

Part Two

Our role and governance



Part Two outlines the role of the NBA in the blood sector. It provides a description of the external and internal governance arrangements that guide the work of the NBA and the nature of its relationships with jurisdictions, stakeholders and suppliers.

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2.1 The NBA role

The National Blood Authority (NBA), 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 National Blood Agreement outline the role of the NBA. This role includes:

- coordinating national supply and demand 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 ensure a value-for-money supply and an agreed single national pricing schedule
- implementing an efficient demand-driven system so that the blood supply system is highly responsive to needs
- collaborating with all governments and other relevant parties to ensure that Australia's blood supply is adequate, safe, secure and affordable
- national contingency planning for blood supplies
- promoting adherence to national safety and quality standards
- developing and implementing national strategies to encourage better use of blood and blood-related products.

The NBA Corporate Plan 2006-09 (approved by all Health Ministers), shows when and how specific activities will be carried out. The execution and timing of these activities depends on the funding provided by governments, the endorsement of priorities by the Jurisdictional Blood Committee (JBC) and decisions made by the Australian Health Ministers' Conference (AHMC).



2.2 Background

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

The 2001 *Review of the Australian Blood Banking and Plasma Product Sector*, chaired by the Rt Hon Sir Ninian Stephen, concluded that Australia's blood supply system was highly fragmented and costly. The report's core recommendation was to introduce a national

approach to managing Australia's blood supply through the establishment of a national blood authority.

The National Blood Agreement was approved by the AHMC in November 2002 and was subsequently signed by all Health Ministers. Legislation allowing for the establishment of the NBA passed through both Houses of Parliament unopposed and the NBA came into existence on 1 July 2003. National Policy objectives for these arrangements are detailed in the National Blood Agreement extract set out in Table 2.1.

Table 2.1 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.

2.3 The blood supply chain

Australia's blood supply consists of fresh, plasma-derived and recombinant products that are vital in the treatment and management of a diverse range of clinical conditions affecting thousands of Australians every day. Australia's blood sector is funded jointly by the Australian and state and territory governments, with contributions of 63% and 37%, respectively. In 2007–08, governments provided the NBA with \$720.6 million to procure and manage Australia's blood supply (see Table 2.2). Since the establishment of the NBA, governments have spent \$2934.7 million on blood and blood-related products.

Table 2.2 Government provided funding to procure and manage the blood supply

Year	Amount (\$ million)	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	720.6	12.7%
Total	2934.7	(average) 11.9%

The following pages outline the roles and responsibilities of the key stakeholders involved in the Australian blood supply chain as set out in Figure 2.1.

Australian, state and territory governments

As signatories to the National Blood Agreement, all governments are responsible for:

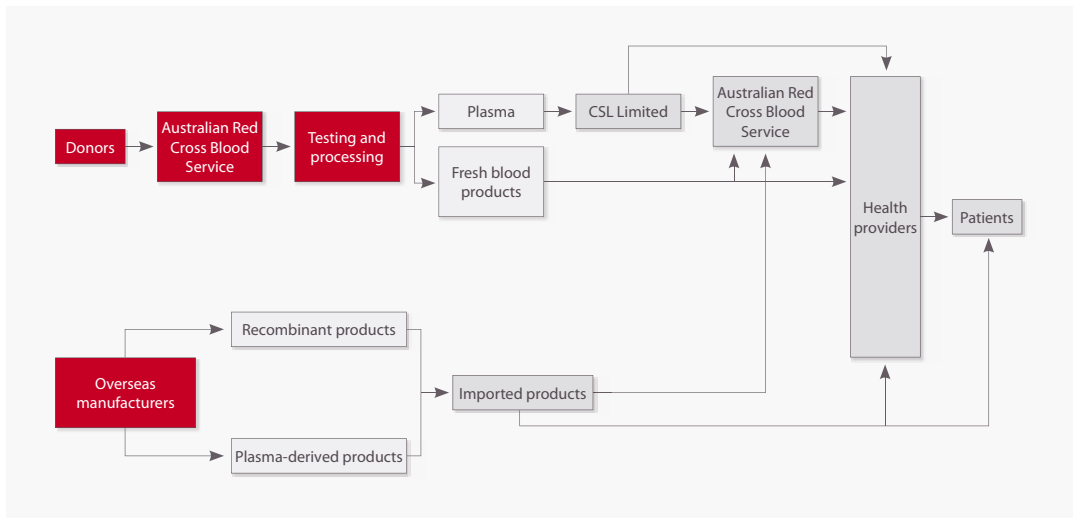
- establishing the policy framework and specific policies relating to the national blood supply
- overseeing the NBA's management of the blood supply arrangement
- fostering the development and implementation of best practice systems to promote efficient use and minimal wastage of blood and blood-related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

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is the regulator for blood and blood-related products in Australia. The TGA 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
- modifying safety standards
- issuing directives such as donor deferral.

Figure 2.1 Australian blood supply chain



Suppliers of blood and blood-related products

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

- the Australian Red Cross Blood Service (ARCBS), 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 products
- other pharmaceutical companies that are responsible for the supply and some distribution of a range of imported blood products; either 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:

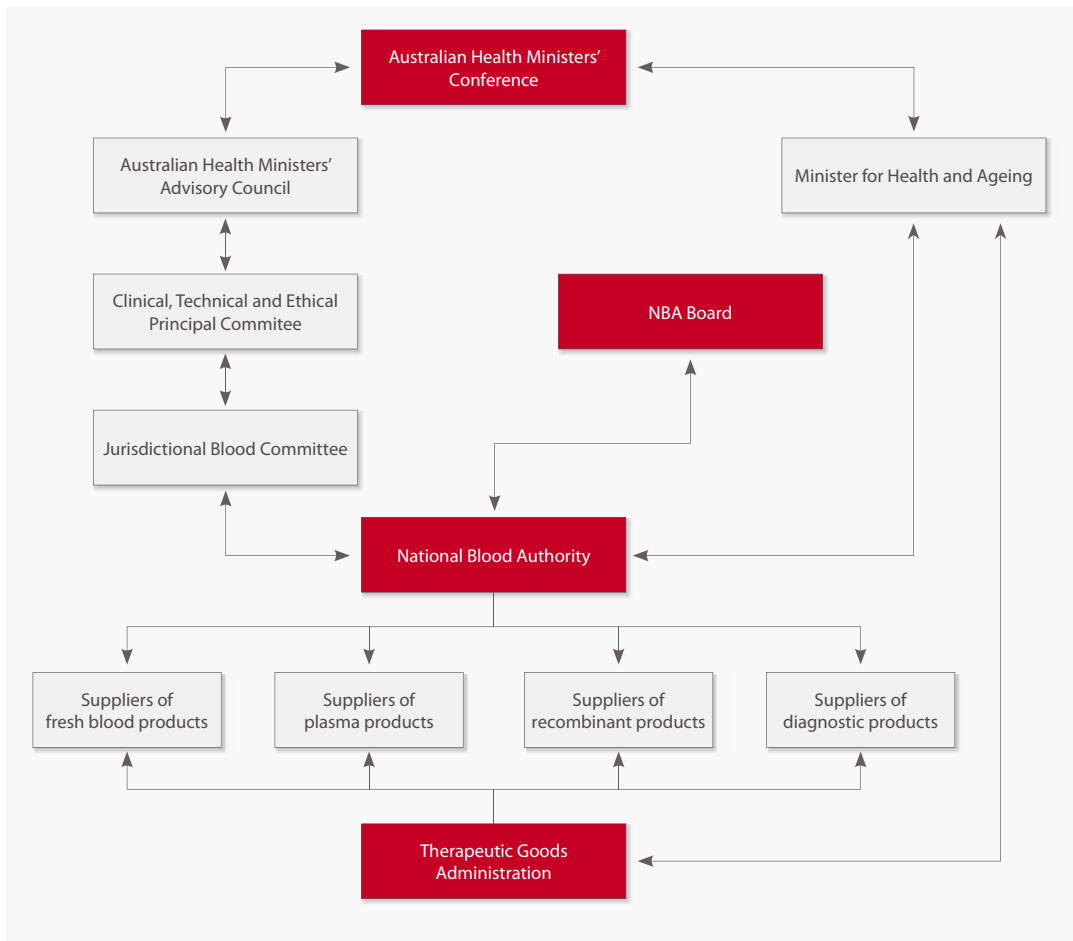
- CSL Ltd, DiaMed Australia Pty Ltd, Ortho-Clinical Diagnostics Inc (USA) and Australian Laboratory Services Pty Ltd for the provision of diagnostic reagents
- CSL Ltd and Octapharma Australia Pty Ltd for the provision of overseas-sourced IVIg
- Baxter Healthcare Pty Ltd, Wyeth Australia Pty Ltd and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

A standing offer is not a contract but a continuing offer by a supplier or suppliers to provide specified goods and services for a predetermined length of time, usually at a predetermined price. No contract is made until an order is placed which invokes the terms and conditions of the standing offer.

2.4 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*. They are depicted in Figure 2.2.

Figure 2.2 Governance structure of the Australian blood sector



Australian Health Ministers' Conference (AHMC)

The AHMC is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates. In 2007–08, key decisions made by the Ministers relevant to the blood sector included:

- funding for the 2008–09 National Supply Plan — which included the implementation strategy for universal leucodepletion and universal bacterial contamination testing, and adherence to several new requirements arising from the Council of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components*, 12th edition (2006)
- funding and indemnity arrangements for the NSW and ACT principal site for ARCBS processing and manufacturing
- endorsing the National Blood Supply Contingency Plan (NBSCP)
- approving the *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia (2007)* and the associated funding policy statement.

Minister for Health and Ageing

The Australian Government Minister for Health and Ageing, the Hon Nicola Roxon MP, 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 NBA and for issuing policy principles the NBA must comply with in the performance of its functions. The Minister carries out these statutory roles with endorsement from all health ministers in the AHMC. The NBA falls within the health and ageing portfolio.

Senator Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing, has portfolio responsibility for blood issues including oversight of the NBA.

Australian Health Ministers' Advisory Council (AHMAC)

The Australian Health Ministers' Advisory Council (AHMAC) provides support to the AHMC. It advises the AHMC 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 (JBC) and the Clinical, Technical and Ethical Principal Committee (CTEPC) and reports, as necessary, to the AHMC. The AHMAC has no statutory power and decisions are reached by consensus.

Clinical, Technical and Ethical Principal Committee

The CTEPC was established in 2006 to consider and provide advice to the AHMAC on clinical, technical and medico-ethical developments that are likely to affect the sector and to determine the policy implications of these developments on the delivery and management of healthcare and other services.

Jurisdictional Blood Committee

All Australian governments are represented on the JBC, which was established by the National Blood Agreement in 2003. The JBC is the conduit between governments and the NBA on blood policy; demand; supply planning and product distribution; funding and evidence-based approaches to emerging products;

services; and technologies. It also oversees the NBA's role in blood supply contracting. JBC is the primary body responsible for providing advice and support on these matters to the AHMC through the CTEPC — of which it has been a subcommittee since September 2006 — and the AHMAC. The NBA provides secretariat services to JBC.

National Blood Authority Board

The NBA Board provides advice to the NBA General Manager regarding 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 hold a governance role.



2.5 Internal governance arrangements

The NBA General Manager is ultimately responsible and accountable for the NBA under the *Financial Management and Accountability Act 1997*. The General Manager is a statutory officer, responsible to the Minister for Health and Ageing. The General Manager is responsible for the management of the NBA and the implementation of blood policy decisions and is the Chief Executive Officer (CEO) of the NBA and Agency Head under the *Public Service Act 1999*.

Under the *National Blood Authority Act 2003*, the General Manager is required to keep the NBA Board advised of the NBA's operations. This involves requesting advice from the NBA Board on strategic matters relating to the functions of the NBA and having regard to this advice. The General Manager also has regard to policy principles issued by the Minister for Health and

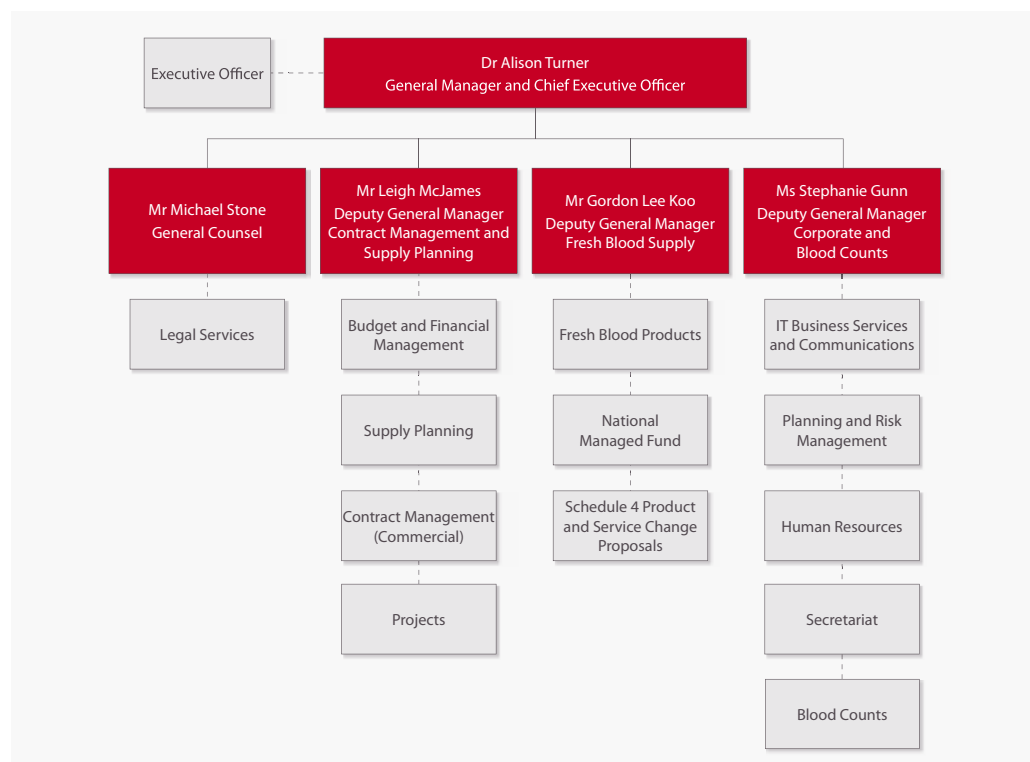
Ageing under the Act; policy decisions of the AHMC and the JBC; and Australian Government policy and compliance requirements relating to Australian Government agencies.

At 30 June 2008, the executive management of the NBA comprised the following staff:

- General Manager and CEO, Dr Alison Turner
- General Counsel, Mr Michael Stone
- Deputy General Manager, Fresh Blood Supply, Ms Helen Fowler (acting for Gordon Lee Koo)
- Deputy General Manager, Corporate and Blood Counts, Ms Stephanie Gunn
- Deputy General Manager, Contract Management and Supply Planning, Mr Leigh McJames.

The NBA's organisational structure is shown in Figure 2.3.

Figure 2.3 The NBA's organisational structure



Senior executive management biographies



Dr Alison Turner

Dr Alison Turner was appointed General Manager and CEO in August 2003. From 1997–2003 she was CEO of the Australian Pesticides and Veterinary Medicines Authority. She has 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 NBA 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 inhouse lawyer for a number of clients. He joined the Legal Services Branch of the Australian Government 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 NBA.

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



Ms Stephanie Gunn

Ms Stephanie Gunn is the NBA Corporate and Blood Counts Manager and has also been responsible for the management of the NBA Blood Counts Program since May 2007. She has qualifications in economics and broad-ranging experience in policy, program and contract management in the analysis of regional, industry, local government and community 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 NBA in November 2003.



Mr Leigh McJames

Mr Leigh McJames oversees the establishment and management of commercial contracts and supply planning. He is the Relationship Manager for the commercial suppliers Baxter Healthcare, CSL Ltd, Octapharma (Australia) Pty Ltd, Novo Nordisk Pharmaceuticals Pty Ltd and Wyeth Australia Pty Ltd. 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 joined the NBA in November 2006.



Mr Gordon Lee Koo

Mr Gordon Lee Koo was the NBA Relationship Manager for the ARCBS until May 2008. He has qualifications in public sector management and business administration. Prior to his appointment to the NBA, Mr Lee Koo was Deputy Chief Executive of 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 commenced at the NBA in March 2005 to May 2008.



Audit Committee Chair

Ms Jennifer Morison FCA, FCPA and FAIM

Ms Morison is a Chartered Accountant (FCA) with twenty seven years of broad experience in the profession and commerce. Her career has included audit, taxation, management consulting, corporate advisory work and consulting to government. In 1996, Ms Morison formed her own business, Morison Consulting Pty Limited which specialises in providing strategic financial management advice to senior executives within the government sector. She was awarded a Centenary medal in 2000 for her services to the accounting profession.

Ms Morison has been a board member of the Gungahlin Development Authority, the Kingston Foreshore Development Authority, Growth Centres Commission (NSW), ACTION and the Institute of Chartered Accountants in Australia. She is currently on the Board of the Australian Institute of Management and is the Deputy Chair of the ACT Land Development Agency.

Ms Morison is a leading consultant in the area of public sector financial management reform in Australia and is an independent member and Chair of a number of Commonwealth and ACT Government department audit and risk committees, including Centrelink, Department of Human Services, Department of Education and Workplace Relations and Department of Families, Housing, Community Services and Indigenous Affairs.

Ms Morison was appointed Chair of the NBA's Audit Committee in 2007, having been a member since 2004.

Executive management framework

The senior executive team is supported in its overall internal governance obligations by the executive management group on a daily basis and through a monthly cycle of performance reporting, improvement and strategic planning as depicted in Figure 2.4.

NBA Audit Committee

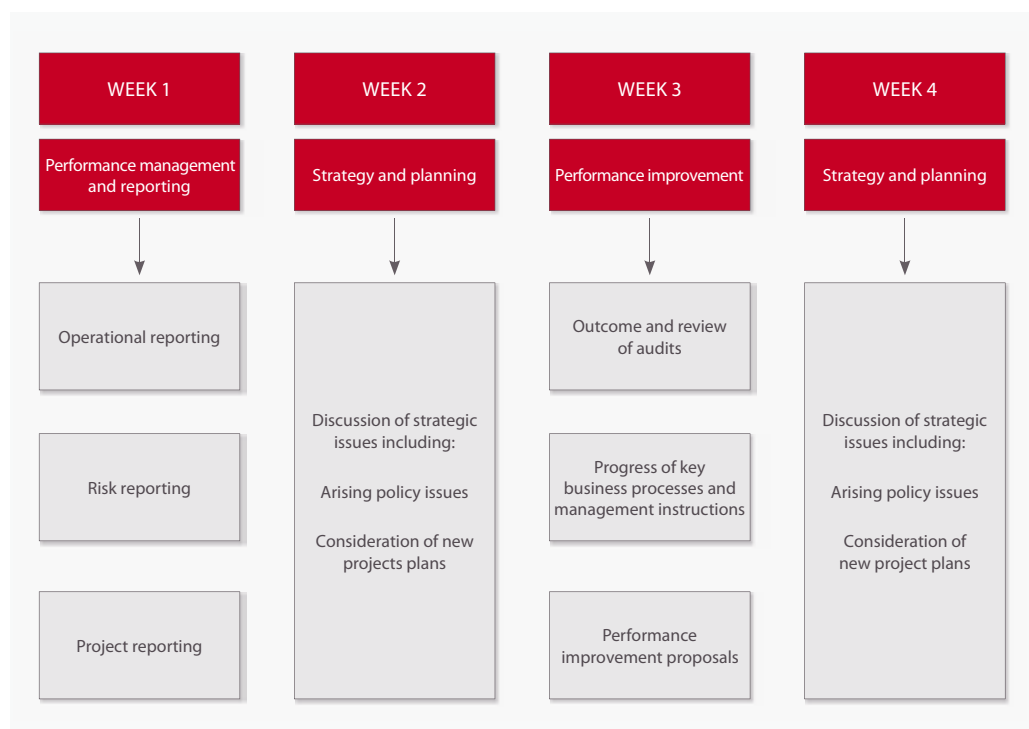
The role of the Audit Committee is to provide expert advice to the General Manager on ways to enhance the NBA's control framework, improve the objectivity and reliability of externally published financial information, and meets with all its compliance requirements and obligations.

The Audit Committee met six times in 2007–08 and assists the NBA in meeting its corporate governance responsibilities. The membership of the Committee included:

- an independent Chair, Ms Jenny Morison
- two members of the NBA Board, Mr David Kalisch and Mr Ken Barker
- a second independent member, Mr Mick Roche.

Representatives from the Australian National Audit Office and the NBA's internal auditors may also attend the Audit Committee meetings as observers.

Figure 2.4 Executive management monthly program



The NBA and the Audit Committee review the audit charter and audit program annually. In 2007–08 the Committee provided advice on the:

- internal audit program, reports and findings
- interim financial reports
- certificate of compliance framework
- NBA key business processes
- NBA's annual financial statements
- compliance with legislative and policy obligations such as the Business Continuity Plan (BCP), the Fraud Control Plan, the Risk Management Plan and Process, revised Chief Executive Instructions and Operational Plan and the NBA Instrument of Delegation

Relationship with external auditors

The NBA acknowledges the assistance provided by our external auditors during 2007–08, which has enabled the NBA to implement improvements in our internal governance and control frameworks.

External liaison and scrutiny

The NBA participated in only one cross agency external audit in 2007–08, focussing on agency management of their websites. The NBA understands that the report from this audit will be released in the first quarter of 2008–09.