

SECTION 4: OTHER REPORTING REQUIREMENTS

4.1: PURCHASER - PROVIDER ARRANGEMENTS

Broadly defined,¹ a purchaser-provider arrangement is one in which:

- the purchaser is the agent who decides what will be produced; and
- the provider is the agent who delivers the agreed outputs or outcomes.

In this subsection, the Department reports a number of arrangements under which its outputs are purchased from another agency, to contribute to the Department's outcomes.

Provider—Aged Care Standards and Accreditation Agency Ltd

Cross Agency Overview

Agency:	Aged Care Standards and Accreditation Agency Ltd (the Agency).
Services:	Manages the accreditation and ongoing supervision of Australian Government-funded aged care homes and promotes high quality care through the provision of information and educational services.
Formal agreement:	The Agency has a Deed of Funding Agreement with the Department.
Outcome:	Department-wide outcomes.

Responsibility

The Agency is responsible to the Minister for Ageing. The Agency reports against its own outcomes within the Portfolio Budget Statements of the Health and Ageing Portfolio. The Agency produces its own Annual Report.

Control Arrangements

The Agency is subject to the *Commonwealth Authorities and Companies Act 1997* and the *Corporations Act 2001*. The Agency has been appointed the 'accreditation body'² under Division 80 of the *Aged Care Act 1997*.

The Deed of Funding Agreement, along with the *Accreditation Grant Principles 1999*, sets out the services that the Agency will provide.

¹ Department of Finance, *Clarifying the Exchange: A Review of Purchaser/Provider Arrangements*. Management Improvement Discussion Series Paper No. 2. Resource Management Improvement Branch, November 1995, page 1.

² Manages the accreditation process for Australian Government-funded aged care homes, promotes high quality care by providing information, education and training to industry, strategically manages services working towards accreditation, and liaises with the Department of Health and Ageing about aged care homes which do not comply with the accreditation standards.

Resourcing

In 2006-07 the Agency will be paid \$20,070,000 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The performance of the Agency in delivering these services is covered by the performance information in Outcome 4 – Aged Care and Population Ageing within the Department's Portfolio Budget Statements.

Provider—Australian Institute of Health and Welfare

Cross Agency Review

Agency:	Australian Institute of Health and Welfare (AIHW).
Services:	National Surveillance and Monitoring of Arthritis and Musculoskeletal conditions in Australia – development of information and statistics.
Formal agreement:	Schedule for the National Centre for Monitoring Arthritis and Musculoskeletal Conditions contained in the Memorandum of Understanding (MoU) between the Department and the AIHW for 2005-10.
Outcome:	Department-wide outcomes.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$450,000 (GST inclusive) for the Better Arthritis Care budget initiative.

Performance Against Outcomes of Purchased Outputs

The performance of the AIHW in delivering these services is covered by the Department's Portfolio Budget Statement outlined in Table 3.2: Performance Information for the AIHW, Output Groups 1 and 2 – (Specific services to the Minister and Parliament, required under the *Australian Institute of Health and Welfare Act 1987* and national leadership in health-related and welfare-related information and statistics).

The AIHW produces its own Annual Report in accordance with the requirements of section 9 of the *Commonwealth Authorities and Companies Act 1997*.

Provider—**Australian Institute of Health and Welfare**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	National Surveillance and Monitoring of Asthma in Australia – development of information and statistics.
Formal agreement:	Schedule for the Australian Centre for Monitoring Asthma contained in the MoU between the Department and the AIHW 2005-10.
Outcome:	Department-wide outcomes.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department’s Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$1,000,000 (GST inclusive) for the 2005-09 Asthma Management Program budget initiative.

Performance Against Outcomes of Purchased Outputs

The performance of the AIHW in delivering these services is covered by the Department’s Portfolio Budget Statement outlined in Table 3.2: Performance Information for the AIHW, Output Groups 1 and 2 – (Specific services to the Minister and Parliament, required under the *Australian Institute of Health and Welfare Act 1987* and national leadership in health-related and welfare-related information and statistics).

The AIHW produces its own Annual Report in accordance with the requirements of section 9 of the *Commonwealth Authorities and Companies Act 1997*.

Provider—**Australian Institute of Health and Welfare**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	<p>The National Centre for Monitoring Diabetes provides expert advice and analysis information on Diabetes.</p> <p>The National Diabetes Register provides a national database for people with insulin-treated diabetes, including Type 1 Diabetes in people under the age of 40.</p> <p>National Centre for Monitoring Heart Stroke and Vascular Health provides analysis reports and advice on cardiovascular disease data to improve national policies and programs for heart, stroke and vascular health.</p>
Formal agreement:	Schedules under the MoU between the Department and the AIHW, focussing on Chronic Disease Management and the National Health Priority Areas.
Outcome:	Outcome 10 – Health System Capacity and Quality: National Health Priority Areas and Chronic Disease, Management.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$1,348,617 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered in the Department's Portfolio Budget Statement within Outcome 10 - Health System Capacity and Quality: National Health Priority Areas and the Chronic Disease Strategy.

Also refer to the AIHW agency chapter in the Department's Portfolio Budget Statements.

Provider—**Australian Institute of Health and Welfare (AIHW)**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	Implementation of the second phase of palliative care information development.
Formal agreement:	Schedule under the MoU between the Department and the AIHW.
Outcome:	Outcome 10 - Health System Capacity and Quality: Palliative Care and Community Assistance.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$172,150 (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The performance of the AIHW is covered in the AIHW agency chapter contained in the Department's Portfolio Budget Statements.

Provider—**Australian Institute of Health and Welfare**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	Develop and publish Allied Health Labour Workforce reports.
Formal agreement:	The Department has a MoU with the AIHW.
Outcome:	Outcome 12 - Health Workforce Capacity: Workforce.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$217,470 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered in the Department's Portfolio Budget Statement within Outcome 12 - Health Workforce Capacity: Workforce.

Also refer to the AIHW agency chapter in the Department's Portfolio Budget Statements.

Provider—Australian Institute of Health and Welfare

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	Production of the First National Sentinel Events Report.
Formal agreement:	The MoU with the AIHW commenced in November 2004 and is due to end in November 2006.
Outcome:	Outcome 10 – Health System Capacity and Quality: Research Capacity.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$67,961 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered in the Department's Portfolio Budget Statement, within Outcome 10 - Health Systems Capacity and Quality: Quality and Safety Based Initiatives.

Provider—**Australian Institute of Health and Welfare**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	Production and distribution of the 2000-02 Maternal Mortality Report.
Formal agreement:	The MoU between the Department and the AIHW commenced in January 2005 and is due to end in December 2006.
Outcome:	Outcome 10 – Health System Capacity and Quality: Research Capacity.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$4,109 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered in the Department's Portfolio Budget Statement, within Outcome 10 - Health Systems Capacity and Quality: Quality and Safety Based Initiatives.

Provider—**Australian Institute of Health and Welfare**

Cross Agency Review

Agency:	Australian Institute of Health and Welfare.
Services:	Development of information and statistics.
Formal agreement:	MoU.
Outcome:	Outcome 1 – Population Health.

Responsibility

The AIHW is a statutory authority within the Health and Ageing Portfolio and reports on its outcomes within the Department's Portfolio Budget Statements. The AIHW produces its own Annual Report.

Control Arrangements

Established under the *Australian Institute of Health and Welfare Act 1987*, the AIHW informs community discussion and decision-making through national leadership and collaboration in developing and providing health and welfare statistics and information.

Resourcing

In 2006-07 the AIHW will be paid \$1,440,343 (GST exclusive) for the Investment in Preventative Health 2002-03 budget measure (renewed in 2004-05).

Performance Against Outcomes of Purchased Outputs

The services provided are covered by the performance information included under Outcome 1 – Population Health, of the Department’s Portfolio Budget Statements.

Provider—**Australian Radiation Protection and Nuclear Safety Agency**

Cross Agency Review

Agency:	Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).
Services:	Testing and evaluation of radiopharmaceutical medicines for human diagnostic and therapeutic use. The services provided, contribute to agency specific outputs of the Therapeutic Goods Administration (TGA) group of regulators. The costs of these services are included in cost recovery arrangements.
Formal agreement:	TGA has a MoU with ARPANSA.
Outcome:	Outcome 1 – Population Health, TGA.

Responsibility

ARPANSA is an agency within the Health and Ageing Portfolio. ARPANSA reports on its outcomes within the Portfolio Budget Statements of the Health and Ageing Portfolio. ARPANSA produces its own Annual Report.

Control Arrangements

ARPANSA is a statutory authority and operates under the *Australian Radiation Protection and Nuclear Safety Act 1998*. ARPANSA is subject to the *Commonwealth Authorities and Companies Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 ARPANSA will be paid \$55,000 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The performance of ARPANSA in delivering these services is covered by the performance information in Outcome 1 – Population Health, TGA group of regulators.

Provider—Australian Sports Commission

Cross Agency Review

Agency:	Australian Sports Commission (ASC).
Services:	To develop and implement local preventive health projects in remote communities.
Formal agreement:	Under the terms of the Funding Agreement, develop a project plan and recruit a project officer to implement the project plan.
Outcome:	Outcome 6 - Rural Health: Rural Health Services.

Responsibility

The ASC is responsible for its own Portfolio Budget Statements and produces its own Annual Report.

Control Arrangements

The ASC was established under the Commonwealth Consolidated Acts (*Australian Sports Commission Act 1989*) and funded by appropriation by the Australian Government.

Resourcing

In 2006-07 ASC will be paid \$8,784 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered within the Department's Portfolio Budget Statements, Outcome 6 - Rural Health: Rural Health Services.

Provider—Centrelink

Cross Agency Review

Agency:	Centrelink.
Services:	Centrelink assesses the income status of aged care residents to assist the Department in determining whether the residents are required to pay an income-tested fee. In 2005-06, this work was extended to cover assets assessments for aged care residents to determine whether residents are eligible for concessional resident status. Centrelink also provides validation data to Medicare Australia for the Pharmaceutical Benefits Scheme Concessional Entitlements Validation Project and to determine the eligibility of families or individuals for the extended Medicare safety net lower threshold.
Formal agreement:	The Department has a Business Partnership Agreement with Centrelink.
Outcome:	Department-wide outcomes.

Responsibility

Centrelink lies within the Finance and Administration Portfolio. Centrelink reports on its outcomes within the Human Services Portfolio Budget Statements. Centrelink produces its own Annual Report.

Control Arrangements

Centrelink is a statutory authority which operates under the *Commonwealth Services Delivery Agency Act 1997*. Centrelink is subject to a range of legislation, including the *Financial Management and Accountability Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 Centrelink will be paid \$11.6 million (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The performance of Centrelink in delivering these services is covered in the Department's Portfolio Budget Statements.

Provider—Department of the Environment and Heritage

Cross Agency Review

Agency:	Department of the Environment and Heritage (DEH).
Services:	Provide advice and the evaluation of the environmental impacts of new and existing industrial chemicals.
Formal agreement:	Service Level Agreement with DEH.
Outcome:	Outcome 1 - Population Health: TGA group of regulators. The costs of these services are included in cost recovery arrangements.
Purchaser:	National Industrial Chemicals Notification and Assessment Scheme.

Responsibility

DEH is responsible for producing its own Portfolio Budget Statements and produces its own Annual Report.

Control Arrangements

DEH is an Australian Government Department and operates under the *Financial Management Accountability Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 DEH will be paid \$673,400 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The performance of DEH in delivering these services is covered by the performance information identified in the Service Level Agreement.

Provider—**General Practice Education and Training Ltd**

Cross Agency Review

Agency:	General Practice Education and Training Ltd (GPET).
Services:	GPET manages the Australian General Practice Training Program which is a regionalised vocational education and training program for general practitioners. GPET subcontracts with 22 regional training providers to deliver training.
Formal agreement:	GPET has a Funding Agreement with the Department to oversee and support the Australian General Practice Training Program.
Outcome:	Outcome 5 – Primary Care: General Practice Registrars.

Responsibility

GPET lies within the Health and Ageing Portfolio. GPET reports on its outcomes within the Department’s Portfolio Budget Statements. GPET produces its own Annual Report.

Control Arrangements

GPET is a Commonwealth company limited by guarantee, operating under the *Commonwealth Authorities and Companies Act 1997*. GPET is accountable under the terms of its Funding Agreement with the Department.

Resourcing

In 2006-07 GPET will be paid \$82.2 million (GST exclusive).

Performance Against Outcomes of Purchased Outputs

Performance information for this Funding Agreement is detailed in the Department’s Portfolio Budget Statements within GPET’s agency chapter.

Provider—**Medicare Australia**

Cross Agency Review

Agency:	Medicare Australia.
Services:	Medicare Australia supplies and manages Identifier Code Provider Numbers to each Medical Rural Bonded (MRB) doctor at the start of their internship and through out their scholarships contract.
Formal agreement:	The Department has a MoU with Medicare Australia which commenced 8 July 2004 and is due to cease 30 June 2009.
Outcome:	Outcome 12 – Health Workforce Capacity: Rural Workforce - Medical Rural Bonded Scholarships.

Responsibility

Medicare Australia lies under the Finance and Administration Portfolio, within the Department of Human Services (DHS) and reports on its outcomes in the Human Services Budget Statements. Medicare Australia produces its own Annual Report.

Control Arrangements

Medicare Australia operates under the *Financial Management and Accountability Act 1997*, the Chief Executive Instructions and the *Public Service Act 1999* – Financial Statements are published in Medicare Australia's Annual Report.

Resourcing

In 2006-07 Medicare Australia will be paid \$233,112 (GST inclusive).

Performance Against Outcomes of Purchased Outputs

The services provided are covered by the Department's Portfolio Budget Statements within Outcome 12 – Health Workforce Capacity: Rural Workforce and Medical Rural Bonded Scholarships.

Provider—Medicare Australia

Cross Agency Review

Agency: Medicare Australia.
Services: To deliver Broadband for health programs.
Formal agreement: Service Arrangement Reference Contract.
Outcome: Outcome 10 - Health System Capacity and Quality.

Responsibility

Medicare Australia lies under the Finance and Administration Portfolio, within the Department of Human Services (DHS) and reports on its outcomes in the Human Services Budget Statements. Medicare Australia produces its own Annual Report.

Control Arrangements

Medicare Australia operates under the *Financial Management and Accountability Act 1997*, the Chief Executive Instructions and the *Public Service Act 1999* – Financial Statements are published in Medicare Australia's Annual Report.

Resourcing

In 2006-07 Medicare Australia will be paid \$341,000 (GST inclusive)

Performance Against Outcomes of Purchased Outputs

The services provided are covered by the Department's Portfolio Budget Statements within Outcome 10 - Health System Capacity and Quality.

Provider—**Medicare Australia**

Cross Agency Review

Agency:	Medicare Australia.
Services:	Administer payments to providers of aged care services and maintain and support of the Department's aged care payments systems.
Formal agreement:	Arrangements for administration of aged care payments are described in a Business Practice Agreement which forms part of a MoU between the Department and Medicare Australia.
Outcome:	Outcome 4 – Aged Care and Population Ageing.

Responsibility

Medicare Australia lies under the Finance and Administration Portfolio, within the Department of Human Services (DHS) and reports on its outcomes in the Human Services Budget Statements. Medicare Australia produces its own Annual Report.

Control Arrangements

Medicare Australia operates under the *Financial Management and Accountability Act 1997*, the Chief Executive Instructions and the *Public Service Act 1999* – Financial Statements are published in Medicare Australia's Annual Report.

Resourcing

In 2006-07 Medicare Australia will be paid \$13.6 million (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The performance of the aged care payments function by Medicare Australia is covered by performance measures identified in a Business Practice Agreement. The Department continues to be responsible for setting policy direction for aged care and service standards for the administration of aged care payments. Additional information about the performance of Medicare Australia is reported in the Budget Statements of the Department of Human Services.

Provider—**National Industrial Chemicals Notification and Assessment Scheme**

Cross Agency Review

Agency:	National Industrial Chemicals Notification and Assessment Scheme (NICNAS).
Services:	The engagement of technical experts from NICNAS to provide coordinated health sector input on two working groups established by the National Environment Protection Council.
Formal agreement:	The Department has a MoU with NICNAS.
Outcome:	Outcome 15 - Biosecurity and Emergency Response.

Responsibility

NICNAS is the Australian Government's regulatory body for industrial chemicals. It is located within the Office of Chemical Safety which is part of the TGA group of regulators, within the Department of Health and Ageing Portfolio. NICNAS reports on its outcomes within the Department's Portfolio Budget Statements. NICNAS produces its own Annual Report.

Control Arrangements

NICNAS is a statutory authority established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989*. NICNAS is subject to a range of legislation, including the *Financial Management and Accountability Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 NICNAS will be paid \$50,000 (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The performance of NICNAS in delivering these services contributes to the Department's Health Emergency Planning and Response Program. Performance will be measured in relation to the quality indicator – timely recognition and development of appropriate responses to emerging threats to human health.

Provider—**Office of the Australian Safety and Compensation Council**

Cross Agency Review

Agency:	Office of the Australian Safety and Compensation Council (OASCC).
Services:	Provision of information services support.
Formal agreement:	MoU with OASCC.
Outcome:	Outcome 1 - Population Health, TGA group of regulators.

Responsibility

OASCC lies within the Employment and Workplace Relations (DEWR) Portfolio. OASCC reports on its outcomes within the Portfolio Budget Statements of DEWR. OASCC produces its own Annual Report.

Control Arrangements

DEWR is an Australian Government Department and is subject to the *Financial Management Accountability Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 the estimated expenditure with OASCC is \$93,600 (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The performance of DEWR in delivering these services is covered by the performance information identified in the MoU. Also refer to the Department's Portfolio Budget Statements, Outcome 1 - Population Health, TGA.

Provider—Therapeutic Goods Administration

Cross Agency Review

Agency:	Australian Pesticides and Veterinary Medicines Authority (APVMA).
Services:	Provision of occupational health and safety and public health risk assessment services to the APVMA on pesticides.
Formal agreement:	The Office of Chemical Safety has a Service Level Agreement with APVMA.
Outcome:	Outcome 1 – Population Health, Therapeutic Goods Administration (TGA) - group of regulators.
Purchaser:	APVMA. The cost of this service is fully cost recovered.

Responsibility

APVMA lies within the Agriculture Fisheries and Forestry Portfolio. APVMA reports on its outcomes within the Portfolio Budget Statements of the Agriculture, Fisheries and Forestry Portfolio. APVMA produces its own Annual Report.

Control Arrangements

In line with the Service Level Agreement, the APVMA is a statutory authority and is subject to the *Commonwealth Authorities and Companies Act 1997* and the *Public Service Act 1999*.

Resourcing

In 2006-07 the estimated cost to be recovered from the APVMA is \$3,202,102 (GST exclusive).

Performance Against Outcomes of Purchased Outputs

The services provided to the APVMA are covered by the performance information included under Outcome 1 – Population Health, TGA group of regulators of the Department's Portfolio Budget Statements.

4.2: COST RECOVERY ARRANGEMENTS

Therapeutic Goods Administration

The Australian community has an expectation that the therapeutic products in the marketplace are safe and of high quality, to a standard equal to that of countries with comparable standards. The Therapeutic Goods Administration (TGA) is one of the world's front line regulators undertaking rigorous scientific and risk assessments of therapeutic products to ensure safety, quality and efficacy, without undue impact on the timely supply of essential products to consumers and patients.

In Australia, regulation is achieved through a risk management approach to pre-market evaluation and approval of therapeutic products intended for supply, licensing of manufacturers and post-market monitoring and surveillance. The principal activities of the regulatory scheme include:

- scientific evaluation of medicines, medical devices, and blood and tissue products for supply in Australia;
- licensing and audit of manufacturing standards;
- monitoring compliance with standards, including testing of products, auditing product data, analysing reportable incidents, investigating complaints, and recalling non-compliant products from the market;
- surveillance, investigation and enforcement of the provisions of the *Therapeutic Goods Act 1989* (the Act);
- industry support activities, including the development of guidelines and promoting international harmonisation; and
- services to Government to support the objects of the Act.

In December 2003 the Australian and New Zealand Government's agreed to establish a joint regulatory scheme for therapeutic products across the Tasman. A fees and charges framework to meet the needs of the joint scheme to come into operation in 2007 will be developed and will be subject to a future Cost Recovery Impact Statement.

Compliance with Cost Recovery Policy

The TGA recovers the full cost of its regulatory activities within the scope of the Act through fees and charges for services provided to product introducers (sponsors) and manufacturers. The full cost of regulating the availability and manufacture of medicines, medical devices, blood and blood components in Australia and for export is recovered through fees and charges on industry. Fees and charges are prescribed in regulations made under the *Therapeutic Goods Act 1989*, *Therapeutic Goods (Medical Devices) Act 2001* and the *Therapeutic Goods (Charges)*

Act 1990. Certain activities undertaken for Government have been funded from departmental allocations.

	2004-05 Actual \$m	2005-06 Estimate \$m	2006-07 Estimate \$m
Industry cost recovery	69.906	73.122	72.890
Government	6.177	1.137	3.478
Price of outputs	76.083	74.259	76.368

Cost Recovery Impact Statement for the Regulation of In-Vitro Diagnostic Devices

The recovery of costs associated with the regulation of in-vitro diagnostic devices represents a significant change to existing cost recovery arrangements undertaken by the TGA.

In-vitro diagnostic devices will be regulated as a subset of general medical devices that are already regulated by the TGA. Regulation will involve various pre-market regulation activities (regulations with which firms or products must comply before a product can be offered for sale) and post-market activities (regulations with which firms or products must comply after a product is available for sale) that involve monitoring compliance with regulations, investigation and enforcement.

Pre-market approvals involve different regulatory processes based on the risk of the device to individuals and to public health. Class 1 represents the lowest risk group which permits administrative assessment and self-certification of conformity with standards prior to market approval. Class 2 and 3 involve increasing risk levels and are subject to application audits, conformity assessments and technical file reviews. Class 4 is the highest risk group and has additional requirements relating to design dossier examinations.

Following approval, companies will be required to maintain certification of conformity (surveillance audits), comply with problem reporting requirements and, for Class 4 devices, participate in ongoing quality assurance programs.

As with all regulatory arrangements, the TGA will provide information and support to the regulated industry and consumers and will be responsible for the maintenance of the regulatory framework (including regulatory development and advice concerning the operation of the scheme). The cost of activities associated with the development of the coding nomenclature and standards through international fora and the provision of advice regarding the operation of the regulatory scheme to the Parliament are driven by the requirement to regulate in-vitro diagnostic devices and are considered integral to regulation and appropriate for inclusion in cost recovery arrangements.

Fees and charges for medical devices are proscribed in the *Therapeutic Goods (Charges) Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Regulatory fees imposed on product sponsors and manufacturers of in-vitro diagnostic devices form part of the cost of bringing products to market and are taken into consideration in determining pricing levels.

Compliance with Cost Recovery Policy for the Regulation of In-Vitro Diagnostic Devices

Many of the regulatory activities and business processes for in-vitro diagnostic devices are common to all medical devices and so the fees that are applicable have been set to be consistent with other medical devices. The fee levels are assessed as being cost reflective as required by the Australian Government's Cost Recovery Guidelines.

A four year transition period has been agreed with industry for the introduction of the new regulatory arrangements for Class 1, 2 and 3 in-vitro diagnostic devices, whilst Class 4 devices will have a 2 year transition period based upon their high risk nature in screening blood and tissue donations. To remove any disincentive for early inclusion of products on the Australian Register of Therapeutic Goods and allow companies to manage the cost impact over four years, the cost recovery model delays the introduction of annual charges until the third year of the scheme.

The cost recovery arrangement is designed to achieve full cost recovery and is forecast to recover a total \$1.4 million in 2006-07. Any under or over recovery of costs will be monitored in consultation with the industry. The TGA has undertaken to review the annual charge pricing levels prior to its introduction in 2008-09.

Consultation

The cost recovery model has been developed in consultation with industry representatives through the peak industry body, the Medical Industry Association of Australia. The TGA has also consulted the Department of Finance and Administration.

Further Review

The Australian and New Zealand governments have agreed to develop a joint scheme for the regulation of therapeutic products across the Tasman, expected to commence in 2007. Fees and charges for the joint scheme will be assessed ahead of the commencement of the scheme, with a full cost recovery assessment to be completed two years following commencement of the joint scheme.

National Industrial Chemicals Notification and Assessment Scheme

Industrial chemicals are regulated in Australia in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS is administered as part of the Office of Chemical Safety, a business unit of the Therapeutic Goods Administration group of regulators in the Department of Health and Ageing.

NICNAS is the national authority for the scientific assessment and management of risks to people and the environment associated with the use of industrial chemicals. Its aim is to encourage the safe and sustainable use of industrial chemicals. The principle activities of the national notification and assessment scheme include:

- assessments of chemical risks associated with the introduction (manufacture or import) of new chemicals into Australia;
- reviews of chemical risks associated with chemicals introduced prior to the commencement of the scheme;

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- making assessments widely available to assist public health and environmental agencies in regulating the use, release and disposal of industrial chemicals and providing risk and safety information to industry, workers and the public; and
- ensuring compliance for inclusion in the Australian Register of Industrial Chemicals and the Register of Chemical Introducers.

Following the review of cost recovery arrangements in 2005, the cost of administering NICNAS is now fully funded from industry through fees relating to new chemical assessments and from NICNAS registration fees and charges, paid by industry and consistent with the Act and associated regulations.

	2004-05 Actual \$m	2005-06 Estimate \$m	2006-07 Estimate \$m
Industry cost recovery	6.681	7.441	7.473
Government	0.897	0.349	0.258
Price of outputs	7.578	7.790	7.731

In accordance with the Australian Government's cost recovery policy, cost recovery arrangements for the scheme were reviewed to ensure they complied with Guidelines issued by the Department of Finance and Administration. Independent consultants were engaged to review current cost recovery arrangements, consult with industry and government stakeholders and undertake an assessment of the basis for setting fees and charges.

Further review

Cost recovery arrangements for NICNAS are due for review in 2010-2011.

