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.

<table>
<thead>
<tr>
<th>Provider—Aged Care Standards and Accreditation Agency Ltd</th>
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</thead>
</table>

Cross agency overview

The Aged Care Standards and Accreditation Agency Ltd, through a Deed of Funding Agreement with the Department, 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.

Responsibility

Responsibility for the Aged Care Standards and Accreditation Agency Ltd lies with the Minister for Ageing. The Aged Care Standards and Accreditation Agency Ltd produces its own annual report.

Control arrangements

The Aged Care Standards and Accreditation Agency Ltd is subject to the Commonwealth Authorities and Companies Act 1997 and the Corporations Act 2001. The Aged Care Standards and Accreditation Agency Ltd has been appointed the ‘accreditation body’ 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 Aged Care Standards and Accreditation Agency Ltd will provide.

Resourcing

The estimated expenditure for 2005-06 under the Deed of Funding Agreement is $8,461,000.

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Budget statements—Department of Health and Ageing

Performance against outcomes of purchased outputs
The performance of the Aged Care Standards and Accreditation Agency Ltd in delivering these services is covered by the performance information discussed for Outcome 3 of the Department’s budget statements.

Provider—Australian Bureau of Statistics

Cross agency overview
The Department of Health and Ageing has an Agreement with the Australian Bureau of Statistics (ABS) for the development of national standards for health surveillance.

Responsibility
Responsibility for the ABS lies within the Treasury portfolio and the ABS reports on outcomes in the ABS Annual Report.

Control arrangements
The ABS operates under the Australian Bureau of Statistics Act 1975 and reports annually to Parliament. The ABS is also subject to a range of other legislation, including the Financial Management and Accountability Act 1997 and the Public Service Act 1999.

Resourcing
$300,000 per year (excluding GST) in 2004-05 and 2005-06 from the Investment in Preventive Health 2002-03 Budget measure (renewed 2004-05).

Performance against outcomes of purchased outputs
The performance of the ABS in delivering these services is covered by performance indicators identified in the Agreement.

Provider—Australian Institute of Health and Welfare

Cross agency overview
Agency: Australian Institute of Health and Welfare (AIHW)
Services: Development of information and statistics
Formal agreement: Memorandum of Understanding (MoU) plus Schedules for Services
Outcomes: Department-wide outcomes

Responsibility
The AIHW is a statutory authority within the Health and Ageing portfolio.
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
Individual program areas pay for agreed AIHW services in accordance with provisions and rates set out in the MoU Pricing Summary and individual Schedules for Services. Commencing from 22 October 2004, the AIHW is required to treat the supply of services to government clients as a taxable supply and therefore GST is applicable to pricing and subsequent invoicing.

Performance against outcomes of purchased outputs
The AIHW produces its own annual report in accordance with the requirements of Section 9 of the *Commonwealth Authorities and Companies Act 1997*.

Cross agency overview
The Office of Chemical Safety has a Memorandum of Understanding (MoU) with the Australian Pesticides Veterinary Medicines Authority (APVMA) to provide occupational health and safety and public health risk assessment services on pesticides. The services undertaken are included in agency specific outputs of the Therapeutic Goods Administration (TGA) group of regulators. The cost of these services is fully cost recovered.

Responsibility
Responsibility for APVMA lies with the Agriculture, Fisheries and Forestry portfolio. APVMA produces its own annual report.

Control arrangements
In line with the MoU above, APVMA is a statutory authority subject to the *Commonwealth Authorities and Companies Act 1997* and the *Public Services Act 1999*.

Resourcing
The estimated costs to be recovered from the APVMA in 2005-06 is $3,750,000.

Performance against outcomes of purchased outputs
The services provided to APVMA are covered by the performance information included under Outcome 1 of the Department’s budget statements TGA group of regulators.
Provider—Australian Radiation Protection and Nuclear Safety Agency

Cross agency overview

The Therapeutic Goods Administration (TGA) has a Memorandum of Understanding (MoU) with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) for testing and evaluation of radiopharmaceutical medicines for human diagnostic and therapeutic use.

The services provided contribute to agency specific outputs of the TGA group of regulators. The costs of these services are included in cost recovery arrangements.

Responsibility

Responsibility for ARPANSA lies with the Health and Ageing portfolio. ARPANSA produces its own annual report.

Control arrangements

In line with the MoU above, ARPANSA is a statutory authority and operates under the Australian Radiation Protection and Nuclear Safety Act 1998. ARPANSA is also subject to the Commonwealth Authorities and Companies Act 1997 and the Public Services Act 1999.

Resourcing

The estimated expenditure for 2005-06 under the two year MoU with ARPANSA is $55,000. The MoU may be extended by mutual agreement.

Performance against outcomes of purchased outputs

The performance of ARPANSA in delivering these services is covered by performance information identified in the MoU.

Provider—Centrelink

Cross agency overview

The Department has a Business Partnership Agreement with Centrelink. 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 will be extended to cover assets assessments for aged care residents to determine whether residents are eligible for concessional resident status. Development work for this aspect is being undertaken in 2004-05.

Responsibility

Responsibility for Centrelink lies within Human Services (part of the Finance and Administration portfolio). Centrelink reports on its outcomes within Human Services’ Portfolio Budget Statements. Centrelink produces its own annual report.
Control arrangements

In addition to the Business Partnership Agreement above, Centrelink is a statutory authority, which operates under the Commonwealth Services Delivery Agency Act 1997. Centrelink is also subject to a range of other legislation, including the Financial Management and Accountability Act 1997 and the Public Service Act 1999.

Resourcing

The budgeted price of purchasing these services from Centrelink for 2005-06 is approximately $12.3 million, subject to finalising negotiations of a new agreement and the development of a new schedule for Fairer Assets Testing.

Performance against outcomes of purchased outputs

The performance of Centrelink in delivering these services is covered by performance information identified in the Business Partnership Agreement.

Cross agency overview

Under the new Medicare safety net announced as part of the Government’s changes to Medicare, Centrelink will be providing the Health Insurance Commission with details of recipients of the Family Tax Benefit.

The Department has an agreement with Centrelink for payment of service provided for 2003-04. The current agreement has been extended and a new agreement is in the process of being finalised.

Responsibility

Responsibility for Centrelink lies within Human Services (part of the Finance and Administration portfolio). Centrelink reports on its outcomes within Human Services’ Portfolio Budget Statements. Centrelink produces its own annual report.

Control arrangements

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

Resourcing

The amount of money to be paid to Centrelink under the purchaser-provider arrangement from 2004-05 to 2006-07 is $2.1 million.

Performance against outcomes of purchased outputs

The Department will monitor the data transferred from Centrelink for accuracy and timeliness.
Provider—Centrelink

Cross agency overview
Due to administrative arrangements families who defer payment of Family Tax Benefit (A) may miss out on additional Medicare benefits owing to them under the Extended Medicare Safety Net program. The Department of Health and Ageing, in conjunction with the Health Insurance Commission and Centrelink have undertaken steps to identify these families and make them aware of their entitlements.

The Department has an Agreement with Centrelink for payment of service provided for 2003-04. The agreement for services provided for 2004-05 and thereafter is in the process of being formalised.

Responsibility
Responsibility for Centrelink lies within Human Services (part of the Finance and Administration portfolio). Centrelink reports on its outcomes within Human Services’ Portfolio Budget Statements. Centrelink produces its own annual report.

Control arrangements
In addition to the Service Agreement above, Centrelink is a statutory authority which operates under the Commonwealth Services Delivery Agency Act 1997. Centrelink is also subject to a range of other legislation, including the Financial Management and Accountability Act 1997 and the Public Service Act 1999.

Resourcing
The amount of money to be paid to Centrelink under the purchaser-provider arrangement is $830,000 in 2004-05.

Performance against outcomes of purchased outputs
This data will contribute to performance measurements specified in the Portfolio Budget Statements relating to Outcome 2.

Provider—Department of Environment and Heritage

Cross agency overview
The Office of Chemical Safety, incorporating the National Industrial Chemical Notification and Assessment Scheme, has a Memorandum of Understanding (MoU) with the Department of Environment and Heritage (DEH) for advice and the evaluation of the environmental impacts of new and existing industrial chemicals.

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.
Responsibility
Responsibility for the DEH lies with the Environment and Heritage portfolio, which produces its own annual report.

Control arrangements
In line with the MoU above, the DEH is an Australian Government department and operates under the Financial Management and Accountability Act 1997 and the Public Service Act 1999.

Resourcing
The estimated expenditure for 2005-06 under the MoU with DEH is $533,000.

Performance against outcomes of purchased outputs
The performance of the DEH in delivering these services is covered by the performance information included in Outcome 1 of the Department’s budget statements (TGA group of regulators).

Provider—General Practice Education and Training Ltd

Cross agency overview
General Practice Education and Training Ltd (GPET) has a funding agreement with the Department of Health and Ageing to oversee and manage the Australian General Practice Training Program.

Responsibility
Responsibility for GPET lies within the Health and Ageing portfolio. 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 agreement with the Department.

Resourcing
The estimated total resources paid to GPET from the Department of Health and Ageing for 2005-06 is $76,311,011 million (GST inclusive).

Performance against outcomes of purchased outputs
GPET is a Commonwealth-owned company, limited by guarantee under the Commonwealth Authorities and Companies Act 1997, and produces its own annual report in accordance with the requirements of Section 9 of the Act. Performance information for the funding agreement is detailed in GPET’s budget statements.
Cross agency overview

The Health Insurance Commission (HIC) has agreed to track Medical Rural Bonded Scholarship Scheme (MRBSS) participants to ensure that the return of service obligations set out in the contract between the Participant and the Commonwealth are being met. MRBSS doctors are bonded to work in rural and remote areas once they have attained Fellowship in either general practice or another specialty.

Under the agreed arrangements, HIC will:

- when an MRBSS participant applies for a Medicare provider number, issue the participant with a provider number that restricts payments of Medicare rebate claims to those for services provided in an eligible Rural, Remote and Metropolitan Areas (RRMA) location;
- monitor compliance with MRBSS participants’ work period obligations under the terms of the MRBSS contract; and
- refuse the issue of provider numbers to those MRBSS doctors who are not working in an eligible RRMA location.

A HIC business requirements document was drafted by the Department of Health and Ageing and accepted by HIC. HIC has provided an indicative costing, for a five year period of $315,949 with the costing for 2004-05 being $87,013.

The purchase outputs belong to Outcome 9.

Responsibility

Responsibility for HIC lies within Human Services, which is part of the Finance and Administration portfolio.

Control arrangements

HIC is a statutory authority within Human Services, which is part of the Finance and Administration portfolio. HIC has a board of Commissioners that provides advice on its operations. HIC is subject to the Health and Insurance Commission Act 1973 and the Commonwealth Authorities and Companies Act 1997.

Resourcing

To date there have been no payments to HIC for their work undertaken. A payment of $87,013 is due to be paid to HIC.

Performance against outcomes of purchased outputs

Outputs for the arrangement with HIC are not specified in the PBS. However under the business requirements, HIC is required to report to the Department on the provision of Medicare
provider numbers to MRBSS participants and on their compliance of those participants with their contracts.

Provider—Health Insurance Commission

Cross agency overview
The service comprises the construction and management of the Coordinated Care Trials (CCT) web-based system which collects data on the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) utilisation by CCT participants. The agreement relating to these services is the CCTs web-based system Schedule to the Strategic Partnership Funding Agreement.

Responsibility
Responsibility for HIC lies within Human Services, which is part of the Finance and Administration portfolio.

Control arrangements
HIC is a statutory authority within Human Services, which is part of the Finance and Administration portfolio. HIC has a board of Commissioners that provides advice on its operations. HIC is subject to the Health Insurance Act 1973 and the Commonwealth Authorities and Companies Act 1997.

Resourcing
Funding for 2005-06 will be $122,100.

Performance against outcomes of purchased outputs
The performance of HIC in delivering these services is covered by performance information identified in the Strategic Partnership Funding Agreement.

Provider—National Institute of Clinical Studies

Cross agency overview
The National Institute of Clinical Studies (NICS) provides a national and integrated focus for work being undertaken to continuously improve the quality of clinical practice, and its delivery to patients in Australia. NICS aims to:

- lead the continuous improvement of clinical practice and its delivery;
- engage stakeholders, including practitioners, consumers, funders, managers and researchers, in the improvement of clinical services; and
- foster, inform and evaluate the implementation of best practice clinical standards, with careful attention to incentives and obstacles.
Responsibility
NICS is governed by a Board of Directors, which is accountable to the Minister for Health and Ageing for all reporting and operations. NICS produces its own annual report.

Control arrangements
NICS was established in December 2000 and was constituted as a public company in January 2001, owned wholly by the Australian Government and limited by guarantee under Australian corporations law.

Resourcing
NICS receives $3.5 million per annum plus indexation via a funding agreement between the Department of Health and Ageing and the Institute. Funding for additional projects is negotiated as required throughout the year.

Performance against outcomes of purchased outputs
NICS is a Commonwealth-owned company, limited by guarantee under the Commonwealth Authorities and Companies Act 1997. NICS produces its own annual report in accordance with the requirements of Section 9 of the Act.

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Provider—Office of the Australian Safety and Compensation Council

Cross agency overview
The Office of Chemical Safety, incorporating the National Industrial Chemical Notification and Assessment Scheme, has a Memorandum of Understanding (MoU) with the Office of the Australian Safety and Compensation Council (OASCC), formerly the National Occupational Health and Safety Commission, for the provision of information services support. The services provided contribute to both policy and agency specific outputs of the Therapeutic Goods Administration group of regulators. The costs of these services are included in cost recovery arrangements.

Responsibility
Responsibility for OASCC lies with the Employment and Workplace Relations portfolio. The Department of Employment and Workplace Relations (DEWR) produces its own annual report.

Control arrangements
In line with the MoU above, DEWR is a Australian Government department. It is also subject to the Financial Management and Accountability Act 1997 and the Public Service Act 1999.

Resourcing
The estimated expenditure for 2005-06 under the MoU with OASCC is $115,000.
Performance against outcomes of purchased outputs

The performance of DEWR in delivering these services is covered by the performance information identified in the MoU.

4.2: COST RECOVERY ARRANGEMENTS

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 Act;
- industry support activities, including the development of guidelines and promoting international harmonisation; and
- services to Government to support the objects of the Act.

The TGA completed a comprehensive review of its cost recovery arrangements to ensure compliance with Australian cost recovery 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.

In December 2003 the Australian and New Zealand Government’s agreed to establish a joint regulatory scheme for therapeutic products across the Tasman. Given the establishment of the scheme, the review also sought to develop a fees and charges framework to meet the needs of the joint scheme that would come into operation in July 2005. However, this cost recovery impact statement is limited to assessing cost recovery arrangements currently in place for the
TGA, and further arrangements relating to the scheme will be considered separately by the Interim Therapeutic Products Ministerial Council and will be subject to a separate 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. Fees and charges are prescribed in regulations made under the *Therapeutic Goods Act 1990*, *Therapeutic Goods (Medical Devices) Act 2001* and the *Therapeutic Goods (Charges) Act 1990*. Certain activities undertaken for Government have been funded from departmental allocations.

<table>
<thead>
<tr>
<th></th>
<th>2003-04 Actual $m</th>
<th>2004-05 Estimate $m</th>
<th>2005-06 Estimate $m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry cost recovery</td>
<td>60.496</td>
<td>68.558</td>
<td>71.151</td>
</tr>
<tr>
<td>Government</td>
<td>6.246</td>
<td>6.177</td>
<td>0.000</td>
</tr>
<tr>
<td>Price of outputs</td>
<td>66.742</td>
<td>74.735</td>
<td>71.151</td>
</tr>
</tbody>
</table>

The review found that the TGA’s cost recovery arrangements were consistent with the Guidelines. The level of recovery from fees was in line with costs, with variations observed attributable to fluctuations in activity levels. Pre-market fees were generally found to be cost reflective, including costs associated with access to essential medicines and clinical trials that are consistent with government policy and supported by industry. Annual charges (‘cost recovery taxes’) reflected product category risks included in the TGA’s monitoring, compliance and industry support activities. The level of activity undertaken by the TGA that was not considered integral to the regulatory scheme was immaterial and did not warrant exclusion from fees and charges. Regulatory fees are part of the cost of bringing or maintaining a product in the market and are taken into consideration in consumer pricing decisions.

The TGA’s costs base was found to be reflective of its activities with no evidence of ‘gold-plating’ of its regulatory activities. Since moving to achieve full cost recovery in 1998-99 the TGA cost base had been contained despite higher input costs and additional regulatory functions, with staffing levels reflecting business requirements. The review noted that TGA’s fee levels compared favourably to those in the United States and Europe, and that the overall cost of regulation represented 0.5 per cent of the more than $10 billion industry.

**Consultation**

Stakeholder consultations were conducted with all of the major industry associations, the Consumer’s Health Forum, and relevant government agencies. Whilst industry accepted cost recovery as an efficient form of funding regulation and the broad structure of fees and charges, associations did not uniformly support full cost recovery. Industry also commented on the need for greater transparency of TGA’s costs and fees, enhanced accountability to industry and improvements to current consultative arrangements. In response, the TGA plans to increase the level of engagement on cost recovery arrangements through the TGA-Industry Consultative Committee. Further consultation on the cost recovery statement will be undertaken ahead of setting fees and charges in 2005-06.
Further review

A further review of cost recovery arrangements will be completed ahead of the commencement of the joint regulatory scheme with New Zealand.

### 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 risk 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;
- 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.

The cost of administering NICNAS is largely funded from industry through fees relating to new chemical assessments and from company registration fees and charges, as set out in the Act and associated regulations. Activities undertaken for Government have been funded from departmental allocations or through specific service agreements.

<table>
<thead>
<tr>
<th></th>
<th>2003-04 Actual $m</th>
<th>2004-05 Estimate $m</th>
<th>2005-06 Estimate $m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services</td>
<td>4.871</td>
<td>5.969</td>
<td>6.236</td>
</tr>
<tr>
<td>Government</td>
<td>0.582</td>
<td>0.627</td>
<td>0.494</td>
</tr>
<tr>
<td>Price of outputs</td>
<td>5.453</td>
<td>6.596</td>
<td>6.730</td>
</tr>
</tbody>
</table>

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.
Compliance with cost recovery policy

The review found that the cost recovery arrangements were consistent with the guidelines and were well accepted by industry stakeholders. The level of recovery from fees for new chemical assessment was in line with costs, with the variation observed attributable to fluctuations in activity levels. Company registration fees and charges were sufficient to recover the cost of all other activities scheme activities, although some costs related to the scheme had not been included in current cost recovery arrangements.

Compliance activities totalling $120,000 currently funded from departmental allocations should be included in recoveries from industry following the extension of NICNAS registration to all chemical introducers in September 2004. Similarly, activities undertaken for government and other international activities totalling $325,000 were considered to be directly related to chemical regulation and should also be included in cost recovery arrangements.

Consultation

Stakeholder consultations were conducted with all of the industrial chemicals industry associations, government agencies concerned with health and environmental risk assessments, and the Department of Finance and Administration. Whilst endorsing cost recovery in principle, industry felt that it should not bear costs incurred by NICNAS from which it did not derive a benefit (ie. government services, international meetings, compliance activities). Industry were opposed to further fee increases, though any changes to fees needed be planned and communicated early following consultation with industry. Further consultation on the cost recovery statement will be undertaken ahead of setting fees and charges in 2005-06.

Further review

Cost recovery arrangements for NICNAS will be reviewed again in five years.