

# Our role

## PART TWO: OUR ROLE

Part Two details the National Blood Authority's role in the blood sector. It provides a description of the external and internal governance arrangements that guide the work of the National Blood Authority and the nature of its relationships with jurisdictions, stakeholders and suppliers.

- 2.1 Introduction
- 2.2 Background
- 2.3 The blood supply chain
- 2.4 External governance arrangements
- 2.5 National Blood Authority's roles and responsibilities
- 2.6 Internal governance arrangements



## Australian Red Cross Blood Service

The Australian Red Cross Blood Service is an operating division of the Australian Red Cross Society. Since 2003–04, the Australian Red Cross Blood Service has been funded jointly by the governments of Australia, with the Australian Government contributing 63 percent of funding and the eight state and territory governments contributing the remaining 37 percent on a proportional basis.



## 2.1 Introduction

Blood and blood-related products play a key role in the treatment and management of a range of clinical conditions. Many life and death situations rely on blood and blood-related products. Without these products, there would be increased patient mortality and reduced clinical outcomes for many patients. Clinicians and hospitals rely on the products on a daily basis to treat and manage their patients.

The National Blood Authority's job is to ensure that product required by clinicians is available within a cost-effective framework and that product use is optimised.

## 2.2 Background

The National Blood Authority was established in July 2003 under the *National Blood Authority Act 2003*, and in accordance with the National Blood Agreement, to improve and enhance the management of the Australian blood banking and plasma product sector at a national level.

Prior to the establishment of the National Blood Authority, there existed over 30 separate agreements between various stakeholders including governments, the Australian Red Cross Blood Service and CSL Limited. In 2001, a review chaired by the Rt Hon. Sir Ninian Stephen identified that supply costs increased significantly between 1991 and 1999 and commented that Australia's blood supply system was highly fragmented and costly.

The review recommended a national approach to strengthen the coordination and oversight of Australia's blood supply. This included the establishment of a national blood authority to manage Australia's blood supply.

The National Blood Agreement was approved by the Australian Health Ministers' Conference in November 2002 and was subsequently signed by all health ministers. At that time an interim Board was also appointed to advise the Australian Government Minister for Health and Ageing on the implementation of the new arrangements in the lead-up to the establishment of the National Blood Authority. A Board was appointed in May 2003 and was chaired by a former Commonwealth Chief Medical Officer, Professor Richard Smallwood.

Legislation allowing for the establishment of the National Blood Authority passed through both Houses of Parliament unopposed, and the National Blood Authority came into existence on 1 July 2003. Policy objectives reflecting the legislation are detailed in the National Blood Agreement extract set out in Table 2.





TABLE 2: EXTRACT FROM THE NATIONAL BLOOD AGREEMENT

Part 1 - Objectives of Governments for the Australian blood sector	
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 the best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sector;
g.	to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector;
h.	to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs;
i.	to ensure public support and confidence in the Australian blood sector; and
j.	to work towards optimal access to blood products and blood related products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction.

## 2.3 The blood supply chain

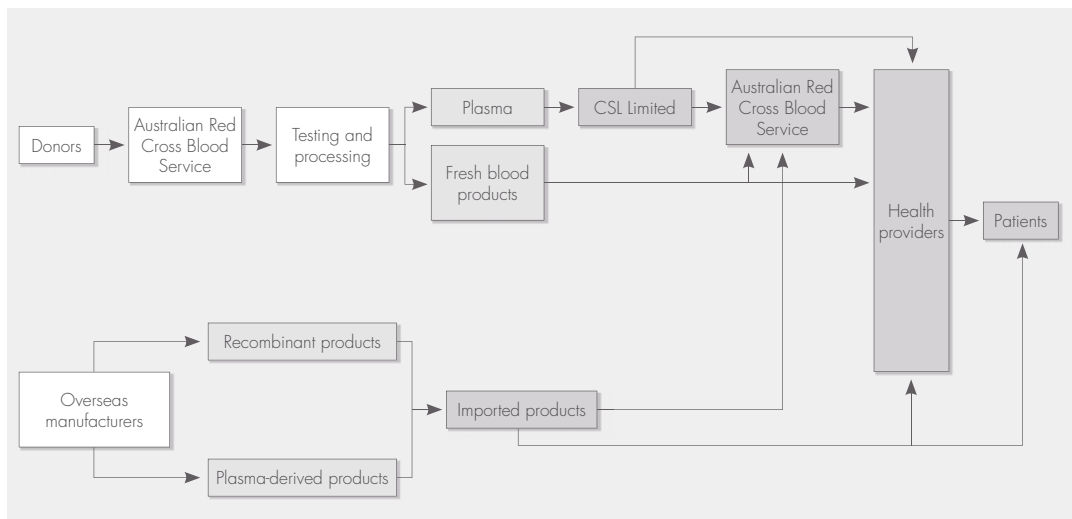
Australia’s blood sector is government funded, with the Australian Government contributing 63 percent of funds and state and territory governments contributing 37 percent. The National Blood Authority is the national contract manager for supplies of blood and blood-related products under these arrangements. In 2006–07, governments provided the National Blood Authority with \$638.3 million to procure and manage the blood supply—see Table 3. Since the commencement of the new arrangements in July 2003, governments have spent \$2.2 billion on blood and blood-related products.

**TABLE 3:** GOVERNMENT FUNDING TO THE NATIONAL BLOOD AUTHORITY FOR THE MANAGEMENT OF THE BLOOD SUPPLY\*

Years	Amount (\$ millions)	% growth
2003–04	460.5	
2004–05	540.9	16.43
2005–06	577.2	12.52
2006–07	637.7	5.79
<b>TOTAL</b>	<b>2,216.3</b>	<b>(average) 11.58</b>

\* This does not equate to the amounts purchased from suppliers as shown in Table 5 due to variations in final end-of-year payments.

**FIGURE 1:** AUSTRALIAN BLOOD SUPPLY CHAIN



2: Our role

The National Blood Authority manages the national planning and purchasing of blood and blood-related products in close cooperation with a number of entities. The following pages outline the roles and responsibilities of the key stakeholders in the Australian blood sector. The Australian blood supply chain is set out in Figure 1.

### 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 National Blood Authority's management of the blood supply arrangements
- fostering the development and implementation of best practice systems to promote efficient use and minimal wastage
- providing information on demand for blood and blood-related products
- managing local issues such as those involving clinical practice.

### Therapeutic Goods Administration

The regulator for blood and blood-related products in Australia is the Therapeutic Goods Administration. The Therapeutic Goods Administration 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 of good manufacturing practice
- product recalls
- modifications to safety standards
- issuing directives such as donor deferral.

### Suppliers of blood and blood-related products

The National Blood Authority contracts with a number of suppliers of blood and blood-related products for specific volumes, 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 Limited

- CSL Limited, for fractionating plasma supplied by the Australian Red Cross Blood Service, and supplying a range of products
- other pharmaceutical companies, which are responsible for the supply and some distribution of a range of imported blood products not produced in Australia, or where domestic production capacity cannot meet demand.

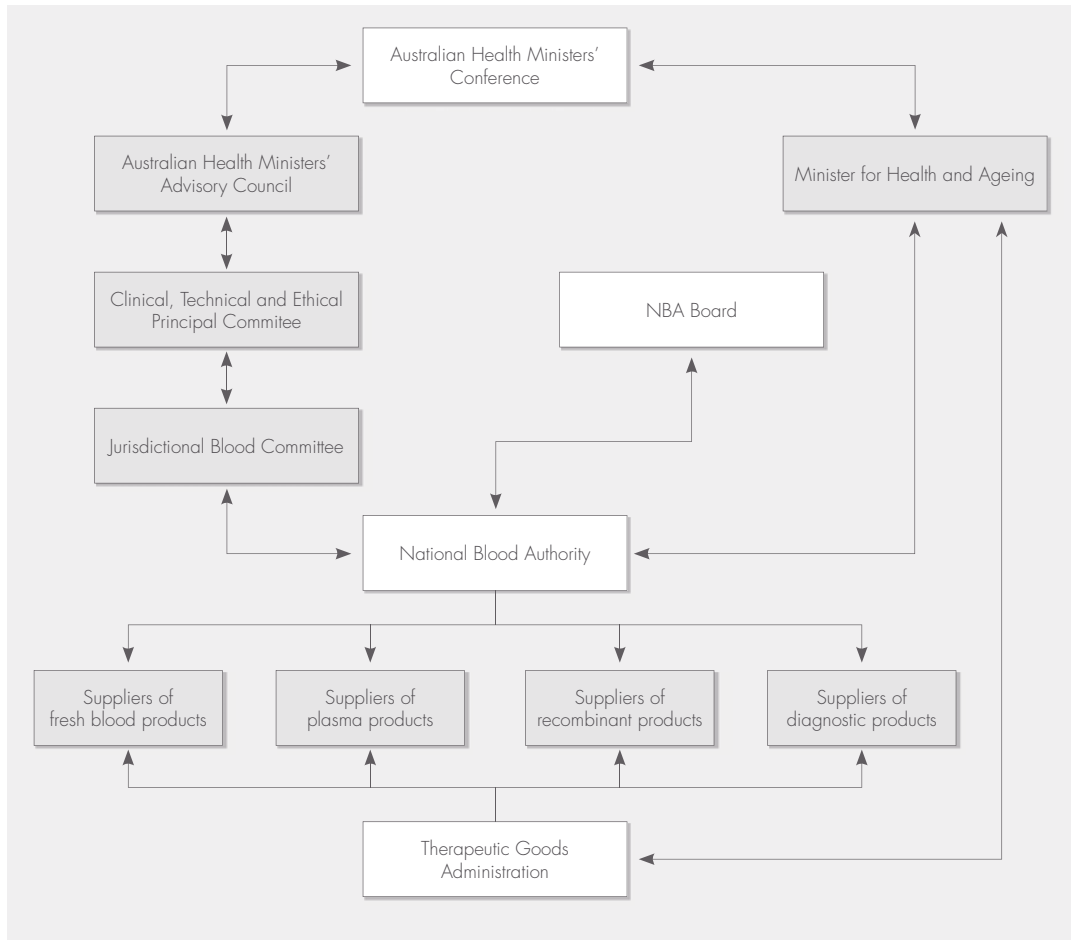
Contracts with suppliers for the provision of blood and blood-related products under standing offer arrangements include:

- CSL Limited, DiaMed Australia Pty Ltd, Ortho-Clinical Diagnostics and Australian Laboratory Services Pty Ltd for the provision of diagnostic reagents
- CSL Limited and Octapharma Australia Pty Ltd for the provision of overseas-sourced IVIg
- Baxter Healthcare Pty Ltd, Wyeth Australia Pty Ltd and Novo Nordisk Pharmaceuticals Pty Ltd for the provision of a range of defined blood products.

## 2.4 External governance arrangements

The key decision makers in the Australian blood sector and their primary roles and relationships with each other are set out in the National Blood Agreement and the *National Blood Authority Act 2003* and are summarised and depicted at Figure 2.

FIGURE 2: GOVERNANCE STRUCTURE OF THE AUSTRALIAN BLOOD SECTOR



## Australian Health Ministers' Conference

The Australian Health Ministers' Conference is ultimately responsible for overseeing and managing the sector in conjunction with the Australian Government. It sets the governance, policy and financial framework under which the National Blood Authority operates. Ministers' key decisions on the management of blood and blood-related products in 2006–07 included:

- endorsement of the implementation of a detailed business study of the operations of the Australian Red Cross Blood Service to determine fair and reasonable funding arrangements
- matters affecting the National Blood Authority's operations relating to the agreement to supply blood products to Australians who are overseas and subsequent amendment of the National Blood Agreement
- agreement to fund universal bacterial contamination testing of platelets and to implement universal leucodepletion.

The health ministers also agreed to the nominees for appointment to the National Blood Authority Board.

## Leucodepletion

Leucodepletion is the process of removing white blood cells (leucocytes) from other cellular blood components (red cells and platelets). The clinical benefits of leucodepletion vary depending on the blood component involved.

## Minister for Health and Ageing

The Minister for Health and Ageing is responsible under the *National Blood Authority Act 2003* for the appointment of the National Blood Authority Board and General Manager, for determining additional functions of the National Blood Authority and for issuing policy principles the National Blood Authority must comply with in the performance of its functions. The Minister carries out these statutory roles with endorsement from all health ministers in the Australian Health Ministers' Conference.

The Minister also has ministerial portfolio responsibility for the National Blood Authority as part of the Health and Ageing portfolio. In 2006, the Minister provided the General Manager with a *Statement of Expectation*, to which the National Blood Authority responded with a *Statement of Intent*. The National Blood Authority's achievements against the *Statement of Intent* are provided at Table 1 in Part One: Overview.

## Australian Health Ministers' Advisory Council

The Australian Health Ministers' Advisory Council is charged with providing effective and efficient support to the Australian Health Ministers' Conference by advising on strategic issues 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 and Clinical, Technical and Ethical Principal Committee and reports, as necessary, to the Australian Health Ministers' Conference. The Australian Health Ministers' Advisory 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 including: clinical, technical and medico-ethical developments that are likely to affect more than one jurisdiction; appropriate options for the 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 implication arising from such issues; the impact of these 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 2003. Since September 2006, it has been a subcommittee

of the Clinical, Technical and Ethical Principal Committee. The Jurisdictional Blood Committee is the conduit between governments and the National Blood Authority. It represents jurisdictional positions on blood policy, demand, supply planning and product distribution, and on funding and evidence-based approaches to emerging products, services and technologies. It oversees the National Blood Authority'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 and Australian Health Ministers' Advisory Council.

### National Blood Authority Board

The primary role of the Board is to provide advice to the General Manager on the performance of the National Blood Authority and to liaise with governments, suppliers and others on matters relating to the National Blood Authority's functions. The Board has no capacity independent from the National Blood Authority to engage personnel, enter into dealings with other parties or hold money, nor does it perform a governance role. It acts as an advisory body to the General Manager, who is ultimately responsible and accountable for the National Blood Authority under the *Financial Management and Accountability Act 1997*.

### National Blood Authority General Manager

The National Blood Authority's General Manager is a statutory officer who reports to the Minister for Health and Ageing. Under the *National Blood Authority Act 2003*, the General Manager is responsible for the management of the National Blood Authority and the implementation of blood policy decisions. The General Manager is prescribed as the chief executive of the National Blood Authority under the *Financial Management and Accountability Act 1997* and as agency head under the *Public Service Act 1999*.

While the General Manager has ultimate responsibility for the management of the National Blood Authority, under the *National Blood Authority Act 2003* the General Manager is responsible for keeping the Board advised of the NBA's operations, requesting advice from the Board on strategic matters relating to the performance of the National Blood Authority's functions, and having regard to this advice. In managing the National Blood Authority, the General Manager also has regard to policy principles issued by the Minister for Health and Ageing under the Act, policy decisions of the Australian Health Ministers' Conference and the Jurisdictional Blood Committee, and Australian Government policy and compliance requirements relating to Commonwealth agencies.

## 2.5 National Blood Authority's roles and responsibilities

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

- coordinating national demand and supply planning on blood and blood-related products and purchasing those products on behalf of all Australian governments
- negotiating and managing contracts with suppliers of blood and blood-related products to enable the development of sufficient and value-for-money supply and an agreed single national pricing schedule
- implementing an efficient demand-driven system, based on evidence and good clinical practice so that the blood supply system is highly responsive to needs
- working in a collaborative manner with all governments and other relevant parties to ensure that Australia's blood supply is adequate, safe, secure and affordable
- national contingency planning
- promoting adherence to national safety and quality standards
- developing and implementing national strategies to encourage better use of blood and blood-related products.

The execution and timing of specific activities to advance these roles are a result of the combination of the *Minister's Statement of Expectation*, the ministerially approved National Blood Authority Corporate Plan, the funding provided by governments, the endorsement of priorities by the Jurisdictional Blood Committee and decisions made by the Australian Health Ministers' Conference.

The National Blood Authority provides secretariat assistance to the Jurisdictional Blood Committee and in conjunction with the jurisdictions, plays a critical role in coordinating an annual National Product List

and National Supply Plan and Budget for approval by health ministers. As part of its role in managing the supply of blood and blood-related products, the National Blood Authority is responsible for:

- collecting data on products issued and reporting to jurisdictions against the approved Supply Plan
- making improvements to the national supply planning process
- monitoring the balance between supply and demand throughout the year
- intensively managing products in short supply.

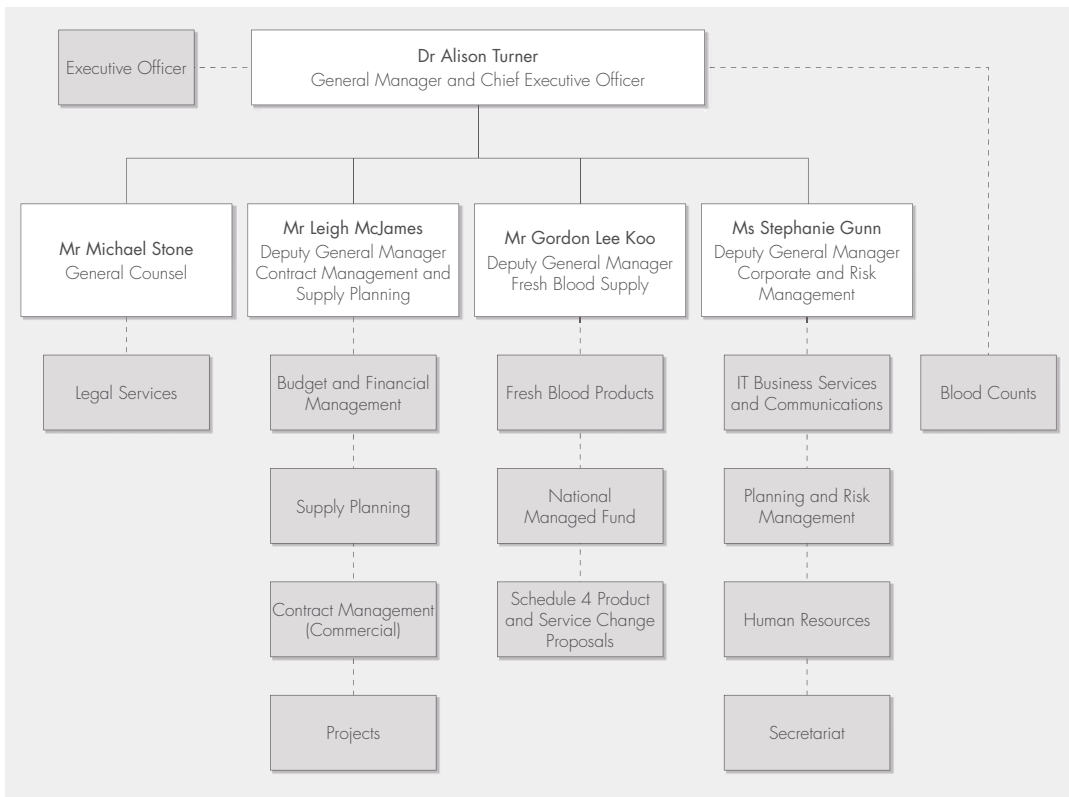
## 2.6 Internal governance arrangements

At 30 June 2007, the executive management of the National Blood Authority comprised the following staff:

- General Manager, Dr Alison Turner
- General Counsel, Mr Michael Stone
- Deputy General Manager, Corporate and Risk Management, Ms Stephanie Gunn
- Deputy General Manager, Fresh Blood Supply, Mr Gordon Lee Koo
- Deputy General Manager, Contract Management and Supply Planning, Mr Leigh McJames.

The National Blood Authority's organisational structure is set out in Figure 3.

FIGURE 3: ORGANISATIONAL STRUCTURE





DR ALISON TURNER

**Dr Alison Turner** was appointed General Manager and Chief Executive Officer of the National Blood Authority in August 2003. From 1997 to 2003 she was Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority. She previously held a number of senior government executive positions in the health and primary industries' sectors and has represented Australia internationally in many forums.

Dr Turner has postgraduate research qualifications in medical pharmacology from Sydney University and holds a Bachelor of Veterinary Science degree from Melbourne University.



MR MICHAEL STONE

**Mr Michael Stone** is the National Blood Authority'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 the development of the National Blood Agreement and the establishment of the National Blood Authority.

Mr Stone has worked with the National Blood Authority since its inception in 2003.



MS STEPHANIE GUNN

**Ms Stephanie Gunn** is the National Blood Authority's Corporate and Risk Manager. She has qualifications in economics and extensive experience in program and project management in the analysis of regional and industry development.

Ms Gunn joined the Australian Government 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 National Blood Authority in November 2003.



MR GORDON LEE KOO

**Mr Gordon Lee Koo** is the National Blood Authority's relationship manager for the Australian Red Cross Blood Service. He has qualifications in public sector management and business administration. Immediately prior to his appointment to the National Blood Authority, Mr Lee Koo was Deputy Chief Executive of the Canberra Hospital. His background includes: health services policy, planning and purchasing; managing the delivery of hospital, community and public health services; and corporate management encompassing finance, human resources and information services.

He has held management and leadership positions in a range of Australian Government, state and territory agencies at the executive level since 1983.

Mr Lee Koo has worked with the National Blood Authority since March 2005.

---



MR LEIGH MCJAMES

**Mr Leigh McJames** is the relationship manager for commercial suppliers Baxter Healthcare, CSL Limited, Octapharma Australia Pty Ltd and Wyeth Australia. He has a varied background in the Department of Defence, including senior roles in the management of government corporate support, acquisition and procurement, logistics and the development and implementation of government strategic defence policy.

He has also filled representational and advisory appointments at the Australian Embassy in Washington and in Baghdad as part of the coalition rebuilding Iraq.

Mr McJames commenced working at the National Blood Authority in November 2006.

---

**Mr Peter DeGraaff** was the National Blood Authority's relationship manager with commercial suppliers Baxter Healthcare, CSL Limited, Octapharma Australia Pty Ltd and Wyeth Australia. Following his first career as an officer in the Australian Army, he has had significant experience in Department of Defence procurement area and other senior management roles in the Industry Commission (now the Productivity Commission), the Australian Government Department of Housing and Regional Development and the Department of Health and Ageing.

Mr DeGraaff resigned from the National Blood Authority in October 2006.

## National Blood Authority Audit Committee

The role of the Audit Committee is to provide expert advice to the General Manager on ways to enhance the organisation's control framework, improve the objectivity and reliability of externally published financial information and comply with legislative requirements and obligations.

The Audit Committee met five times in 2006–07 and assisted the NBA to meet its corporate governance responsibilities. The membership of the Audit Committee included:

- a National Blood Authority Board Member as chair (Mr Ken Barker)
- a National Blood Authority Board Member in addition to the Chair (Mr David Kalisch)
- an independent non-National Blood Authority Board member (Ms Jenny Morison)
- representatives from the Australian National Audit Office and the National Blood Authority's internal auditors as observers.

In 2006–07 the Audit Committee reviewed the audit charter, monitored progress against the audit program and implemented a protocol in line with the Australian National Audit Office better practice guidelines.

It also provided advice on the National Blood Authority's:

- internal audit program, reports and findings
- interim financial reports
- Certificate of Compliance framework for 2006–07
- annual financial statements
- compliance with legislative obligations such as the Business Continuity Plan, the Fraud Control Plan, the Risk Management Plan and its processes, revised Chief Executive's Instructions and the Operational Plan.

## Internal audit program

The National Blood Authority's internal audit program focused on reviewing and analysing performance against key operational and financial risks, including contract negotiation and management. Findings from these internal audits have been minimal and, after consideration by the executive management committee, were addressed by the development of, or refinement to, the National Blood Authority's key business processes. Improvements made this year included:

- training for staff members in procurement guidelines and procedures
- drafting of more detailed guidelines on non-blood procurement
- implementing revised receipt of goods procedures.

The National Blood Authority has mandated that staff members attend training sessions on identified areas which are critical to the management of risk. Participation in courses run by the Australian Public Service Commission has ensured that staff members are aware of their obligations to stakeholders, governments and the Australian public on accountability and professionalism.

## Fraud control program

The Audit Committee provided valuable advice on the implementation of the Fraud Control Plan. Key initiatives of the plan that were implemented this year included:

- educating and training staff members in fraud identification and reporting strategies
- regular random audits of portable and attractive items.

## Relationship with external auditors

The National Blood Authority acknowledges the assistance provided by external auditors, including the Australian National Audit Office, in 2006–07, which has enabled the National Blood Authority to implement improvements. These improvements included changes to information communication technology infrastructure and the implementation of additional practices to support delegated activities.

## External scrutiny

In 2006–07 the National Blood Authority was involved in a cross-agency audit for the *Senate Order on Departmental and Agency Contracts (Calendar Year 2006 Compliance)*. The audit report on this matter is yet to be tabled.

## Executive management arrangements

Issues arising from the internal governance procedures outlined above are given careful consideration through a monthly cycle of performance reporting, improvement and strategic planning as depicted in Figure 4.

FIGURE 4: EXECUTIVE MANAGEMENT ARRANGEMENTS

