Outcome 7

HEALTH INFRASTRUCTURE, REGULATION, SAFETY AND QUALITY

Improved capacity, quality and safety of Australia's health care system to meet current and future health needs including through investment in health infrastructure, regulation, international health policy engagement, research into health care, and support for blood and organ donation services

Outcome Strategy

The Australian Government, through Outcome 7, aims to support a sustainable world class health system in Australia through support for deregulation, effective regulation, quality and safety, and strategic investments in health infrastructure and research.

Consistent with the Government's productivity agenda, the Department will invest in work to strengthen safety and quality across the health system to reduce patient risks and generate efficiencies.

The $20 billion capital-preserved Medical Research Future Fund (MRFF) will deliver a major additional injection of funds into the medical research sector. The MRFF will provide additional funding to support the sustainability of the health system and drive medical innovation through transforming how health and medical research is conducted in Australia.

The Government also aims to provide Australians with access to an adequate, safe, secure and affordable blood supply and access to life saving and life-transforming organ and tissue transplants.

Consistent with the Government's broader deregulation agenda, the Department will ensure the delivery of appropriate and effective regulation across the portfolio, maintaining desired outcomes while safeguarding the health and wellbeing of the community. The Government has a red tape reduction target of $1 billion per annum across the whole-of-government for businesses, community organisations and individuals.

The Australian Government is committed to a national shared electronic health record system. In response to the Review of the Personally Controlled Electronic Health Record (PCEHR), the Government will redevelop the system to improve its usability and clinical utility, strengthen eHealth governance and operations, and trial new participation arrangements. The PCEHR will be renamed *My Health Record* and the Australian Commission for eHealth will be established to manage governance, operation and ongoing delivery for eHealth from 1 July 2016.

The Department will also provide human health risk assessment advice on the regulation of agricultural and veterinary chemical products, medicines and poisons.

The Department will continue to work with stakeholders to improve the Quality Use of Medicines, a key objective of Australia's National Medicines Policy.

Outcome 7 is the responsibility of Acute Care Division, Best Practice Regulation and Deregulation Division, eHealth Division, Pharmaceutical Benefits Division, Portfolio Strategies Division, Primary and Mental Health Care Division, the Therapeutic Goods Administration, the Office of Chemical Safety, and the Office of the Gene Technology Regulator.

Programmes Contributing to Outcome 7

Programme 7.1: eHealth

Programme 7.2: Health Information

Programme 7.3: International Policy Engagement

Programme 7.4: Research Capacity and Quality

Programme 7.5: Health Infrastructure

Programme 7.6: Blood and Organ Donation

Programme 7.7: Regulatory Policy

Outcome 7 Budgeted Expenses and Resources

Table 7.1 provides an overview of the total expenses for Outcome 7 by programme.

Table 7.1: Budgeted Expenses and Resources for Outcome 7

	2014-15 Estimated actual expenses $'000	2015-16 Estimated expenses $'000
Programme 7.1: eHealth[1]		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	135,221	135,981
Non cash expenses[2]	18,309	18,309
Departmental expenses		
Departmental appropriation[3]	22,189	20,367
Expenses not requiring appropriation in the budget year[4]	938	462
Total for Programme 7.1	**176,657**	**175,119**
Programme 7.2: Health Information		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	27,914	22,176
Departmental expenses		
Departmental appropriation[3]	1,577	1,457
Expenses not requiring appropriation in the budget year[4]	76	38
Total for Programme 7.2	**29,567**	**23,671**
Programme 7.3: International Policy Engagement		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	14,912	14,412
Departmental expenses		
Departmental appropriation[3]	12	11
Expenses not requiring appropriation in the budget year[4]	1	1
Total for Programme 7.3	**14,925**	**14,424**
Programme 7.4: Research Capacity and Quality[1]		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	82,152	80,459
Special Accounts		
Medical Research Future Fund	-	10,000
Departmental expenses		
Departmental appropriation[3]	15,996	14,857
Expenses not requiring appropriation in the budget year[4]	723	356
Total for Programme 7.4	**98,871**	**105,672**

Table 7.1: Budgeted Expenses and Resources for Outcome 7 (continued)

	2014-15 Estimated actual expenses $'000	2015-16 Estimated expenses $'000
Programme 7.5: Health Infrastructure[1]		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	62,076	26,418
Special Accounts		
Health and Hospitals Fund Health Portfolio Special Account[5, 6]	719,802	315,944
Departmental expenses		
Departmental appropriation[3]	9,192	8,508
Expenses not requiring appropriation in the budget year[4]	435	214
Total for Programme 7.5	**791,505**	**351,084**
Programme 7.6: Blood and Organ Donation[1]		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	18,058	16,364
Special appropriations		
National Health Act 1953 - blood fractionation, products and blood related products - to National Blood Authority	535,345	721,297
Departmental expenses		
Departmental appropriation[3]	4,982	4,249
Expenses not requiring appropriation in the budget year[4]	232	114
Total for Programme 7.6	**558,617**	**742,024**
Programme 7.7: Regulatory Policy		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	105	270
Departmental expenses		
Departmental appropriation[3]	31,509	25,778
to Special Accounts	(17,484)	(15,206)
Expenses not requiring appropriation in the budget year[4]	612	301
Special Accounts		
OGTR Special Account[7]	7,981	7,906
NICNAS Special Account[8]	13,267	19,620
TGA Special Account[9]	149,392	140,921
Expense adjustment[10]	(8,521)	(6,920)
Total for Programme 7.7	**176,861**	**172,670**

Table 7.1: Budgeted Expenses and Resources for Outcome 7 (continued)

	2014-15 Estimated actual expenses $'000	2015-16 Estimated expenses $'000
Outcome 7 totals by appropriation type		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	340,438	296,080
Non cash expenses[2]	18,309	18,309
Special Accounts	719,802	325,944
Special appropriations	535,345	721,297
Departmental expenses		
Departmental appropriation[3]	85,457	75,227
to Special Accounts	(17,484)	(15,206)
Expenses not requiring appropriation in the budget year[4]	3,017	1,486
Special Accounts	162,119	161,527
Total expenses for Outcome 7	**1,847,003**	**1,584,664**

	2014-15	2015-16
Average staffing level (number)	1,134	1,142

1 This programme includes National Partnerships paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework. National Partnerships are listed in this chapter under each programme. For Budget estimates relating to the National Partnership component of the programme, please refer to Budget Paper 3 or Programme 1.9 of the Treasury's Portfolio Budget Statements.
2 "Non cash expenses" relates to the depreciation of computer software.
3 Departmental appropriation combines "Ordinary annual services (Appropriation Bill No. 1)" and "Revenue from independent sources (s74)".
4 "Expenses not requiring appropriation in the Budget year" is made up of depreciation expense, amortisation expense, makegood expense and audit fees.
5 The Health and Hospitals Fund is recorded as an expense by this Department and by the Treasury. For more detailed estimates relating to this programme refer Budget Paper 3.
6 The Health and Hospitals Fund (HHF) is established and funded under the *Nation-building Funds Act 2008*. Following the transfer of the uncommitted balance of the HHF to the Medical Research Future Fund, the *Nation-building Funds Act 2008* is due to be repealed and funding for existing activity is expected to be met by Special appropriation provisions from 1 August 2015.
7 Office of the Gene Technology Regulator Special Account.
8 National Industrial Chemicals Notification and Assessment Scheme Special Account.
9 Therapeutic Goods Administration Special Account.
10 Special Accounts are reported on a cash basis. This adjustment reflects the differences between expense and cash, and eliminates inter-entity transactions between the core Department and TGA.

Programme 7.1: eHealth

Programme Objectives

Redevelop and operate a national shared eHealth record system

The report from the Review of the Personally Controlled Electronic Health Record, released in May 2014, made recommendations aimed at improving the operation of the system and increasing use by healthcare providers and individuals. In 2015-16, the Government will work with stakeholders to implement key recommendations from the review including: usability improvements; renaming the system as *My Health Record*; revised incentives; and education and training for healthcare providers. The Government will also commence trials of new participation arrangements, including an opt-out system recommended by the review, to inform future strategies for increasing uptake and meaningful use of the *My Health Record*.

Provide national eHealth leadership

The Australian Government will continue to lead the national roll out of eHealth technology and services, and work with the States and Territories to support eHealth foundations, and finalise a national eHealth strategy. This strategy will identify the priorities for future Commonwealth and jurisdictional investment in eHealth.

In 2015-16, an Implementation Taskforce will be established to oversee and manage the transition of governance arrangements and eHealth operations from the National eHealth Transition Authority and the Department of Health to the Australian Commission for eHealth. This Commission will assume responsibility for the governance, operation and ongoing delivery of all eHealth across Australia, including the *My Health Record* from 1 July 2016.

In 2015-16, the Practice Incentives Programme (PIP) eHealth Incentive will be reviewed with the aim of encouraging general practices to contribute to and use the *My Health Record* system to improve clinical decision-making and the continuity of care for their patients.

Programme 7.1 is linked as follows:

- This Programme includes National Partnership payments for:
  - *Tasmanian electronic patient information sharing.*

  National Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.9 of the Treasury's Portfolio Budget Statements.
- The Department of Human Services (Services to the Community – Health Programme 1.2) to support operation of the *My Health Record*.
- The Department of Industry and Science (Business and Market Development – Programme 3.2) to expedite clinical trial reform in Australia.

Programme 7.1: Expenses

Table 7.2: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	135,221	135,981	129,963	120,944	5,062
Non cash expenses[1]	18,309	18,309	18,308	-	-
Programme support	23,127	20,829	10,515	10,577	10,830
Total Programme 7.1 expenses	**176,657**	**175,119**	**158,786**	**131,521**	**15,892**

1 "Non cash expenses" relates to the depreciation of computer software.

Programme 7.1: Deliverables

Qualitative Deliverables for Programme 7.1

Redevelop and operate a national shared eHealth record system

Qualitative Deliverables	2015-16 Reference Point or Target
Good practice principles and methods are applied to the operation and support of the *My Health Record* system.	The *My Health Record* system operations and practices are regularly reviewed to improve performance and usability.
Trials of new participation arrangements are undertaken, including for an opt-out system.	Trials to commence in 2016.

Provide national eHealth leadership

Qualitative Deliverable	2015-16 Reference Point or Target
New eHealth governance arrangements are implemented, including establishment of the Australian Commission for eHealth.	The Commission is operational from 1 July 2016.

Programme 7.1: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 7.1

Redevelop and operate a national shared eHealth record system

Qualitative Indicator	2015-16 Reference Point or Target
Participation trial findings inform future planning to increase participation in, and meaningful use of, the *My Health Record.*	Trials to commence in 2016.

Quantitative Key Performance Indicators for Programme 7.1

Redevelop and operate a national shared eHealth record system

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
System availability	99% of the time (excluding planned outages)	99% of the time (excluding planned outages)	99% of the time (excluding planned outages)	99% of the time (excluding planned outages)	N/A[1]

Programme 7.2: Health Information

Programme Objectives

Provide support to the Council of Australian Governments (COAG) Health Council and the Australian Health Ministers' Advisory Council (AHMAC)

To ensure a nationally consistent focus on achieving better health outcomes, the Australian Government facilitates collaborative policy development with States and Territories through the COAG Health Council, AHMAC and its six Principal Committees.

The Department will work to ensure that relevant Australian Government priorities are reflected in the activities of the COAG Health Council.

Support the Australian Government with informed policy advice and facilitate engagement with the health sector

The Australian Government recognises the important role national peak and advisory bodies in the health sector play in informing and supporting the achievement of positive health outcomes. In 2015-16, the Australian Government will continue to support and engage with national peak and advisory bodies to inform the development of policies and programmes that contribute to the Australian Government's health agenda. This will be done through effective consultation and information sharing between members, the wider health community and the Government; and the provision of well-informed and impartial advice.

[1] The Government has agreed to continue and improve the operation of eHealth records for three years, ending 30 June 2018.

Programme 7.2: Expenses

Table 7.3: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	27,914	22,176	21,136	20,587	21,593
Programme support	1,653	1,495	1,363	1,360	1,381
Total Programme 7.2 expenses	**29,567**	**23,671**	**22,499**	**21,947**	**22,974**

Programme 7.2: Deliverables

Qualitative Deliverables for Programme 7.2

Provide support to the COAG Health Council and AHMAC

Qualitative Deliverable	2015-16 Reference Point or Target
Australian Government initiated activities undertaken by AHMAC and its Principal Committees support the COAG Health Council in providing leadership on national health issues.	Relevant Australian Government priorities are highlighted and progressed in the activities of the COAG Health Council.

Support the Australian Government with informed policy advice and facilitate engagement with the health sector

Qualitative Deliverable	2015-16 Reference Point or Target
Advice obtained from national peak and advisory bodies informs policy and programme development.	Negotiation and execution of appropriate funding agreements with a range of national peak and advisory bodies to be completed by 31 December 2015.

Programme 7.3: International Policy Engagement

Programme Objectives

Facilitate international engagement on global health issues

The Department will continue to pursue Australia's global health interests through multilateral engagements and country-to-country partnerships. The Health portfolio maintains lead responsibility in Australia's relationship with the World Health Organization (WHO). In 2015-16, together with fellow Member States, Australia will focus on: continuing the process to reform the WHO; strengthening the WHO's ability to respond to global health security threats (including through preparedness and surveillance activities); building resilient health systems; the prevention and treatment of malaria, tuberculosis and HIV/AIDS; and non-communicable disease prevention and control (including tobacco control).

In 2015-16, the Department will look to further strengthen the Organisation for Economic Co-operation and Development's (OECD) health stream of work, particularly in regard to comparative data and information on health systems including: quality of health care; measuring outcomes; achieving value for money in health spending; and health system financing.

The Department will also lead Australia's efforts to ensure the region has a strategic approach to managing health challenges, by actively participating in the development of regional health architecture, and engagement on regional health priorities with the East Asia Summit and the Asia-Pacific Economic Cooperation (APEC) Health Working Group.

Additionally, the Department will influence international regulatory policy in relation to therapeutic goods through continued participation in fora such as the International Coalition of Medicines Regulatory Authorities and the International Medical Devices Regulators' Forum.[2]

Bilaterally, the Department will continue to partner with the Department of Foreign Affairs and Trade (DFAT) in promoting regional and global strategic interests as they relate to health.

Programme 7.3: Expenses

Table 7.4: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	14,912	14,412	14,412	14,412	14,412
Programme support	13	12	11	11	11
Total Programme 7.3 expenses	**14,925**	**14,424**	**14,423**	**14,423**	**14,423**

[2] Refer to Programme 7.7 in this chapter for more information about the Therapeutic Goods Administration.

Programme 7.3: Deliverables

Quantitative Deliverables for Programme 7.3

Facilitate international engagement on global health issues

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of international health delegation visits facilitated by the Department.[3]	20-25	15-20	15-20	15-20	15-20

Programme 7.3: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 7.3

Facilitate international engagement on global health issues

Qualitative Indicator	2015-16 Reference Point or Target
Australia's interests secured at relevant meetings of key international health bodies and organisations.[4]	Departmental representatives will have actively engaged in meetings of the WHO governing bodies, OECD Health Committee, APEC Health Working Group and other international fora.

Programme 7.4: Research Capacity and Quality

Programme Objectives

Improve research capacity

The capital-preserved $20 billion Medical Research Future Fund (MRFF) will provide a sustainable source of funding for vital medical research over the medium to longer term, support the sustainability of the health system into the future, and drive further medical innovation. Discoveries in medical research and important medical innovations will continue to contribute to improving the health and wellbeing of Australians. The first distribution from the MRFF will be made in 2015-16, following the passage of legislation.

Medical research is vital for the future of the Australian health system, and the Australian economy. The MRFF will inform strategies to address the challenges facing our health services and to deliver high quality health care into the future.

[3] The number of international health delegation visits has been revised down from the *2014-15 Portfolio Budget Statements* as it is expected that fewer visits will be facilitated now that policy for aged care and population ageing and some Indigenous health programmes have moved to other portfolios under Machinery of Government changes.

[4] The 2014-15 Key Performance Indicator relating to the WHO Executive Board has been removed as the Department is no longer a member.

The MRFF may lead to the discovery and development of new medicines and technologies. It will encourage innovation in research and in business.

Medical research is a key driver of productivity and innovation in the health care sector, which employs more than one million Australians. Every $1 spent on health and medical research generates a health benefit valued at $2.17 – a return on investment of over 100 per cent. Expenditure from the MRFF will add to the research funding allocated by the National Health and Medical Research Council (NHMRC).[5]

Clinical trials are a critical element of translating research into better care. The Department is working with key stakeholders (including the NHMRC, the Department of Industry and Science, and State and Territory Health Departments) to implement a range of strategies to make Australia more competitive in this arena.

The recommendations of the *Strategic Review of Health and Medical Research – Better Health Through Research* (McKeon Review released in April 2013) are continuing to inform future policy directions.

Monitor the use of diagnostics, therapeutics and pathology

Through the Quality Use of Diagnostics, Therapeutics and Pathology Fund, the Government currently supports National Prescribing Service (NPS) MedicineWise to provide information to consumers and health professionals on quality use of medicines and medical testing. This is aimed at improving health outcomes and assisting the ongoing sustainability of the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule. The fund also supports the National Return and Disposal of Unwanted Medicines Programme (NatRUM) to collect consumers' expired and unwanted medicines and help avoid accidental childhood poisoning and medication misuse.

The Government has extended the services of NPS MedicineWise and NatRUM for a period of three years, with key focus areas of supporting health professionals and consumers to reduce inappropriate care by choosing medical treatments and procedures wisely, continuing to support the appropriate prescribing and use of antibiotics to reduce antimicrobial resistance, and providing a safe and environmentally-friendly service for the disposal of unwanted medicines through community pharmacies.

Improve safety and quality in health care

In 2015-16, the Department, with States and Territories, will provide policy direction and funding to the Australian Commission on Safety and Quality in Health Care (ACSQHC)[6] to continue its work strengthening safety and quality across the health system to reduce patient risks and generate efficiencies. In 2015-16, the Australian Government will examine healthcare variation in specific

[5] For further information on the work of the NHMRC, refer to the NHMRC chapter in these Portfolio Budget Statements.

[6] For further information on the work of the ACSQHC, refer to the ACSQHC chapter in these Portfolio Budget Statements.

clinical areas to determine to what degree it may be unwarranted and what might be done to promote more appropriate care.

Programme 7.4 is linked as follows:

- This Programme includes National Partnership payments for:

  – *Vaccine-preventable diseases surveillance*

  National Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.9 of the Treasury's Portfolio Budget Statements.

Programme 7.4: Expenses

Table 7.5: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	82,152	80,459	70,176	68,407	66,358
Special Account expenses					
Medical Research Future Fund	-	10,000	53,232	130,340	224,258
Programme support	16,719	15,213	13,961	13,933	14,129
Total Programme 7.4 expenses	**98,871**	**105,672**	**137,369**	**212,680**	**304,745**

Programme 7.4: Deliverables

Qualitative Deliverables for Programme 7.4

Improve research capacity

Qualitative Deliverable	2015-16 Reference Point or Target
Stakeholders are engaged in developing strategies to improve clinical trials processes.	Agreement reached by jurisdictions on strategies to improve clinical trials processes.

Monitor the use of diagnostics, therapeutics and pathology

Qualitative Deliverable	2015-16 Reference Point or Target
Information regarding quality use of medicines newly listed on the PBS is provided to health professionals where appropriate.	The Department will provide funding for the provision of quality use of medicines information to be available in a variety of formats throughout the year, designed to support clinicians and consumers.

Improve safety and quality in health care

Qualitative Deliverable	2015-16 Reference Point or Target
Relevant evidence-based resources are available to help reduce unwarranted healthcare variation by changing clinical practice.	Tools are available to consumers, clinicians and health services to promote adoption of clinical best practice.

Programme 7.4: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 7.4

Improve research capacity

Qualitative Indicators	2015-16 Reference Point or Target
Clinical trials reform continues to deliver improved processes and drive further investment.	Adoption of national metrics system by all jurisdictions as a mechanism for quality improvement.
Investment in medical research supports sustainability for the health system and drives innovation.	Strategic investment of total available funding in 2015-16.

Improve safety and quality in health care

Qualitative Indicator	2015-16 Reference Point or Target
Identification of potential unwarranted healthcare variation.	Agreement with relevant stakeholders on unwarranted healthcare variation for further investigation.

Programme 7.5: Health Infrastructure

Programme Objectives

Improve primary health care infrastructure

The Government will provide Rural and Regional Teaching Infrastructure Grants to enable regional and rural GP practices to extend or renovate existing premises to provide additional space for supervision, teaching and training. This will enable the GP practices to engage medical students and supervising GP registrars.

Invest in other major health infrastructure

Construction will continue on projects funded under the Health and Hospitals Fund (HHF). The Department will actively monitor the progress of all projects, especially those nearing completion. It is expected that 52 projects will be completed in 2015-16.

Australia has a world class cancer care and research system. The Department will continue to monitor the progress of cancer infrastructure projects across the country, which once complete, will significantly enhance existing care and research

capacity. This will include the Victorian Comprehensive Cancer Centre in Melbourne, and the important regional cancer centre projects that will allow cancer patients living outside metropolitan areas to access treatment and support services close to their community and family.

Programme 7.5 is linked as follows:

- This Programme includes National Partnership payments for:
  - *Health and Hospitals Fund - hospital infrastructure and other projects of national significance*; and
  - *Health and Hospitals Fund - regional priority rounds.*

  National Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.9 of the Treasury's Portfolio Budget Statements.

Programme 7.5: Expenses

Table 7.6: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	62,076	26,418	11,054	7,017	7,115
Special Account expenses					
Health and Hospital Fund					
Health Portfolio[1,2]	719,802	315,944	129,089	33,987	-
Programme support	9,627	8,722	7,922	7,906	8,024
Total Programme 7.5 expenses	**791,505**	**351,084**	**148,065**	**48,910**	**15,139**

1 The Health and Hospitals Fund is recorded as an expense by this Department and by the Treasury. For more detailed estimates relating to this programme refer Budget Paper 3.

2 The Health and Hospitals Fund (HHF) is established and funded under the *Nation-building Funds Act 2008*. Following the transfer of the uncommitted balance of the HHF to the Medical Research Future Fund, the *Nation-building Funds Act 2008* is due to be repealed and funding for existing activity is expected to be met by Special appropriation provisions from 1 August 2015.

Programme 7.5: Deliverables

Qualitative Deliverables for Programme 7.5

Invest in other major health infrastructure

Qualitative Deliverable	2015-16 Reference Point or Target
Funding arrangements in place for all successful projects under the 2010 and 2011 Regional Priority Round of HHF grants.	Remaining six funding agreements signed by 31 December 2015.

Programme 7.5: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.5

Improve primary health care infrastructure

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of grants to support the provision of additional space for teaching and training to strengthen the rural workforce.	100	75	N/A[7]	N/A	N/A

Qualitative Key Performance Indicators for Programme 7.5

Invest in other major health infrastructure

Qualitative Indicator	2015-16 Reference Point or Target
Effective monitoring of HHF projects for compliance with agreed outputs.	Reports are received for all projects in the required timeframe and remedial action taken as required.

Programme 7.6: Blood and Organ Donation

Programme Objectives

Improve Australians' access to organ and tissue transplants

The Government will support a national approach by continuing to work with other Commonwealth entities, States and Territories to coordinate, monitor and increase organ and tissue donation for transplantation and to improve Australians' access to life-saving and life-transforming transplants. In the 2015-16 Budget, funding will be provided for two years, from 1 July 2015, to accelerate growth in organ and tissue donation for transplantation.

In 2015-16, as part of this initiative, the Government will provide further funding to support living organ donors through the Supporting Leave for Living Organ Donors Programme. This programme will continue efforts to reduce the financial stress that can be experienced by people who take leave from work to undergo organ donation surgery.

To provide patients in need of life-saving stem cell transplants with the best possible chance of finding a stem cell match, the Government will support the Australian Bone Marrow Donor Registry and the National Cord Blood Collection Network (Network). In 2015-16, the Government will consider the findings of a

[7] No new activities will commence in 2016-17, however funding will continue to be available for activities commenced in previous years.

review of the Network Clinical Services Plan and work with the States, Territories and the Network to further assess its structure.

The 2015-16 Budget will consolidate the International Searches Programme and the Bone Marrow Transplant Programme into a single Haemopoietic Progenitor Cell Programme, to provide a seamless and more efficient process for patients and clinicians.

Support access to blood and blood products

In 2015-16, the Government will work with States and Territories under the National Blood Agreement to fund, in the ratio of 63 per cent for the Commonwealth and 37 per cent for the States and Territories, the supply of blood and a range of essential blood products to meet Australia's clinical need, and as much as is possible to ensure that their use is efficient, effective, and evidence-based.

The Government will also work with States and Territories to further reduce avoidable inventory wastage and variations in transfusion practice, and support the strengthening of clinical access arrangements for a range of funded products, particularly immunoglobulins.

Programme 7.6 is linked as follows:

- This Programme includes National Partnership payments for:
  - *Hepatitis C settlement fund.*

  National Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.9 of the Treasury's Portfolio Budget Statements.
- The Department of Human Services (Services to the Community – Health Programme 1.2) to administer the Australian Organ Donor Register.

Programme 7.6: Expenses

Table 7.7: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	18,058	16,364	17,363	17,756	18,949
Special appropriations					
National Health Act 1953 - Blood fractionation, products and blood related products - to National Blood Authority	535,345	721,297	781,772	833,954	890,500
Programme support	5,214	4,363	3,824	3,815	3,877
Total Programme 7.6 expenses	**558,617**	**742,024**	**802,959**	**855,525**	**913,326**

Programme 7.6: Deliverables

Qualitative Deliverables for Programme 7.6

Improve Australians' access to organ and tissue transplants

Qualitative Deliverable	2015-16 Reference Point or Target
Support the Australian Bone Marrow Donor Registry and the National Cord Blood Collection Network to identify matched donors and stem cells for transplant.	Increased diversity of tissue types of donors and cord blood units available for transplant.

Support access to blood and blood products

Qualitative Deliverable	2015-16 Reference Point or Target
Effective planning of the annual blood supply through the National Supply Plan and Budget.	Implementation of the 2015-16 National Supply Plan and Budget that was agreed by all Health Ministers in 2014-15.

Quantitative Deliverables for Programme 7.6

Improve Australians' access to organ and tissue transplants

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target[8]	2016-17 Forward Year 1	2017-18 Forward Year 2[9]	2018-19 Forward Year 3
Number of banked cord blood units:					
• Total	2,379	1,600	1,600	N/A	N/A
• Indigenous	129	50	50	N/A	N/A

[8] Revised targets for 2015-16 and 2016-17 as proposed to Health Ministers following a review concluded late 2014. Targets have been reduced as they are now for 'banked and searchable' cord blood units, rather than 'banked', which requires the units to have been tissue typed and to have met all regulatory requirements, and therefore to be available for use by patients.

[9] Targets for forward years two and three to be determined by Health Ministers after a follow up analysis of the Network scheduled for 2015-16.

Programme 7.6: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 7.6

Improve Australians' access to organ and tissue transplants

Qualitative Indicator	2015-16 Reference Point or Target
Support provided to the Australian Bone Marrow Donor Registry to search for (and transport) matched donors and stem cells internationally, when a domestic match is unavailable for transplant.	Funding is provided to meet the Commonwealth's agreement with the Australian Bone Marrow Donor Registry.

Support access to blood and blood products

Qualitative Indicator	2015-16 Reference Point or Target
The supply of blood and essential blood products are effectively supported in order to meet Australia's clinical need.	Funding is provided to meet the Commonwealth's contribution under the National Blood Agreement.

Programme 7.7: Regulatory Policy

In 2015-16, the Department will continue to provide direction and national leadership in regulatory policy across the Health Portfolio, including in gene technology, and to maintain and improve the therapeutic goods and industrial chemicals regulatory frameworks.

The Health portfolio has a focus on best-practice regulation, which involves effective engagement with risk, and the use of proportionate and appropriate regulatory levers to achieve the desired behavioural outcomes. This is achieved through the review of regulatory frameworks and legislation, through the assessment of policy settings over time, and drawing on the experiences of other jurisdictions, including internationally. Risk is identified and managed, including with appropriate protections for health and safety, and without imposing unnecessary 'red tape' on the end user, whether they be businesses or individuals.

The regulatory performance of the Department, its statutory agencies and traditional regulators will be reflected in Deregulation Annual Reports under the Deregulation Agenda and through the Regulator Performance Framework which applies to all Commonwealth Regulators.

Programme 7.7: Expenses

Table 7.8: Programme Expenses

	2014-15 Estimated actual $'000	2015-16 Budget $'000	2016-17 Forward Year 1 $'000	2017-18 Forward Year 2 $'000	2018-19 Forward Year 3 $'000
Annual administered expenses					
Ordinary annual services	105	270	272	272	284
Programme support	14,637	10,873	9,815	9,791	9,956
Departmental Special Accounts					
OGTR Special Account[1]	7,981	7,906	9,835	7,092	5,909
NICNAS Special Account[2]	13,267	19,620	19,489	13,533	14,085
TGA Special Account[3]	149,392	140,921	139,039	137,254	132,094
Expense adjustment[4]	(8,521)	(6,920)	(5,434)	5,035	11,760
Total Programme 7.7 expenses	**176,861**	**172,670**	**173,016**	**172,977**	**174,088**

1 Office of the Gene Technology Regulator Special Account.
2 National Industrial Chemicals Notification and Assessment Scheme Special Account.
3 Therapeutic Goods Administration Special Account.
4 Special Accounts are reported on a cash basis. This adjustment reflects the differences between expense and cash and the elimination of interagency transactions.

Therapeutic Goods

Regulate therapeutic goods for safety, effectiveness/performance and quality

The TGA will continue to provide a world class, efficient and timely regulatory system for therapeutic goods, which effectively involves and engages stakeholders and participants to ensure the safe use of medicines, medical devices, cell and tissue products, blood and blood products.

The TGA will also continue to administer a licencing and permit regime for controlled drugs in line with Australian legislation and international conventions.

Participate in international regulatory convergence and work sharing

The TGA participates in international harmonisation and collaborative activities with many international agencies and overseas regulators. These ongoing activities help to reduce effort in pre- and post-market evaluation of therapeutic goods, while enabling more informed and consistent regulatory decisions about the safety, quality and effectiveness of therapeutic goods available in Australia.

This work also includes identifying opportunities for Australia to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

Continue the quality improvement and regulatory reform process

In 2015-16, the TGA will continue implementation of a comprehensive reform agenda that will improve the way the TGA communicates with the public about the benefits and risks of therapeutic goods and will optimise a range of regulatory processes.

The Department will also continue to identify opportunities and implement actions to reduce regulatory burden on industry, consistent with the Government's deregulation and red tape reduction agenda, while continuing to meet the objectives of safeguarding and enhancing the health of the Australian community.

Subject to the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation, the Department will develop an implementation plan for identified reforms. The review was established to identify areas of unnecessary, duplicative or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia.

Deliverables

Qualitative Deliverables for Therapeutic Goods

Regulate therapeutic goods for safety, effectiveness/performance and quality

Qualitative Deliverables	2015-16 Reference Point or Target
Continue to regulate therapeutic goods for safety, effectiveness/performance and quality.	Effective premarket evaluation and post-market monitoring and assessment of therapeutic goods, as required under the *Therapeutic Goods Act 1989* and associated regulations.
Update and maintain the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for medicines.	SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the *Therapeutic Goods Regulations 1990*.

Participate in international regulatory convergence and work sharing activities

Qualitative Deliverable	2015-16 Reference Point or Target
Implement international harmonisation and work sharing activities with comparable international regulators.	Enhanced cooperation and work sharing, including increased reliance on medicines evaluation and facilities inspection information from international regulators, as outlined in TGA's *International Engagement Strategy 2013-2015*.

Continue the quality improvement and regulatory reform process

Qualitative Deliverables	2015-16 Reference Point or Target
Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to reduce red tape.	Opportunities to reduce regulatory and red tape burden are identified and contribute to the Government's $1 billion per annum regulation reduction target.
Implement reforms that enhance TGA's current regulatory processes and are consistent with the Government's deregulation and red tape reduction agenda.	Begin implementation of the Government's response to the Review of Medicines and Medical Devices Regulation.

Quantitative Deliverables for Therapeutic Goods

Regulate therapeutic goods for safety, effectiveness/performance and quality

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of applications for the import, export, and manufacture of controlled substances that are assessed and processed within agreed timeframes.	95%	95%	95%	95%	95%

Participate in international regulatory convergence and work sharing activities

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of good manufacturing practice clearances of overseas manufacturers that take into account approvals by equivalent international regulators.	85%	85%	85%	85%	85%

Continue the quality improvement and regulatory reform process

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of reforms implemented to enhance TGA's regulatory processes.[10]	2	9	N/A	N/A	N/A

[10] The TGA Reform Blueprint included 48 recommendations for implementation over the financial years 2011-12 to 2015-16. All of the recommendations are expected to be implemented by 2015-16. The reference targets have changed as implementation of a small number of recommendations are on hold pending the consideration of the Expert Panel Review of Medicines and Medical Device Regulation.

Key Performance Indicators

Quantitative Key Performance Indicators for Therapeutic Goods

Regulate therapeutic goods for safety, effectiveness/performance and quality

Quantitative Indicators	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of evaluations/assessments completed within legislated timeframes:[11] a) Applications lodged under prescription medicines registration (Category 1 applications) processed within 255 working days b) Quality related evaluations of prescription medicines (Category 3 applications) processed within 45 working days c) Conformity assessments for medical devices processed within 255 working days.	100%	100%	100%	100%	100%
Percentage of alleged breaches of the *Therapeutic Goods Act 1989* received that are assessed within 10 working days and an appropriate response initiated.	100%	100%	100%	100%	100%
Percentage of licensing and surveillance inspections closed out within target timeframes.	85%	85%	85%	85%	85%

[11] Further information available at: www.tga.gov.au. Legislated timeframes refers to various timeframes specified in the *Therapeutic Goods Act 1989* and subordinate regulations.

Chemical Safety

Aid in the protection of the Australian people by assessing the risks of chemicals and providing information to promote their safe use

The Department's Office of Chemical Safety manages the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which registers introducers of industrial chemicals, assesses industrial chemicals for their risks to human health and the environment, and makes recommendations to applicable regulatory authorities regarding risk mitigation.

In 2015-16, the Department will review the NICNAS Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework. The IMAP framework assesses the risks to human health and the environment of selected chemicals already in use, prioritised based on: volume of use; risk management requirements in comparable countries; and detection in human cord blood.

The Department's Office of Chemical Safety will also continue to provide human health risk assessment advice and set health standards relating to the regulation of agricultural and veterinary chemicals, and determine the need for chemicals to be considered for inclusion in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Consistent with the Government's Industry Innovation and Competitiveness Agenda, the Department will commence implementation of reforms to improve the efficiency and effectiveness of the regulation of industrial chemicals, including the increased use of trusted international assessment materials. Consistent with the Government's broader deregulation agenda, the reforms will remove unnecessary regulatory burden while maintaining the protection of public health, worker safety and the environment.

Programme 7.7 is linked as follows:

- The Department of Immigration and Border Protection (Border Management – Programme 1.2) for reviewing importation of industrial chemicals.
- The Department of Industry and Science (Programme Support – Programme 4) in relation to COAG chemical reforms.
- The Department of the Environment (Management of Hazardous Wastes, Substances and Pollutants – Programme 1.6), the Department of Employment (Safe Work Australia – Programme 1 for reform of and improvements to Australian health work and safety, and worker's compensation arrangements), and the Treasury (Australian Competition and Consumer Commission – Programme 1.1) for managing risks arising from industrial chemicals.
- The Department of Agriculture (Australian Pesticides and Veterinary Medicines Authority – Programme 1.1) to improve harmonisation of regulatory requirements.

Deliverables

Qualitative Deliverables for Chemical Safety

Aid in the protection of the Australian people by assessing the risks of chemicals and providing information to promote their safe use

Qualitative Deliverables	2015-16 Reference Point or Target
Scientifically robust assessments of new and existing industrial chemicals.	Peer review and stakeholder feedback support assessment outcomes.
High quality assessment outcomes are produced through effective use of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.	The IMAP framework will be reviewed to inform future assessment approaches for industrial chemicals already in use.
Contribution to the international harmonisation of regulatory approaches and methodologies for assessing industrial chemicals by reviewing Australian processes.	Regulatory approaches are reviewed and methodologies developed by the OECD Chemicals Committee and its key sub-committees for their application to NICNAS assessments of industrial chemicals.
All introducers of industrial chemicals are aware of their legal obligations.	Identified introducers are registered and provided with regular information updates.
The costs associated with the regulation of industrial chemicals are adequately balanced against the benefits to worker health and safety, public health and the environment.	Reforms to NICNAS more efficiently and effectively achieve the objects of the *Industrial Chemicals (Notification and Assessment) Act 1989*.
Update and maintain the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for chemical poisons.	SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the *Therapeutic Goods Regulations 1990*.

Key Performance Indicators

Qualitative Key Performance Indicators for Chemical Safety

Aid in the protection of the Australian people by assessing the risks of chemicals and providing information to promote their safe use

Qualitative Indicators	2015-16 Reference Point or Target
Effective use of international information.	In order to better utilise and increase the acceptance of international risk assessment materials, the Office of Chemical Safety will work with trusted overseas regulators to harmonise assessment approaches.
Human health risk assessments for agricultural and veterinary chemicals are performed in a timely manner.	Chemical assessments and public health regulation completed in accordance with the service level agreement between Health and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Quantitative Key Performance Indicators for Chemical Safety

Aid in the protection of the Australian people by assessing the risks of chemicals and providing information to promote their safe use

Quantitative Indicators	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of new industrial chemical assessments completed within legislated timeframes.	96%	96%	96%	96%	96%
Cumulative percentage of Stage One industrial chemicals[12] assessed through effective application of IMAP framework.	90%	95%	N/A[13]	N/A	N/A
Percentage of Level C and D introducers[14] of industrial chemicals assessed for compliance with their new chemicals obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989*.	40%	45%	45%	45%	45%

Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

The Australian Government, through the Gene Technology Regulator, will administer the national scheme for the regulation of gene technology to protect the health and safety of people and the environment.

During 2015-16, Office of the Gene Technology Regulator (OGTR) will commence a technical review of the *Gene Technology Regulations 2001* to ensure the level of regulation of activities with GMOs remains commensurate with risk according to current science. Consistent with the Government's deregulation agenda, the review will seek to identify opportunities to decrease regulatory burden for stakeholders while ensuring protection of human health and the environment where it is appropriate to do so.

[12] In July 2012, NICNAS started assessing around 3,000 existing chemicals using the IMAP framework. The chemicals in the first group are identified as 'Stage One Chemicals'.

[13] Forward Years 1-3 are subject to the outcome of the programme review in 2015-16.

[14] Level C and Level D introducers are those NICNAS registrants introducing at least $500,000 worth of relevant industrial chemicals annually.

In 2015-16, OGTR will continue to ensure that all risk assessments of GMOs are based on current scientific evidence and represent international best practice by consulting with experts and key stakeholders, and by keeping pace with advances in scientific knowledge and regulatory practice worldwide. OGTR will also engage in bilateral arrangements with other Australian Government regulators to enhance the reciprocal provision of advice on applications to support timely, efficient and comprehensive assessment of GMOs and genetically modified products. OGTR will work with the Department of Agriculture to improve harmonisation of regulatory requirements for containment facilities. OGTR will also engage in international harmonisation activities including collaborations in the region.

Deliverables

Qualitative Deliverables for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Qualitative Deliverables	2015-16 Reference Point or Target
Commence technical review of the *Gene Technology Regulations 2001*.	Review undertaken in consultation with relevant stakeholders.
Provide open, effective and transparent regulation of GMOs.	Risk assessments and risk management plans prepared for 100% of applications for licensed dealings and made publicly available. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment. Record of GMO dealings and maps of all field trial sites maintained and made publicly available on the OGTR website.[15]

Quantitative Deliverables for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of field trial sites and higher level containment facilities inspected.	≥20%	≥20%	≥20%	≥20%	≥20%

[15] Available at: www.ogtr.gov.au

Key Performance Indicators

Qualitative Key Performance Indicators for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Qualitative Indicators	2015-16 Reference Point or Target
Protect people and the environment through identification and management of risks from GMOs.	Comprehensive and effective risk assessment and risk management of GMOs. High level of compliance with the gene technology legislation and no adverse effect on human health or environment from authorised GMOs.
Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and/or genetically modified products.	High degree of cooperation with relevant regulatory agencies and provision of timely advice.

Quantitative Key Performance Indicators for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of licence decisions made within statutory timeframes.	100%	100%	100%	100%	100%