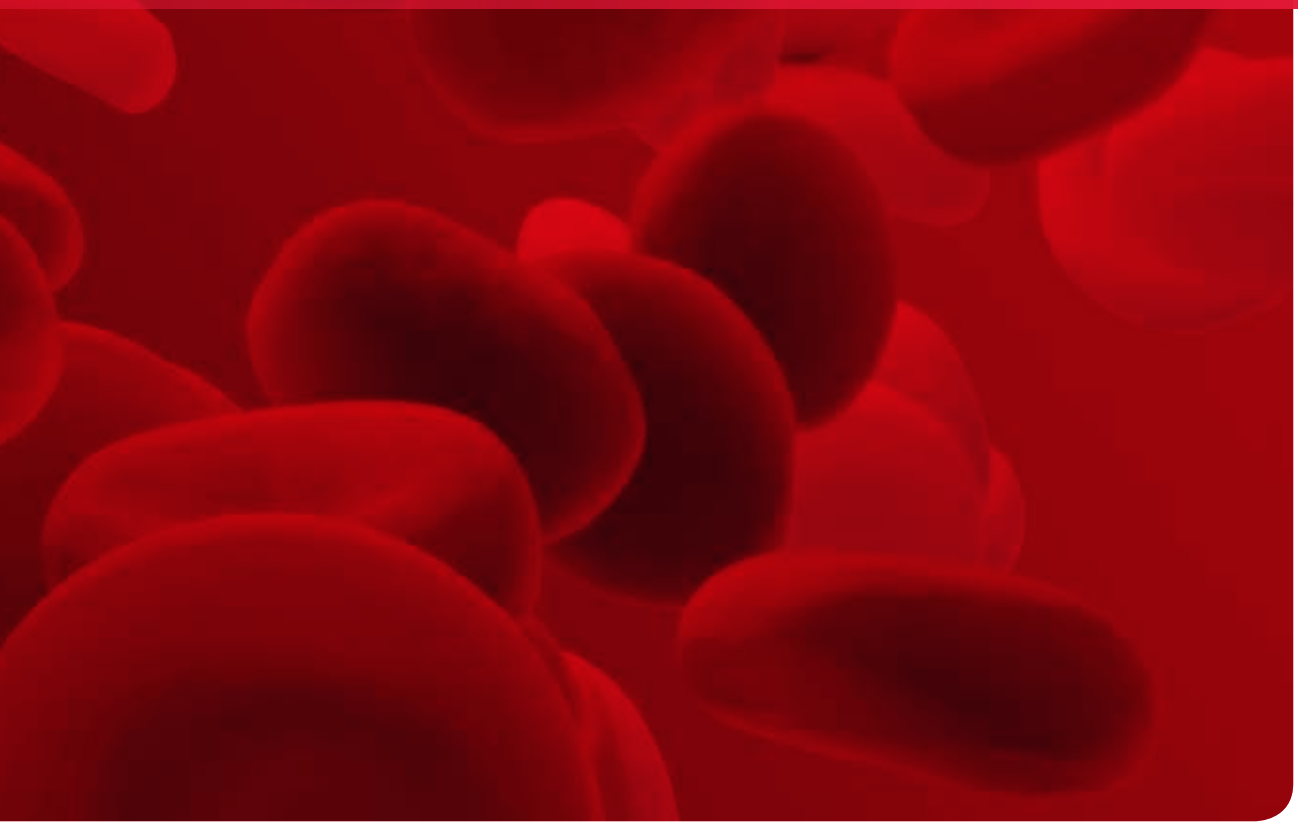
Outcome and output structure

The NBA's performance obligations are determined by the Agency Outcome and Output Group, as reported in the *Health and Ageing Portfolio Budget Statements 2008–09*. Part 2 provides details on the performance against these key performance indicators and other specific activities in 2008–09.



PART TWO.
OUR PERFORMANCE

PART TWO REPORTS ON PERFORMANCE AGAINST THE NBA'S OPERATIONAL PLAN 2008–09. IT PROVIDES AN ANALYSIS OF THE NBA'S PERFORMANCE AGAINST THE AGENCY OUTCOMES AND OUTPUT GROUPS WITHIN THE *HEALTH AND AGEING PORTFOLIO BUDGET STATEMENTS 2008–09* AND DESCRIBES THE NBA'S ACHIEVEMENTS DURING THE YEAR.



2.1 PERFORMANCE BY OUTCOME

The National Blood Authority operates as a single Agency Outcome and single Output Group, as specified in the *Health and Ageing Portfolio Budget Statements 2008-09.*

Summary of agency outcome and output

OUTCOME	OUTPUT GROUP
Australia's blood supply is secure and well managed	Output Group 1—Meet Product Demand through Effective Planning and Management of Supply Arrangements

Performance information

The Budget specified four key performance indicators and targets for assessing the NBA's performance. Tables 2.1 and 2.2 show these indicators and targets and provide a summary assessment of performance against the targets.

TABLE 2.1 *NBA's performance indicators and targets for administered programs*

INDICATOR	REFERENCE POINT OR TARGET	ASSESSMENT SUMMARY
Informed decisions on the quality of use, and demand for, blood and blood services. Measured through the implementation of systems and processes which provide accurate and timely data.	Australian Bleeding Disorders Registry implemented by June 2009.	Met. Implemented December 2008.
	National IVIg management system fully planned by June 2009.	Met. Specifications finalised March 2009.
	Recommendations from the Distribution Review to the Jurisdictional Blood Committee by June 2009.	Met. Phase 1 recommendations to JBC in February 2009.
	Demonstrable progress on other projects.	Met. See assessment against sector data and sector improvement projects.

TABLE 2.2 NBA's performance indicators and targets for departmental programs

INDICATOR	REFERENCE POINT OR TARGET	ASSESSMENT SUMMARY
Efficient management and coordination of Australia's blood supply in accordance with the National Blood Agreement between the Australian, state and territory governments. Measured by the level of satisfaction of all funding jurisdictions with planning, management and coordination of blood supply.	A high level of satisfaction from all funding jurisdictions.	Met. 96.3% of recommendations proposed in JBC papers accepted.
	Product available meets jurisdictional identified clinical needs.	Met. Product was available to meet clinical needs at all times. Activation of the National Blood Supply Contingency Plan and Budget in August 2008 in response to red cell shortages. Remedial action resulted in clinical needs being met at all times.
The NBA uses contestability and expertise to drive improvements in product prices and product quality.	New product prices favourable in real terms with previous prices and as compared to available international benchmarks. .	Met. Prices obtained less than CPI. See assessment of performance against National Supply Plan and Budget activities and contract management activities.
	Stakeholders are satisfied that product quality is improving	Met. Latest generation of recombinant products provided under most recently negotiated NBA contracts.
Agreed risk management/ mitigation plans in place for the security of supply with the blood sector and the supply of most products is secure and exceptions managed effectively.	Total demand for blood and blood products is within a 5% variance of total demand predictions by the NBA.	Met. End-of-year financial result was within 0.4% of AHMC-approved supply plan. Within-year predictions varied based on demand trends but were under 5% variance from actual year-end result. See also discussion on risk management activities for the sector.

2.2 ASSESSMENT AGAINST KEY STRATEGIC DIRECTIONS

In 2008–09 the NBA's three key strategic directions were to manage and implement governments' blood sector policy, planning, funding and risk management, to ensure the supply of all required blood and blood products through effective supply contracts with capable suppliers, and to effectively engage with the clinical community in monitoring and improving the appropriate and safe use of blood and blood products to improve patient outcomes.

2.2.1 Management and implementation of planning, funding and risk management activities in the sector

Effective performance for this strategic objective, as identified in the Portfolio Budget Statements, involves the NBA in developing the National Supply Plan and Budget, ensuring awareness and appropriate management of risks to the supply of blood products, and identifying and implementing a range of activities to drive performance. Having an adequate and secure blood supply are core objectives of the National Blood Agreement, noting that supply shortages of plasma, recombinant and fresh products have been a feature of the global industry for many years. NBA activities during 2008–09 contributing to these objectives are detailed in the sections that follow.

The National Supply Plan and Budget

The NBA plays the key role in coordinating both the annual National Product and Services List, and the National Supply Plan and Budget for approval by health ministers. It:

- collects data on product use and reports to jurisdictions against the approved supply plan
- makes improvements to the national supply planning process
- monitors the balance between supply and demand throughout the year
- intensively manages products in short supply.

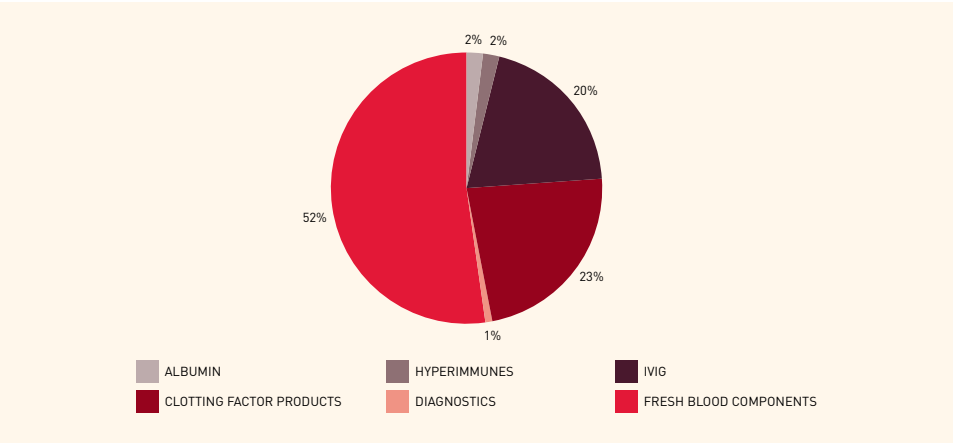
The National Supply Budget for 2008–09 for the supply of blood and blood products and related services was $804.4 million as approved by the Australian Health Ministers Conference. The actual demand for 2008–09 for all jurisdictions amounted to $806.8 million, representing. an $87.3 million increase on 2007–08. Figure 2.1 shows the allocation of this funding to each product category. Products the NBA purchased from suppliers to meet this demand are shown in Table 2.3.

TABLE 2.3 Blood and blood-related products purchased, by supplier, 2007–08 and 2008–09

SUPPLIER	PRODUCTS PURCHASED	2007–08 ($M)	2008–09 ($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 Overseas blood products Factors XI and XIII IVIg standing offer Management of National Reserve	159.90	162.09
Australian Red Cross Blood Service	Fresh blood components whole blood red cells platelets clinical fresh frozen plasma cryoprecipitate plasma for fractionation	385.03	432.62
Baxter Healthcare Pty Ltd	Overseas blood products Recombinant Factor VIII Protein C Factor VII concentrate Factor Eight Inhibitor Bypass Agent WinRho	80.09	84.09
Wyeth Australia Pty Ltd	Overseas blood products Recombinant Factor VIII Recombinant Factor IX	42.38	48.65
Novo Nordisk Pharmaceuticals Pty Ltd	Overseas blood products Recombinant Factor VIIa	17.43	17.40
Octapharma Australia Pty Ltd	Overseas blood products IVIg Standing Offer	34.26	46.90
DiaMed Australia Pty Ltd	Diagnostic reagent products blood grouping sera reagent red cell products	0.94	0.92
Ortho-Clinical Diagnostics	Diagnostic reagent products blood grouping sera reagent red cell products	0.37	0.47
Australian Laboratory Services Pty Ltd	Diagnostic reagent products blood grouping sera reagent red cell products	0.05	0.04
Total		**720.45**	**793.18**

Note: Totals do not include interest or the National Managed Fund.

FIGURE 2.1 *Funding by product category, 2008–09*



Blood expenditure continues to grow at a high rate. The growth in recent years is explained by three major factors:

- demand—driven by an ageing population and the increasing use of intravenous immunoglobulin
- safety measures—such as universal leucodepletion, bacterial testing and the introduction of recombinant products
- the cost of fresh blood products from the Australian Red Cross Blood Service.

These factors are best illustrated by analysing the three main elements of growth in blood expenditure in the past six years.

Plasma and recombinant products

Despite increasing expenditure on plasma and recombinant products, the effect of an overarching commitment to 'value for money' can be seen in Figure 2.2, which shows that there has not been any real increase in prices paid for these products since the inception of the NBA. The increased expenditure has arisen from:

- increased demand for intravenous immunoglobulin and some clotting factors—growing at an annual rate of around 12 per cent
- safety increases through replacement of plasma-based clotting factors by recombinant products.

The magnitude of the annual savings achieved by current commercial contracts, compared with indexed costs of arrangements before the establishment of the NBA, is also shown in Figure 2.2. In 2008–09 this equated to $39.8 million. The NBA continues to achieve excellent outcomes in price containment, through well-informed and commercially attuned procurement and negotiations.

Achieving further savings on imported plasma and recombinant product prices is unlikely as Australia now pays prices that are competitive in global terms. Any future opportunities to improve affordability are likely to arise from policy and program changes.

Fresh blood

The NBA has limited opportunity to influence the costs of fresh blood components. In the six years to 2008–09 funding for fresh blood and plasma collections has increased from $243 million to $417 million. Of this, $82 million is due to price increases, which have averaged 5.2 per cent a year. Increased demand for fresh products—principally red cells and platelets—has been running at 3.3 per cent a year, resulting in additional expenditure of $36 million. A further $56 million is a consequence of the introduction of government-approved 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 4.3 per cent a year. The combined effect of these measures can be seen in Figure 2.3.

Steps taken by the NBA, governments and the Australian Red Cross Blood Service in the past two years, such as the KPMG business study, will further support the achievement of business efficiencies within the ARCBS.

The NBA and the Jurisdictional Blood Committee are supporting initiatives to minimise demand increases by exploring the scope to reduce wastage and increase the use of products in accordance with best-practice standards. In 2008–09 the NBA continued a range of activities to gain commitment to these objectives from, and to engage, pathology services, hospitals and clinicians.

FIGURE 2.2 *Plasma-derived and imported product expenditure, 2003–04 to 2008–09*

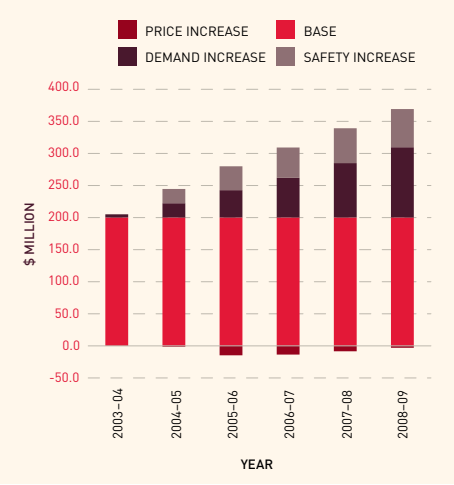
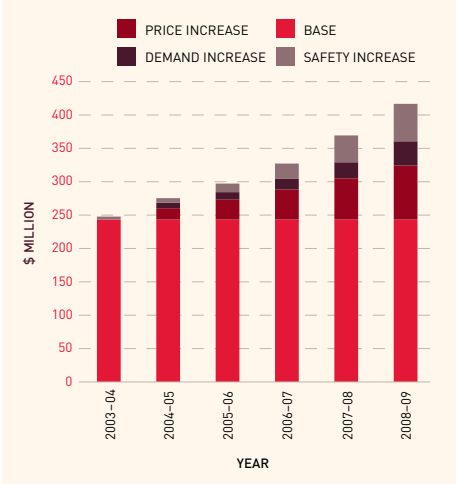


FIGURE 2.3 *Fresh blood expenditure, 2003–04 to 2008–09*



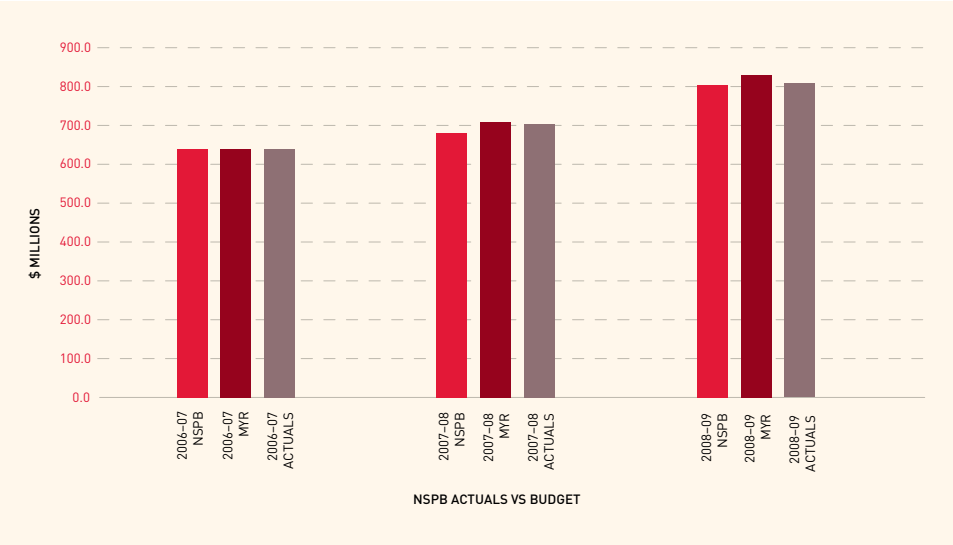
Note: Increases are cumulative, with 2003–04 as the base year.

Administered budget performance

The NBA administered budget, which is used principally to purchase blood and blood products, is developed annually as part of the National Supply Plan and Budget (NSPB) process agreed by the Australian Health Ministers Conference. In consultation with the jurisdictions, the NBA reviews the National Supply Plan and Budget as part of the mid-year review process, to adjust jurisdictional funding requirements as a result of the demand seen in the preceding six months.

The end-of-year result against the NSPB approved by the Australian Health Ministers Conference varied by only 0.4 per cent, despite higher than expected growth seen for most clotting factor products during the first six months. This resulted in a mid-year increase of $24.8m as shown in Figure 2.4 and Table 2.4. However, in the second six months the growth rates for these clotting factor products slowed considerably, so the anticipated increased need for funds did not eventuate. The NBA continues to be hampered in its ability to explain changes in demand by the lack of data. Full implementation of the Australian Bleeding Disorders Registry should improve our capabilities in this area in future years.

FIGURE 2.4 *Actual issues performance against the National Supply Plan and Budget and the mid-year review, 2006–07 to 2008–09.*



Note: 'NSPB' denotes National Supply Plan and Budget; 'MYR' denotes mid-year review.

TABLE 2.4 Actual issues compared with the National Supply Plan and Budget and the mid-year review, by major product category, 2007–08 and 2008–09

	2007-08 ACTUAL $ ISSUED	2008-09 NSPB $	2008-09 MID YEAR REVIEW $	2008-09 ACTUAL $ ISSUED
Albumin	13,485,878	15,202,965	14,862,753	14,809,333
Total IVIg	133,464,493	159,213,886	157,627,222	155,682,634
Total Factor VIII	98,011,446	106,340,959	112,901,071	104,155,865
Total Factor IX	22,170,203	22,638,609	27,636,278	26,064,039
Factor VIIa	17,432,671	17,770,894	20,613,661	17,403,879
FEIBA	11,952,350	10,222,500	17,472,500	13,476,300
	296,517,041	**331,389,813**	**351,113,485**	**331,592,049**

Risk management

The NBA has always given 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 2008–09, this required the NBA to:

- continue scrutiny of compliance with and the quality of supplier risk management strategies
- 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 the provision of products and services are identified and avoided or mitigated as far as possible.

The National Blood Supply Contingency Plan

The National Blood Supply Contingency Plan was officially launched by Senator the Hon Jan McLucas, then Parliamentary Secretary for Health and Ageing, at the National Blood Sector Conference held on 6 and 7 November 2008.

NBA staff preparing to mail out the Plan.

The Plan consists of two parts:

- the main document, which outlines the governance and decision-making framework for managing a supply shortage or increased product requirements due to a demand surge. This framework has been integrated with broader health emergency management arrangements. The Australian Health Protection Committee becomes involved when supply problems lead to broader impacts on the capacity of the health system to maintain normal practice or where an issue in the health sector requires the involvement of the blood sector

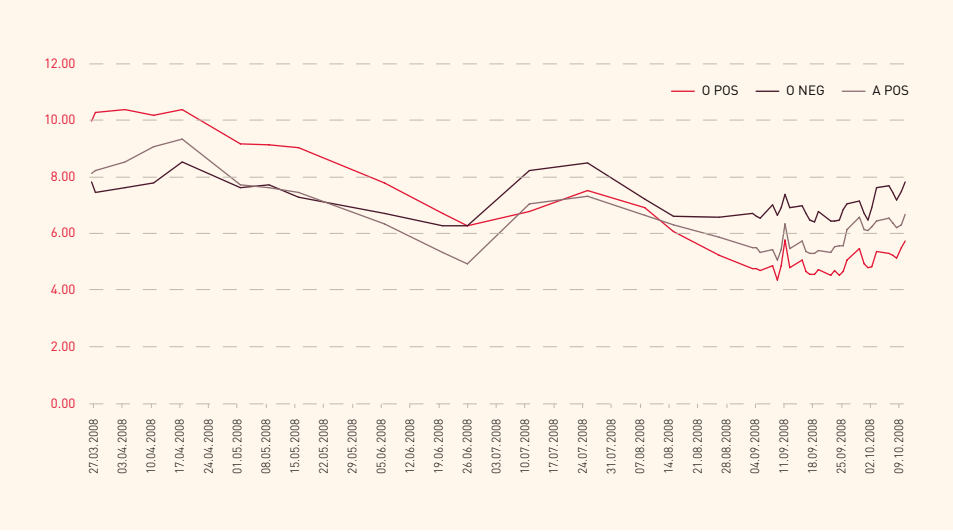
- red cell and plasma and recombinant annexes that outline the triggers, roles and responsibilities of the major stakeholders for a specific product group or event. A third annexe covering the management of a transfusion transmitted infection in the blood supply is under development and is expected to be finalised during 2009–10.

The Plan was activated for the first time on 22 August 2008 and remained at 'White Alert' until 23 October 2008 in the light of a continued tight supply of red cells.

Figure 2.5 shows the decline in stocks of red cells, beginning in April with A positive stocks. This then resulted in a more rapid decrease in O negative stocks than anticipated, which, when combined with the usual reduction in stock due to seasonal flu and a long tail to the flu season, put sustained pressure on red cell stocks. This supply situation necessitated weekly teleconferences to monitor stock levels and trends and to engage treating clinicians in maintaining a normal operating environment despite reduced inventories. During the reporting year the combined red cell inventory of the Australian Red Cross Blood Service and Australian health providers fell below the minimum stock level of five days for a total of eight days. Effective monitoring of stocks at the time and continual communication with health care providers by jurisdictions and the ARCBS meant that no further action was required.

A number of improvements to the National Blood Supply Contingency Plan have been agreed as a result of this, the first activation of the plan. These include the development of an intensive product management protocol for red cells to ensure that early warning signs of a risk to supply are acted on in a timely manner, thereby reducing the need to activate the plan.

FIGURE 2.5 *Days of red cell supply, by blood type, March to October 2008*

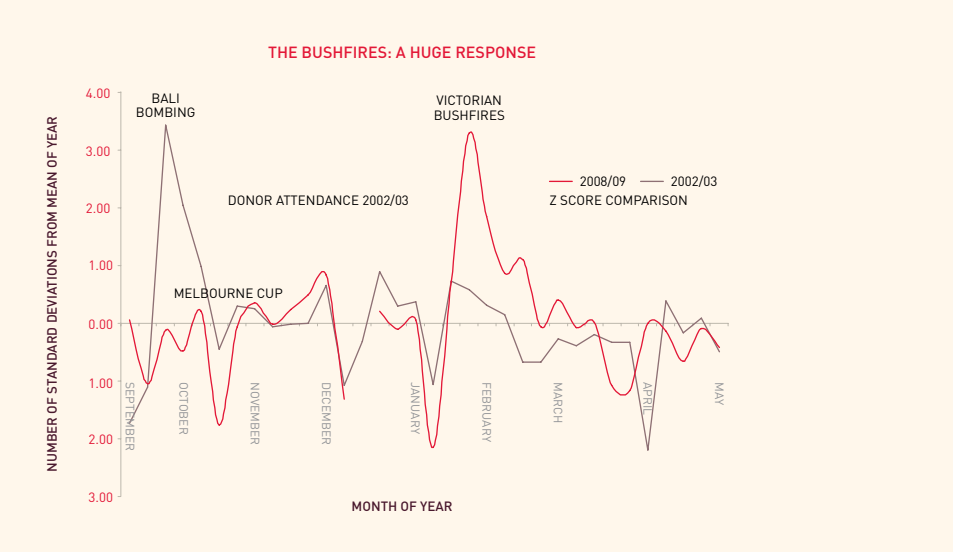


Response to specific incidents

In response to the Victorian bushfires and the Ashmore Reef incident, the NBA worked collaboratively with the Australian Red Cross Blood Service to provide regular information to governments on stocks, ensuring the movement of stock to where need was greatest. While the jurisdictions and the NBA were very active in monitoring demand and participating in whole-of-government processes when necessary, the actual requirement for additional blood products was low and easily managed within existing inventories.

The tragedy of the bushfires demonstrated the generosity of the Australian public in donating blood at times of crisis. Figure 2.6 shows the dramatic increases in fresh blood donations at the time of the Bali bombing and after the Victorian bushfires. The number of new donors in February 2009 was the highest ever recorded for the Australian Red Cross Blood Service.

FIGURE 2.6 *Donor attendances in response to a disaster*



Notes: Figure is a Z score comparison.
Source: Australian Red Cross Blood Service.

In response to the outbreak of pandemic (H1N1) 2009 virus, the NBA closely monitored stocks and the evolving international analysis. The increased rate of infection by the virus has the potential to have two major impacts on the blood supply:

- a reduction in the number of donors due to illness, caring, forced social isolation or fear of infection
- a reduction in ARCBS capability due to staff illness.

The NBA has worked closely with the ARCBS to monitor the situation and to ensure that planning is appropriate. Current activities include modelling the possible impact of the pandemic (H1N1) 2009 virus on inventory and refining strategies to target donors of the most essential types of blood components, such as platelets and O negative red cells, should these be required.

Following action by the NBA, the ARCBS was the first international blood service to announce a response to the pandemic (H1N1) 2009 virus. This included:

- deferral of receipt of donation from travellers who had been to Mexico for 14 days after their departure from that country
- acceptance of donors with a history of travelling to the United States and Canada for plasma donations only
- increased vigilance in the screening of all donors for flu-like symptoms.

As the rate of infection continued to grow, the NBA increased the frequency of its communication with the ARCBS to confirm that appropriate response strategies were being planned. ARCBS activities included:

- ensuring the supply of personal protective equipment for staff
- ensuring the ability to establish donor triage stations—to physically separate potentially infectious donors
- liaison with international counterparts to determine best-practice and/or additional measures.

The NBA will continue to provide to all governments regular reports on stock levels and timely advice on inventory trends. If these trends indicate a risk to the blood supply, the NBA will activate the National Blood Supply Contingency Plan to ensure that available stocks are managed in the most efficient manner. The impact of the pandemic (H1N1) 2009 outbreak on blood supplies will be a continuing issue in 2009–10.

Sector improvement initiatives

The NBA has a number of projects designed to improve the overall efficiency of the sector as a key element of improving affordability and risk minimisation. These projects require detailed research and are always implemented with the continual input and guidance of stakeholders and experts in the field of inquiry. During 2008–09 these activities involved the NBA in:

- developing evaluation methodologies for product change proposals
- reviewing distribution arrangements for plasma and recombinant blood products
- exploring the scope to increase accountability for, and awareness of, stewardship obligations for those who receive blood products for dispensing to patients
- undertaking data capture and analysis projects.

Evaluation methodologies for product change proposals

Under the National Blood Agreement, interested parties can make proposals for changes to products or services on the National Product and Services 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. To date, the Jurisdictional Blood Committee, on the NBA's advice, has been effective in assessing new products when they are similar to, and hence can be directly compared with, existing products, and there are no new policy considerations. The procedures are detailed in a document entitled *Information and guidance for applicants on submitting a national blood supply change proposal*, available at www.nba.gov.au.

In 2008–09 the NBA commenced development of a comprehensive framework to support complex assessment of products in the context of the objectives of the National Blood Agreement. Typically, these products raise complex policy considerations or the cost-effectiveness evaluation has complex impacts beyond the blood sector. The NBA's framework has 13 criteria:

1.	Security of supply
2.	Comparative health gain
3.	Comparative safety gain
4.	Comparative cost-effectiveness
5a.	Financial implications for the national *blood* budget
5b.	Financial implications for government *health* budgets
6a.	Self-sufficiency—*reliance* on domestic production
6b.	Self-sufficiency—*efficiency* of domestic production
7.	Donations
8.	Accessibility and utility
9.	Feasibility
10.	Clinical need
11.	International practice

This framework:

- aligns blood sector assessment methodology with that used for the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme
- quantifies consideration of each of the objectives of the National Blood Agreement
- provides consistent rigour for the assessment process.

The evaluation process clearly defines the assessment criteria and an evaluation pathway and is arguably more robust than processes that apply to blood products elsewhere in the world. The framework has been agreed in principle by the Jurisdictional Blood Committee and is currently the subject of consultation.

Review of distribution arrangements for plasma and recombinant blood products

In 2007 governments endorsed a recommendation in the review of Australia's plasma fractionation arrangements that the NBA should also review existing arrangements for distributing blood products. This review was to focus on the distribution supply chain for plasma-derived and recombinant products but not include supply chain analysis for fresh blood. Phase 1 of the review was undertaken in 2008–09 and concluded that current arrangements are neither ideal nor optimal from cost and governance perspectives and that there are significant opportunities to rationalise activity. The review identified three potential areas for improvement, and in February 2009 the Jurisdictional Blood Committee agreed to implement Phase 2 of the study. This phase will explore the potential costs and benefits of the changes required to achieve these improvements.

The Statement of Expectations project

The Statement of Expectations project, previously described as the Agreement to Supply project, has arisen because of concern that there are no specific accountability obligations on laboratories or other institutions that receive blood products for dispensing to patients. These facilities are regulated for safety and quality by other agencies, but they have no stewardship obligations under the National Blood Agreement, even though they receive the products free of charge. In particular, the NBA expects that, as a key part of the blood supply chain, the facilities will use rare and expensive products in an efficient and respectful manner. The NBA and the Jurisdictional Blood Committee consider that the facilities should be encouraged to undertake appropriate inventory management and reporting, implement appropriate ordering and receipt verification, encourage adherence to relevant guidelines, standards and legislation, and provide data, including adverse event data. Following stakeholder consultation, the NBA has reconsidered the best way forward on this project and will be submitting its proposal to government in early 2009–10.

Sector data capture and analysis

Implementation of systems and processes that provide accurate and timely data is essential to ensure quality and informed decisions on the use of and demand for blood and blood products and services. During 2008–09 the NBA progressed activities in the areas detailed in the following paragraphs.

Australian Bleeding Disorders Registry

The redeveloped Australian Bleeding Disorders Registry 'went live' on 18 December 2008 and was rolled out to all users, representing the culmination of significant work on the part of NBA staff in collaboration with a range of sector stakeholders.

The aim of the ABDR project is to develop and implement a system that provides to all stakeholders information on patients with haemophilia and other bleeding disorders. The NBA and the states and territories have a strong interest in improving understanding of the nature of product demand and use, which will enable more reliable supply forecasting and planning. Use of the ABDR will also enable the high-cost patient pool to be calculated. Implementation of the ABDR, in a multitude of different hospital IT and administration systems, has proved especially daunting.

The NBA is assisting haemophilia treatment centres, which are entering data, in the transition to the new system. Reporting requirements are among the highest priority items outstanding, and these are currently being finalised.

Integrated Data Management System

The aim of the Integrated Data Management System is to provide the NBA with an enhanced internal capability for data management. This will improve budgeting and forecasting of supply and demand for blood and blood-related products, inventory management, contract administration, and management of *Financial Management and Accountability Act 1997* reporting obligations.

The system became operational at the end of June 2008, but there have been a number of hurdles to overcome before it is fully useable. Several successful enhancement and defect builds were carried out during 2008–09, and a final verification and reconciliation was completed in March 2009. Work on the business intelligence reporting tool is under way, and it is expected that the Integrated Data Management System will become integral to our operations during 2009–10.

National IVIg Management System

The National IVIg Management System was initiated to capture information about the use of intravenous immunoglobulin to ensure alignment with the *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia*. The system will enable the collection of data on requesting, ordering, authorisation and treatment outcomes for IVIg and will provide accurate and comprehensive information on the use and efficacy of IVIg, which will be reported back to the clinical community. The increasing and competing pressure for access to limited product highlights the need for greater awareness of the efficacy of IVIg for a range of conditions, so that supplies can be directed to areas where the product is likely to be of clinical benefit.

During the development of the technical specifications for the system there has been extensive research and consultation with stakeholders. In addition, there are several existing data capture systems in use that meet some of the user requirements for the new system. In 2008–09 detailed specification documentation was developed, and systems within the broader sector were reviewed to identify opportunities for leveraging from the Australian Red Cross Blood Service's STARS (Supply Tracking and Reporting System) and Queensland Health's ORBS (Ordering and Receipting Blood System).

The potential for development of the National IVIg Management System within the ORBS and/or Australian Bleeding Disorders Registry frameworks, and further sector IT integration, is the subject of ongoing work. The NBA will explore options for a more integrated, innovative and broad approach to the overall management framework for blood products in Australia, including IVIg, during 2009–10.

2.2.2 Supply of blood and blood products

In 2008–09 the NBA managed 13 blood supply contracts and arrangements. No new contracts were entered into during the year, but four contracts were subject to variation and extension. Optimal NBA performance in this key strategic area is essential to ensuring continued 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 Blood Service, improvement projects required of the ARCBS by ministers and the negotiation of a revised Deed to apply from 1 July 2009
- management of Australia's plasma product and recombinant product requirements through
  - management of the Plasma Products Agreement with CSL Ltd and commencement of negotiations for a new agreement
  - negotiation of the extension to a number of contracts for the provision of imported products
  - management of contracts for the provision of diagnostic reagents required by the sector.

Management of fresh blood components

The Australian Red Cross Blood Service collects fresh blood from voluntary donors in order to produce a variety of blood components that are used for the treatment of medical conditions such as cancer, heart disease, stomach and bowel disease and liver and kidney disease, as well as to treat newborn babies and pregnant women. Donated blood is also used to help people who suffer from traumatic incidents such as accidents and burns and during or as a result of surgery. The ARCBS also collects plasma, which is provided to CSL Ltd for fractionation into a variety of products that are then purchased through the NBA contract with CSL.

The NBA and ARCBS contract management teams.

The NBA manages the relationship with the ARCBS—the sole supplier of fresh blood-related products in Australia—and is responsible for negotiating and managing the ARCBS Deed of Agreement. The NBA also manages a number of projects involving the ARCBS and provides secretariat and project management support for the National Managed Fund.

Australian Red Cross Blood Service funding and product mix

Funding for the ARCBS increased from actual funding of $369.1 million in 2007–08 to an agreed budget of $417.2 million in 2008–09 (see Table 2.5).

TABLE 2.5 *Australian Red Cross Blood Service: annual funding, 2003–04 to 2008–09*

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[a]
2008–09	417.2	13.0
Total	**1935.9**	**11 (average)**

a: This figure differs from that presented in the 2007–08 annual report due to adjustments made after receipt of the ARCBS final reconciliation.

The growth in funding reflects increased demand (see Figure 2.3) and changes in the product mix for fresh blood components. For example, Figure 2.7 shows the continued decline in demand for red cells derived from whole blood and the progressive implementation of 100 per cent leucodepleted red cells. Figure 2.8 shows that the total number of red cells issued per 1000 population increased from 2007–08 to 2008–09. The drop in 2007–08 was, however, mainly due to a 6 per cent decrease in demand in New South Wales in response to a range of measures the state government introduced to improve accountability and management focus at the area health service level.

FIGURE 2.7 *Product mix of red cells issued by the Australian Red Cross Blood Service 2003–04 to 2008–09*

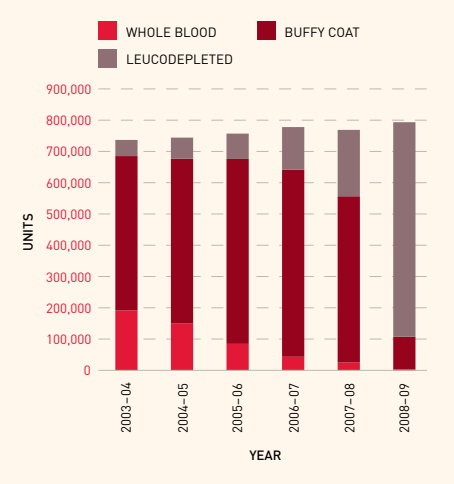


FIGURE 2.8 *Red cells issued per 1000 head of population, 2003-04 to 2008-09*

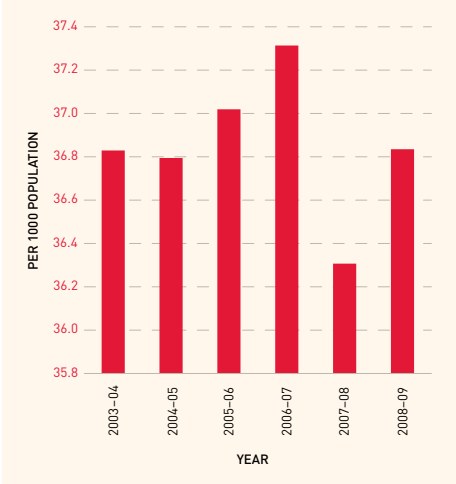


Figure 2.9 shows the change in demand for platelets derived from whole blood donations compared with those derived from apheresis processes. Figure 2.10 shows that the rate of growth in platelet issues per 1000 head of population remained relatively stable from 2006–07 to 2008–09.

FIGURE 2.9 *Product mix of platelets issued by the Australian Red Cross Blood Service, 2003–04 to 2008–09*

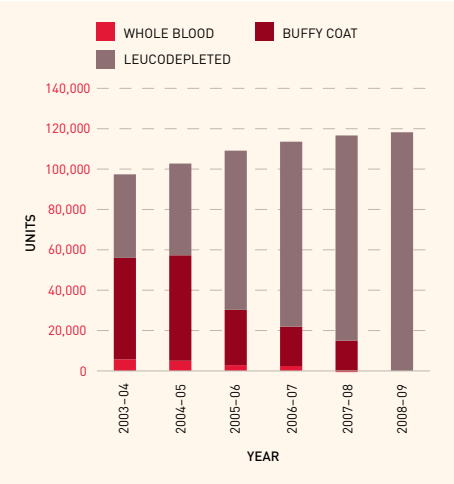
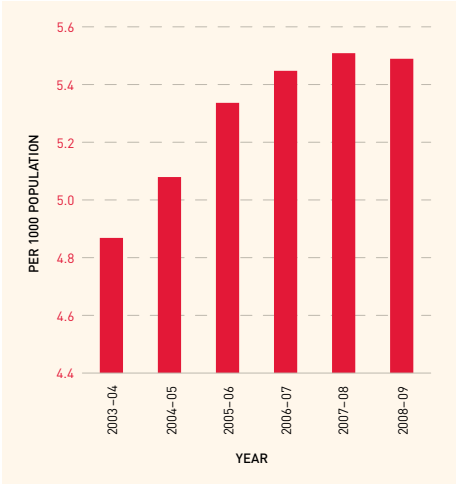


FIGURE 2.10 *Platelets issued per 1000 head of population, 2003–04 to 2008–09*



The Australian Red Cross Blood Service Deed of Agreement

The current ARCBS Deed of Agreement was due to expire on 1 July 2009. Several of the current Deed's requirements are not yet finalised, and a number of the recommendations of the business study have implications for the next Deed, including the development and implementation of an output-based funding model. In light of these considerations, the NBA and the ARCBS agreed to extend the existing Deed, with several variations, by 12 months until 30 June 2010. The variations, incorporated at the request of jurisdictions in the interest of increased efficiencies, include changes to the funding formula, extension of the Change Program Funding arrangements for a further 12 months, and revisions to key performance indicators to increase clarity.

The next Deed will be negotiated once the development of an output-based funding model has been agreed by the ARCBS and governments. It will also be informed by the outcomes of the review of distribution arrangements and the new CSL Domestic Fractionation Agreement.

The ARCBS business study

On 22 July 2008 the Australian Health Ministers Conference agreed on the combined government response and implementation strategy for the recommendations of the ARCBS business study. Ministers also agreed that the Minister for Health and Ageing write to the Australian Red Cross Society (ARCS) and ARCBS Boards, advising of governments' response to the business study and establishing ministers' expectations of the ARCBS. The Australian Health Ministers Conference directed the Jurisdictional Blood Committee to present a progress report in 2009 on the implementation of agreed recommendations.

The ARCS and ARCBS Boards have confirmed their commitment to implementing the business study recommendations, which cover a range of areas in five domains:

- ARCBS financial governance arrangements
- improving ARCBS efficiency and effectiveness through better planning
- improving ARCBS financial and capital management
- an output-based funding model
- safety business cases.

The first scorecard report to the Australian Health Ministers Conference on the status of implementation of the business study recommendations is to be provided in September 2009. Progress on improvements recommended in the business study has been sound, with 32 per cent of the recommendations now fully implemented. Current progress on two major areas of work—the output-based funding model and the planning framework—are described in the following paragraphs.

Moving forward on an ARCBS output-based funding model

Governments have agreed to fund the ARCBS through a three-year output-based model starting from 2010–11. This means that the ARCBS will be paid for products issued, which will result in a greater alignment of supply to demand. Work has begun in developing five interrelated aspects:

- business and strategic planning processes that involve robust three-year supply forecasts from jurisdictions and reporting against agreed performance indicators
- agreement on the definition and scope of products and services to be delivered
- development of appropriate product costing and attribution processes
- translation of standard product level costs to product unit prices
- determining revenue, cash flow and financial support arrangements that will need to be implemented by both the ARCBS and the NBA to ensure that the model can be implemented.

The ARCBS strategic and business planning process

The recommendations of the business study gave renewed impetus to the original Deed of Agreement objective of integrated long-term planning. This objective was progressed through planning forums in August 2008 and May 2009 that have:

- plotted a detailed annual business planning cycle to provide adequate opportunity for governments to influence the ARCBS's forward planning through the provision of an annual statement of expectation
- agreed to a three-year rolling planning cycle, to commence from the beginning of 2010–11, to provide an opportunity for the ARCBS, the NBA and governments to evaluate, plan and set the directions for the next three years. This plan will then form the basis of the three-year output-based funding.

The ARCBS Strategic Capital Investment Plan

The ARCBS Strategic Capital Investment Plan details the intended capital expenditure required to sustain fixed assets, including replacement of assets such as vehicles, laboratory equipment and premises (for example, refurbishments, relocations and new sites). The Plan, covering a three-year period, is prepared by the ARCBS annually and submitted to the Jurisdictional Blood Committee as part of the approval process for the National Supply Plan and Budget.

Under the Deed of Agreement the annual capital funding provided to the ARCBS covers 10 per cent of the service's main operating program. For 2008–09 this represented $38 million. Table 2.6 shows the value of the approved annual capital plans from 2006–07 to 2008–09.

TABLE 2.6 *ARCBS annual capital plan funding, 2006–07 to 2008–09*

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

In addition to the approved annual capital plans, governments have agreed to fund, as appropriate, the redevelopment of the principal manufacturing sites in NSW and Victoria in order to update and expand the capacity of the ARCBS.

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 ARCBS 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 CBD and Kingsford-Smith Airport. Construction began in late June 2009 and is expected to be completed by mid-2010. When complete in 2010, the development will comprise 12 450 square metres of purpose-built manufacturing space, at a cost of about $188 million. The new facility will be responsible for the processing and distribution of all blood and blood components in New South Wales and the Australian Capital Territory.

The Victoria and Tasmania principal site

In December 2008 health ministers approved in-principle additional funding for the ARCBS over 20 years to meet the costs of building and outfitting leases for a new principal blood-manufacturing site in Melbourne. The ARCBS subsequently undertook an extensive tender process to identify the optimum relocation site, based on the then requirement from government that the property be occupied by way of a 20-year lease with two 5-year option periods.

Responding to the in-principle approval of funding, by May 2009 the ARCBS had brought the required contractual elements for this development close to finalisation pending final policy and indemnities approval by health ministers.

On 12 May 2009 the Treasurer announced in the 2009–10 Federal Budget that the ARCBS would receive $120 million (allocated as capital over two years) for the Victoria and Tasmania principal site development, to be provided through the Health and Hospitals Fund, and that this would require the jurisdictions to fund the remainder of the project costs. The change in the nature of the funding, while offering cost savings to governments in the long term, has required the NBA, the ARCBS, the Health and Hospitals Fund, the likely developer and the jurisdictions to rapidly develop alternative arrangements to meet the ARCBS's timetable.

The new facility, to be located in Melbourne, will accommodate the ARCBS's blood-manufacturing operations for Victoria and Tasmania. It will contribute 25–30 per cent of Australia's fresh blood supply. Building works are expected to commence in mid-August 2009, and the facility is expected to be operational by September 2011.

Other capital programs

A key component of the ARCBS's Annual Capital Plan and 2009–14 Strategic Capital Investment Plan was the inclusion of $14 million in investment across three years to replace the current National Blood Management System. Other programs supported during the 2008–09 included:

- implementation of an automated nucleic acid testing (NAT) program on the Chiron-developed TIGRIS platform
- release two of the Corporate Information Management and Reporting System
- optimisation of call centre operations.

Improving governance

Quarterly meetings between the Chief Executive Officers and Chief Financial Officers continued during the reporting year, with a clear focus on improving overall governance and ensuring progress against agreed performance targets.

While acknowledging the operational effectiveness of these meetings, the business study recommended increased engagement at the board level to drive a higher level of accountability and a tighter focus on governance and strategic longer term performance. This engagement is discussed by the Chair of the NBA Board in his report.

The NBA reached agreement with the ARCBS to implement the first of the third-party reviews required under the Deed of Agreement. This review was designed to analyse the extent to which the ARCBS complies with Governance Standard AS 8000–2003 Good Governance Principles and the extent to which this has resulted in and continues to provide good governance within the ARCBS.

Fresh blood relationship manager Mr Andrew Mead

The review, conducted in February–March 2009, found that the ARCBS demonstrated a high level of commitment to effective governance against the standards, although some opportunities for further development were identified—in particular, the benefit of establishing new simplified outcome-based and control system status reporting to the NBA. At the May CEOs meeting it was agreed that this should become one of the objectives of the new Deed.

ARCBS supply performance

Donor management

Development of approaches for increasing donor retention rates and increasing the number of donations per donor are priorities required by government. The ARCBS exceeded its planned parameter of 536 307 whole blood donors, with a total of 541 848 such donors in 2008–09. Apheresis plasma and platelet donors were under plan, by 1.95 per cent and 4.7 per cent respectively. Nevertheless, these donor panels continue to grow slowly but steadily.

The proportion of new donors in the total donor panel continued to increase after the surge in the third quarter that reflected the overwhelming public response to the Victorian bushfires, in addition to increased public awareness through the Year of the Blood Donor.

There was a corresponding increase in product inventory, as well as a shift in the proportion of new donors in the panel.

Supply chain management

In 2008–09 process-related recall incidents occurring after the supply of product were significantly below the planning parameter of 0.65 per 10 000 collections.

Whole blood collection conversion to supply fell below the 2008–09 target by 2.4 per cent. ARCBS explained that this shortfall was due to implementation of the new edition of the Council of Europe *Guide to the preparation, use and quality assurance of blood components*, with red cells not suitable for clinical use and an increased discarding of red cells following the introduction of 100 per cent screening for bacterial contamination.

The actual supply of fresh blood products for 2008–09 compared with the annual supply estimates agreed by the Australian Health Ministers Conference (including the move to 100 per cent leucodepletion in 2008–09) is highlighted in Table 2.7.

TABLE 2.7 *Variance between actual supply of fresh blood components and the annual supply estimates*

		VARIANCE TO NSP&B VOLUME	VOLUME % VAR
Total Red Cells	Units	5 280	0.7%
Total Platelets	Units	(2 902)	-2.4%
Total Clinical Fresh Frozen Plasma	Units	(856)	-0.6%
Plasma for Fractionation	Kgs	10 207	2.7%

The quantity of plasma for fractionation was 2.7 per cent over the annual supply requirement. The increase in collections of plasma in 2008–09 followed implementation of the new Council of Europe guidelines, in which the total average plasma collection allowable from each apheresis donation was increased.

Leucodepletion of red cells throughout Australia was achieved in October 2008, and significant savings are being realised through the standardisation of blood bags that was undertaken at the same time.

The National Managed Fund

The National Managed Fund is designed to cover future liability claims made against the ARCBS in relation to the supply of blood and blood-related products in Australia. Sound progress on administrative and governance arrangements was achieved in 2008–09.

ARCBS business case assessments

The Deed of Agreement acknowledges that the ARCBS might have to seek additional government assistance in order to implement reforms. Several business cases requesting such assistance were assessed during the reporting year. The ARCBS continued to use funding approved by the Jurisdictional Blood Committee to address the impact on the blood supply of new requirements under the new edition of the Council of Europe guidelines. In particular, the provisions in relation to the management of donors with a history of malaria, acupuncture and body piercing were updated.

Change Program funding

Twelve projects costing $7 million in total have now been funded under the Change Program to help the ARCBS transition to a national operation, to deliver cost savings, or to otherwise increase the efficiency of the production of goods and services under the Deed of Agreement. Table 2.8 summarises the nature of these projects and their status.

In line with the extension of the Deed of Agreement, the Jurisdictional Blood Committee approved the extension of Change Program funding for a further year, to 30 June 2010.

TABLE 2.8 ARCBS Change Program funding for projects 2006–07 to 2008–09

PROJECT	APPROVED BUDGET ($M)	STATUS
Deed transition program—phases 2 & 3	$0.9	In progress
Third party reviews	$0.2	In progress
Deed operations initiative	$0.1	Complete
Product costings and forecasting—phase 2	$0.6	In progress
Finance Deed transition	$0.1	Complete
Asset management	$0.7	In progress
Governance standards implementation	$0.3	In progress
Handover plan	$0.5	In progress
Corporate information management and reporting—release 1	$0.6	Complete
Automated budget	$0.6	In progress
Workforce planning	$1.6	In progress
Learning project	$0.7	In progress

Management of plasma and recombinant products

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 blood products
- diagnostic reagents.

Locally produced plasma-derived products: the Plasma Products Agreement

In Australia, CSL Ltd fractionates plasma collected by the ARCBS to produce products to meet the needs of the Australian health sector. Plasma fractionation arrangements are governed by the Plasma Products Agreement between the NBA and CSL Ltd; the Agreement covers pricing, invoicing, supply planning and monitoring, risk management, and ordering and delivery.

Funding to CSL Ltd for the Plasma Products Agreement increased from $155.9 million in 2007–08 to $158.1 million in 2008–09 (see Table 2.9).

TABLE 2.9 CSL Ltd: annual funding commitments under the Plasma Products Agreements, 2003–04 to 2008–09

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
Total	**868.0**	**2.4 (average)**

CSL Ltd achieved all of the key performance indicators specified in the agreement (see Table 2.10).

TABLE 2.10 CSL Ltd Plasma Products Agreement: key performance indicators, 2008–09

KEY PERFORMANCE INDICATOR	ACHIEVEMENT
Yield of Group 1 products	5.26 g IVIg per kilogram starting plasma
Loss of Group 2 plasma or Group 2 finished products	0.04%
Fulfilment of orders	99.5%

The new CSL Domestic Fractionation Agreement

The current Agreement with CSL Ltd expires on 31 December 2009. The NBA has implemented a comprehensive project to negotiate a new agreement with CSL Ltd that will continue to deliver improved value for money for government. The approach has been informed by feedback from key stakeholders through a discussion paper that sought comment on a range of subjects relating to the adequacy of the current Agreement. Issues raised through this process have been further refined in expert workshops and bilateral consultations. The Jurisdictional Blood Committee has provided policy guidance for the new Agreement and the NBA expects that the new Agreement will be in place by January 2010.

Imported plasma-derived and recombinant blood products

The NBA has established a range of contracts with overseas suppliers for the importation of selected plasma-derived and recombinant blood products to augment domestic supply and obtain products that cannot be manufactured in Australia, either because the technical capacity is not available or because it is not economically viable to do so. Since 2006 the NBA has managed contracts with Baxter Healthcare Pty Ltd, Wyeth Australia Pty Ltd and Novo Nordisk Pharmaceuticals Pty Ltd. In 2008–09 the NBA spent $150.1 million under these contracts for the supply of imported blood products (see Table 2.11).

TABLE 2.11 Annual expenditure on imported products, (excluding IVIg) by company, 2003–04 to 2008–09,

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	69.4	$10.9	96.5	$18.8	28.6
2005–06	$69.9	28.2	$15.9	45.5	$23.4	24.5
2006–07	$71.5	2.3	$33.8	45.5	$26.9	15.3
2007–08	$80.1	12.0	$42.4	25.3	$17.4	–35.3
2008–09	$84.1	5.0	$48.6	14.8	$17.4	–0.2
Total	**$392.3**	**23.4 (avg.)**	**$157.1**	**59.1 (avg.)**	**$118.5**	**6.6 (avg.)**

A high degree of performance against contractual key performance indicators was again demonstrated in 2008–09 (see Table 2.12).

TABLE 2.12 Imported recombinant blood product contracts: key performance indicators, by supplier, 2008–09

KEY PERFORMANCE INDICATORS	BAXTER	WYETH	NOVO NORDISK
Delivery performance	Achieved	Achieved	Achieved
In-country reserve	Achieved	Achieved	Achieved
Ordering	Achieved	Achieved	Achieved
Record keeping	Achieved	Achieved	Achieved
Reporting	Achieved	Achieved	Achieved
Shelf life of products to approved recipients	Achieved	Achieved	Achieved

The contracts with the three suppliers were due to expire on 30 June 2009. They all have extension provisions and during 2008–09 the NBA investigated the scope for further improving value for money. The review process demonstrated that product pricing in the current contracts provides value for money for governments, and the Jurisdictional Blood Committee considered that the existing product range should remain for the time being. The NBA has negotiated with the three suppliers to extend their contracts, achieving prices below consumer price index rises in most cases.

Supply analysis

Analysis of trend information shows a continued increase in demand for Factor VIII overall—in particular, a growth in demand for recombinant, compared with plasma-derived, Factor VIII (see Figure 2.11) and an increase in the issuing per 1000 population of these products (see Figure 2.12). Some of this demand increase is explained by the fact that people with bleeding disorders are living longer, and there is an increase in product use for prophylaxis. Figure 2.13 shows the market share for specific recombinant products since 2006–07.

FIGURE 2.11 *Issues of Factor VIII products, 2003–04 to 2008–09*

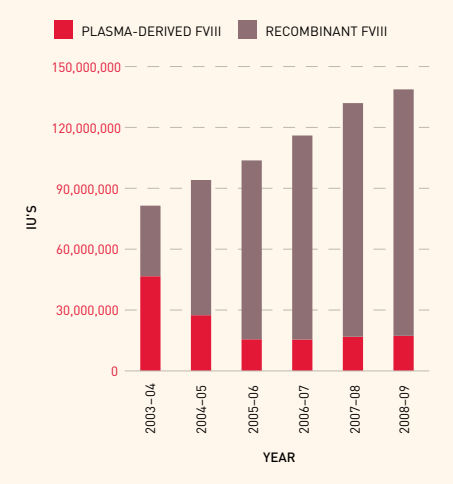


FIGURE 2.12 *Issues of total Factor VIII per 1000 population, 2003–04 to 2008–09*

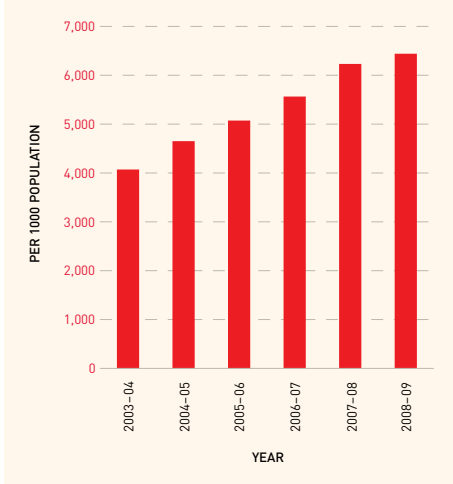
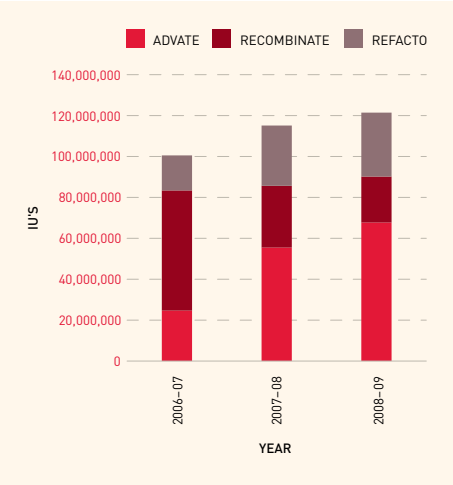


FIGURE 2.13 *Recombinant Factor VIII issues: market share, 2006–07 to 2008–09*



Similarly, there has been a continued increase in the total demand for Factor IX products and a move away from plasma-derived Factor IX (see Figure 2.14). Figure 2.15 shows this increase in demand reflected in total issues per 1000 population.

FIGURE 2.14 *Issues of Factor IX products, 2003–04 to 2008–09*

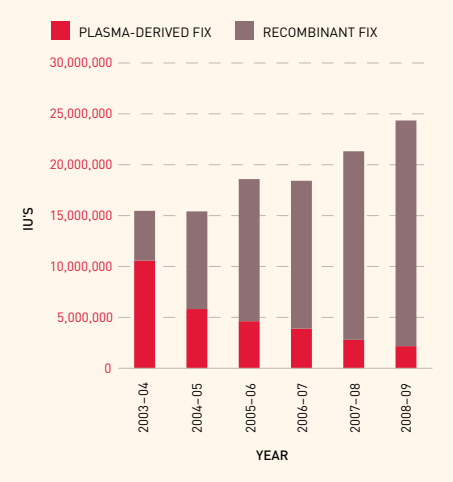
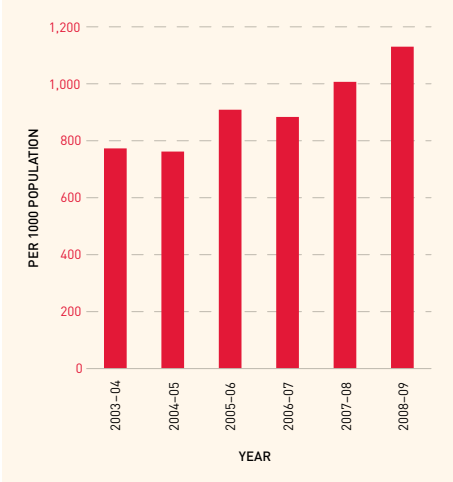


FIGURE 2.15 *Issues of total Factor IX per 1000 population, 2003–04 to 2008–09*



Demand for recombinant Factor VIIa, which is used for patients with inhibitors to Factor VIII, decreased in 2008–09 (see Figure 2.16). However, with the small number of patients using this product, demand is hard to predict as it can be strongly influenced by the health status of one or two patients. It is possible that some patients have transferred from Factor VIIa to Factor Eight Inhibitor Bypassing Activity (FEIBA), as FEIBA showed a significant increase in the reporting year (see Figure 2.17). The Australian Bleeding Disorders Registry should offer the NBA increased capacity to examine these trends in 2009–10.

FIGURE 2.16 *Issues of recombinant Factor VIIa, 2003–04 to 2008–09*

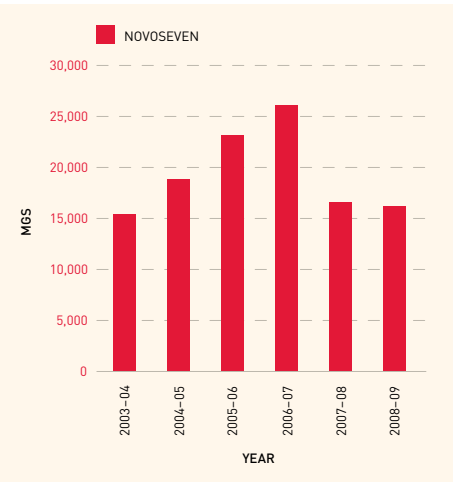
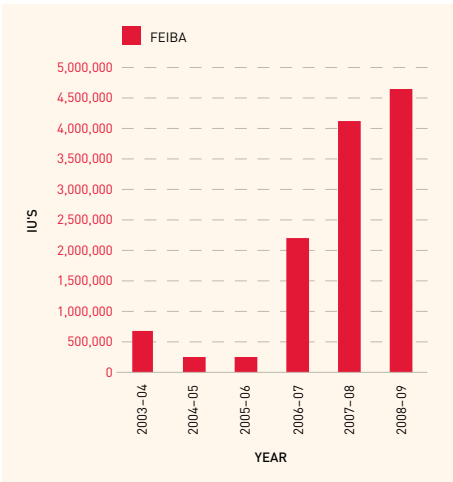


FIGURE 2.17 *Issues of FEIBA, 2003–04 to 2008–09*



Imported IVIg standing offer

In 2008–09 the NBA continued imports of intravenous immunoglobulin to allow us to fully meet domestic clinical demand. The cost of intravenous immunoglobulin purchased from Octapharma Australia Pty Ltd under the fixed price contract increased from $34.3 million in 2007–08 to $46.9 million in 2008–09 due to increased demand for this product and the need to build the reserves of domestic product to mitigate supply risks.

Figures 2.18 and 2.19 show that the continuing increase in demand for IVIg (measured by issues per 1000 population), has been in excess of the growth in domestic plasma collections. This has meant the percentage of imported IVIg grew from 17.9% in 2007–08 to 27.6% in 2008–09.

FIGURE 2.18 *Issues of IVIg products, 2003–04 to 2008–09*

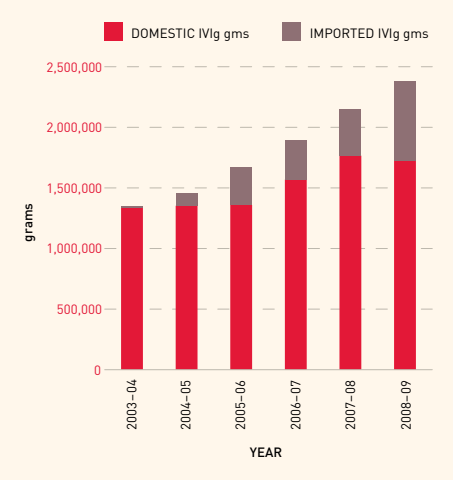
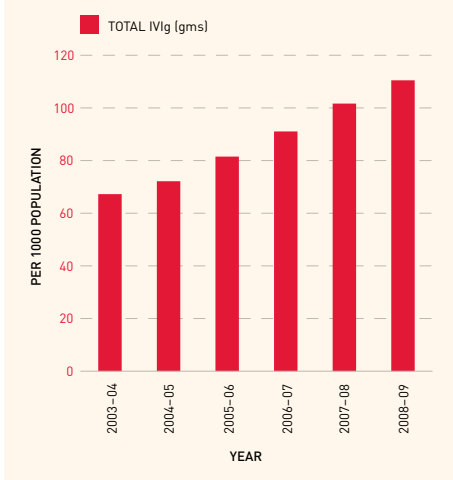


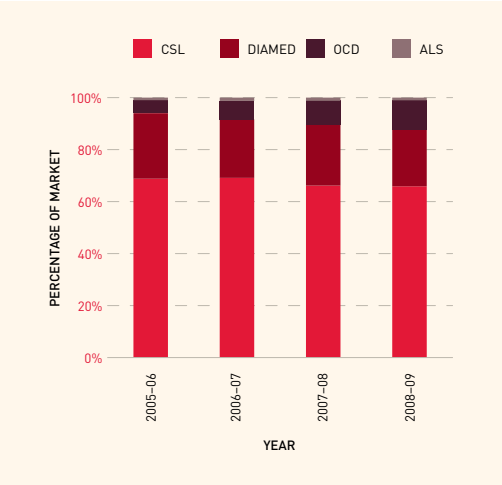
FIGURE 2.19 *Issues of IVIg per 1000 population, 2003–04 to 2008–09*



Diagnostic reagent products

Contracts with four suppliers of diagnostic reagents—Australian Laboratory Services Pty Ltd (ALS), CSL Ltd, DiaMed Australia Pty Ltd (DIAMED) and Ortho-Clinical Diagnostics (OCD)—are due to expire on 31 October 2009. The NBA has commenced negotiations to ensure continuity of supply for these essential products beyond this date. Figure 2.20 shows that the total market share of each supplier remains relatively stable.

FIGURE 2.20 *Market share for suppliers of diagnostic products, 2005–06 to 2008–09*



2.2.3 Monitoring and improving the appropriateness and safe use of products

In 2008–09 there was continued progress on a number of activities designed to move forward with the second major objective of the National Blood Agreement—increased appropriateness of use of blood and blood products.

The Australian National Haemovigilance Program

In 2008–09 the NBA made good progress towards implementing the recommendations of the *Initial Australian Haemovigilance Report 2008*. Governance arrangements for the enduring National Haemovigilance Program in Australia were endorsed by the Jurisdictional Blood Committee, and funding was allocated to support direct program delivery. National minimum haemovigilance data set definitions were finalised, and governance arrangements for the ongoing Haemovigilance Advisory Committee were developed for consideration by the Committee at its first meeting in July 2009.

To help the states and territories implement the minimum national data set, specifications were developed to enable them to analyse the capability of their health care information systems to provide haemovigilance data. Assessments have been completed in Victoria, Tasmania and the Australian Capital Territory, and all other jurisdictions are due to report on their capability before the end of 2009.

National indicators project

In the mid to long term, the needs of data collection projects would best be met if suitable clinical coding existed. This would simplify obtaining data by unifying the data sources such that all relevant data on blood-related activities resided in hospital systems' central patient records. Currently, ICD-10-AM codes and AR-DRG codes are not specific enough to directly capture blood-specific data and treatments involving blood data. Neither are the specifications in SNOMED-CT. However, a number of agencies in Australia are working to change and update the ICD and SNOMED codes and standards.

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

If Australia can begin to implement definitions for blood management and transfusion-related data, it will lay the groundwork internationally with the World Health Organisation for ICD-11. Australia has a strong international reputation in this field, and many countries have previously adopted Australian coding standards. This would be an excellent opportunity for Australia to again lead the way. The Haemovigilance Advisory Committee is exploring the processes for defining new clinical coding standards for transfusion-related adverse events in the ICD-10-AM codes via the National Centre for Classification in Health. Further work will also be carried out with the SNOMED Clinical Terminology from the National eHealth Transition Authority.

Implementation and revision of the *Criteria for the clinical use of Intravenous Immunoglobulin (IVIg) in Australia*

Analysis of use against the conditions within the Criteria indicates an increase of 10.6 per cent in the number of grams issued from 2007–08 to 2008–09, and the top 12 primary diagnoses accounted for 76.6 per cent of issues. The largest increases were found in chronic inflammatory demyelinating polyneuropathy, common variable immunodeficiency disease, multiple myeloma, and myasthenia gravis. Inter-jurisdictional variations (in grams issued per 1000 population) were found in most diagnoses.

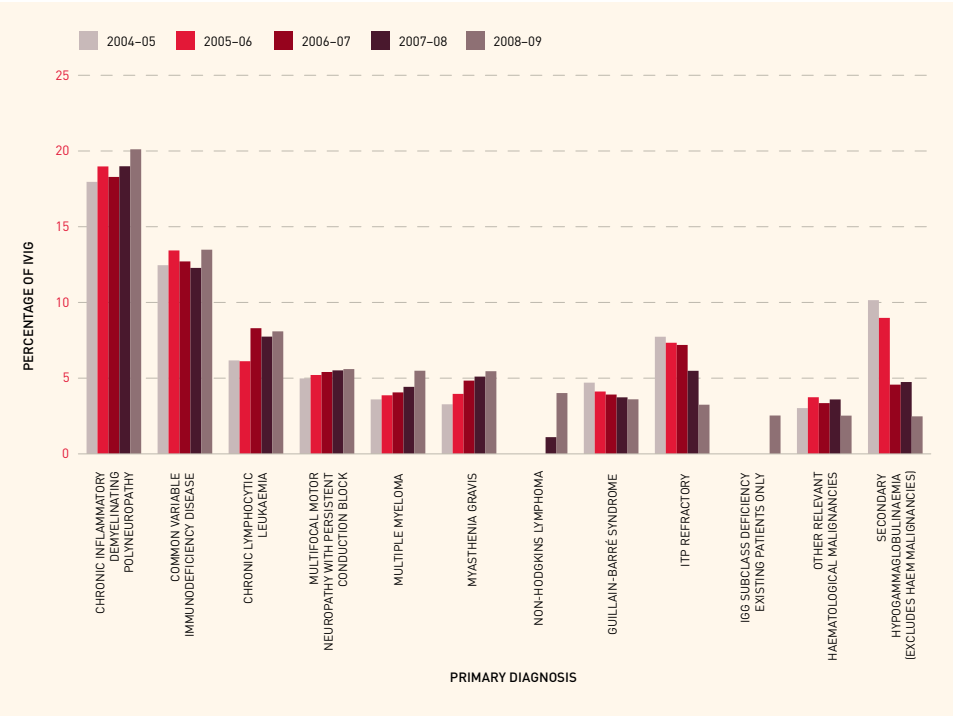
The top 12 uses of IVIg and the changes in these uses over time are shown in Figure 2.21.

The NBA established a group, endorsed by the Jurisdictional Blood Committee, to respond to questions arising from implementation of the Criteria. This group includes representatives of IVIg gatekeepers in each state and territory, IVIg discipline sub-groups (formed when the Criteria were developed), the Commonwealth and the JBC. A smaller 'resolution' group was also formed, consisting of a clinical representative of the Commonwealth, a JBC representative and the chairs of the IVIg discipline sub-groups.

Seventeen issues have been considered so far, and resolution has been provided on the majority—for example, on ambiguities in the wording of the Criteria.

Issues requesting the addition of an indication to the Criteria fall outside the scope of the process and will be considered in the context of the JBC-endorsed triennial formal review, due to commence in December 2009.

FIGURE 2.21 Top 12 uses of IVIg, 2004–05 to 2008–09



Red cell usage analysis

The purpose of the red cell utilisation project is to support the application of a data linkage model in each state and territory that:

- would provide a nationally consistent data set of (and ultimately a national report on) red cell use in Australia
- would make available data that could be used to drive and influence clinical practice via peer-based review
- is cognisant of broader safety and quality agendas in each jurisdiction
- could at some stage be broadened to incorporate other blood components.

All jurisdictions have agreed in principle to implement a data linkage exercise in their state and territory. They have agreed that this should be a national initiative and have identified a number of matters that need to be addressed, including:

- clarification of scope
- clinical grouping of the data sets
- impact on jurisdictional resources
- issues associated with privacy requirements
- requirements in some jurisdictions to obtain ethical approval.

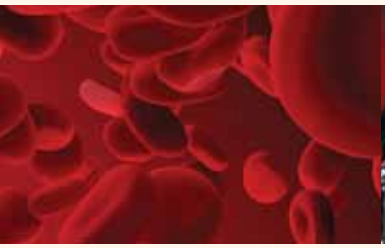
The first meeting of the project's working group occurred in May 2009, and a work plan and an implementation strategy were prepared. Discussion began with the data required and led members to identify an ideal set of data. The feasibility of obtaining the data will be determined by a business analyst, who is to be engaged to support the project.

The Blood Sector Conference

The 2008 National Blood Sector Conference, *'Better Blood Management in Australia—what's stopping us?'* was held at the Coogee Beach Crown Plaza hotel on 6 and 7 November 2008. The theme of the conference was to share, discuss and explore actions that can be taken to remove barriers to the wider adoption of best practice in the blood sector.

The focus of the conference was to provide a forum in which leading clinical and administrative practice in use and management of blood, blood products and their alternatives could be demonstrated and advanced, thereby building sector capacity. The conference attracted strong interest from all parts of the blood sector and provided a focused opportunity to learn about clinical change initiatives both locally and internationally.

CASE STUDY
WHAT'S STOPPING US?



The 2008 blood sector conference called for action by the audience to ensure a successful and sustainable future for the sector through exemplary stewardship from all players in careful management of both blood supply and blood demand.

The conference covered the following subjects:

- clinical system and governance strategies to achieve sustainable change
- national and supplier planning for emergencies
- the role of data in supporting change
- the cost of blood internationally and in Australia
- practical examples of patient blood management strategies and activities in action.

The conference also provided examples of leading clinical practice in cardiothoracic surgery, obstetrics, and intensive care and anaemia management. It attracted almost 170 national and international delegates and generated strong interest in and support for the adoption of a new paradigm in the management of blood. Participants especially enjoyed the lively and entertaining 'Hypothetical: The blood sector – what to expect in the next 10 years', facilitated by Doctor Norman Swan, that concluded the conference.

The conference proceedings (presentations and audio recordings) were provided on a CD to all delegates. Copies of the proceedings are available via the NBA website. Since the conference there have been 78 downloads of the proceedings.

Review of the National Health and Medical Research Council / Australasian Society of Blood Transfusion, Clinical Practice Guidelines on the use of blood components

The *Clinical Practice Guidelines on the use of blood components* were published in 2001. At the time some important areas of practice (specifically obstetrics and paediatrics) were omitted from the original publication, and since the guidelines' publication new clinical and scientific data have emerged. The current review is providing an opportunity to include these areas and also to fill other gaps in coverage—such as critical bleeding scenarios, haemodynamically unstable patients and chronic transfusion recipients. The aim of the review is to develop evidence-based recommendations to guide health practitioners in effectively managing patients who require blood management intervention. This focus is consistent with the draft national safety and quality framework released by the Australian Commission on Safety and Quality in Health Care in early 2009 which advocates a patient centred approach to care.

Jen Roberts (left) from the NBA with NHMRC expert working group co-chairs, Dr Amanda Thompson and Dr Craig French.

The management framework for coordinating the review consists of an overarching steering committee and an expert working group made up of nominees provided by relevant colleges and societies. The expert working group is responsible for clinical oversight of the guidelines—in particular, ensuring that the research undertaken is comprehensive and the quality of the revised guidelines meets with clinical approval. Clinical and consumer reference groups are providing essential specific and expert knowledge to guide the development of the guidelines and advice on the guidelines' relevance to and utility for the target audience. All levels of the management framework are assisted by a Guidelines Assessment Register expert appointed by the NHMRC.

The NBA has completed an extensive search for blood-related guidelines developed internationally to inform the expert working group on the scope and possible questions to guide the systematic review. In response, the expert working group has decided to produce a range of guidelines, as follows:

- general circumstances of use, which will be similar to 'product information' sheets
- product guidelines, to provide a general overview of indications and adverse events
- a series of guidelines providing patient blood management recommendations in specific clinical scenarios, including:

- Phase1 — Peri-operative (Patient) Blood Management Guideline
  Critical Bleeding (Patient) Blood Management Guideline
- Phase 2 — Medical Conditions (Patient) Blood Management Guideline
  Obstetrics (Patient) Blood Management Guideline
- Phase 3 — Paediatrics/Neonatal (Patient) Blood Management Guideline.

The role of the clinical and consumer reference groups, while important in confirming the scope of the questions, will become ever more important as the research and outcomes of the systematic review become available and final recommendations or consensus statements are developed.

The guidelines will be externally reviewed prior to being considered for endorsement by the NHMRC.

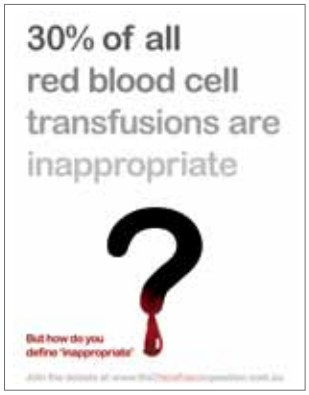
Web-based transfusion debate

The NBA and the New South Wales Clinical Excellence Commission have co-sponsored an innovative approach to communicating the latest evidence on patient blood management to surgeons. The web-based transfusion debate and information portal http://thetransfusionquestion.com.au was aimed at promoting robust debate between eminent patient blood management practitioners from the international community and Australian surgeons and anaesthetists who prescribe blood components.

Seven debating streams were made available: inappropriate red cell transfusion; dosage (one versus two units); infection and transfusion; the true cost of blood; pre-operative assessment and measures; intra-operative management; and 'What is patient blood management?'. A group of about 20 international experts contributed to and monitored the debates. In addition, a 'Research' section on the website provided details of relevant recent peer-reviewed publications in transfusion and cardiac surgery, anaemia management and red cell transfusion avoidance, transfusion practice in orthopaedics, the cost of blood and transfusion risks.

The site has proved to be popular and well supported, with over 3000 visits from 59 countries; Australia and the United States account for the largest groups. The success of the project will assist in informing future change management strategies in light of the new focus of the National Health and Medical Research Council guidelines.

The website was promoted by the development of posters that challenged common views about transfusions.



The 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 and midwives, and courier or porter staff that transport blood products. The eLearning tool has been successfully used in South Australia, and other states and territories have expressed considerable interest. During 2008 a total of 10 176 registrations were received, of which 97.7 per cent were from professionals working throughout Australia. The registration rate continues to be strong. The nursing profession is the most prevalent user of the program. Nationally, the completion rate for local participants is about 65 per cent.

During 2008–09 the NBA worked with South Australia Health to develop governance arrangements to enable this tool to become sustainable nationally. A steering committee has been established, with membership from the states and territories, the NBA, the Australian Red Cross Blood Service and the Australian and New Zealand Society of Blood Transfusion. The steering committee developed recommendations for consideration by the JBC at its meeting in May 2009 and a three-year project has now been agreed to expand the use of the tool nationally.

The Graduate Certificate in Transfusion Practice

In February 2009 the NBA obtained approval from the JBC 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 in the 2010 academic year. The course, developed, owned and managed by the Victorian Department of Human Services, is the only formal transfusion-specific tertiary qualification especially intended for transfusion improvement among practitioners working in Australasia. It is available online and has been completed by students from other states and territories.

Redevelopment of the course will enable the inclusion of emerging transfusion patient safety and quality requirements, and alignment with the role of a transfusion nurse or practitioner; it also provides an opportunity for Victoria to incorporate national input into the curriculum's content. To this end the NBA participated in a national workshop in April 2009. The workshop discussed every aspect of the course and its materials in the context of the evolving roles of transfusion nurses and practitioners, with the express intention of translating national best-practice guidelines into everyday transfusion practice.

The program has now been accredited by the Academic Board of the University of Melbourne, which provides academic input to the program's development and delivery. This accreditation will result in a co-branded qualification from the Australian Red Cross Blood Service and the Victorian Department of Human Services. The course is administered by the School of Nursing and will continue to be delivered in partnership with the ARCBS under the auspices of the 'Blood Matters: better, safer transfusion program' with the objective of increased national uptake.

Patient Blood Management

'Patient blood management' is defined as a 'multidisciplinary team approach to the appropriate use of blood products, utilising techniques that minimise blood loss and avoid unnecessary transfusions by optimising a patient's anaemia tolerance and red cell mass'[1,2].

There is growing interest in and commitment to advancing the principles of appropriate blood use. This was clearly evident at the November 2008 National Blood Sector Conference, at which a number of presentations variously described the Western Australian blood management program, the American experience in blood management, and the importance of anaemia management. Appropriate patient blood management techniques are increasingly being assessed as being better for the patient and—importantly in the current economic environment—for hospitals and state and territory health systems. It is also clear that a whole-of-institution approach is essential to implementing and maintaining an effective blood management system.

During 2008–09 the NBA organised presentations to the Jurisdictional Blood Committee on a number of aspects of patient blood management, and in February 2009 the JBC endorsed a National Patient Blood Management Program. The NBA has begun the first phase of the work program, focusing on the establishment of appropriate governance arrangements to create national leadership, and conducting research into:

- anaemia management, to be achieved via a national 'think tank'
- enablers and barriers to appropriate use, with emphasis on:
  - iron products, both oral and intravenous
  - peri-operative cell salvage
  - autologous donations
  - cross-matching incentives
- linkages between standards, training and qualifications and employment for specific roles in the sector.

1 Hannon T. 'Blood management issues and opportunities'. http://bloodmanagement.com/blood-emanagement-learning-system/blood-management-issues-opportunities.html.

2 Trovarelli T, Kahn B, Vernon S. Transfusion-free surgery is a treatment plan for all patients. AORN J 1998 Nov;68(5):773–8, 780–4. Abstract only via http://www.ncbi.nlm.nih.gov/pubmed.

The Blood Measures project

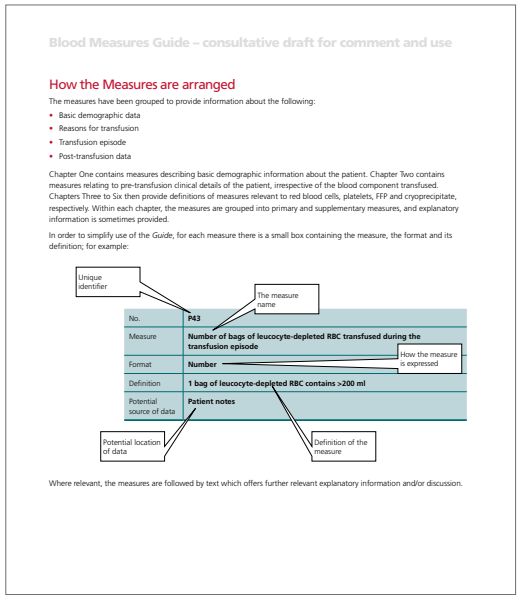
The Blood Measures project is a collaboration between the NBA and the ARCBS and addresses the current difficulty in obtaining good quality data on the clinical effectiveness and use of blood components. Although there have been a number of separate initiatives to investigate the use of blood components within Australia, comparison between these studies is problematic due to the differences in data types, definitions and methodologies. The project aims to achieve widespread adoption of standard parameters that are indicators of blood-related use across a range of clinical scenarios.

A Steering Committee chaired by Professor James Isbister commissioned the Department of Epidemiology and Preventive Medicine at Monash University to undertake a desktop review of a range of indicators of blood product use in Australia and internationally. A National Working Group was convened, comprising clinicians in a range of disciplines and other stakeholders such as nurses, transfusion scientists, epidemiologists and hospital administrators.

The National Blood Measures Working Group has now developed a draft national guide containing suggested standard measures and data definitions that can be used in any study of transfusion practice. Where possible, the measures are epidemiologically sound—that is, the data are routinely collected, routinely accessible and can be consistently interpreted.

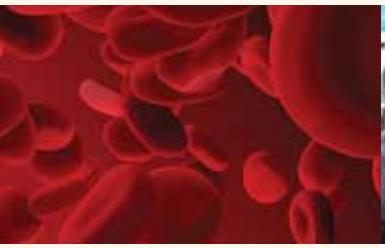
The draft guide became available on the NBA website in June 2009 in order to obtain further input from blood sector-specific stakeholders. The NBA will work in accordance with the national health data governance framework in finalising the standardised set of blood measures.

The Blood Measures Guide



A sample measure

CASE STUDY
THE BLOOD MEASURES GUIDE

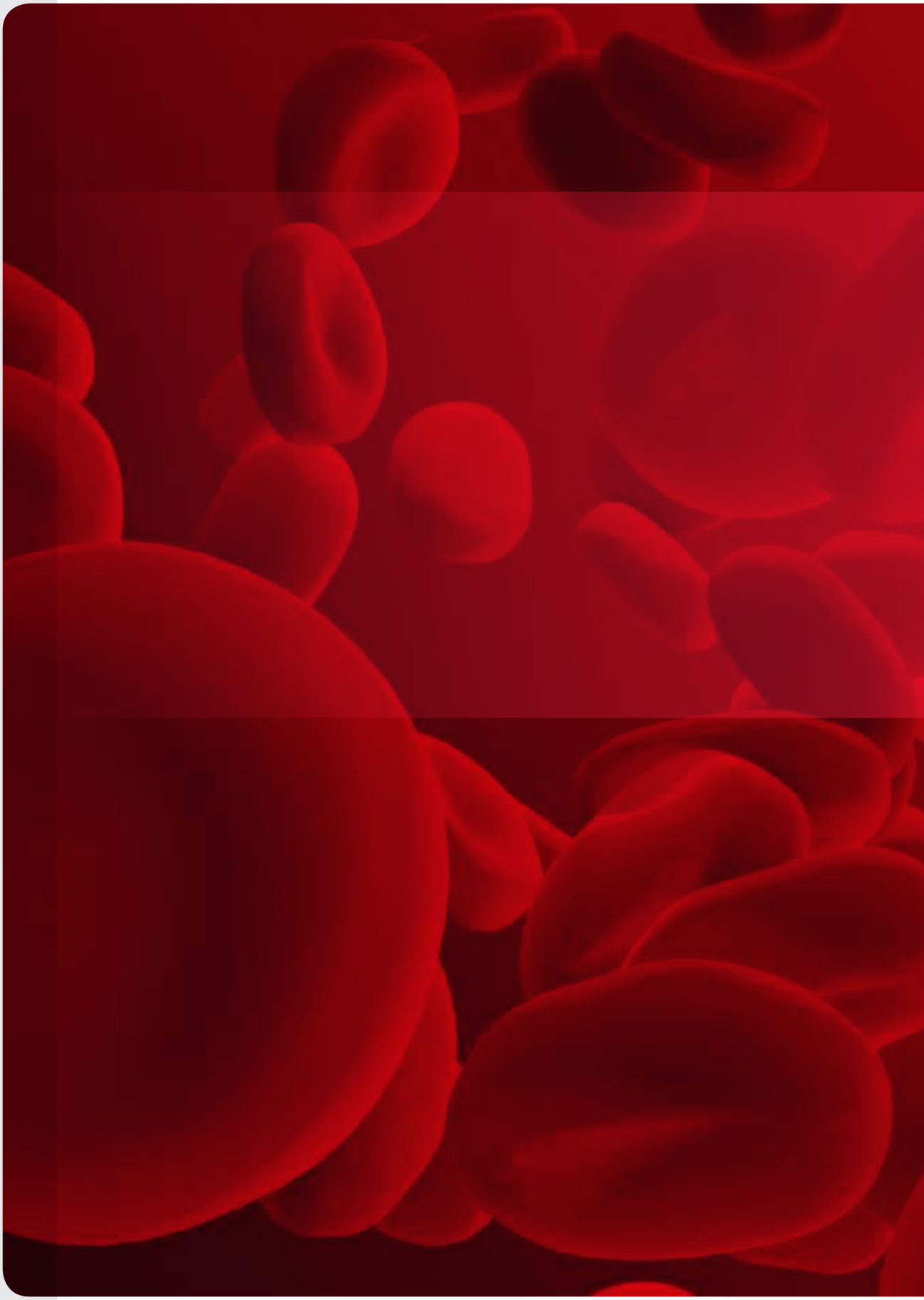


The aim of the *Consultative draft guide to the set of standard indicators for use in measuring fresh blood components in Australia* is to provide a tool that can be used by those investigating the use of fresh blood components. It contains a nationally agreed set of standard measures that can be used in any investigation of blood or blood component use. Perhaps surprisingly, this is the first time such a guide has been prepared anywhere in the world.

The Blood Measures project focuses on the patient end of the blood supply chain, providing advice on the collection of reliable, accessible, consistently interpreted and objective data on the use of fresh blood components. An easily accessible set of standard measures that can be used for any data collection project would be useful throughout the health sector, and we hope that this guide will be used by clinicians, nurses, auditors, transfusion scientists and researchers.

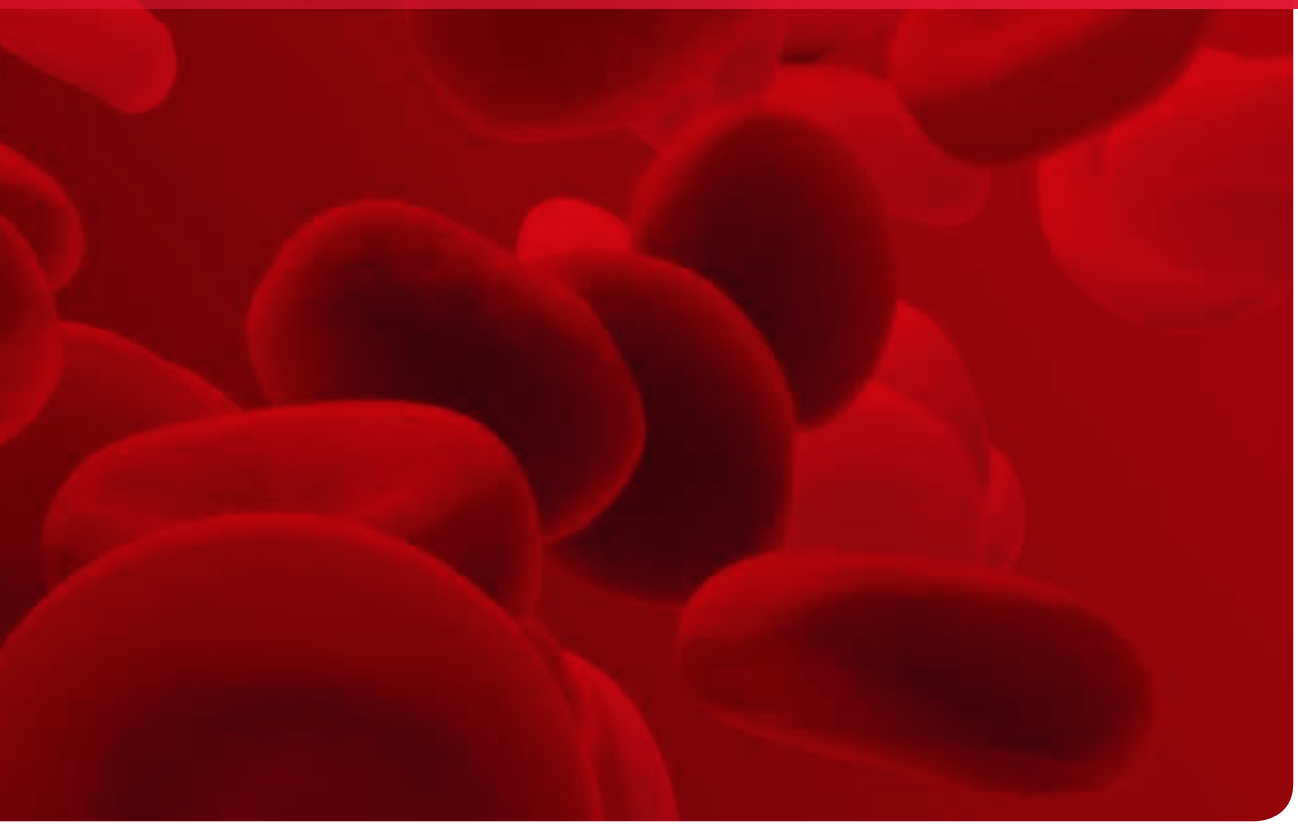
The National Working Group developed the guide during 2008–09 and the NBA is grateful for members' valuable contribution. There was wide-ranging consultation about the importance of measures, their definitions and how they should be expressed.

The resulting draft guide was uploaded onto the NBA website at the end of June 2009. Although use is voluntary, we hope the guide will be widely used and the measures given a thorough trial. Users are encouraged to comment on which measures work well, which need further refinement, which are irrelevant, and which might be missing. The NBA will consider all the feedback in consultation with the National Working Group and then re-publish the guide.



PART THREE.
FUTURE TRENDS AND HORIZON SCANNING

PART THREE DESCRIBES EXTERNAL INFLUENCES THAT COULD AFFECT THE WAY THE NBA DOES BUSINESS IN THE FUTURE. IT DESCRIBES 2008–09 CHANGES TO OUR EXTERNAL ENVIRONMENT, IDENTIFIES FACTORS THAT MAY AFFECT GLOBAL SUPPLY, DEMAND AND PRICING, AND NOTES A RANGE OF INTERNATIONAL TRENDS IN REGULATORY AND BLOOD-RELATED PRACTICE.



3.1 INTRODUCTION

Under the *National Blood Authority Act 2003* the National Blood Authority is required to liaise with and gather information from governments, suppliers and others about matters relating to blood products and services.

This function supports two of government's secondary objectives under clause 2 of the National Blood Agreement:

- to monitor the national and international environment in which the Australian blood sector operates for new technological, clinical, risk or other developments that might affect the national blood supply
- to undertake national information gathering, monitoring of new developments and reporting and research in relation to the Australian blood sector.

The rationale for the function is that the NBA and our suppliers operate in a global environment in which we access Australian and global product and technology markets to meet Australia's clinical need for safe and effective products. In addition, our population's health status is influenced by changing global health patterns. As a result, the monitoring of our external environment identifies factors—including emerging risks, new product developments, international trends in regulatory and blood practice, and market developments—that can have an impact on global supply, demand and pricing.

To ensure that this function was being fulfilled in accordance with the expectations of government, the NBA reported in its 2007–08 annual report that it had embarked on a review of new technologies, new techniques and new products. The review confirmed the need for the NBA to be more active in this area.

The NBA has therefore continued to monitor local and international markets to ensure that governments are well advised of developments, pressures and opportunities that could affect the strategies adopted to assure supply, maintain safety, ensure appropriate use, manage costs and monitor available alternatives.

Focus of horizon scanning

With this context in mind, the NBA monitors:

- emerging risks to the blood supply
- information that might influence global supply, demand and pricing—such as changes in company structure, capacity, organisation and ownership
- potential new product and technological developments and applications
- global regulatory trends.

The following pages offer a selection of matters of interest that were tracked in 2008–09 and commentary on the potential implications of these matters for the Australian blood sector. This report also provides some indication of the time frame in which issues may become of relevance for policy consideration.

3.2 FRESH BLOOD

2008–09 saw rapid changes in the spread and nature of transmissible diseases, including transfusion-transmissible infections, and major advancements in testing and manufacturing processes.

3.2.1 Transmissible diseases

A core focus of horizon scanning has been changes in the community infection rates of transmissible diseases, including transfusion-transmissible infections. Any upsurge in community infection—bacterial, viral or parasitic—has the capacity to increase the risk from fresh blood components unless risk-mitigation measures, such as increasing deferrals of blood donors, are introduced. Increased donor deferrals can contribute to a shortage of blood and blood components. Red cell donations from people with any of the diseases identified in the following sections cannot be used since the infectious agents in question reside only in the cellular components of blood. However, plasma from such donors remains a very valuable resource: the fractionation process is known to destroy such viruses if present in the plasma component of the donation.

Mosquito-borne diseases

Dengue

During the Australian summer in 2008–09 blood supplies in Far North and North Queensland were seriously affected by a regional epidemic of dengue fever, the worst for some time, as shown in Table 3.1

TABLE 3.1 Notifications of dengue virus infection by year by jurisdiction, 1999–2008 and year to date 2009

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	AUST
1999	2	0	31	61	7	0	0	18	119
2000	1	1	94	85	7	0	4	7	199
2001	11	0	43	42	7	2	6	15	126
2002	3	16	32	81	8	1	11	18	170
2003	7	68	21	725	9	1	13	17	861
2004	6	30	19	274	4	1	10	7	351
2005	2	48	14	116	5	0	15	20	220
2006	6	51	21	77	11	0	5	16	187
2007	2	80	16	119	23	3	16	54	313
2008	6	154	23	232	31	6	8	98	558
2009	9	96	21	985	10	2	20	96	1239

Source: National Notifiable Diseases Surveillance System. DOHA website

Dengue fever has been a major challenge in many parts of the world in recent months, and our own region—for example, Indonesia, Singapore and Malaysia—has increased its activity in mosquito control. A number of research programs around the world have been aimed at devising affordable and easily portable equipment that will attract and destroy mosquitoes. One team has successfully halved the lifespan of the *Aedes aegypti* mosquito by introducing the *Wolbachia* bacterium into the laboratory population. The bacterium spreads through the population, being passed on by female mosquitoes.

Interestingly, many companies are now aiming to produce a commercial dengue vaccine, among them Sanofi Pasteur, Vical and Novartis. Central to much of this work is a focus on a vaccine that is effective against all four strains of the virus and on a drug to combat the associated fever.

Although the blood supply situation was manageable, with products being supplied from other areas of Australia, the affected region could become much larger in future seasons.

Chikungunya

Countries in our region have also been coping with another mosquito-borne disease, chikungunya virus infection, which is characterised by an acute febrile phase that lasts for two to three days and is followed by prolonged arthralgic disease that affects the extremities. The pain associated with the virus persists for weeks or months, in some cases, years. The virus is not endemic to Australia at this time, but a small number of travellers do return home with it. It has, however, emerged in areas that were previously free of the virus. For example, chikungunya has infected people in northern Italy and in swampland near the France–Belgium border. International experts are concerned about the potential arrival in Europe of the Asian tiger mosquito, which could spread chikungunya more widely. This increased spread is largely attributed to unusually warm, damp weather in Europe.

Many companies are working to develop a vaccine against chikungunya, among them TopInstitute Pharma, which has formed a consortium with Wageningen University Medical Centre and Nobilon (a subsidiary of Schering–Plough) to develop a 'proof of concept' vaccine. In addition, trials on the genetically modified mosquito engineered by researchers at the University of Oxford—to control dengue and chikungunya—have begun at a laboratory near Chennai, India.

Malaria

Malaria is a parasitic infection, that includes a blood phase, transmitted by bites from mosquitoes. Increased travel has led to malaria being identified more widely internationally. Researchers are using an array of strategies to combat its further spread, including:

- fungal pathogens to limit the lifespan of malaria vectors
- biopesticides, as illustrated by the Walter Reed Army Institute of Research model, which kills the mosquito within a few days of its taking the bait, and also kills the malaria
- chemicals to destroy the mosquito larvae
- chemical compounds developed at Monash University that effectively switch off the malarial parasite's digestive enzyme
- vaccines developed by GlaxoSmithKline to boost the immune response.

Murray Valley encephalitis and Ross River virus

The Murray Valley encephalitis and Ross River viruses now occur in areas well beyond their original range, and both were reported in the Northern Territory and the north of Western Australia during the summer of 2008–09.

The NBA will continue to monitor developments and is working towards the development of models to better predict the impact of these and other viruses on the long-term availability of suitable blood donations.

Influenza

Each winter seasonal flu reduces the supply of blood and blood components through donor deferral, due either to sickness or to caring responsibilities, and the Australian Red Cross Blood Service is well versed in adjusting collection volumes and locations to best meet continued demand. The late and protracted flu season, from July to October in 2008, contributed to an ongoing shortage of red cells during the period, which necessitated activation of the National Blood Supply Contingency Plan.

In a pandemic a much larger proportion of the population is likely to be affected—swiftly, simultaneously and possibly more severely—and the NBA's pandemic flu planning clearly identifies the potential for this to lead to major problems in supply. Accordingly, our research in 2008–09 not only focussed on monitoring flu patterns internationally and the impact of the pandemic (H1N1) 2009, but also on the developments that could support prevention of infection through effective vaccination and developments in the capacity to treat infection quickly and successfully.

Pandemic (H1N1) 2009

At the onset of winter 2009 national attention was strongly focused on the impact of the pandemic (H1N1) 2009 ('swine flu'). Jurisdictions' efforts in attempting to prevent the virus from spreading—with testing, home quarantine and the issue of anti-viral drugs—have provided a good foundation for further modelling the impact of this and other flu pandemics on the blood supply. This will also provide useful data to inform future inventory risk management models.

Research to be undertaken through the National Health and Medical Research Council has commenced: the results, expected to be reported by December 2009, will be vitally important to future planning.

There has been intense competition between drug makers to create a commercially viable vaccine against pandemic (H1N1) 2009. The first such vaccines are, according to the World Health Organisation, likely to be approved and ready for sale after September 2009.

The increase in rapidly developed vaccines has led to some interesting innovations in the sector, including:

- growing vaccines in cells rather than eggs
- a new technology that strings together amino acids to form peptides chemically, not biologically. The peptides are designed to stimulate the body's production of immune cells against specific threats, such as influenza
- fusion-protein vaccines that insert genes for two key proteins into *E. coli* bacteria, prompting the bacteria to churn out the fusion protein that goes into the vaccine.

These technologies are important because they provide a glimpse of the changes in the time frames in the future in which intensive product management might be required for blood supplies in the event of a pandemic.

Seasonal flu

The recent emphasis on pandemic (H1N1) 2009 vaccine has not diminished the need for producing seasonal flu vaccine, although there was some discussion of whether pandemic (H1N1) 2009 vaccine could be added to the coverage of the seasonal flu vaccine. CSL Ltd expects to double shipments of its seasonal flu vaccine in 2009–10 after the vaccine sold out in US pre-season orders. CSL Ltd may generate $A102 million in sales of its Alfuria flu shot in 2009–10, exporting as many as nine million doses of the vaccine, the US military being expected to be a major buyer.

When the H1N1 2009 virus was notified as a pandemic, governments around the world relied heavily on Tamiflu, the leading relevant antiviral drug. Yet in the previous winter in the United States, the most widely circulating seasonal flu strain exhibited resistance to Tamiflu. Relenza, a powder that must be inhaled, also remained effective against the strain, but it is not recommended for children younger than seven years. The US Centers for Disease Control and Prevention recommended that doctors treat children with seasonal flu with a combination of Tamiflu and an older drug, Flumadine, to which the strain is not resistant. The emergence of a widely circulating strain that resisted Tamiflu highlighted the vulnerability of the world's small stock of antivirals and provides yet another scenario for modelling purposes.

H5N1 avian influenza virus

Both domestic and wild bird flocks around the world continue to become infected with bird flu. Most countries destroy diseased flocks. In Egypt, where there is no compensation for destroyed flocks, the reporting level is low and transmission to humans is significant, as is the number of deaths, although lower than in places such as Indonesia and Vietnam. Infectious diseases experts have expressed concern that a recent spike in human H5N1 avian influenza cases in China appears to have occurred in the absence of the hallmark of nearby poultry outbreaks, a development that could signal asymptomatic infections in birds.

Concern at a possible avian flu pandemic has led to the commercial development of a number of vaccines that it is hoped will be relevant to the prevailing strain. The US Food and Drug Administration has cleared for marketing a new, more rapid test for the detection of influenza A/H5N1, a disease-causing subtype of avian influenza A. The AVantage A/H5N1 Flu Test detects influenza A/H5N1 in throat or nose swab samples.

Two distinct teams of scientists announced they had found an antibody with affinity for both seasonal flu virus and the H5N1 pandemic flu strains. This discovery was suggested as leading to new treatments and possibly a universal flu vaccine.

Variant Creutzfeldt–Jacob disease

During the reporting year the Spanish Government confirmed Spain's fifth fatality from vCJD.

In the United Kingdom, the Health Protection Agency reported that vCJD prions had been identified at post-mortem in the spleen of a haemophilia patient. The patient was aged over 70, and had died of an unrelated condition. He had been treated with UK-sourced clotting factors prior to 1999.

Australia remains free of vCJD due to a high level of vigilance in our animal and food product trade. In response to the UK case, the Transmissible Spongiform Encephalopathy Advisory Committee assessed the risks to the blood sector of the reported situation and confirmed there was no need for any change in current policies. The policies in place, including donor deferral if the donor had lived in the United Kingdom for more than six months between 1 January 1980 and 31 December 1996, and adoption of the use of recombinant products for frequent users of clotting factors, plus prion clearance standards for Therapeutic Goods Administration registered products, provide a strong framework for protection against this disease.

During 2008–09 the NBA provided detailed comments on Australia's draft response to the vCJD Plan. The plan now allows for the transfer of information to, and the involvement of, the blood sector in tracking and assessing the potential impact of any confirmed case of vCJD on the blood supply.

Tuberculosis

Tuberculosis is a major cause of illness and death worldwide but, despite 14.4 million prevalent cases, 9.2 million new cases and 1.7 million deaths in 2006, the small and rapidly declining burden of disease in the seven major markets has limited drug and vaccine development activities until recently. Drug developers and research foundations are trialling several novel vaccines and therapeutic strategies for prevention and treatment of tuberculosis.

3.2.2 Testing and manufacturing

Developments in testing and manufacturing processes are of major interest because they are often designed to lead to increased safety for the recipients of blood products. One of the challenges for blood sectors worldwide, however, is to ensure that increases in the safety profiles of products outweigh the often very large costs of moving to new technology and in determining an appropriate time frame for the implementation. Development of the multi-criteria analysis framework for assessing proposals submitted under Schedule 4 of the National Blood Agreement will present an opportunity for governments to make an informed examination of the benefits and costs of such innovations.

There were many potentially relevant developments in testing and manufacturing in 2008–09; the areas of pathogen inactivation and viral detection provide examples.

Pathogen inactivation

Foremost among innovations globally during 2008–09 are the changes in, and the increasing uptake of, pathogen inactivation technologies for fresh blood components. These include:

- Cerus Corporation's INTERCEPT Blood System, which provides for pathogen inactivation of plasma and, increasingly, platelet concentrates, was adopted by a growing number of countries in the reporting year. Further innovations led to the approval in Europe of a single treatment procedure producing two pathogen-inactivated platelet units for transfusion. The supplier claims this will lower blood centre costs.
- In the case of Caridian BCT's Mirasol pathogen reduction technology, which uses riboflavin (vitamin B2) and ultraviolet light to reduce the levels of infectious pathogens and inactivate white cells, their current European approval has been extended from platelet concentrates to also include plasma for transfusion.

At present Australia uses testing and donor deferral rather than pathogen inactivation. These strategies have been very effective in reducing the risk of transfusion-transmitted diseases, but are principally effective against known pathogens, as opposed to currently unknown infectious agents. The developments in pathogen inactivation technology raise the possibility of increasing pressure to consider the move to this new approach to reducing the risk of transfusion-transmitted diseases. This could have significant impact on the overall cost of manufacturing and processing of blood products.

Viral detection

Technology to test for viral infection in blood using improved assays also changed during the reporting year:

- Chiron, a Novartis business, is funding the development of Gen-Probe's PANTHER instrument, a fully automated molecular testing platform, for the blood screening market. The US Food and Drug Administration approved use of the Procleix Ultrio assay to screen donated blood for the hepatitis B virus. This means the assay is now approved to screen donated blood, plasma, organs and tissue for three viruses—hepatitis B, hepatitis C and HIV-1—in individual blood donations or in pools of up to 16 blood samples.
- Amorfix Life Sciences has tested 10 000 blood donations in France using its EP-vCJD test as part of a large-scale study aimed at demonstrating the feasibility of routine testing of blood donations for variant Creutzfeldt–Jacob prions. The NBA is monitoring this testing capability very closely in order to understand its costs compared with emerging technology to filter each donation for the vCJD prions.
- The US Food and Drug Administration issued draft guidance for industry on the use of serological tests to reduce the risk of transmission of *Trypanosoma cruzi* (Chagas disease) infection in whole blood and blood components for transfusion, and human cells, tissues, and cellular and tissue-based products. Medecins Sans Frontieres reports that Chagas is endemic in several Latin American countries but worldwide migration means that more and more cases are being reported in the United States, Europe, Australia, and Japan. This disease has to date posed a major challenge for blood services because there was no suitable test. If the spread of the disease continues, the cost and effectiveness of these tests could become of increasing interest to the blood sector in Australia.

Synthetic blood products and oxygen carriers

During the reporting year work on oxygen carriers has been against the backdrop of a 2008 United States analysis of studies of five different blood-substitute products. The analysis suggested that, as a class, the products were linked to relatively high rates of death and myocardial infarction.

Possible future extensions to the blood supply

The prospective use of stem cells as the basis for extending the supply of blood and blood products is controversial, and there are a number of projects under way overseas. While research is progressing, the core question is scalability, so it is unlikely that these activities could contribute to the blood supply in the short term. The following are examples of this research in 2008–09:

- Cellular Dynamics International, which is focused on industrialising stem cell technology, expects, among other activities, to produce red cells for transfusion.
- Researchers at US company Advanced Cell Technology claim they have refined the technique to produce billions of synthetic red cells from embryonic stem cells in the test tube. However, donated blood contains a higher concentration of red cells.
- Researchers are attempting to secure funds and the legal permission required for developing surplus IVF embryo stem cells. The key to the three-year trial is developing a stem cell line coded for functional synthetic O Rd(D) negative blood. O Rh(D) negative blood is found in less than nine percent of the Australian population but is usually compatible in all people, no matter their blood type. A successful line could be commercially scaled to produce unlimited supplies of disease-free, compatible blood for emergency transfusions.
- In February 2009 French researchers began enrolling subjects in the first human clinical trial of stem cell-derived red cells to examine the life span of these cells in humans and see how that life span compares with the 120 days that a normal red cell lasts and the approximate 30-day life span of a transfused donor red cell.
- Researchers have identified a signalling pathway that helps regulate the movement of blood-forming stem cells in the body. This could lead to improvements in the efficiency of bone marrow transplants.
- After much debate, Canada is expected to decide in 2009 whether to support a jointly financed first phase of a Canadian public cord blood bank to store a domestic supply.

3.2.3 Blood management techniques

Internationally there is increasing interest in the scope for reducing the need for red cell transfusions through the more targeted use of a range of blood and blood products and through the use of other products and techniques. The National Health and Medical Research Council guidelines that are being redeveloped will provide a detailed assessment of the current evidence and make recommendations for immediate adoption in Australia.

Patient safety

The NBA produced the initial national haemovigilance report for Australia in February 2008. The first haemovigilance tracking capacity in the United States was announced during 2008–09. At the same time the European Haemovigilance Network decided to change its focus to reflect a broader scope of engagement; it is now known as the International Haemovigilance Network (IHN) to ensure increased engagement by blood services and government agencies in its agenda. The NBA's Principal Medical Officer attends network meetings on behalf of the Australian program. International developments should provide valuable benchmarking data and further stimulate the collection, analysis and understanding of adverse events arising from, or associated with, blood transfusions.

3.3 PLASMA PRODUCTS

During 2008–09, the NBA closely monitored product developments, particularly alternative uses of plasma products and changes in plasma market structure. In particular, research on treatment regimes using IVIg have potential for a major impact on our blood sector.

3.3.1 New plasma-derived products

The rate of development of innovations based on both human plasma-derived and recombinant products continues apace. The developments have the potential to change clinical practice and improve patient safety, but at the same time they bring increased costs. Understanding these developments is central to Australia being well placed in the timing and design of tenders and in contract negotiations. The following are some of the most significant product developments that emerged in 2008–09:

- new immunoglobulin products—including those administered subcutaneously
- an intravenous fibrinogen concentrate produced by CSL Ltd
- an anthrax immunoglobulin produced by Talecris Biotherapeutics Inc
- a rabies human monoclonal antibody product by Dutch company Crucell with Sanofi Pasteur as its commercial partner and a synthetic anti-rabies immunoglobulin, which is being developed by US and South Korean interests
- plasmin (human) to treat acute peripheral arterial occlusion, being developed by Talecris Biotherapeutics
- the development of 'follow-on biologics'
- Halozyme Therapeutics, along with Baxter Healthcare Corporation, starting a Phase III clinical trial of the latter's Gammagard Liquid for the treatment of primary immunodeficiency. The key benefit of this product, if approved, is that patients could receive a full monthly dose in a single injection site in their home setting
- Baxter presenting data suggesting it can make antibody therapy more convenient for patients with primary immunodeficiency by subcutaneous delivery using an enzyme to disperse the antibodies in the appropriate phase
- French group LFB announcing the availability for humans of its first two therapeutic monoclonal antibodies. One is an anti-Rh(D) product. The company has also filed a biological licence application for a new-generation multivalent human immunoglobulin. LFB's new nano-filtered fibrinogen is also likely to gain marketing authorisation later in 2009.

3.3.2 Substitutes for plasma products

Alternatives to plasma products are being developed for a number of conditions. These advances are crucial to a full and informed understanding of future likely demand trends and include the following:

- Two new drugs have become available to boost platelet production—electrombopag (trade name Promacta or Revolade) and romiplostim (trade name NPlate). In Australia around 7 per cent of current intravenous immunoglobulin use is in treating chronic immune thrombocytopenic purpura. In the United States this use accounts for around 15 per cent of IVIg use.
- Studies suggest that a new vaccine from Sanofi blocks about half of primary cytomegalovirus infection in young women, which could ultimately reduce the need for CMV immunoglobulin to prevent health problems in newborns.
- Work is also occurring overseas on anti-Rh(D) products. If this is successful, it could ultimately reduce the need for Rh(D) immunoglobulin. Danish company Symphogen, for instance, is interested in an anti-Rh(D) recombinant polyclonal antibody.

3.3.3 Developments in intravenous immunoglobulin

In 2008–09 IVIg accounted for 20 per cent of the total spend by governments in Australia on blood and blood products and used 380.5 tonnes of plasma collected by the Australian Red Cross Blood Service. This tonnage was supplemented by the importation of 27.5 per cent of total IVIg demand. Demand has grown by 10–14 per cent per annum in the past six years. Accordingly, any changes in the development and use of IVIg can potentially have a large impact on Australia's blood budget and on the pressures in the system for collection of plasma.

There was initial concern during the reporting year that global demand for IVIg would outstrip supply and cause significant price increases. The possible global supply shortage has, however, been mitigated in the short term by the current economic downturn in the United States, which has increased the number of donors wanting to donate plasma and receive financial compensation. Meanwhile, the pressure on demand has been slightly eased by the development of alternative treatments for some conditions.

The recent comparative stability in IVIg prices could disappear if the current major trial of its use in treating Alzheimer's disease produces a positive result. Baxter Healthcare Corporation announced a Phase III clinical trial following a US Food and Drug Administration review of its investigational new drug application to evaluate Gammagard Liquid[3] (IVIg) for treatment of mild to moderate Alzheimer's disease. It is a prospective, 18-month, randomised, double-blind, placebo-controlled, two dose-arm parallel study of 360 subjects, from both genders and aged 50 to 89 years, with dementia severity ranging from mild to moderate.

There is concern that a successful outcome for this study could have major implications for IVIg demand, adequacy of supply and price. In Australia, for instance, between 1998 and 2007 the number of deaths from dementia and Alzheimer's disease more than doubled—from 2.6 to 5.3 per cent of all deaths. There is therefore strong interest in Australia and internationally in other Alzheimer's treatments, not based on plasma, which are being developed and trialled.

3 Marketed as Kiovig in the European Union

Amongst drugs of interest are Pfizer/ Medivation's Dimebon, Elan/Wyeth's bapineuzumab, and Eli Lilly's solanezumab. The NBA is closely monitoring these developments and others to ensure potential impacts on the IVIg markets are fully understood.

An additional pressure may arise from the publication in April 2009 by Talecris Biotherapeutics, of health-related quality-of-life results from the largest clinical trial ever conducted in patients with chronic inflammatory demyelinating polyneuropathy. The data demonstrate that long-term treatment with Gamunex (immune globulin intravenous (human), 10 per cent caprylate/ chromatography purified) improves and maintains health-related quality of life in patients with the condition, which affects two to seven individuals per 100 000 worldwide, and can occur at any age and in both genders, although it is more common in young adults and in men. It is the top user of IVIg in Australia (see Figure 2.21).

3.3.4 New recombinant products

Developments in recombinant products offer great scope for replacement of plasma-derived products and therefore for improving the sustainability of the sector. Many companies are working to develop products; the following paragraphs summarise a selection of developments.

Transgenic products

A significant development during the reporting year was the approval for use in both Europe and the United States of the first product from transgenic animals:

- GTC Biotherapeutics, in partnership with LFB Biotechnologies, developed ATryn(R), a recombinant human antithrombin produced from the milk of transgenic goats and used in patients with a hereditary deficiency.
- GTC Biotherapeutics has also entered into a collaboration with New Zealand-based AgResearch Ltd to develop transgenic founder animals that produce bio-similar monoclonal antibodies. AgResearch will establish transgenic founder production lines, mainly funded by a grant from the New Zealand Government.
- GTC Biotherapeutics, again in collaboration with LFB Biotechnologies and using its transgenic production platform, is also developing recombinant human coagulation Factors VIIa and IX.

Factors VIII, IX and VIIa

Other companies are working to develop a recombinant Factor IX to compete with Wyeth's Benefix in what is currently a monopolistic market or to develop Factor VIIa products to compete with Novo Nordisk's Novo Seven:

- In mid-2008 Bayer acquired Maxygen's haemophilia program assets, including a next-generation recombinant Factor VIIa protein known as MAXY-VII. Bayer's goal is to market this next-generation Factor VIIa product in 2012.
- Avid Bioservices has been developing its Factor VIIa candidate, CB 813.
- Inspiration Biopharmaceuticals announced the initiation of a Phase 1 clinical trial of IB1001, an intravenous (IV) recombinant Factor IX product for control and prevention of haemorrhagic episodes in patients with haemophilia B.
- Baxter Healthcare Corporation has acquired rights to Avigen's early-stage blood coagulation compound, intended as an oral treatment for bleeding disorders such as haemophilia A. If the promise of pre-clinical studies is realised this could be a stand-alone treatment or an adjunct to treatment with Factor VIII or Factor IX concentrates.

Other products

- CSL Ltd, Talecris and GlaxoSmithKline have individually signed agreements with DSM Biologics and Crucell to develop protein therapeutics on their PER.C6(R) platform. This allows large-scale manufacture of recombinant proteins including monoclonal antibodies.
- ProFibrix BV has a commercial licence agreement with Crucell for PER.C6(R), its human protein production platform. The company's lead product, Fibrocaps, is based on fibrinogen derived from human blood plasma and is a dry powder topical haemostat that stops acute and severe bleeding during surgery or after trauma injury. The company is planning to develop recombinant fibrinogen for systemic applications in haemostasis and later on for the development of tissue repair products.
- A recombinant human polyclonal antibody is being developed for future prevention of haemolytic disease of the newborn, which can occur in Rh(D) negative mothers carrying an Rh(D) positive foetus. Currently in Australia this is managed using Rh(D) immunoglobulin.
- Wyeth has produced an albumin-free version of its recombinant Factor VIII, ReFacto. It intends to phase out supply of the original ReFacto.
- Origen Therapeutics of California and Genavia Therapeutics of Auckland announced an agreement granting Genavia access to Origen's transgenic technology for the production of therapeutic proteins in the whites of chicken eggs. Genavia will initially apply the avian transgenic technology to produce human Factor VIII.
- Stem Cell Innovations announced in Houston that its C3A human liver cell line is capable of producing bio-similar serum proteins for follow-on biologics and has stated that Factors VIII and IX are its first target indications.
- Amgen announced that the European Commission has granted marketing authorisation for Nplate(R) (romiplostim) for the treatment of splenectomised adult chronic immune (idiopathic) thrombocytopenic purpura patients who are refractory to other treatments (for example, corticosteroids and immunoglobulins).

3.3.5 Plasma market structure

Sales and profits in the plasma products industry have largely withstood the depressing effect of the global financial crisis. Growth and changes in the plasma market were intense during the reporting year. In summary:

- CSL Ltd bid $US3.1 billion for Talecris Biotherapeutics. The private equity companies that owned Talecris agreed with the bid, but it was opposed by the US Federal Trade Commission on the grounds that the combination of the second- and third-largest operators in the US plasma products business would reduce competition and adversely affect consumers. CSL withdrew its interest and in August 2008 decided to return $A1.59 billion of the $2 billion it raised from shareholders to fund the deal.
- Speculation continues as to who will purchase Talecris or whether in the strong market conditions for plasma products it will return to earlier plans for a public offering of shares.
- Biotest Pharmaceuticals (formerly the biologics unit at Nabi Parmaceuticals) has been expanding its plasma plant in Florida to increase production of its hepatitis treatment, Nabi HB.

- Biotest AG, headquartered in Germany, has expressed a desire to expand in the United States and might also be interested in acquiring some or all of Talecris's assets. At present 73 per cent of group sales are outside Germany. Biotest has broadened its basis for future growth by signing a further cooperation agreement with the Belgian organisation CAF-DCF.
- Grifols, headquartered in Spain, has been expanding production capacity significantly in the United States and announced it expected a 50 per cent rise in its plasma production by 2013. Its new IVIg production facility in Los Angeles will represent $US135 million of the $US600 million long-range investment plans announced in October 2007. Grifols inducted its first class of students into the Grifols Academy of Plasmapheresis in Glendale, Arizona. Adjacent to a fully operational plasma donor facility, the site will serve as the company's central location for employee education, training and development.
- Octapharma has been increasing its ownership of US collection facilities.
- China Biologic Products gained control of plasma products company Qianfeng Biological Products Co. Ltd. This makes China Biologic the country's largest non-state owned enterprise in the plasma products sector. It now accounts for 14.3 per cent of the Chinese market.

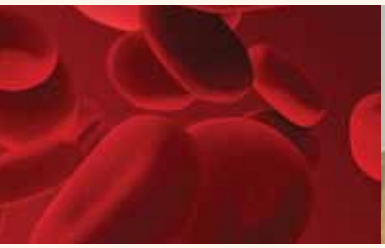
To better understand how to deal with these market changes the NBA instigated the collaboration of National Plasma Product Supply Planners. The first meeting of the group was held in March 2009.

3.4 THE REGULATORY ENVIRONMENT

In addition to the continual upgrade of manufacturing requirements and standards that affect the sector, several company decisions were of note during 2008–09:

- In the United States Roche is reported to have resigned from the Pharmaceutical Research and Manufacturers Association and signed up to the biotechnology regulator, the Biotech Industry Organisation.
- In the United Kingdom Roche has decided not to renew its membership of the Association of the British Pharmaceutical Industry, putting a question mark over the viability of self-regulation in the United Kingdom.
  - While the Medicines and Healthcare Products Regulatory Agency possesses the legal power to take pharmaceutical groups to court for any wrongdoing, it is generally the Association's Prescription Medicines Code of Practice Authority that deals out penalties to its member companies.
  - Roche had its membership suspended for six months until February 2009 for breaching the Association's Code of Practice. The company says its time away from the Association gave it the opportunity to 'reflect upon the nature' of its relationship with the trade body. Roche says it remains committed to working within the bounds of the Association's Code of Practice.
- the US Federal Trade Commission released a report, entitled *Follow-on biologic drug competition*, that examines whether the price of products manufactured using living tissues and micro-organisms could be reduced by competition from so-called follow-on biologics, having a price impact similar to that of generic drugs. No pathway currently exists for follow-on-biologics to enter the market and compete with their pioneer counterparts. The Commission's report concludes that giving the Food and Drug Administration the authority to approve follow-on-biologics would be an efficient way to bring these lower priced drugs to market.

CASE STUDY
THE COLLABORATION OF NATIONAL PLASMA PRODUCT SUPPLY PLANNERS



In early 2008, after informal discussions between several representatives of national agencies, an idea developed to establish an informal collaboration of national agencies that have oversight responsibility for plasma products, particularly from an appropriate use, purchasing and/or supply planning perspective.

In June 2008 a few interested agencies took the opportunity to hold scoping meetings in the margins of international conferences, and the idea quickly developed into the Collaboration of National Plasma Product Supply Planners, or NPPSpa. In order to progress the group, the NBA undertook the role of secretariat to coordinate the inaugural meeting, to be held in Paris during March 2009.

The NBA's General Manager chaired the inaugural meeting, which was attended by representatives of member agencies—from Canada, Finland, Italy, New Zealand and Australia. The agenda included confirmation of the terms of reference, a brief presentation by each member outlining their agency's role, and extensive opportunity for members to discuss topics of interest—including self-sufficiency, the fate of surplus products, trends and issues in IVIg use, and approaches to new product listing. In addition, several invited suppliers made presentations to members on the topic of 'Innovation in process technologies'. The 2010 meeting will be hosted by Italy, with the NBA providing both the chair and secretariat support.

One of the key capabilities of the NBA is the expertise gained through good international networks that provide information about what similar organisations are doing overseas. We hope that other national agencies facing similar challenges will consider participating in NPPSpa: it is proving to be an excellent and cost-effective way of learning about the latest thinking in organisations with similar mandates.

3.5 INQUIRIES AND LEGAL ACTIONS

During 2008–09 the Archer Report was released in the United Kingdom. It examines the use of contaminated blood products in the National Health Service during the 1970s and 1980s, which led to the spread of HIV, hepatitis and other blood-borne diseases. The report says the National Health Service purchased blood products such as Factor VIII from US suppliers that obtained blood from prison inmates and other high-risk groups. The report concludes that 'Commercial priorities should never again override the interests of public health' and suggests that ministers might apologise to survivors and their families and that the government should provide compensation payments and no-cost health care for survivors. The report does not propose that criminal charges be brought.

In Scotland Lord Penrose is chairing a public inquiry into the deaths in 2003 of two people who contracted hepatitis C and HIV through National Health Service blood products. At the inquiry's opening session in March 2009, Lord Penrose said it would not be possible to find individuals or institutions legally liable, in either a criminal or a civil sense, although he noted it was possible his report would contain criticisms of 'individuals, groups, agencies and institutions'.

A US judge has ruled that a claim by Taiwanese haemophiliacs may be heard in the United States. The claim concerns HIV-contaminated anti-haemophilia factor concentrate allegedly exported from the United States. Previously haemophiliacs in Argentina, Israel and the United Kingdom were not able to have their claims heard in the United States, but the judge ruled that the circumstances of the Taiwan cases differed sufficiently to justify continuing their suits.

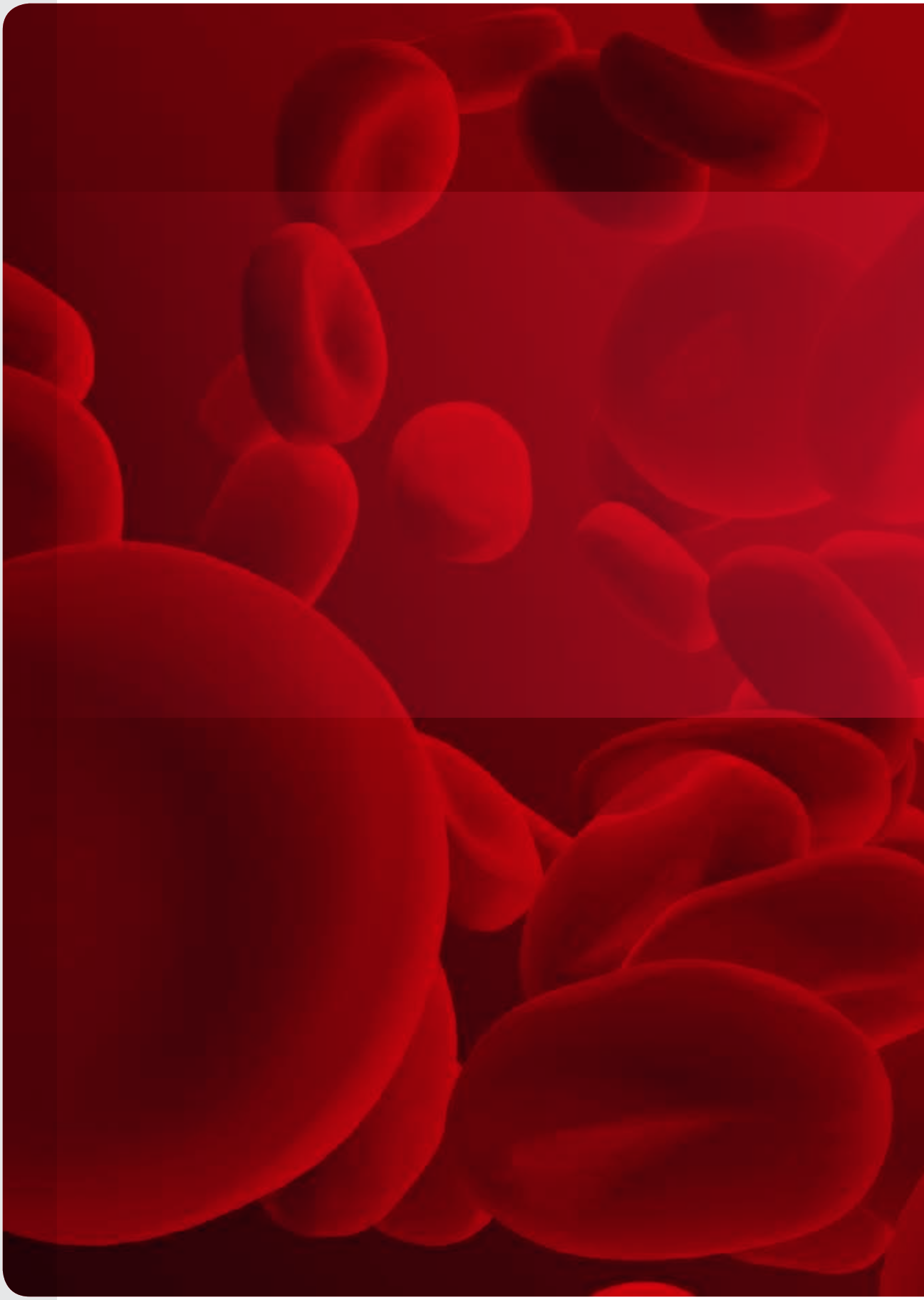
These inquires provide a reminder of the need for intense discipline in the collection, manufacturing and distribution of blood and blood products. Australia was one of the first countries in the world to implement effective testing of blood donors for HIV (in 1985) and hepatitis C (in 1990), and is well served by the Therapeutic Goods Administration's continuing oversight of the requirements for good manufacturing practice and licensing in the blood sector. The Senate Community Affairs Committee conducted an inquiry on 'Hepatitis C and the Blood Supply in Australia' in 2004.

3.6 CONCLUSION

Table 3.2 summarises the developments identified in Part 3 and shows the likely time frames in which these matters will need to be considered in a formal manner by the Jurisdictional Blood Committee and governments for their policy implications.

TABLE 3.2 *Potential of impacts and time frames of technological developments: a summary*

ISSUE	POTENTIAL FOR IMPACT	LIKELY TIME FRAME
Transmissible diseases	High	Immediate and ongoing
Testing and manufacturing	High	Medium to long
Blood management techniques	Medium	Medium to long
Patient safety	Low	Short to medium
New products	High	Short to medium
IVIg developments	High	Medium to long
Development of substitutes for plasma-derived products	Medium	Medium to long
New recombinant products	Medium	Medium
Market structure	Low	Medium
Research	Medium	Medium
Inquiries and legal action	Low	Medium



PART FOUR.
OUR MANAGEMENT

PART FOUR 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.

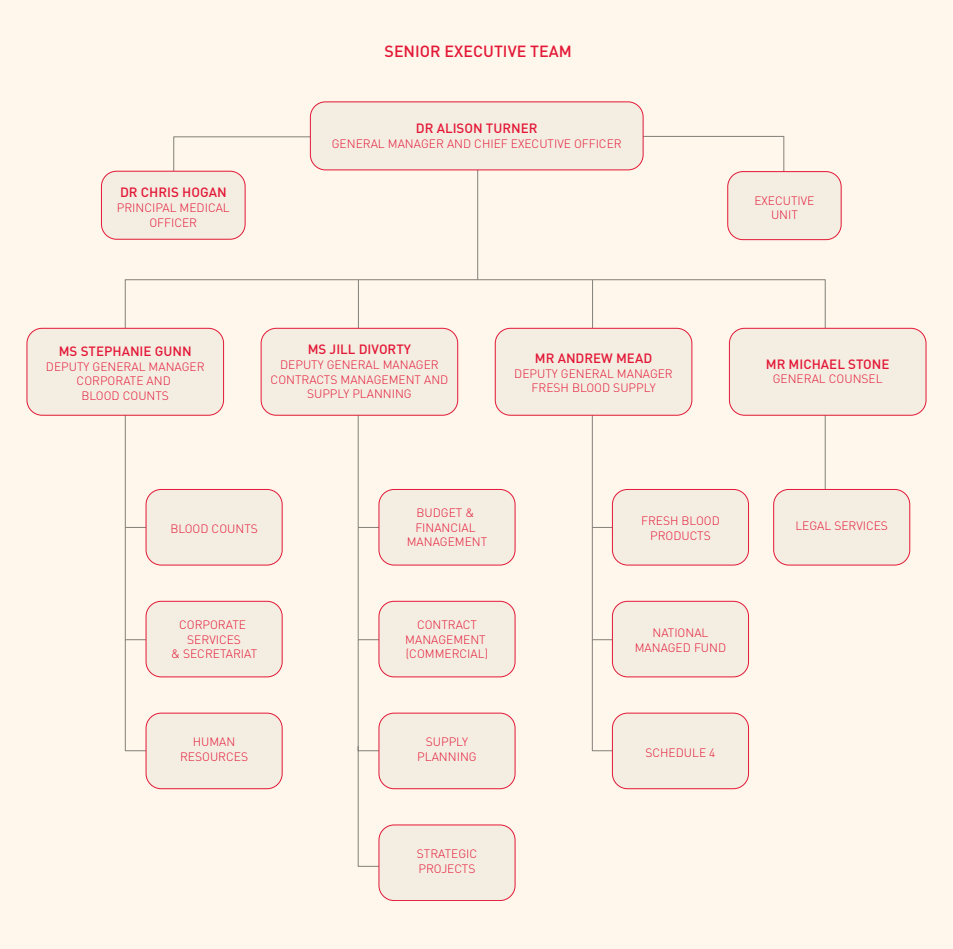
4.1 CORPORATE GOVERNANCE

At 30 June 2009 the executive management of the National Blood Authority comprised the following staff:

- General Manager and Chief Executive Officer, Dr Alison Turner
- General Counsel, Mr Michael Stone
- Deputy General Manager, Contract Management and Supply Planning, Ms Jill Divorty
- Deputy General Manager, Corporate and Blood Counts, Ms Stephanie Gunn
- Principal Medical Officer, Dr Chris Hogan
- Deputy General Manager, Fresh Blood Supply, Mr Andrew Mead.

Figure 4.1 shows the NBA's organisational structure.

FIGURE 4.1 *NBA's Organisational structure*



Staff celebrating NBA's 5th birthday.

Senior Executive Service

Mr Michael Stone is the NBA's General Counsel. He 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.

Mr Stone practised for eight years with the Australian Government Solicitor, including as an outposted in-house lawyer for a number of clients. He joined the Legal Services Branch of the Department of Health and Ageing to work on a range of significant 'blood' matters—including development of the National Blood Agreement and establishment of the NBA.

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

Ms Jill Divorty oversees the establishment and management of commercial contracts and supply planning for plasma-derived and recombinant blood products. She is the Relationship Manager for the commercial suppliers, among them CSL Ltd, Baxter Healthcare Pty Ltd, Octapharma Australia Pty Ltd, Novo Nordisk Pharmaceuticals Pty Ltd and Wyeth Australia Pty Ltd.

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

Ms Divorty joined the NBA in August 2008, replacing Mr Leigh McJames, who took leave from the NBA at that time and resigned on 1 July 2009.

Ms Stephanie Gunn is the NBA's Corporate and Blood Counts Manager and provides leadership to NBA projects driving appropriateness of use. 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, and 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 Contract and Relationship Manager for Fresh Blood Supply-Australian Red Cross Blood Service. 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. Previous positions held include 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 tertiary referral and regional and rural hospitals. He has also held academic appointments at Charles Stuart University in health management and paediatrics, including the delivery of health service management development programs in Indonesia.

Mr Mead joined the NBA in July 2008, replacing Mr Gordon Lee Koo, who left the NBA in May 2008.

Audit Committee Chair

Ms Jennifer Morison FCA, FCPA, FAIM, is the chair of the Audit Committee. She is a chartered accountant with 27 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 Commonwealth 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.

Governance structure

The NBA has three formal governance committees. During 2008–09 a number of changes were made to the governance framework to increase the focus of the NBA executive on planning for and managing core strategic projects and stakeholder concerns. These changes were implemented progressively during 2009 with particular focus on:

- maintenance of 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 concepts and ideas for continual improvement.

The 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. The Committee meets three times a month. During 2008–09 the Committee:

- provided leadership and strategic direction for the NBA, particularly in the management of stakeholder issues
- considered options and took decisions on operational planning, resource allocation and prioritisation
- determined priorities for policy and program directions, human resources and corporate strategy, performance improvement, organisational change, and maintenance of the Australian Public Service Code of Conduct
- monitored and devised strategies to maintain momentum in performance improvement and organisational change programs
- guided the development of NBA corporate and operational plans
- signed off on external reports and documentation—for example, the corporate plan and the annual report—before consideration by external approving bodies.

The Executive Managers Committee

The Executive Managers Committee is designed to focus on performance reporting and improvement and meets monthly. It is responsible for:

- ensuring that all areas of the NBA are adequately monitored so that the necessary elements of the governance framework and related processes are in place
- ensuring that all areas of the NBA are operating effectively
- pro-actively managing operational risks and issues
- effectively progressing priorities within agreed resources.

The Audit Committee

The role of the Audit Committee is to provide expert advice to the General Manager on the need for, and strategies to enhance, the organisation's control framework, to improve the objectivity and reliability of externally published financial information, and to comply with legislative requirements and obligations. The Committee met six times in 2008–09, and its membership was:

- an independent Chair, Ms Jennifer Morison
- two NBA board members, Mr David Kalisch (until May 2009) and Mr Ken Barker
- an independent member, Mr Mick Roche.

Representatives from the Australian National Audit Office and the NBA's internal auditors also attend as observers for most matters.

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

Risk management

Effective implementation of our governance framework is integral to the NBA's overall planning and risk management framework. Figure 4.2 shows the process used to determine and monitor risks and operational activities.

FIGURE 4.2 *How the NBA manages risk*

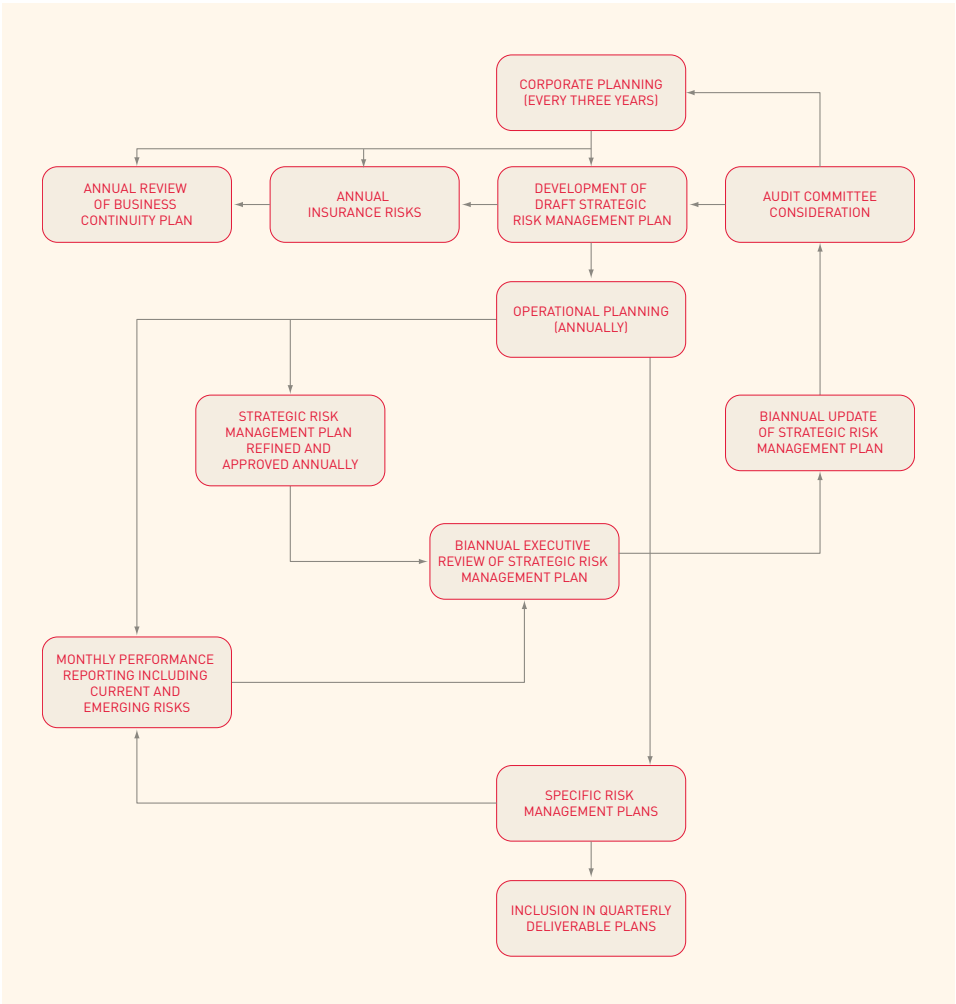


TABLE 4.1 *Major risks to the NBA and remedial action taken, 2008–09.*

RISK DESCRIPTION	ACTIONS IMPLEMENTED
Suboptimal outcomes for the blood sector due to lack of integration with the wider health sector	– NBSCP integrated with health emergency planning and response capabilities – Integration of coding and standards relevant to the blood sector with those used and being developed for the wider health sector – Use of MBS and PBS criteria for assessment of blood sector proposals
Failure to use NBA internal capacities and processes to ensure an efficient organisation that can maintain capacity, skills and knowledge, even when staff depart	– Implementation of the NBA's capability strategy, including the staff capability survey, knowledge retention processes and changes to our recruitment strategy
Inability to ensure supply of fresh blood products due to poor contract negotiation or contract management	– Variation to the Deed with ARCBS agreed to allow development of output-based funding model – Improved regular inventory reporting
Inability to ensure supply of fresh blood components due to default or corporate failure by the Australian Red Cross Blood Service	– Third party review of ARCBS governance arrangements completed – Planning framework between NBA and ARCBS agreed
Potential infection due to a new blood-borne disease	– Horizon scanning maintained and shared with ARCBS
Inadequate resources to perform NBA legislative functions	– Rollover of unexpended revenue approved – Corporate plan unchanged until priorities agreed through the review of the arrangements – Stakeholder consultations undertaken and restructure implemented to target priorities as they stand now
Inability to meet financial liabilities	– In budgeting for operational expenditure in future years, the NBA ensures that there are sufficient financial assets (that is, cash and receivables) to meet financial liabilities (that is, creditors, and so on) and all employee entitlements – Under the National Blood Agreement, all jurisdictions have agreed to meet appropriate shares of any expenses incurred by the NBA
Inability to ensure supply of plasma-derived and recombinant products due to poor contract negotiation or contract management	– Contracts negotiated in a timely manner
Serious non-compliance with government procurement arrangements (breach of the *Financial Management and Accountability Act 1997*)	– Appointment of new internal auditors – Training in the Chief Executive Instructions for all staff and other mandatory forums for staff
NBA or officers' actions or inactions lead to criminal or civil charges	– Regular program of mandated training in procurement and APS Code of Conduct
Inadequate IT systems or support for work of NBA	– Implementation of a restructure to increase resources and effort in this area

This framework integrates risk considerations into all planning activities and ensures:

- annual development of the Strategic Risk Management Plan—assessed against corporate plan objectives and specific annual priorities
- six-monthly review of the Strategic Risk Management Plan by the Executive Managers Committee
- development of detailed actions within the annual operational plan to address core risks
- monthly reporting to the Executive Managers Committee against the operational plan and status of core risks
- regular reporting to the NBA Board against the operational plan and the status of core risks.

The major risks to the NBA, against which actions were implemented during the year are summarised in Table 4.1.

Participation in the 2009 Comcover Risk Management Benchmarking Program has resulted in an increase in our benchmarked score from 6.7 out of a possible 10 in 2008 to 7.2 in 2009. This score retains the NBA at the level of 'comprehensive', which indicates a high level of competency in implementing an enterprise-wide risk management framework. The remaining key area identified by the survey for improvement in 2009–10 is monitoring and review.

The comprehensiveness of our approach to business continuity planning was acknowledged though multiple references to our practices in the latest Australian National Audit Office *Business continuity plan best practice guide*.

Internal audit

A key element of ensuring appropriate risk management is the NBA's internal audit program, guided by the Audit Committee. In 2008–09 the agreed program of audits focused on reviewing and analysing performance against key operational and financial risks, including payroll and leave management and procurement processes for non-blood goods and services. The negative findings resulting from these internal audits were minimal and were addressed by minor refinements to the NBA's key business processes. During the reporting year the Audit Committee focused on exploring the adequacy of mechanisms to ensure compliance with relevant legislation and regulatory requirements. A number of presentations on our internal monitoring and assessment processes were provided to the Audit Committee, and a new checklist was developed and will now be reported on at regular intervals.

The Audit Committee accepted that the proposed 2007–10 Internal Audit Plan 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 for three years. The internal auditor will commence work in mid-July 2009 by undertaking a risk threat assessment.

There was sound progress with the Audit Committee's work program during 2008–09. Activities included:

- review and recommendation to the Chief Executive for the 2007–08 financial statements
- review and recommendation to the Chief Executive for the certificate of compliance
- provision of advice on key business process procedures
- review and advice on the financial management risk plan
- provision of advice on financial management and the fraud control plan.

The fraud control plan

The Audit Committee provided valuable advice on the implementation of the fraud control plan. Key initiatives included:

- a revised fraud risk assessment of the NBA's security arrangements, including IT, personnel and physical security, and subsequent recommendations
- establishment of an online flex and leave recording system.

The NBA's legal counsel Michael Stone.

The existing contract for fraud control services expired in early 2008, requiring the NBA to undertake a procurement exercise for fraud risk assessment and training services for the next three years. This assessment resulted in the development of a new fraud control plan, as required by the Commonwealth guidelines on fraud control.

The findings of the 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. From this assessment and as a result of our continual monitoring of accountability and control frameworks, the NBA has met the specific needs of the agency and complies with the Commonwealth Fraud Control Guidelines.

No instances of fraud were detected during the reporting year.

Relationship with external auditors

The NBA acknowledges the assistance provided by its external auditors, the Australian National Audit Office, in 2008–09. This enabled the NBA to provide assurance of compliance and appropriate accountability and to identify scope for continual improvement in our activities.

External scrutiny

There was no formal external scrutiny of the NBA in 2008–09.

4.2 PLANNING AND SERVICE DELIVERY

Performance of the 2008–09 Operational Plan

The reporting year was a very successful one for the NBA, with 95 per cent of activities delivered to the planned outcomes. This compares with 81 per cent in 2007–08.

For the four outstanding items, progress was made, although not in accord with our planned time frames. Three of these items relate to IT data-gathering projects. Capability to improve performance in this area will be strengthened through the restructure implemented from 6 July 2009. Work is underway on the final item, which relates to the development of indemnification guidelines by the National Indemnity Reference Group for the National Managed Fund.

The 2009–10 Operational Plan

Finalisation of our 2009–10 operational plan was delayed until July 2009 to allow the new teams formed on 6 July to consider the plan and for the NBA Board to provide comments at its meeting in late July. It is expected that the 2009–10 operational plan will continue our focus on professional contract management at the same time as increasing our effort in relation to sector systems and data capture and analysis.

Corporate

The Jurisdictional Blood Committee secretariat

During 2008–09 the NBA provided secretariat services for four face-to-face meetings and five teleconferences of the JBC. Key performance indicators set by the NBA relate to the quality and timeliness of support provided. Table 4.2 shows how the NBA performed against these indicators.

TABLE 4.2 NBA Performance indicators for Jurisdictional Blood Committee support, 2008–09

MEETING	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
28 August 2008	100	94.8
20 November 2008	100	93.3
19 February 2009	95 (one late paper)	97.1
6 April 2009	100	50
15 May 2009	94 (one late paper)	100
5 June 2009	100	80

Papers for the teleconferences held on 17 September 2008, 20 March 2009 and 1 June 2009 were not prepared by the NBA, and hence no statistics are included for these meetings.

Secretariat services were also provided to the NBA Board, which met three times in Canberra and once in Adelaide during 2008–09. The Adelaide meeting was the first meeting of the NBA and the ARCBS Boards.

Information communication and technology

The development of SMS broadcast functionality and a secure online portal for the National Blood Supply Contingency Plan has been completed. Feedback so far has been very positive. These projects are significantly enhancing the NBA's capacity to respond if the National Blood Supply Contingency Plan is activated.

A Jurisdictional Blood Committee portal has also been established and was launched at the May meeting of the JBC. Work on the establishment of a NBA Board portal is under way. These initiatives will allow JBC members access to all meeting papers and minutes (including historical papers) in an electronically searchable and secure environment at any time and ensure productivity improvements in the secretariat team.

The 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, which was developed in early 2007.

During the reporting year the NBA received 16 feedback responses. Of these, two clarified issues; the remainder were positive. The feedback received was wide-ranging, from reactions to the Blood Sector Conference to interactions with stakeholders. The NBA addressed any issues in line with the Charter's requirements.

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

4.3 PEOPLE MANAGEMENT

Staffing profile

The total number of staff employed in the NBA fell from 52 in 2007–08 to 44 at the end of June 2009. These changes were implemented at the EL1 and APS 6 levels. The reduction in staffing numbers has necessitated a redesign of a number of functions and a remodelling of our internal service delivery models. The changes were implemented as part of our process of ensuring that we are allocating our resources to best meet the needs of stakeholders. Table 4.3 shows NBA staff numbers, by classification, at 30 June 2009

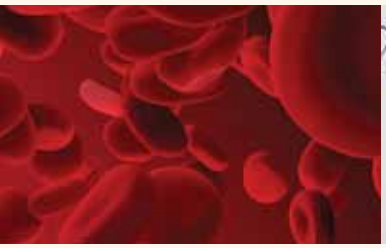
TABLE 4.3 Number of NBA staff at 30 June 2009

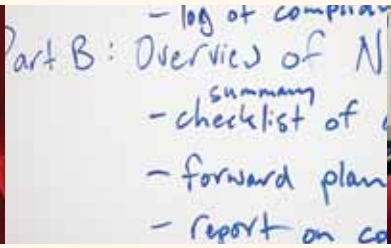
SUBSTANTIVE ROLE CLASSIFICATION	FEMALE (FULL TIME)	FEMALE (PART TIME)	MALE (FULL TIME)	MALE (PART TIME)	TOTAL
Statutory office holder	1				1
Senior Executive Service	2		2		4
Health Economist		1			1
Principal Medical Officer				1	1
EL 2	4		3		7
EL Legal					0
APS 6 Legal					0
EL 1	8		10		18
APS 6	5		1		6
APS 5	2	1			3
APS 4	2	1			3
APS 3					0
Total	24	3	16	1	44

Workforce planning, staff turnover and retention

Staff turnover in 2008–09 significantly reduced from previous years to just 16 per cent. This is an important achievement for the NBA since staff loss was previously a risk. The average length of service for NBA staff is now 2.7 years. More than 61 per cent of our staff have now been with the NBA for more than two years. Within this stable staff profile we are fortunate to have a diverse range of skills, experience and backgrounds. To illustrate the diversity of the age, experience and knowledge of our staff, this 2008–09 annual report sees the commencement of a series of profiles on our staff. We hope you will enjoy getting to know us.

STAFF PROFILE
SUSAN BAMBRICK





Emeritus Professor Susan Bambrick is one of our most distinguished staff members. She is the NBA's research analyst, undertaking horizon scanning, locating new products and identifying trends.

An economist with experience in many areas of her discipline, she graduated from the University of Queensland after honours studies in public finance and international economics. Her PhD is from the Research School of Social Sciences at The Australian National University, with a thesis on Australian price indexes. At ANU she taught micro-economics, macro-economics, resource economics, international economics, and industrial organisation. Many of her publications have been on the subject of industry economics. She was awarded an OBE 'for service to education, particularly in the field of mineral and energy economics'. Cambridge University Press selected her to edit the Cambridge Encyclopaedia of Australia.

Susan was awarded the first Australian Scholar-in-Residence to the United States, headquartered at Pennsylvania State University and with extended visits to Harvard, the University of Texas at Austin and the University of Oregon. She has also been a Visiting Fellow at the East–West Center, Hawaii. In addition, Susan has served on a number of councils for the Commonwealth—including the Council of the National Library of Australia, the Trade Development Council, the CSIRO Advisory Council and the Uranium Advisory Council. She has served on the Science and Industry Forum of the Australian Academy of Science and has been Federal President of the Australian Institute of Energy. Susan has also worked for the Commonwealth Grants Commission. She is an OzReader for the Australian Research Council and an assessor for the Australian Learning and Teaching Council.

Susan was Pro Vice-Chancellor (Academic and Access) at La Trobe University in Victoria and Deputy Vice-Chancellor (Academic) at the University of Southern Queensland. She has lived and worked in three states and the Australian Capital Territory, in both metropolitan and regional areas and has been appointed to state and territory committees dealing with a range of matters, including restrictive trade practices, regional development and multiculturalism.

She spent several years as President of the Board of Management of the University Pre-School and Child Care Centre at The Australian National University, was Deputy Chair of the Board of Canberra Grammar School and is now a board member of Canberra Girls' Grammar School. She has also served on school boards in Victoria, New South Wales and Queensland.

Susan is a Professor Emeritus of the University of Southern Queensland and an Honorary Fellow (as well as former Master) of University House at The Australian National University.

This stability in our staff profile might to some extent reflect the uncertainty in the wider economy, but it also reflects our recruitment strategy and our commitment to understanding staff preferences for work styles and providing a responsive and reasonably flexible work environment. It also demonstrates our achievements against the capability strategy developed in 2007, which was designed to minimise the impact of staff turnover.

During 2008–09 the NBA conducted two surveys—one to assess current staff skills and capabilities and the other to gauge staff satisfaction.

Understanding skills and capabilities

In March 2006 the NBA conducted a skills and capabilities audit. The analysis from this audit showed that at that time the NBA had a very good level of competency and knowledge in relation to its core business. The main gaps that were reported and were subsequently addressed through targeted training commitments included presentation skills, negotiation skills, ability to understand the physiology of blood, project management, and team building.

To ensure the continued effective targeting of our training efforts, the NBA conducted a new skills survey in late 2008. This survey showed that 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 in further improving their skills in the broader public sector context, such as knowledge of parliamentary processes and accountability arrangements, and training in project management, cause-and-effect analysis, targeted research and demand analysis.

Options for the most cost-effective delivery of this training are being identified, and a detailed program of training will begin early in 2009–10.

Staff satisfaction

In November 2006 the NBA conducted a survey designed to gauge staff's overall job satisfaction and understanding of their work environment and to highlight any areas for improvement. Management also gave a commitment to conduct a further survey in two years' time. Communication, leadership and stakeholder relations were areas in which the majority of staff felt we could improve.

The results of the 2008–09 survey show sound progress against core concerns and have highlight the need to continue to focus on our communication processes and in particular better developing our culture of working across teams effectively.

Strategies to address these issues will be developed by each team, and priorities for action will be agreed with the staff participation forum.

Features of employment tools

Employment tools

Table 4.4 shows the numbers of NBA employees covered by the NBA Collective Agreement (CA), common law agreements or section 24 determinations, and Australian Workplace Agreements (AWA), at 30 June 2009.

TABLE 4.4 Numbers of NBA staff on types of employment agreements

STAFF	CA	AWA	COMMON LAW OR S.24
SES	Nil		7
Non-SES	23	10	4

Collective Agreement salary rates

The second NBA Collective Agreement was signed in October 2007, and staff are due to receive the second pay increase payable under this agreement on 1 July 2009. Table 4.5 shows salary levels at 30 June 2009.

TABLE 4.5 NBA Collective Agreement: 30 June 2009 salary levels

CLASSIFICATION	MINIMUM	MAXIMUM
Executive Level 2	95 743	107 914
Executive Level 1	80 247	91 540
Legal 1	80 250	97 159
Legal APS Level 6	64 212	71 780
APS Level 6	65 302	73 669
APS Level 5	59 195	62 477
APS Level 4	54 424	57 506
APS Level 3	48 036	53 246

Non-salary benefits

The Collective Agreement and other employment frameworks provide a range of non-salary benefits in addition to those consistent with national minimum employment standards. These benefits are commensurate with the NBA's status as a small agency with limited scope for further productivity gains. The benefits that are provided are similar to those provided by many other agencies. They are detailed in the NBA Collective Agreement, available on the NBA website, and can be summarised as follows:

NON-SENIOR EXECUTIVE SERVICE STAFF
– access to the Employee Assistance Program
– maternity and adoption leave
– parental leave
– leave for compassionate purposes
– access to paid leave at half pay
– flex-time (not all officers)
– flexible working arrangements with time off in lieu where appropriate
– access to lap-top computers, dial-in facilities, and mobile phones

– 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
– recognition of travel time
– annual close-down

SENIOR EXECUTIVE SERVICE STAFF AND OTHERS ON AUSTRALIAN WORKPLACE AGREEMENTS, COMMON LAW AGREEMENTS OR S.24 DETERMINATIONS
– all the foregoing benefits except flex-time
– car parking
– airport lounge membership
– vehicle leasing arrangements made available for office duties during work hours or salary in lieu.

Performance pay

Information on performance-based pay awarded during 2008–09 is not included in this report because of the very small number of individuals involved.

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 activities during a year. A wide range of training programs are available to staff so they can extend their knowledge and skills.

The NBA attaches high priority to developing staff in various areas to enhance skills, through either 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:

- Dr E Gorina, Bayer Healthcare Pty Ltd, on Kogenate FS in Haemophilia A—present and future
- Mr Ken Davis, Royal Adelaide Hospital, on blood transfusion—laboratory to patient
- Dr Jan Bult, Plasma Protein Therapeutics Association, on the global plasma fractionation industry
- Professor Ann Gardulf, Karolinska Institute, Sweden, on IVIg treatment at home—advantages of the subcutaneous administration route
- Dr Colin Mackenzie, Trauma Shock Centre, Baltimore, Unites States, about his experience in the trauma centre and using artificial haemoglobin replacement products
- Associate Professor Sean Riminton, Concord Repatriation Hospital, on the role of immunologists and the use of IVIg in immunology
- In addition our Principal Medical Officer, Dr Chris Hogan, made a number of presentations to staff—for example, on haematopoiesis, haemostasis, and the structure and function of red cells.

As in other years, the knowledge forums continue to provide the opportunity for us to ensure that all staff attend a selected range of mandated training sessions. In 2008–09 these included:

- the Australian Public Service Code of Conduct
- fraud awareness
- records management
- security
- business continuity planning
- risk management frameworks.

The effectiveness of this training is assessed through quarterly discussions between staff and managers in relation to their personal development agreements, focusing on the core deliverables that staff must meet to ensure achievement of the goals in the operational plan. A central part of the discussion is to have clear agreement on the support and skills needed by staff members to achieve these goals. At the end of each quarter progress in obtaining the required skills and the relevance and value of the training provided are discussed.

Staff contributions and activities

The NBA Staff Wellbeing Program continued in 2008–09, with staff participating in a range of activities throughout the year, including a cardio fitness class, yoga and a walking club. Staff also contributed to a range of community causes, including:

- morning tea fundraising for the Victorian bushfire appeal, breast cancer awareness and prostate cancer awareness
- the Australian Bureau of Statistics fun run for charity
- The Phillips Fox corporate triathlon
- donating blood to the Australian Red Cross Blood Service, gaining sixth place for government agencies in Canberra.

The NBA fun run tee shirt.

Lunchtime Yoga

4.4 BUDGET AND FINANCIAL MANAGEMENT

This section provides an overview of the NBA's financial management and outcome in 2008–09. 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 2003*, the *Financial Management and Accountability Act 1997*, the *Public Service Act 1999*, and ministerial, parliamentary and financial reporting requirements.

Under the National Blood Agreement, the NBA is funded 63 per cent by the Australian Government and 37 per cent 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 accounts within the Consolidated Revenue Fund for setting aside and recording amounts to be used for specified purposes. Funding received from the Australian, state and territory governments 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 2003*.

The National Managed Fund (Blood and Blood Products) Special Account was established under section 20 of the *Financial Management and Accountability Act 1997*. 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 ARCBS. In addition, interest is received on special account balances.

For budgeting and accounting, the NBA's financial transactions are classified as either departmental or administered revenues or expenses. Departmental activities involve the use of assets, liabilities, revenues and expenses controlled by the agency in its own right—that is, for the operations of the NBA. Administered activities involve the management or oversight by the NBA on behalf of government, of activities and expenses controlled or incurred—mainly through the procurement of the products and services that make up the blood supply.

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.

Members of the NBA's finance team

Table 4.6 below summarises the NBA's revenue and expenditure for 2008–09. The NBA's Agency Resource Statement and Total Resources for Outcome tables are included as Appendix 2.

***TABLE 4.6** Overall funding and expenditure for the NBA, 2008–09: a summary*

	FUNDING INCL. APPROPRIATIONS ($M)	EXPENDITURE ($M)
Departmental—NBA operations	9.854	9.749
Administered—national blood and blood product supply	840.083	793.056

Overview of financial performance in 2008–09

This section provides a summary of the NBA's financial performance for 2008–09. 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 2008–09.

Departmental finances

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

Funding for the NBA over 2005–06 to 2008–09 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 the progress of implementation to slip, resulting in an accumulation of funds not yet spent.

Drawing on these accumulated funds to meet the staffing and other costs of completing these initiatives will result in operating deficits in 2009–10, 2010–11 and 2011–12. These deficits have been approved by the Minister for Finance and Deregulation.

Operating result

The NBA's income statement reports a 2008–09 operating surplus of $0.105 million; this compares with an operating surplus of $1.380 million in 2007–08. Table 4.7 shows the NBA's key results for 2007–08 and 2008–09.

TABLE 4.7 Key results in financial performance, 2008–09 and 2007–08

REVENUE AND EXPENSES	2008–09 ($'000)	2007–08 ($'000)	MOVEMENT (PER CENT)
Contributions from the Australian Government	5 865	5 993	–2
Contributions from states and territories and other revenue	3 989	4 408	–10
Total revenue	**9 854**	**10 401**	**–5**
Employee expenses	6 162	5 826	6
Supplier expenses	2 709	2 621	3
Other expenses	878	574	53
Total expenses	**9 749**	**9 021**	**8**
Operating result	**105**	**1 380**	**–92**

Income statement

Revenue

Total departmental revenue received in 2008–09 amounted to $9.854 million, made up of $5.865 million in funding from the Australian Government, $3.877 million in contributions received from the states and territories and other revenue, and $0.112 million for resources received free of charge. This represents a reduction of $0.547 million (4.9 per cent) on revenue received in 2007–08.

('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 2008–09 amounted to $9.749 million—8 per cent higher than in 2007–08. Almost half the increase was due to higher depreciation and amortisation expenses following the implementation of the internally developed Integrated Data Management System. Increases in employee expenses and supplier costs mainly reflected wage and cost increases and the level of activities carried out by the NBA in the 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 $0.022 million at 30 June 2009. 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 this item is classified as a receivable. The funds represent amounts intended to be used for implementing key IT 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 IT equipment and furniture and fittings.

Payables

The NBA achieved a substantial $1.429 million reduction in payables in 2008–09. This was made up of a reduction in trade creditors, from $0.999 million to $0.381 million, and by accessing funds provided in earlier years for specific activities.

Provisions

Employee provisions, which cover annual and long service leave entitlements, increased by $0.244 million largely because of accrued leave balances brought to the NBA by new staff. Much of the increase was accompanied by offsetting cash receipts to the value of the entitlements which is brought to account as revenue.

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 Australian, 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 2008–09 is presented in Table 4.8. Because funding is provided to meet the cost of supplying blood and blood products, the increase of $129.6 million in funding (19 per cent) mainly reflects the increasing demand for blood and blood products in the year.

TABLE 4.8 *Administered revenue, 2008–09 and 2007–08*

ADMINISTERED REVENUE	2008–09 ($000)	2007–08 ($000)	MOVEMENT (PER CENT)
Funding for supply of blood and blood products	829 190	699 596	19
Total administered revenues	**829 190**	**699 596**	**19**

Expenses

Table 4.9 shows the NBA's administered expenses in 2008–09 and 2007–08.

TABLE 4.9 *Key results of administered expenses, 2007–08 and 2008–09*

ADMINISTERED EXPENSE	2008–09 ($'000)	2007–08 ($'000)	MOVEMENT (PER CENT)
Grants to the private sector—non-profit organisation	433 385	385 029	13
Rendering of goods and services—external entities	356 568	340 749	5
Other	3 103		
Total administered expenses	**793 056**	**725 778**	**9**

Administered expenses for 2008–09 increased by 9 per cent over those for 2007–08. Total payments to commercial suppliers rose by 5 per cent due to increased demand for most products and some price increases; payments to the Australian Red Cross Blood Service have increased by 13 per cent.

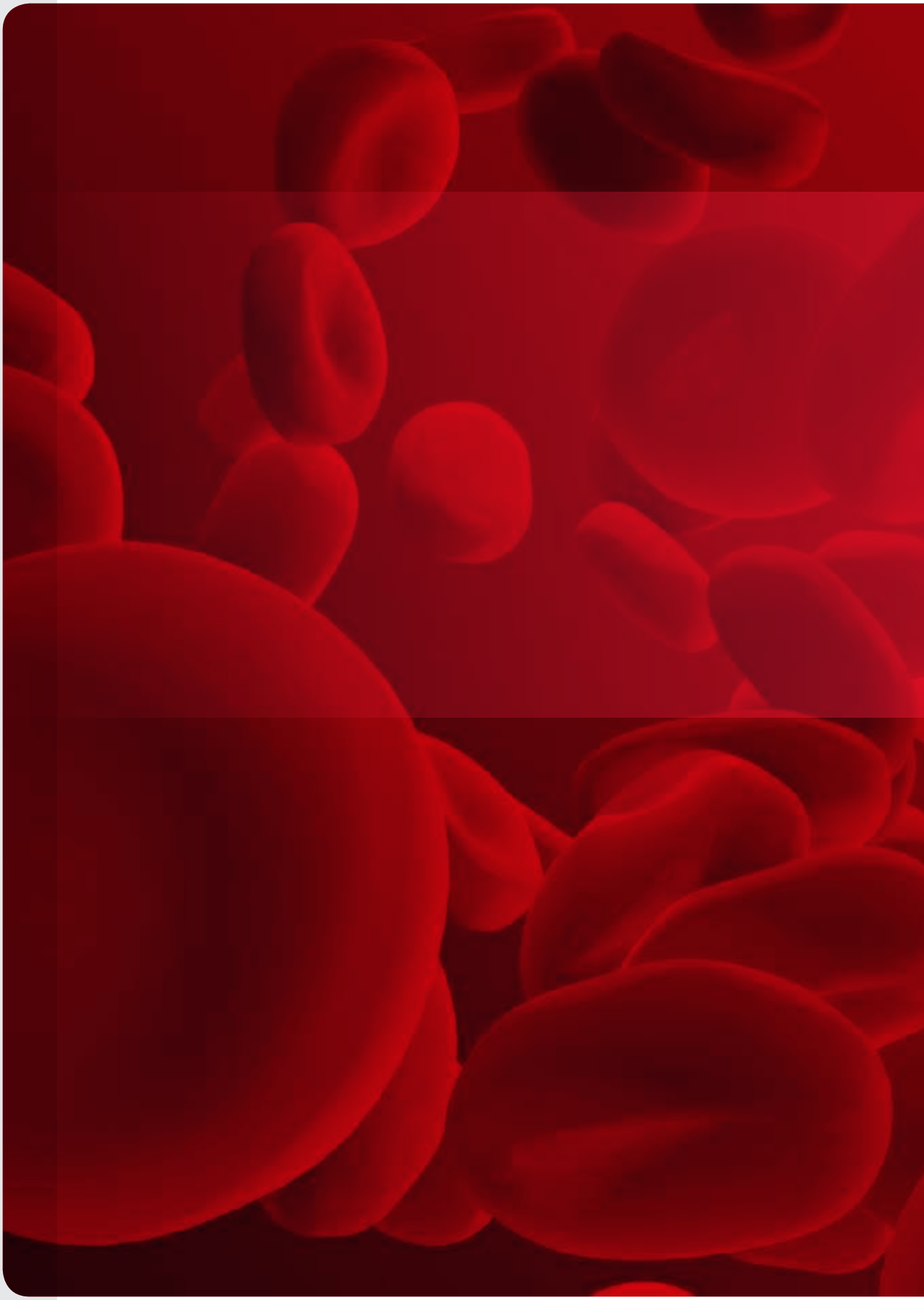
Administered assets and liabilities

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 2008–09.

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



PART FIVE.
OUR ACCOUNTABILITY

PART FIVE SPECIFIES HOW THE NBA COMPLIES WITH A RANGE OF EXTERNAL POLICIES. AMONG THE SUBJECTS COVERED ARE DISABILITY, OCCUPATIONAL HEALTH AND SAFETY, PRODUCTIVITY GAINS, ECOLOGICALLY SUSTAINABLE DEVELOPMENT, AND FREEDOM OF INFORMATION.

5.1 PURCHASING

The National Blood Authority adheres to the principles of the *Commonwealth Procurement Guidelines and Best Practice Guidance* when undertaking procurement. The guidelines are applied to the NBA's activities through chief executive and management instructions and key business processes.

Since one of our primary functions is to procure blood and blood products, the NBA has developed key business processes to ensure that the knowledge and best practices developed within the agency are captured and are available to new staff, and relevant procedures and processes are documented and followed. During 2008–09 the NBA developed and finalised a procurement process to be used by staff when procuring non-blood product goods and services. Over the last three years the internal auditor has completed a number of audit programs that tested this process to ensure that it meets government policy and better practice. The audit findings were consistently favourable in relation to complying with mandatory processes and offered the NBA some improvement opportunities to deliver an optimal process for the future. The findings are being 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's relationship manager for commerical supplies Ms Jill Divorty

The NBA completed several open-source procurements during 2008–09 in line with the annual procurement plan. The key procurements for the year were arrangements for:

- the National Health and Medical Research Council Guidelines Systematic Review
- finance and business advice—CSL Ltd negotiations
- graphic design services
- internal audit services
- fraud risk assessment services
- printing services.

In addition the NBA used extension provisions to extend several current contracts following a value-for-money assessment.

The NBA has outsourced all air travel bookings. As part of our service delivery requirements with our provider, the NBA requires 'best fare of the day' when procuring air travel for all NBA employees. As part of the Australian Government requirements, the NBA is also required to set a minimum smaller airlines use of 25 per cent on the Canberra–Sydney route for officers engaging in official air travel. The NBA achieved 60 per cent in 2008–09.

The NBA did not administer any discretionary grants during 2008–09.

Exempt contracts

The Chief Executive Officer did not issue any exemptions from the required publication of any contract or standing offer in AusTender during 2008–09.

Competitive tendering and contracting

There were no contracts of $100 000 or more (inclusive of GST) let in 2008–09 that did not provide for the Auditor-General to have access to the contractor's premises.

Advertising and market research

Section 311A of the *Commonwealth Electoral Act 1918* requires reporting of 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 2008–09.

Consultants

In 2008–09, 14 new consultancy contracts were entered into, involving total actual expenditure of $849 641 (GST inclusive). In addition, nine ongoing consultancy contracts were active during the year, involving actual expenditure of $147 435 (GST inclusive). Total expenditure on consultancies in 2008–09 was $997 076. 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 at 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 5.1 shows total expenditure on all consultancy services from 2006–07 to 2008–09, covering both new contracts let in the applicable year and ongoing contracts let in previous years.

TABLE 5.1 *Expenditure on consultancy services, 2006–07 to 2008–09*

2006–07		2007–08		2008–09	
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 ($)**
7	582 366	9	1 624 081	14	997 076

Table 5.2 provides details of consultancy contracts by the NBA in 2008–09 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 5.2 *Consultancy services of $10 000 or more, 2008–09*

CONSULTANT NAME	DESCRIPTION	CONTRACT PRICE (GST INCL.)	SELECTION PROCESS	JUSTIFICATION
Workplace Research Associates	For the provision of professional services to conduct a staff survey, prepare reports and relevant recommendations	$26 125	Direct sourcing	A
Cordelta Pty Ltd	For the provision of specialist technical advice to the NBA on system development activities	$66 000	Open tender	B
Workplace Research Associates	For the provision of professional services to conduct a staff skill assessment, prepare reports and relevant recommendations	$24 200	Direct sourcing	A
McGrathNicol Advisory Partnership	Analysis and modelling services related to the negotiation of the new Plasma Products Agreement with CSL Ltd	$166 014	Open tender	A
Walterturnbull Pty Ltd	For the provision of fraud control services	$25 658	Select tender	B
Gaudin Consultancy Limited	For the provision of professional services to provide independent advice on funding models	$66 000	Direct sourcing	A

CONSULTANT NAME	DESCRIPTION	CONTRACT PRICE (GST INCL.)	SELECTION PROCESS	JUSTIFICATION
Bayside Health Service	For the provision of research and investigating services on a barcoding translation device	$112 322	Direct sourcing	A
Logistics Bureau	Review of distribution of blood products	$353 876	Open tender	B
Property Concept & Management Pty Ltd	Independent review for Victoria and Tasmania principal site	$20 372	Select tender	B
Australian Continuous Improvement Group P/L	Services for a third party review	$54 340	Open tender	B
Australian Healthcare Associates Pty Ltd	Business analysis of Haemovigilance	$61 250	Select tender	A
IMS Australia Pty Ltd	Procurement of systematic reviewer	$396 000	Open tender	A

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.

5.2 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.

5.3 THE COMMONWEALTH DISABILITY STRATEGY

The NBA's recruitment and employment practices are consistent with the principles of the Commonwealth Disability Strategy. Our internal staff training incorporates education in and information about the needs of people with disabilities in the workplace through our discussions in relation to the Code of Conduct and harassment and bullying in the workplace. The NBA continues to make the organisation accessible for people with disabilities by:

- ensuring that employment policies and procedures comply with the *Disability Discrimination Act 1992*
- ensuring that managers and recruitment officers apply 'reasonable adjustment' policies
- conducting training and staff development programs that are considerate of the needs of people with disabilities, including providing information on disability issues
- using complaint and grievance mechanisms to address any potential issues raised by staff or the public.

Our commitment to reasonable adjustment is illustrated by the flexible support provided to a staff member who suffered a severe non-work related injury. We developed a detailed return-to-work program with an element of working from home and high flexibility in working hours, and provided technology assistance such as a headset and wireless phone for use at home for work-related activities. We maintained engagement with the staff member throughout the period of disability, including receiving regular updates on the progress of projects.

5.4 OCCUPATIONAL HEALTH AND SAFETY

Our annual occupational health and safety assessments, conducted by an external occupational health and safety expert, have resulted in a relatively clean bill of health but emphasised the need for more effective storage solutions. In response, the NBA consolidated records held on site to create space for storage.

All new employees, and existing staff on request, have work station assessments. This has proved to be a cost-effective approach to minimising injuries resulting from computer use.

During 2008–09 one staff member suffered a minor injury. In response to this, our manual handling guidelines have been updated.

5.5 PRODUCTIVITY GAINS

The NBA has achieved considerable benefits from the reduction in staff turnover in 2008–09. This has allowed us to reduce our recruitment budget and allocate additional resources to other functions. However, the main benefit has been that we have retained the knowledge and expertise of our staff, and this enhances our ability to meet a higher proportion of our operational goals.

5.6 ECOLOGICALLY SUSTAINABLE DEVELOPMENT

The NBA has continued to build on our efforts in recent years to reduce our carbon footprint. In 2008–09 our operations resulted in less than 100 direct tonnes of carbon dioxide being emitted (after offsets for air travel, fleet vehicles and the purchase of all electricity from renewable sources are applied). Of these 100 tonnes, just over half relate to travel to and from work by staff members and contractors. To put this in perspective, the average Australian is directly responsible for emitting 7.2 tonnes of carbon dioxide a year.

We have continued to decrease our overall electricity consumption and significantly increased the percentage of meetings conducted by teleconference.

The NBA has worked closely with the Australian Government Information Management Office, through membership of the Green ICT Quick Wins Working Party, to ensure that the needs of small agencies are reflected in the guidelines issued to agencies. The NBA has already implemented the majority of items identified in the guidelines to reduce the carbon footprint of our ICT operations. This work was complemented by formal training received by NBA ICT staff in Green ICT.

As part of the NBA's commitment to professional development, a carbon footprint educational workshop for all our employees will be held later in 2009, with the objective of identifying further ways of reducing the organisation's carbon footprint.

5.7 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 2008–09 the NBA:

- received one request for access to documents under the *Freedom of Information Act 1982*
- received one request for internal review under the *Freedom of Information Act 1982*
- was not involved in any Administrative Appeals Tribunal matters in respect of the *Freedom of Information Act 1982*.

National Blood Authority functions and powers

Information on the NBA's structure and functions is included in this publication, as is performance information.

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 products 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 5.3 shows the categories of documents held by the NBA.

TABLE 5.3 Categories of documents held by the NBA

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	The annual report 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.

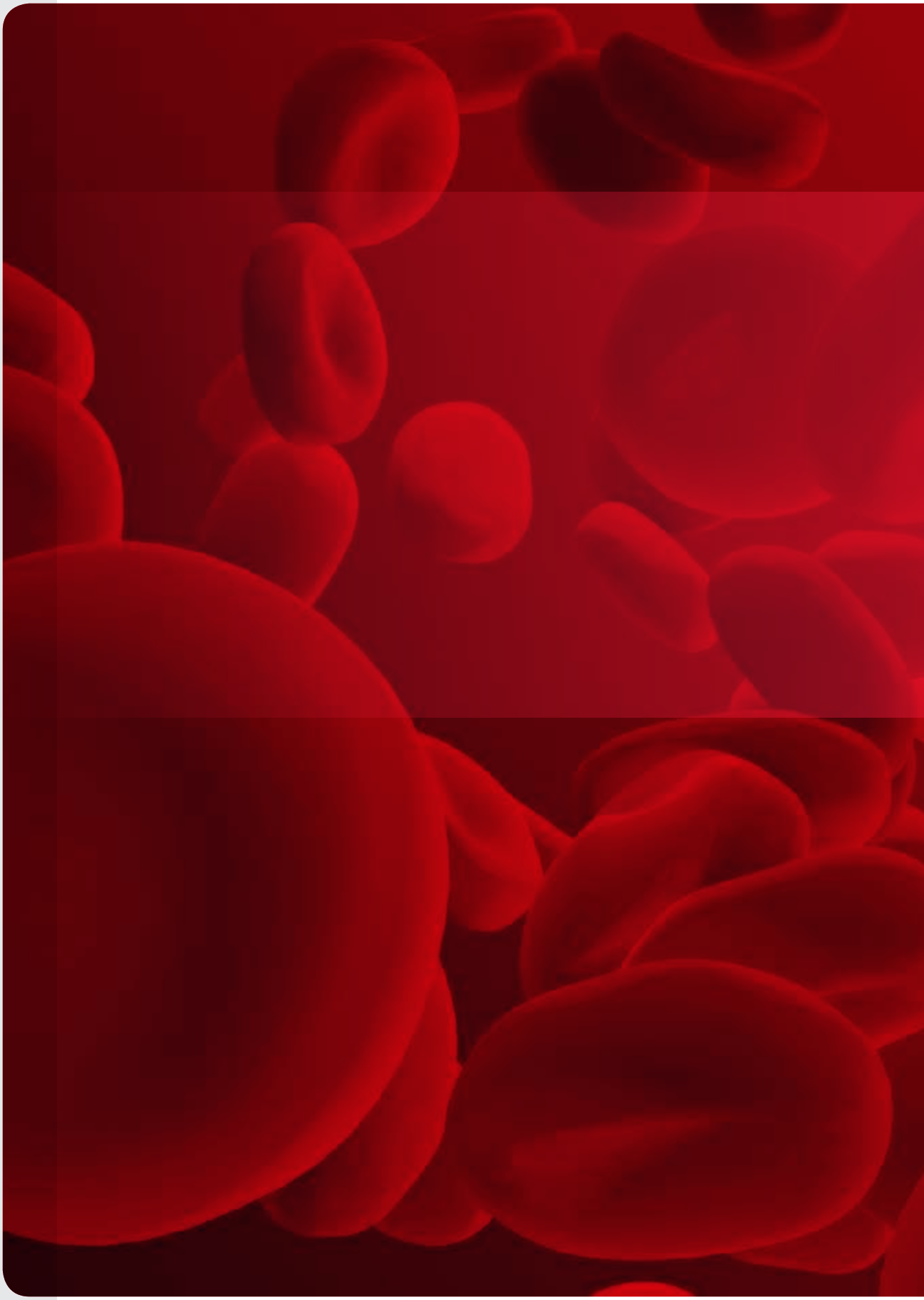
To enable a prompt response and to help the NBA meet its obligations under the *Freedom of Information Act 1982*, applicants should provide as much information as possible about the document(s) sought. We also ask that the applicant include a telephone number or an electronic mail address to allow NBA 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:

Freedom of Information Coordinator
National Blood Authority
Locked Bag 8430
CANBERRA ACT 2601

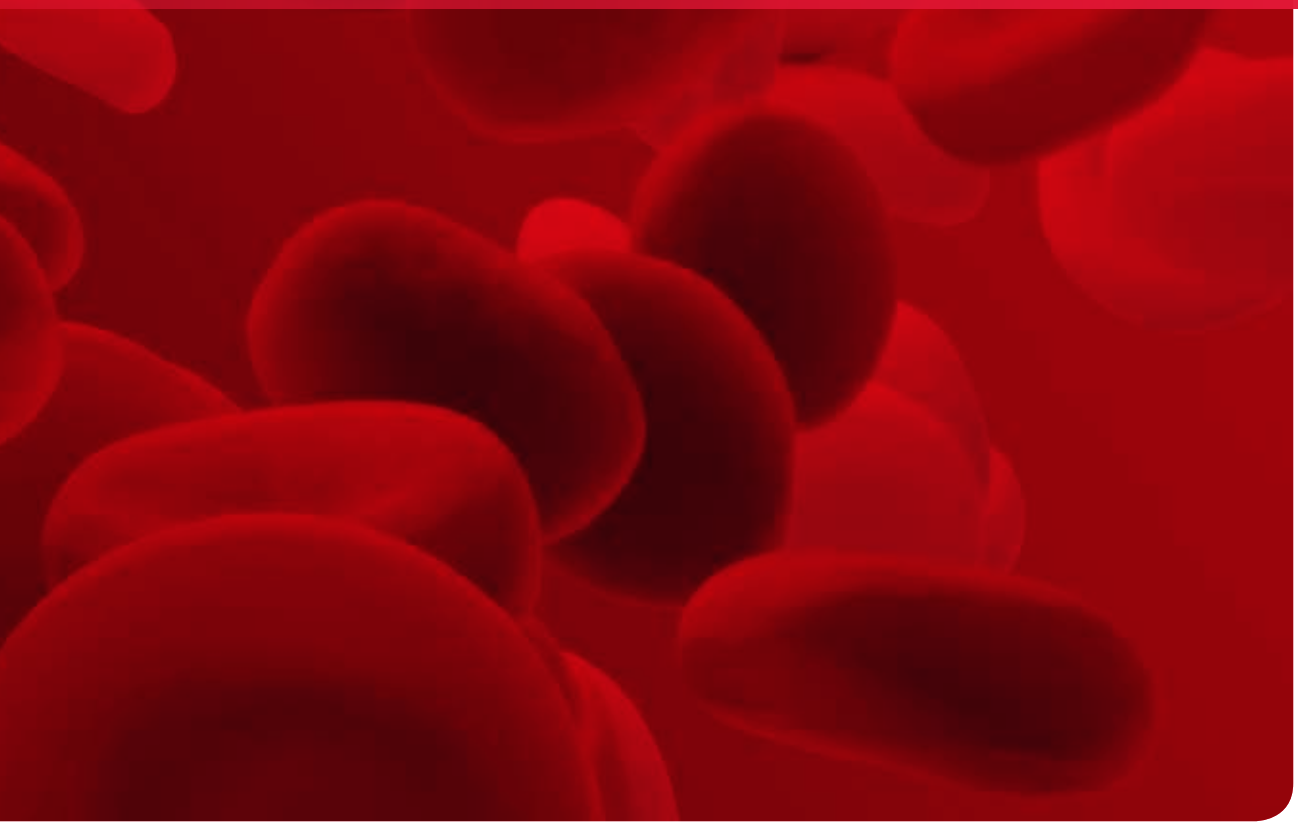
Facilities for access

Physical access to documents at the NBA's premises can be arranged. Inquiries should be directed to the Freedom of Information Coordinator at the address above.



PART SIX.
FINANCIAL STATEMENTS

PART SIX PRESENTS THE NBA'S FINANCIAL STATEMENTS
FOR THE YEAR ENDING 30 JUNE 2009.



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 2009, which comprise: a Statement by the Chief Executive Officer and Chief Finance Officer; Income Statement; Balance Sheet; Statement of Changes in Equity; Cash Flow Statement; Schedule of Commitments and Contingencies; Schedule of Administered Items; and Notes to and Forming Part of the Financial Statements, including a Summary of Significant Accounting Policies.

The Responsibility of Chief Executive for the Financial Statements

The National Blood Authority's Chief Executive Officer 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 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

GPO Box 707 CANBERRA ACT 2601
19 National Circuit BARTON ACT 2600
Phone (02) 6203 7300 Fax (02) 6203 7777

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.

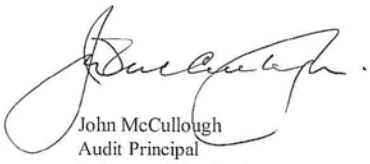
Auditor's Opinion

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 2009 and its financial performance and cash flows for the year then ended.

Australian National Audit Office



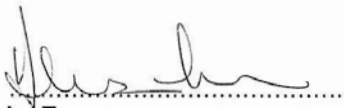
John McCullough
Audit Principal
Delegate of the Auditor-General

Canberra
13 August 2009

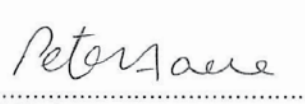
National Blood Authority
Financial Statements
For the year ended 30 June 2009

Statement by the Chief Executive Officer and Chief Finance Officer

In our opinion, the attached financial statements for the year ended 30 June 2009 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
13 August 2009



P G Hade
Chief Finance Officer
13 August 2009

NATIONAL BLOOD AUTHORITY
INCOME STATEMENT
for the year ended 30 June 2009

	Notes	**2009**	2008
		$'000	$'000
INCOME			
Revenue			
Revenue from Government	3A	**5 865**	5 993
Sale of goods and rendering of services	3B	**3 877**	4 294
Total revenue		**9 742**	10 287
Gains			
Other gains	3C	**112**	114
Total gains		**112**	114
Total income		**9 854**	10 401
EXPENSES			
Employee benefits	4A	**6 162**	5 826
Suppliers	4B	**2 709**	2 621
Depreciation and amortisation	4C	**867**	554
Write-down and impairment of assets	4D	**-**	20
Losses from asset sales	4E	**11**	-
Total expenses		**9 749**	9 021
Surplus		**105**	1 380
Surplus attributable to the Australian Government		**105**	1 380

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
BALANCE SHEET
as at 30 June 2009

	Notes	2009 $'000	2008 $'000
ASSETS			
Financial Assets			
Cash and cash equivalents	5A,9	**22**	63
Trade and other receivables	5B	**8 536**	9 252
Total financial assets		**8 558**	9 315
Non-Financial Assets			
Leasehold improvements	6A, 6D	**96**	144
Infrastructure, plant and equipment	6B, 6D	**483**	726
Intangibles	6C, 6D	**1 647**	1 689
Other non-financial assets	6E	**77**	67
Total non-financial assets		**2 303**	2 626
Total Assets		**10 861**	11 941
LIABILITIES			
Payables			
Suppliers	7A	**381**	999
Other payables	7B	**2 286**	3 097
Total payables		**2 667**	4 096
Provisions			
Employee provisions	8	**1 201**	957
Total provisions		**1 201**	957
Total Liabilities		**3 868**	5 053
Net Assets		**6 993**	6 888
EQUITY			
Parent Entity Interest			
Contributed equity		**812**	812
Reserves		**15**	15
Retained surplus		**6 166**	6 061
Total Parent Entity Interest		**6 993**	6 888
Total Equity		**6 993**	6 888
Current Assets		**8 635**	9 382
Non-Current Assets		**2 226**	2 559
Current Liabilities		**3 637**	4 927
Non-Current Liabilities		**231**	126

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
STATEMENT OF CHANGES IN EQUITY
as at 30 June 2009

Item	Retained Earnings		Asset Revaluation Reserve		Contributed Equity/Capital		Total Equity	
	2009 $'000	2008 $'000	**2009 $'000**	2008 $'000	**2009 $'000**	2008 $'000	**2009 $'000**	2008 $'000
Opening balance								
Balance carried forward from previous period	**6 061**	4 439	**15**	15	**812**	812	**6 888**	5 266
Adjustment for errors	**-**	242	**-**	-	**-**	-	**-**	242
Adjustment for changes in accounting policies	**-**	-	**-**	-	**-**	-	**-**	-
Adjusted opening balance	**6 061**	4 681	**15**	15	**812**	812	**6 888**	5 508
Income and expenses								
Revaluation adjustment	**-**	-	**-**	-	**-**	-	**-**	-
Sub-total income and expenses recognised directly in equity	**6 061**	4 681	**15**	15	**812**	812	**6 888**	5 508
Surplus for the period	**105**	1 380	**-**	-	**-**	-	**105**	1 380
Total income and expenses	**6 166**	6 061	**15**	15	**812**	812	**6 993**	6 888
of which:								
attributable to Australian Government	**6 166**	6 061	**15**	15	**-**	-	**6 181**	6 076
Transactions with owners								
Distributions to owners								
Returns of capital	**-**	-	**-**	-	**-**	-	**-**	-
Contributions by owners								
Appropriation (equity injection)	**-**	-	**-**	-	**-**	-	**-**	-
Sub-total transactions with owners	-	**-**	**-**	**-**	**-**	-	**-**	-
Transfers between equity components	**-**	-	**-**	-	**-**	-	-	-
Closing balance as at 30 June	**6 166**	6 061	**15**	15	**812**	812	**6 993**	6 888
Closing balance attributable to the Australian Government	**6 166**	6 061	**15**	15	**812**	**812**	**6 993**	6 888

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
CASHFLOW STATEMENT
for the year ended 30 June 2009

	Notes	**2009** **$'000**	2008 $'000
OPERATING ACTIVITIES			
Cash received			
Goods and services		**3 709**	3 637
Appropriations		**5 447**	5 993
Net GST received		**401**	463
Total cash received		**9 557**	10 093
Cash used			
Employees		**5 551**	5 816
Suppliers		**3 904**	2 555
Total cash used		**9 455**	8 371
Net cash flows from operating activities	9	**102**	1 722
INVESTING ACTIVITIES			
Cash used			
Purchase of property, plant and equipment		**121**	1 308
Purchase of intangibles		**423**	417
Total cash used		**544**	1 725
Net cash flows used by investing activities		**(544)**	(1 725)
FINANCING ACTIVITIES			
Cash received			
Contributed equity		**-**	317
Total cash received		**-**	317
Net cash flows from financing activities		**-**	317
Net increase (decrease) in cash held		**(442)**	314
Cash and cash equivalents at the beginning of the reporting period		**63**	53
Cash transferred to (from) the Official Public Account		**401**	(304)
Cash and cash equivalents at the end of the reporting period	5A	**22**	63

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF COMMITMENTS AND CONTINGENCIES
as at 30 June 2009

SCHEDULE OF COMMITMENTS	2009 $'000	2008 $'000
BY TYPE		
Commitments receivable		
GST recoverable on commitments	**161**	175
Total commitments receivable	**161**	175
Commitments payable		
Capital commitments		
Infrastructure, plant and equipment	**-**	-
Intangibles	**373**	373
Other capital commitments	**-**	-
Total capital commitments	**373**	373
Other commitments		
Operating leases [1]	**1 029**	630
Other commitments	**364**	918
Total other commitments	**1 393**	1 548
Net commitments by type	**1 605**	1 746
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**82**	136
From one to five years	**79**	39
Total other commitments receivable	**161**	175
Commitments payable		
Capital commitments		
One year or less	**263**	195
From one to five years	**110**	178
Total capital commitments	**373**	373
Operating lease commitments		
One year or less	**449**	504
From one to five years	**580**	126
Total operating lease commitments	**1 029**	630
Other commitments		
One year or less	**191**	799
From one to five years	**173**	119
Total other commitments	**364**	918
Net commitments by maturity	**1 605**	1 746

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 expires on 31 October 2009. As at 30 June 2009, no future lease agreement has been signed.
Agreements for the provision of motor vehicles to senior executive officers	Non-contingent rentals exist. There are no renewal or purchase options available to the Authority.

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 ADMINISTERED ITEMS

Income administered on behalf of Government *for the year ended 30 June 2009*	**Notes**	**2009** **$'000**	2008 $'000
Revenue			
Non-taxation revenue			
Sale of goods and rendering of services	14	**829 190**	699 596
Total income administered on behalf of Government		**829 190**	699 596
Expenses administered on behalf of Government *for the year ended 30 June 2009*			
Grants	15A	**433 385**	385 029
Suppliers	15B	**356 568**	340 749
Amortisation	15C	**66**	-
Write-down and impairment of assets	15D	**3 037**	-
Total expenses administered on behalf of Government		**793 056**	725 778

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 2009*	**Notes**	**2009** **$'000**	2008 $'000
Financial assets			
Receivables	16A	**9 969**	12 535
Total financial assets		**9 969**	12 535
Non-financial assets			
Inventories	16B	**65 462**	60 364
Intangibles	16C	**498**	296
Other non-financial assets	16D	**12**	-
Total non-financial assets		**65 972**	60 660
Total assets administered on behalf of Government		**75 941**	73 195
Liabilities administered on behalf of Government *as at 30 June 2009*			
Payables			
Suppliers	17A	**36 908**	34 518
Other payables	17B	**-**	206
Total payables		**36 908**	34 724
Total liabilities administered on behalf of Government		**36 908**	34 724

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

	Notes	2009 $'000	2008 $'000
Administered Cash Flows			
for the year ended 30 June 2009			
OPERATING ACTIVITIES			
Cash received			
Commonwealth contributions		**523 807**	443 364
State and territory contributions		**303 833**	253 316
Net GST received		**79 139**	69 469
Other		**1 420**	-
Total cash received		**908 199**	766 149
Cash used			
Grant payments		**477 058**	423 318
Suppliers		**395 302**	352 030
Total cash used		**872 360**	775 348
Net cash flows from (used by) operating activities		**35 839**	(9 199)
INVESTING ACTIVITIES			
Cash used			
Purchase of intangibles		**267**	**296**
Total cash used		**267**	296
Net cash flows used by investing activities		**(267)**	(296)
Net increase (decrease) in Cash Held		**35 572**	(9 495)
Cash and cash equivalents at the beginning of the reporting period		**-**	-
Cash from Official Public Account for:			
- Appropriations		**10 893**	7 606
- Special accounts		**872 627**	775 644
		883 520	783 250
Cash to Official Public Account for:			
- Special accounts		**919 092**	773 755
		919 092	773 755
Cash and cash equivalents at the end of the reporting period		**-**	-

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 2009*	**2009** **$'000**	2008 $'000
BY TYPE		
Commitments receivable		
GST recoverable on commitments	**81 619**	83 731
Total commitments receivable	**81 619**	83 731
Commitments payable		
Capital commitments		
Intangibles [1]	**372**	1 071
Total capital commitments	**372**	1 071
Other commitments		
Other commitments [2]	**897 433**	919 967
Total other commitments	**897 433**	919 967
Net commitments by type	**816 186**	837 307
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**64 137**	70 153
From one to five years	**17 482**	13 578
Total other commitments receivable	**81 619**	83 731
Commitments payable		
Capital commitments		
One year or less	**165**	330
From one to five years	**207**	741
Total capital commitments	**372**	1 071
Other commitments		
One year or less	**705 346**	771 354
From one to five years	**192 087**	148 613
Total other commitments [1]	**897 433**	919 967
Net commitments by maturity	**816 186**	837 307

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.

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Administered Contingencies
as at 30 June 2009

There were no quantifiable administered contingent liabilities as at 30 June 2009.

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 overall costs in the blood sector 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 and Portfolio Additional Estimates for 2008 - 09 which have been tabled in Parliament.

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 year ended 30 June 2009

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 2009

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 overall costs in the blood sector 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 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 and notes are required by Section 49 of the *Financial Management and Accountability Act 1997* and are a general purpose financial report.

The financial statements and notes have been prepared in accordance with:

- Finance Minister's Orders (or FMO) for reporting periods ending on or after 1 July 2008; and
- Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that apply for the reporting period.

The financial report has been prepared on an accrual basis and is in accordance with the historical cost convention, except for certain assets 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 2009

1.2 Basis of Preparation of the Financial Report (cont..)

Unless an alternative treatment is specifically required by an accounting standard or the FMO, 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 income statement when and only when the flow, consumption or loss of economic benefits has occurred and can be reliably measured.

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 were applicable to the current reporting period and had a disclosure impact on the NBA:

- AASB 1004 Contributions
- AASB 1050 Administered Items

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 financial 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

The following 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 financial officer, which are expected to have a financial impact on the NBA for future reporting periods:

- AASB 101 Presentation of Financial Statements

- AASB 2008-5 Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 5, 7, 101, 102, 107, 108, 110, 116, 118, 119, 120, 123, 127, 128, 129, 131, 132, 134, 136, 138, 139, 140, 141, 1023 & 1038]

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 financial 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 2009

1.5 Revenue

Revenue from Government

Amounts appropriated for departmental output appropriations 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 nor 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 entity.

Receivables for goods and services, which have 30 day terms, are recognised at the nominal amounts due less any impairment allowance account. 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.

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)

Resources received free of charge are recorded as either revenue or gains depending on their nature.

Sale of Assets

Gains from the disposal of non-current assets are recognised when control of the asset has passed to the buyer.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

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 services rendered by employees are recognised at the reporting date to the extent that they have not been settled.

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 applied 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 2009. The estimate of the present value of the liability takes into account 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 2009

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 non-current 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 notes and coins held and any 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 2009

1.11 Financial Assets (cont..)

Loans and Receivables

Trade receivables, appropriations and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'loans and receivables'. They are included in current assets and 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 income statement.

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 2009

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 (other than where they form part of a group of similar items which are significant in total).

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 'makegood' 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 'makegood' 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, infrastructure, 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 through operating result. Revaluation decrements for a class of assets are recognised directly through operating result 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 infrastructure, 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
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for the year ended 30 June 2009

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	**2008 - 09**	2007 - 08
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 4C.

Impairment
All assets were assessed for impairment at 30 June 2009. 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.

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	**2008 - 09**	2007 - 08
Purchased software	**3 years**	3 years
Internally developed software	**5 years**	3 years

All software assets were assessed for indications of impairment at 30 June 2009.

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 and assets are recognised net of GST:

- except where the amount of the GST incurred is not recoverable from the Australian Taxation Office; and
- except for receivables and payables.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

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.

Change in Accounting Treatment and Prior Year Comparatives

In the current year an exemption has been granted from Order 86.1 of the Finance Minister's Orders. The impact of the exemption is that, with the exception of administered appropriations, all administered transactions between the NBA and other wholly owned Australian Government entities and relevant assets and liabilities are recognised in the Schedule of Administered Items. Where necessary, prior year comparative figures have also been adjusted accordingly.

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. The schedule of administered items largely reflects the Government's transactions, through the NBA, with parties outside the Government.

Revenue

All administered revenues are revenues relating to the course of ordinary activities performed by the NBA on behalf of the Australian Government.

Administered fee revenue is recognised when access occurs. 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 Australian Government controls the National Reserve of Blood and Blood Related Products (the "Reserve"). There are three significant input costs to the Reserve:

- Collection costs of raw plasma product provided by the Australian Red Cross Blood Service (ARCBS);
- Purchase costs paid to CSL Limited (CSL) for the plasma product; and
- Purchase costs paid to other suppliers for blood related products.

NATIONAL BLOOD AUTHORITY
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for the year ended 30 June 2009

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 will be reviewed annually to ensure reliability and appropriateness.

The NBA negotiated and implemented new arrangements with CSL in December 2004. These arrangements formalised the control of an inventory buffer, known as Post Payment Inventory of Blood Products ("PoPI"), held at CSL for use by Governments.

The Australian Government now controls PoPI and from 2004-05 it has been disclosed in the financial statements for the NBA. There are two significant input costs to PoPI:

- Collection costs of raw plasma product provided by the ARCBS; and
- Purchase costs paid to CSL Ltd for the plasma product.

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 now controls ARCBS inventory and from 2006-07 it has been disclosed in the financial statements for 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 will be reviewed annually to ensure reliability and appropriateness.

Movements in the Reserve, PoPI and ARCBS are funded from the Australian Government and State and Territories 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 2009 is $63,597,682 (30 June 2008: $51,817,761). 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
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NOTE 2 Events after the Balance Sheet Date

There were no significant events occurring after 30 June 2009.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009	2008
	$'000	$'000
NOTE 3 Income		
Revenue		
Note 3A - Revenue from Government		
Appropriations:		
Departmental outputs	**5 865**	5 993
Total revenue from Government	**5 865**	5 993
Departmental outputs includes $417,925 revenue (2008: $nil) which had been previously received and recognised as unearned revenue (Refer Note 7B).		
Note 3B - Sale of Goods and Rendering of Services		
Rendering of services - related entities	**409**	634
Rendering of services - external parties	**3 468**	3 660
Total sale of goods and rendering of services	**3 877**	4 294
Gains		
Note 3C - Other Gains		
Resources received free of charge	**112**	114
Total other gains	**112**	114

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009 $'000	2008 $'000
NOTE 4 Expenses		
Note 4A - Employee Benefits		
Wages and salaries	**4 010**	3 514
Superannuation:		
Defined contribution plans	**299**	222
Defined benefit plans	**465**	426
Leave and other entitlements	**1 043**	787
Other employee expenses	**345**	877
Total employee benefits	**6 162**	5 826
Note 4B - Suppliers		
Provision of goods - external parties	**218**	196
Rendering of services - related entities	**241**	161
Rendering of services - external parties	**1 798**	1 872
Operating lease rentals - external parties:		
Minimum lease payments	**390**	354
Workers compensation premiums	**62**	38
Total supplier expenses	**2 709**	2 621
Note 4C - Depreciation and Amortisation		
Depreciation:		
Infrastructure, plant and equipment	**331**	339
Leasehold improvements	**70**	99
Total depreciation	**401**	438
Intangibles:		
Computer Software	**466**	116
Total amortisation	**466**	116
Total depreciation and amortisation	**867**	554
Note 4D - Write-Down and Impairment of Assets		
Asset write-downs and impairments from:		
Impairment of infrastructure, plant and equipment	**-**	20
Total write-down and impairment of assets	**-**	20
Note 4E - Losses from Asset Sales		
Infrastructure, plant and equipment		
Proceeds from sale - trade in value	**(13)**	-
Carrying value of assets sold	**24**	-
Total losses from asset sales	**11**	-

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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	2009	2008
	$'000	$'000
NOTE 5 Financial Assets		
Note 5A - Cash and Cash Equivalents		
Cash on hand or on deposit	**22**	63
Total cash and cash equivalents	**22**	63
Note 5B - Trade and Other Receivables		
Goods and services - external parties	**-**	250
GST receivable from the Australian Taxation Office	**51**	116
Special Account - Cash held in the OPA	**8 485**	8 886
Total trade and other receivables (net)	**8 536**	9 252

All receivables are current assets. No impairment allowance account is required.

Credit terms are net 30 days (2007-08: 30 days).

Receivables are aged as follows:		
Not overdue	**8 485**	8 886
Overdue by less than 30 days	**51**	366
Total receivables (gross)	**8 536**	9 252

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009 **$'000**	2008 $'000
NOTE 6 Non-Financial Assets		
Note 6A - Leasehold improvements		
Fair value	**265**	243
Accumulated depreciation	**(169)**	(99)
Total leasehold improvements (non-current)	**96**	144

No indicators of impairment were found for leasehold improvements.

Note 6B - Infrastructure, Plant and Equipment		
Gross carrying value (at fair value)	**1 135**	1 061
Accumulated depreciation	**(652)**	(335)
Total infrastructure, plant and equipment (non-current)	**483**	726

All revaluations were conducted in accordance with the revaluation policy stated at Note 1.

No indicators of impairment were found for infrastructure, plant and equipment.

Note 6C - Intangibles		
Computer software - at cost		
Internally developed - in progress	**-**	1 437
Internally developed - in use	**1 839**	39
Purchased - in use	**555**	533
Total computer software	**2 394**	2 009
Accumulated amortisation - internally developed	**(337)**	(39)
Accumulated amortisation - purchased	**(410)**	(281)
Total intangibles (non-current)	**1 647**	1 689

No indicators of impairment were found for intangible assets.

NOTE 6 Non-Financial Assets (cont..)

Note 6D - Analysis of Property, Plant and Equipment and Intangibles

Table A - Reconciliation of the opening and closing balances of property, plant and equipment, and intangibles (2008-09)

Item	Leasehold improvements	Infrastructure plant and equipment	Total Property, Plant and Equipment	Intangibles - Computer software internally developed	Intangibles - Computer software purchased	Total Intangibles
	$'000	$'000	$'000	$'000	$'000	$'000
As at 1 July 2008						
Gross book value	243	1 061	1 304	39	533	572
Accumulated depreciation/amortisation and impairment	(99)	(335)	(434)	(39)	(281)	(320)
Net book value 1 July 2008	**144**	**726**	**870**	**-**	**252**	**252**
Additions:						
By purchase/internally developed	22	112	134	1 839	22	1 861
Depreciation/amortisation expense	(70)	(331)	(401)	(337)	(129)	(466)
Disposals:						
Other disposals	-	(24)	(24)	-	-	-
Net book value 30 June 2009	**96**	**483**	**579**	**1 502**	**145**	**1 647**
Net book value as of 30 June 2009 represented by:						
Gross book value	265	1 135	1 400	1 839	555	2 394
Accumulated depreciation/amortisation and impairment	(169)	(652)	(821)	(337)	(410)	(747)
Closing Net book value	**96**	**483**	**579**	**1 502**	**145**	**1 647**
Total of all assets	**96**	**483**	**579**	**1 502**	**145**	**1 647**

Table B - Reconciliation of the opening and closing balances of property, plant and equipment, and intangibles (2007-08)

Item	Leasehold improvements	Infrastructure plant and equipment	Total Property, Plant and Equipment	Intangibles - Computer software internally developed	Intangibles - Computer software purchased	Total Intangibles
	$'000	$'000		$'000	$'000	$'000
As at 1 July 2007						
Gross book value	228	241	469	39	204	243
Accumulated depreciation/amortisation and impairment	-	(1)	(1)	(39)	(165)	(204)
Net book value 1 July 2007	**228**	**240**	**468**	**-**	**39**	**39**
Additions:						
By purchase/internally developed	15	845	860	-	329	329
Depreciation/amortisation expense	(99)	(339)	(438)	-	(116)	(116)
Disposals:						
Other disposals	-	(20)	(20)	-	-	-
Net book value 30 June 2008	**144**	**726**	**870**	**-**	**252**	**252**
Net book value as of 30 June 2008 represented by:						
Gross book value	243	1 061	1 304	39	533	572
Accumulated depreciation/amortisation and impairment	(99)	(335)	(434)	(39)	(281)	(320)
Closing Net book value	**144**	**726**	**870**	**-**	**252**	**252**
Internally developed software - in progress	-	-	-	1 437	-	1 437
Total of all assets	**144**	**726**	**870**	**1 437**	**252**	**1 689**

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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	2009 $'000	2008 $'000
NOTE 6 Non-Financial Assets (cont..)		
Note 6E - Other Non-Financial Assets		
Prepayments	**77**	67
Total other non-financial assets	**77**	67

All other non-financial assets were current assets.
No indicators of impairment were found for other non-financial assets.

NOTE 7 Payables		
Note 7A - Suppliers		
Trade creditors	**381**	999
Total supplier payables	**381**	999
Supplier payables - related entities are represented by:		
Current	**19**	51
Supplier payables - external parties are represented by:		
Current	**362**	948
Total supplier payables	**381**	999

Settlement is usually made net 30 days.

Note 7B - Other Payables		
Salaries and wages	**82**	55
Unearned revenue from States and Territories	**928**	1 198
Unearned revenue from outputs	**1 276**	1 694
Unearned revenue - S31 receipts	**-**	150
Total Other Payables	**2 286**	3 097

All other payables are current liabilities.

NOTE 8 Provisions		
Note 8 - Employee Provisions		
Leave	**1 201**	957
Total employee provisions	**1 201**	957
Employee provisions are represented by:		
Current	**970**	831
Non-current	**231**	126
Total employee provisions	**1 201**	957

The classification of current employee provisions includes amounts for which there is not an unconditional right tc defer settlement by one year, hence in the case of employee provisions the above classification does not represent the amount expected to be settled within one year of reporting date. Employee provisions expected to be settled in twelve months from the reporting date are $875,270 (2008: $646,203), and in excess of one year $325,892 (2008: $310,974).

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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	2009	2008
	$'000	$'000
NOTE 9 Cash Flow Reconciliation		
Reconciliation of cash and cash equivalents as per Balance Sheet to Cash Flow Statement		
Report cash and cash equivalents as per:		
Cash flow statement	**22**	63
Balance sheet	**22**	63
Difference	**-**	-
Reconciliation of operating result to net cash from operating activities:		
Operating result	**105**	1 380
Depreciation/amortisation	**867**	554
Net write-down of non-financial assets	**-**	-
Adjustment for errors in retained earnings	**-**	242
Loss on disposal of assets	**11**	-
Decrease in net receivables	**314**	15
Decrease/(increase) in non-financial assets	**(10)**	89
Increase in employee provisions	**244**	43
Increase/(decrease) in supplier payables	**(618)**	48
(Decrease) in other payables	**(811)**	(649)
Net cash from operating activities	**102**	1 722

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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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.

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

	2009	2008
The number of senior executives who received or were due to receive total remuneration of $130,000 or more:		
$175 000 to $189 999	**1**	3
$205 000 to $219 999	**2**	-
$220 000 to $234 999	**-**	1
$250 000 to $264 999	**1**	-
$280 000 to $294 999	**-**	1
$310 000 to $324 999	**1**	-
	5	5
	$	$
The aggregate amount of total remuneration of senior executives shown above.	**1 181 679**	1 070 842
The aggregate amount of separation and redundancy/termination benefit payments during the year to executives shown above.	**-**	-

NOTE 12 Remuneration of Auditors

	2009 **$'000**	2008 $'000
Financial statement audit services were provided free of charge to the NBA.		
The fair value of the services provided was	**112**	114
	112	114

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 2009

	2009	2008
	$'000	$'000
NOTE 13 Financial Instruments		
NOTE 13A Categories of Financial Instruments		
Financial Assets		
Loans and receivables:		
Cash at Bank	**22**	63
Trade and other receivables	**51**	366
Carrying amount of financial assets	**73**	429
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**381**	999
Carrying amount of financial liabilities	**381**	999

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 financia 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'.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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NOTES TO THE SCHEDULE OF ADMINISTERED ITEMS

	2009	2008
NOTE 14 Income Administered on Behalf of Government	**$'000**	$'000
Revenue		
Non-Taxation Revenue		
Commonwealth contributions	**523 807**	443 364
State & Territory contributions	**303 833**	256 232
Other	**1 550**	-
Total non-taxation revenue	**829 190**	699 596
NOTE 15 Expenses Administered on Behalf of Government		
Expenses		
Note 15A: Grants		
Private sector:		
Non-profit organisations	**433 385**	385 029
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.		
Total grants	**433 385**	385 029
Note 15B: Suppliers		
Provision of goods - external parties	**355 462**	340 749
Rendering of services - external parties	**1 106**	-
Total suppliers	**356 568**	340 749
Note 15C: Amortisation		
Intangibles		
Computer software	**66**	-
Total amortisation	**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**	-

NATIONAL BLOOD AUTHORITY
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NOTE 16 Assets Administered on Behalf of Government	2009 $'000	2008 $'000
Financial Assets		
Note 16A - Receivables		
Goods and services receivable - external parties	**3 270**	3 037
Other receivables:		
GST receivable from ATO	**9 736**	9 498
Total receivables	**13 006**	12 535
Less impairment allowance account:		
Goods and services	**(3 037)**	-
Total receivables (net)	**9 969**	12 535
Receivables were aged as follows:		
Not overdue	**9 969**	9 498
Overdue by:		
More than 90 days	**3 037**	3 037
Total receivables	**13 006**	12 535
The impairment allowance account is aged as follows:		
Overdue by:		
More than 90 days	**(3 037)**	-
Total impairment allowance account	**(3 037)**	-
Credit terms are net 30 days from date of invoice (2008: 30 days).		
Reconciliation of the impairment allowance account		
Movements in relation to 2009		
Other Receivables		
Opening balance	**-**	-
Increase recognised in net surplus	**(3 037)**	-
Closing balance	**(3 037)**	-
Non-Financial Assets		
Note 16B - Inventories		
National Reserve inventory held for distribution	**37 539**	28 816
Other inventory held for distribution	**27 923**	31 548
Total inventories	**65 462**	60 364
Inventories held for distribution in the current year include a net write-off of damaged and expired stock to the value of $1,015,214 (2008: $nil).		
Note 16C - Intangibles		
Computer software internally developed - at cost	**564**	-
Computer software internally developed - accumulated amortisation	**(66)**	-
Computer software internally developed (net)	**498**	-
Computer software internally developed - in progress	**-**	296
Total intangibles (non-current)	**498**	296

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

NOTE 16 Assets Administered on Behalf of Government (cont…)

Note 16C - Intangibles (cont..)

Table C - 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 or internally developed	564
Depreciation/amortisation expense	(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)
Closing Net book value	**498**
Total of all assets	**498**

Table C - Reconciliation of the opening and closing balances of intangibles (2007-08)

Item	Intangibles - Computer software internally developed
	$'000
As at 1 July 2007	
Gross book value	-
Accumulated amortisation and impairment	-
Net book value 1 July 2007	**-**
Additions:	
By purchase/internally developed	-
Depreciation/amortisation expense	-
Net book value 30 June 2008	**-**

Net book value as of 30 June 2008 represented by:	
Gross book value	-
Accumulated amortisation and impairment	-
Closing Net book value	**-**
Internally developed software - in progress	296
Total of all assets	**296**

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NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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NOTE 16 Assets Administered on Behalf of Government (cont…)	2009 $'000	2008 $'000
Note 16D - Other Non-Financial Assets		
Prepayments	**12**	-
Total other non-financial assets	**12**	-
NOTE 17 Liabilities Administered on Behalf of Government		
Payables		
Note 17A - Suppliers		
Trade Creditors	**36 908**	34 518
Total suppliers	**36 908**	34 518
Supplier payables - external parties are represented by:		
Current	**36 908**	34 518
Total suppliers	**36 908**	34 518
Note 17B - Other Payables		
Unearned income - other	**-**	206
Total other payables	**-**	206
Total liabilities administered on behalf of Government	**36 908**	34 724

All liabilities are expected to be settled within 12 months of balance date.

NOTE 18 Administered Reconciliation Table		
Opening administered assets less administered liabilities as at 1 July	**38 471**	55 158
Plus Administered income	**829 190**	699 596
Less Administered expenses (non CAC)	**(793 056)**	(725 778)
Appropriation transfers from OPA:		
Annual appropriations for administered expenses (non CAC)	**10 893**	7 606
Special account:		
Transfers from OPA	**872 627**	775 644
Transfers to OPA	**(919 092)**	(773 755)
Closing administered assets less administered liabilities as at 30 June	**39 033**	38 471

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

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 ARCBS 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 (ARCS) and the NBA in relation to the operation of the ARCBS includes certain indemnities and a limit of liability in favour of ARCS. These cover a defined set of potential business, product and employee risks and liabilities arising from the operations of ARCBS. 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 Australian Red Cross Society (ARCS) and the NBA indemnifies the ARCS in relation to the NSW and ACT Principal Site (NAPS) development funding arrangements. If the NAPS funding arrangements cease, the NBA indemnifies the ARCS in respect of its liability to make on-going NAPS related payments.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009 $'000	2008 $'000
NOTE 20 Administered Financial Instruments		
NOTE 20A Categories of Financial Instruments		
Financial Assets		
Loans and receivables:		
Trade and other receivables	**9 969**	12 535
Carrying amount of financial assets	**9 969**	12 535
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**36 908**	34 518
Carrying amount of financial liabilities	**36 908**	34 518

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 financia 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 Liquidity 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 2009

Note 21 Appropriations

Table A - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Ordinary Annual Services Appropriations

Particulars	Administered Expenses *Outcome 1*		Departmental Outputs		Total	
	2009	2008	**2009**	2008	**2009**	2008
	$	$	$	$	$	$
Balance brought forward from previous period *(Appropriation Acts)*					-	-
Appropriation Act:						
Appropriation Act (No. 1) 2008-2009 as passed	**10 893 000**	7 606 000	**4 891 000**	6 021 000	**15 784 000**	13 627 000
Appropriation Act (No. 3) 2008-2009 as passed			**556 000**		**556 000**	-
Appropriation Act (No. 5) 2008-2009 as passed					-	-
Other annual appropriation acts as passed					-	-
Departmental appropriations reduced (*Appropriation Act* section 10)				28 000	-	28 000
Administered appropriations reduced (non CAC) (*Appropriation Act* s 11)					-	-
CAC Act body payment items reduced (*Appropriation Act* section 12)					-	-
Advance to the Finance Minister (*Appropriation Act* section 14)					-	-
Advance to the Finance Minister recovered (2007-2008 only)					-	-
Flexible funding pool receipts (*Appropriation Act* section 15)					-	-
FMA Act:						
Repayments to the Commonwealth (*FMA Act* section 30)					-	-
Appropriations to take account of recoverable GST (*FMA Act* section 30A)					-	-
Relevant agency receipts (*FMA Act* s 31)			**532 119**	54 487	**532 119**	54 487
Adjustment of appropriations on change of agency function (*FMA Act* s 32)					-	-
Total appropriation available for payments	**10 893 000**	7 606 000	**5 979 119**	6 047 487	**16 872 119**	13 653 487
Cash payments made during the year (GST inclusive)					-	-
Appropriations credited to special accounts (GST exclusive)	**10 893 000**	7 606 000	**5 979 119**	6 047 487	**16 872 119**	13 653 487
Balance of authority to draw cash from the Consolidated Revenue Fund for ordinary annual services appropriations and as represented by:	-	-	-	-	-	-
					-	-
Cash at bank and on hand				-	-	-
Departmental appropriations receivable				-	-	-
Undrawn, unlapsed administered appropriations				-	-	-
Adjustments under s 101.13 of the Finance Minister's Orders not reflected above				-	-	-
Total as at 30 June	-	-	-	-	-	-
Reduction in administered items:					-	-
Total administered items appropriated					-	-
Less administered items required by the agency per *Appropriation Act* s 11:					-	-
Appropriation Act (No. 1) 2008-2009					-	-
Appropriation Act (No. 3) 2008-2009					-	-
Appropriation Act (No. 5) 2008-2009					-	-
Other annual appropriation acts					-	-
Total administered items required by the agency					-	-
Total reduction in administered items - effective 2009-2010	-	-	-	-	-	-

Note 21 Appropriations

Table B - Acquittal of Authority to Draw Cash from the Consolidated Revenue Fund for Other than Ordinary Annual Services Appropriations

Particulars	Non Operating *EQUITY*		Total	
	2009	2008	**2009**	2008
	$	$	**$**	$
Balance brought forward from previous period *(Appropriation Acts)*	**-**	317 136	**-**	317 136
Appropriation Act:				
Appropriation Act (No. 2) 2008-2009 as passed			**-**	-
Appropriation Act (No. 4) 2008-2009 as passed			**-**	-
Appropriation Act (No. 6) 2008-2009 as passed			**-**	-
Other annual appropriation acts as passed			**-**	-
Departmental appropriations reduced (*Appropriation Act* section 13)			**-**	-
Administered appropriations reduced (non CAC) (*Appropriation Act* s 12, 13)			**-**	-
CAC Act body payment items reduced (*Appropriation Act* section 14)			**-**	-
Advance to the Finance Minister (*Appropriation Act* section 15)			**-**	-
Advance to the Finance Minister recovered (2007-2008 only)			**-**	-
FMA Act:				
Repayments to the Commonwealth (*FMA Act* section 30)			**-**	-
Appropriations to take account of recoverable GST (*FMA Act* section 30A)			**-**	-
Adjustment of appropriations on change of agency function (*FMA Act* s 32)			**-**	-
Total appropriation available for payments	**-**	317 136	**-**	317 136
Cash payments made during the year (GST inclusive)			**-**	-
Appropriations credited to special accounts (GST exclusive)		317 136	**-**	317 136
Balance of authority to draw cash from the Consolidated Revenue Fund for ordinary annual services appropriations and as represented by:	**-**	-	**-**	-
			-	-
Cash at bank and on hand			**-**	-
Departmental appropriations receivable			**-**	-
Undrawn, unlapsed administered appropriations			**-**	-
Adjustments under s 101.13 of the Finance Minister's Orders not reflected above			**-**	-
Total as at 30 June	**-**	-	**-**	-
Reduction in administered items:			**-**	-
Total administered items appropriated			**-**	-
Less administered items required by the agency per *Appropriation Act* s 12:			**-**	-
Appropriation Act (No. 2) 2008-2009			**-**	-
Appropriation Act (No. 4) 2008-2009			**-**	-
Appropriation Act (No. 6) 2008-2009			**-**	-
Other annual appropriation acts			**-**	-
Total administered items required by the agency			**-**	-
Total reduction in administered items - effective 2009-2010	**-**	-	**-**	-

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009 $	2008 $

NOTE 22 Special Accounts

THE NATIONAL BLOOD ACCOUNT

Legal Authority: National Blood Authority Act 2003
Appropriation: Financial Management and Accountability Act 1997 section 21

Purpose: The National Blood Authority was established on 1 July 2003 with the principal role of managing the national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood and blood products. The funding for blood and blood products is funded from a special account established under the *National Blood Authority Act 2003 , section 40*. The NBA's activities contributing to its outcome are classified as either departmental or administered. Departmental activities involve the use of assets, liabilities, revenues and expenses controlled by the agency 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.

National Blood Account - Departmental

Balance carried from previous period	**8 949 037**	8 634 860
Appropriations transferred to special account - Appropriation Act (No.1)	**4 891 000**	5 993 000
Appropriations transferred to special account - Appropriation Act (No.2)	**-**	317 136
Appropriations transferred to special account - Appropriation Act (No.3)	**556 000**	-
Other receipts - State and Territory contributions	**3 177 203**	3 582 202
Other receipts (*FMA Act* section 31)	**532 119**	54 487
GST credits (*FMA Act* section 30A)	**401 166**	462 538
Total credits	**18 506 525**	19 044 223
Payments made to employees	**5 550 668**	5 816 339
Payments made to suppliers	**4 448 615**	4 278 847
Total debits	**9 999 283**	10 095 186
Balance carried to next period	**8 507 242**	8 949 037
Represented by:		
Cash - held by the NBA	**22 079**	63 400
Cash - transferred to the Official Public Account	**8 485 163**	8 885 637
Total balance carried to the next period	**8 507 242**	8 949 037

National Blood Account - Administered

Balance carried from previous period	**124 585 263**	133 740 539
Appropriations transferred to special account	**6 978 000**	5 276 000
Other receipts - Commonwealth contributions	**518 870 890**	438 427 887
Other receipts - State and Territory contributions	**300 933 937**	253 316 104
Other Receipts - External parties	**1 244 100**	-
GST credits (*FMA Act* section 30A)	**79 139 102**	69 468 506
Total credits	**1 031 751 292**	900 229 036
Payments made to suppliers	**872 480 799**	775 643 773
Total debits	**872 480 799**	775 643 773
Balance carried to next period	**159 270 493**	124 585 263
Represented by:		
Cash - transferred to the Official Public Account	**159 270 493**	124 585 263
Total balance carried to the next period	**159 270 493**	124 585 263

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

	2009 $	2008 $
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 carried from previous period	**51 817 761**	41 686 565
Appropriations transferred to special account	**3 915 000**	2 330 000
Other receipts - Commonwealth contributions	**4 936 113**	4 936 114
Other receipts - State and Territory contributions	**2 898 987**	2 915 483
Other receipts - External entities	**175 890**	175 890
GST credits (*FMA Act* section 30A)	**(237)**	-
Total credits	**63 743 514**	52 044 052
Payments made to suppliers	**145 832**	226 291
Total debits	**145 832**	226 291
Balance carried to next period	**63 597 682**	51 817 761
Represented by:		
Cash - transferred to the Official Public Account	**63 597 682**	51 817 761
Total balance carried to the next period	**63 597 682**	51 817 761

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 2008 - 09, 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.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

NOTE 23 Compensation and Debt Relief

Administered

No 'Act of Grace' expenses were incurred during the reporting period. (2008: 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*. (2008: no waivers)

No ex gratia payments were provided during the reporting period. (2008: no payments)

Departmental

No payments were made under the Defective Administration Scheme during the reporting period. (2008: no payments)

No payments were made under section 73 of the *Public Service Act 1999* during the reporting period. (2008: no payments)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

Note 24 Reporting of Outcomes

Note 24A - Net Cost of Outcome Delivery

Particulars		Outcome 1	
		2009	2008
		$'000	$'000
Expenses			
	Administered	**793 056**	725 778
	Departmental	**9 749**	9 021
	Total expenses	**802 805**	734 799
Costs recovered from provision of goods and services to the non government sector			
	Administered	**305 383**	256 232
	Departmental	**3 877**	4 294
	Total costs recovered	**309 260**	260 526
Net cost/(contribution) of outcome		**493 545**	474 273

Costs recovered include contributions from State and Territory governments.

The National Blood Authority operates under one outcome and one output. Transactions reported under this output are reported in the Income Statement and the Balance Sheet.

Note 24B - Major Classes of Departmental Income and Expenses by Output Groups and Outputs

Particulars		Output 1	
		2009	2008
		$'000	$'000
Departmental expenses			
	Employees	**6 162**	5 826
	Suppliers	**2 709**	2 621
	Depreciation and amortisation	**867**	554
	Other expenses	**11**	20
Total departmental expenses		**9 749**	9 021
Funded by:			
	Income from government	**5 865**	5 993
	Sales of goods and services	**3 877**	4 294
	Other non-taxation revenue	**112**	114
Total departmental income		**9 854**	10 401

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2009

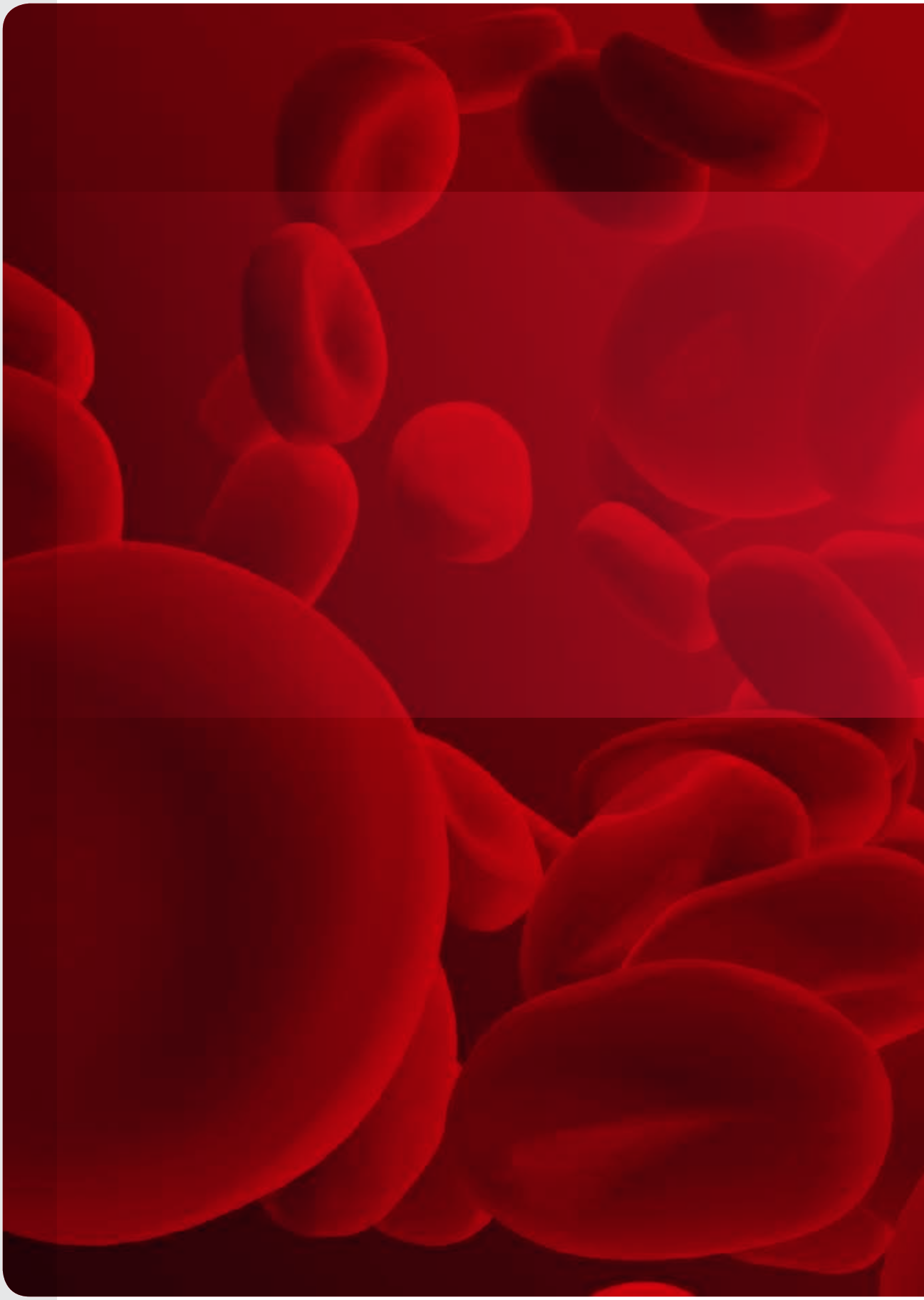
Note 24 Reporting of Outcomes (cont…)

Note 24C - Major Classes of Departmental Assets and Liabilities by Outcomes

Particulars	Outcome 1	
	2009	2008
	$'000	$'000
Departmental assets		
Cash	**22**	63
Trade and other receivables	**8 536**	9 252
Leasehold Improvements	**96**	144
Infrastructure, plant and equipment	**483**	726
Intangibles	**1 647**	1 689
Other non-financial assets	**77**	67
Total departmental assets	**10 861**	11 941
Departmental liabilities		
Suppliers	**381**	999
Other payables	**2 286**	3 097
Employee provisions	**1 201**	957
Total departmental liabilities	**3 868**	5 053

Note 24D - Major Classes of Administered Income, Expenses, Assets and Liabilities by Outcomes

Particulars	Outcome 1	
	2009	2008
	$'000	$'000
Administered expenses		
Grants	**433 385**	385 029
Suppliers	**356 568**	340 749
Amortisation	**66**	-
Write-down and impairment of assets	**3 037**	-
Total administered expenses	**793 056**	725 778
Administered income		
Provision of goods - related entities	**523 807**	443 364
Provision of goods - external parties	**303 833**	256 232
Other	**1 550**	-
Total administered income	**829 190**	699 596
Administered assets		
Receivables	**9 969**	12 535
Inventories	**65 462**	60 364
Intangibles	**498**	296
Other non-financial assets	**12**	-
Total Administered Assets	**75 941**	73 195
Administered liabilities		
Suppliers	**36 908**	34 518
Other payables	**-**	206
Total Administered liabilities	**36 908**	34 724



APPENDICES

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; and
   (b) to promote safe, high quality management and use of blood products, blood-related products and blood-related services in Australia.

2 In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:
   (a) to meet international obligations and standards;
   (b) to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma;
   (c) to promote national self-sufficiency;
   (d) to provide products to patients, free of charge and based on clinical need and appropriate clinical practice;
   (e) to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards;
   (f) to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sectors;
   (g) to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sectors;
   (h) to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs;
   (i) to ensure public support and confidence in the Australian blood sector; and
   (j) to work towards optimal access to blood products and blood-related products across the nation, ensuring that patients continue to access the blood products and blood-related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood-related products that are prescribed and received in their jurisdiction.

APPENDIX 2. NATIONAL BLOOD AUTHORITY: AGENCY RESOURCE STATEMENT

The Agency Resource Statement provides details of the funding sources that the NBA drew upon in 2008–09. In addition it provides information about special accounts balances to be carried over to 2009–10.

	Actual Available Appropriations for 2008–09 ($'000)	Payments Made 2008–09 ($'000)	Balance Remaining 2008–09 ($'000)
Ordinary Annual Services			
Departmental appropriation			
Departmental appropriation	5 447	5 447	-
Total	**5 447**	**5 447**	**-**
Administered expenses			
Outcome 1:	10 893	10 893	
Total	**10 893**	**10 893**	
Total ordinary annual services	**16 340**	**16 340**	
Special Accounts			
Opening balance	185 352		
Appropriation receipts	16 340		
Non-appropriation receipts	912 309		
Payments made		882 626	
Closing Balance			231 375
Total Resourcing and Payments	1 114 000	882 626	

Resources for Outcomes

This table is intended to provide details of the total funding for each Outcome. In 2008–09 the NBA operated under a single outcome.

Outcome 1 – Australia's blood supply is secure and well managed

	Budget 2008–09 ($'000)	Actual Expenses 2008–09 ($'000)	Variation 2008–09 ($'000)
Output Group 1			
Special Accounts			
Administered Items	808 722	793 056	15 666
Departmental Outputs	9 376	9 749	(373)
Total for Outcome 1	**818 098**	**802 805**	**15 293**
Average Staffing level (number)		**50**	

APPENDIX 3. FRESH BLOOD COMPONENTS LISTED ON THE NATIONAL PRODUCT AND SERVICES LIST 2008–09

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
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 complying with AHMAC Guidelines
7c	Therapeutic Venesections for Whole Blood for Discard
7d	Serum Eye Drops – Single Collection Unit

APPENDIX 4. PLASMA AND RECOMBINANT PRODUCTS SUPPLIED UNDER CONTRACT IN 2008–09

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
	Clotting factors	
	Biostate®	Used to treat Factor VIII deficiency, known as haemophilia A
	MonoFIX®-VF	Used to treat patients who have Factor IX deficiency, known as haemophilia B or Christmas disease
	Prothrombinex®-VF	Used to manage some bleeding disorders (concentrated clotting factors) and warfarin reversal
	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
CSL Limited	Sandoglobulin®	Used to reduce susceptibility to infections and manage many immune system disorders
Octapharma Australia Pty Ltd	Octagam®	Used to reduce susceptibility to infections and manage many immune system disorders

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 to treat bleeding episodes including surgical interventions in haemophilia A and B patients with inhibitors
Baxter Healthcare Pty Ltd	Protein C/Ceprotin®	Used to treat congenital Protein C deficiency
Baxter Healthcare Pty Ltd	FVII concentrate	Used to treat Factor VII deficiency
Baxter Healthcare Pty Ltd	WinRho	Used to prevent a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers
CSL Limited	FXI/BPL Factor XI	Used to treat people with Factor XI deficiency (sometimes called haemophilia C)
CSL Limited	FXIII/Fibrogammin® P	Used to treat people with Factor XIII deficiency
CSL Limited	Rh (D) Immunoglobulin/ WinRho®	Used to prevent haemolytic disease of the newborn (HDNB), a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers

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 to treat bleeding episodes including surgical intervention in haemophilia A or B patients with inhibitors to Factor VIII or Factor IX; also used to treat complex bleeding episodes in surgery, trauma and septicaemia
Baxter Healthcare Pty Ltd	rFVIII/Recombinate®	Used to treat Factor VIII deficiency, known as haemophilia A
Baxter Healthcare Pty Ltd	rFVIII/Advate®	Used to treat Factor VIII deficiency, known as haemophilia A
Wyeth Australia Pty Ltd	rFVIII/Refacto®	Used to treat Factor VIII deficiency, known as haemophilia A
Wyeth Australia Pty Ltd	rFIX/BeneFIX®	Used to treat patients who have Factor IX deficiency, known as haemophilia B or Christmas disease

APPENDIX 5. UNITS OF RED CELLS, PLATELETS AND IVIG, ISSUED PER 1000 POPULATION BY STATE AND TERRITORY 2006–07 TO 2008–09

FIGURE A5.1 *Units of red cells issued per 1000 head of population by state and territory, 2006–07 to 2008–09*

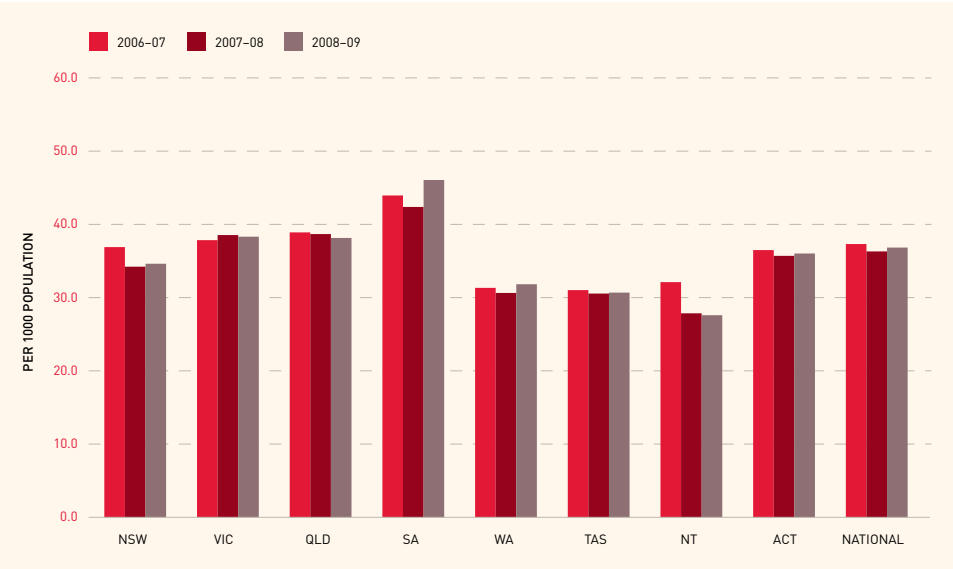


FIGURE A5.2 *Units of platelets issued per 1000 head of population by state and territory, 2006–07 to 2008–09*

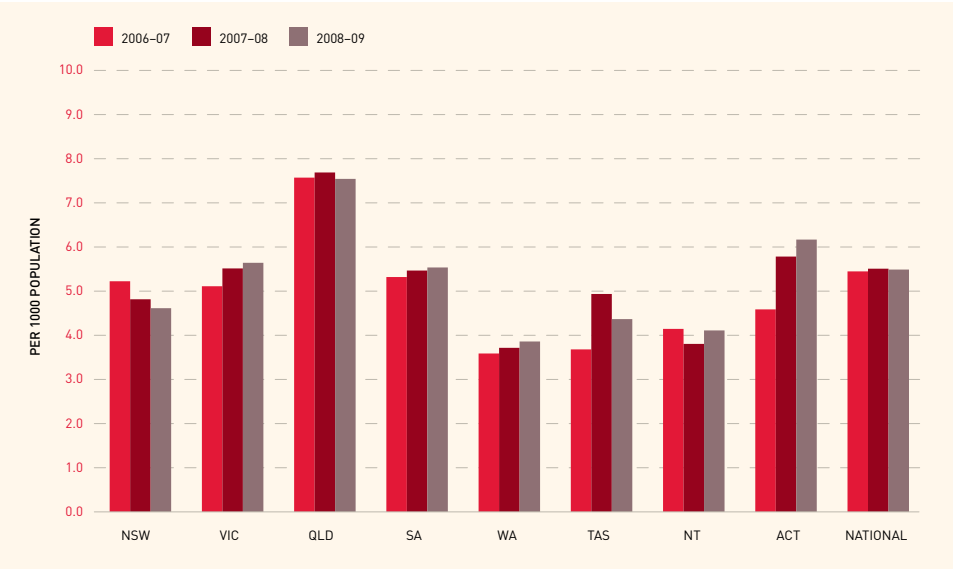
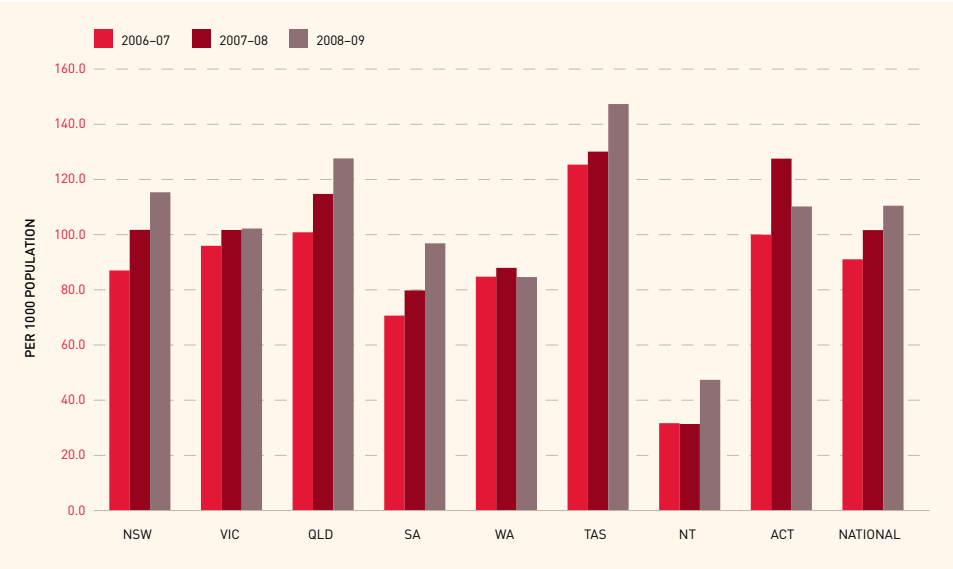


FIGURE A5.3 *IVIg issued per 1000 head of population by state and territory, 2006–07 to 2008–09*



APPENDIX 6. ACRONYMS

ABDR	Australian Bleeding Disorders Registry
AHMAC	Australian Health Ministers Advisory Council
AHMC	Australian Health Ministers Conference
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ALS	Australian Laboratory Services Pty Ltd
AORNJ	Association of Peri-Operative Registered Nurses Journal
APS	Australian Public Service
ARCS	Australian Red Cross Society
ARCBS	Australian Red Cross Blood Service
AR-DRG	Australian Refined Diagnosis Related Groups
AWA	Australian Workplace Agreement
CA	Collective Agreement
CBD	central business district
CEO	chief executive officer
CFO	chief financial officer
CPI	consumer price index
CMV	cytomegalovirus
CTEPC	Clinical, Technical and Ethical Principal Committee
FEIBA	Factor Eight Inhibitor Bypass Agent
GST	goods and services tax
HIV	human immunodeficiency virus
ICD-10-AM	International Classification of Diseases—10th revision– Australian Modification
IDMS	Integrated Data Management System
IHN	International Haemovigilance Network
IT	information technology
IVF	in vitro fertilisation
IVIg	intravenous immunoglobulin
JBC	Jurisdictional Blood Committee
KPI	key performance indicator
MBS	Medical Benefits Scheme
NBA	National Blood Authority
NBSCP	National Blood Supply Contingency Plan
NHMRC	National Health and Medical Research Council
NHS	National Health Service (United Kingdom)
NIMS	National IVIg Management System
NPPSpa	Collaboration of National Plasma Product Supply Planners
NSPB	National Supply Plan and Budget
OCD	Ortho-Clinical Diagnostics

OECD	Organisation for Economic Co-operation and Development
PBS	Pharmaceutical Benefits Scheme
PFR	Plasma Fractionation Review
PPA	Plasma Products Agreement
ORBS	Ordering and Receipting Blood System (Queensland)
SMS	short message service
SNOMED-CT	Systemised nomenclature of medicine-clinical terms
STARS	Supply Tracking and Reporting System (ARCBS)
TGA	Therapeutic Goods Administration
TSEAC	Transmissible Spongiform Encephalopathy Advisory Committee
vCJD	variant Creutzfeldt–Jacob disease
WHO	World Health Organization

APPENDIX 7. INDEX

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NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT

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Locked Bag 8430 CANBERRA ACT 2601
Phone 02 6211 8300 . Fax 02 6211 8330
Email nba@nba.gov.au . Web **www.nba.gov.au**