Our Purpose

Lead and shape Australia's health and aged care system and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation

In 2015-16, we undertook activities which contributed to achieving Our Purpose, including under Outcome 7

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

Analysis of performance – **Outcome 7** Health Infrastructure, Regulation, Safety and Quality

In 2015-16, the Department continued to deliver appropriate and effective regulation, safeguarding the health and wellbeing of the community. In working to ensure the health system meets future needs, the Department established the Australian Digital Health Agency, which will lead the ongoing development of the national digital health capability. The Medical Research Future Fund Advisory Board was established in April 2016 and undertook extensive public consultations which will assist in determining the Australian Medical Research and Innovation Strategy and related Priorities.

These activities have contributed to the Department's achievement of objectives under Outcome 7 and Our Purpose.

Key community benefits for **Outcome 7** in 2015-16

Ongoing development of Australia's digital health capability

Work in 2015-16 ensured the commencement of the Australian Digital Health Agency on 1 July 2016. The development of the national digital health capability will allow health care providers, professionals and patients to share health information, improving availability of treatment and health outcomes.

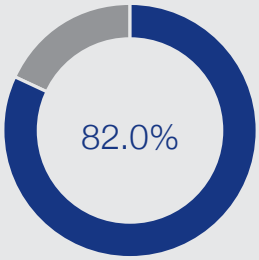
International engagement on global health issues

The Department represented Australia at the 66th Session of the WHO Western Pacific Regional Committee meeting. The Department secured critical outcomes on regional action plans and frameworks on viral hepatitis, tuberculosis, universal health coverage and urban health. This active engagement improves health practice and knowledge internationally, and contributes to better health outcomes for all Australians.

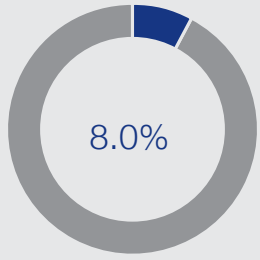
Improvements to Australia's research capacity

Agreement was reached with States and Territories through the *Clinical Trials Framework for Action* to improve the environment for clinical trials. Agreement will ensure a cohesive and strategic national approach across Australia, contributing to long term health care benefits to the Australian community.

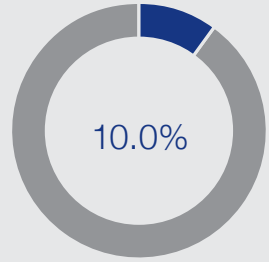
Summary of performance criteria results for **Outcome 7**



Met



Substantially met



Not met

Looking ahead

- Evaluate trials of My Health Record participation arrangements with findings used to inform the development of future strategies.
- Continue to monitor international health policy trends and actively engage in international dialogue on health policy challenges.
- Enhance investment in health and medical research by strategic investment of the Medical Research Future Fund (MRFF), with guidance from the Australian Medical Research Advisory Board.
- Redesign the Rural and Regional Teaching Infrastructure Grants Program to help deliver improved rural health services.
- Continue to promote best practice regulation.

Programs and program objectives contributing to **Outcome 7**

Program 7.1: eHealth

- Redevelop and operate a national shared eHealth record system
- Provide national eHealth leadership

Program 7.2: Health Information

- Provide support to the Council of Australian Governments (COAG) Health Council and the Australian Health Ministers' Advisory Council (AHMAC)
- Support the Australian Government with informed policy advice and facilitate engagement with the health sector

Program 7.3: International Policy Engagement

- Facilitate international engagement on global health issues

Program 7.4: Research Capacity and Quality

- Improve research capacity
- Monitor the use of diagnostics, therapeutics and pathology
- Improve safety and quality in health care

Program 7.5: Health Infrastructure

- Invest in other major health infrastructure
- Improve primary health care infrastructure

Program 7.6: Blood and Organ Donation

- Improve Australians' access to organ and tissue transplants
- Support access to blood and blood products

Program 7.7: Regulatory Policy

- Continue the quality improvement and regulatory reform process

Therapeutic goods

- Regulate therapeutic goods for safety, effectiveness/performance and quality
- Participate in international regulatory convergence and work sharing activities
- Continue the quality improvement and regulatory reform process

Chemical safety

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

Gene technology regulation

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

Analysis of performance – Program 7.1: eHealth

The Department met all the performance targets for Program 7.1: eHealth. In 2015-16, the Department implemented key recommendations from the Review of the Personally Controlled Electronic Health Record. The system was renamed to My Health Record and improvements were made to its usability and clinical content. My Health Record enables improved coordination of health care and the ability for consumers to share their health information seamlessly and securely across multiple health care providers.

National Digital Health governance arrangements and My Health Record system operations transitioned from the Department and the National eHealth Transition Authority to the newly established Australian Digital Health Agency (the Agency) on 1 July 2016. The Agency will lead the ongoing evolution of national digital health systems, which will connect and drive efficiencies in the health system and result in better health outcomes for all individuals. For further information about the Agency refer Appendix 5: *Australian Digital Health Agency 2015-16 Annual Report*.

The Department is currently trialling new participation arrangements, including an opt-out system, as well as innovative approaches utilising the current opt-in system. Outcomes from these trials will inform future participation arrangements in the My Health Record system.

My Health Record

In March 2016, My Health Record was launched. This is a secure online summary of a person's medications, diagnosed illnesses, treatments, allergies and tests. More than four million Australians already have a My Health Record and more are registering every day.

Each person can control what goes onto their My Health Record, and who is allowed to see it.

For health care providers, knowing more about a patient's medical history can lead to a better understanding of what is happening, and result in better treatment decisions. In any week, one in three GPs will see a patient for whom they have little or no health information. More than one in five GPs face this situation every day. With My Health Record, registered health care providers can have access to important information about their patient anytime and anywhere they need it.

Pharmacist Shane Jackson recognises the benefits of the My Health Record: "I am absolutely thrilled in the potential of the My Health Record system. More appropriate and timely access to patient information allows me to deliver better clinical care to my patients."

My Health Record enables people to take a more active role in managing their own health – both in preventing lifestyle-related chronic diseases, and managing conditions they already have. It can benefit all Australians, and is particularly helpful for people who have complex health conditions or continuing medical treatments and are being seen by a range of health care providers.

To find out more about the benefits of a My Health Record, and to sign up, visit: www.myhealthrecord.gov.au

Redevelop and operate a national shared eHealth record system

Good practice principles and methods are applied to the operation and support of the My Health Record system.
Source: 2015-16 Health Portfolio Budget Statements, p. 119

2015-16 Target	2015-16 Result
The My Health Record system operations and practices are regularly reviewed to improve performance and usability.	The My Health Record system operations and practices are regularly reviewed to improve performance and usability. Monthly governance meetings have been held throughout 2015-16 to manage the My Health Record program and monitor system operations and performance. These are underpinned by standard system design and operations processes and regular testing and assurance of system functions. **Result: Met** ✓

In applying and developing good practice principles and methods for the operation of the My Health Record system, the Department has taken into consideration expert advice, feedback and recommendations from a range of stakeholders, as well as the Operations Management Committee, Jurisdictional Advisory Committee and the Independent Advisory Council.

A number of improvements, informed by user research, have been made to the My Health Record system in order to improve the system operations and useability for individuals and providers.

Trials of new participation arrangements are undertaken, including for an opt-out system.
Source: 2015-16 Health Portfolio Budget Statements, p. 119

Participation trial findings inform future planning to increase participation in, and meaningful use of, the My Health Record.[55]
Source: 2015-16 Health Portfolio Budget Statements, p. 119 & 2015-16 Corporate Plan, p. 15

2015-16 Target	2015-16 Result
Trials to commence in 2016.	Opt-out trials commenced in March 2016. Opt-in trials commenced in July 2016. **Result: Met** ✓

On 28 October 2015, the Minister for Health announced that the opt-out trial sites would cover the Northern Queensland and Nepean Blue Mountains Primary Health Network regions. These trials commenced in March 2016, following the Ministerial launch of the My Health Record on 4 March 2016.

In April 2016, two trials of innovative approaches to increasing participation and use of the My Health Record system utilising the current opt-in registration arrangements were announced. These two trials are taking place in Western Australia, and Ballarat in western Victoria.

As a result of the opt-out trials in Northern Queensland and the Nepean Blue Mountains, over 970,000 new My Health Records have been created.

The Ballarat trial will seek to register patients being admitted to the Ballarat hospital for a My Health Record. It is estimated that 27,000 individuals will register over the 6 month period of the trial.

[55] This performance criterion was originally published under the 'Provide national eHealth leadership' program objective.

The Western Australia trial will seek to increase registration of chronically ill patients when they establish a care plan with their doctor. It is estimated that 15,000 chronically ill patients will register as part of the trial.

The relative effectiveness of an opt-out system to increase participation and use of the system by consumers and health care providers is being assessed against the outcomes from the two trials of innovative opt-in approaches and the current national opt-in system, to inform future strategies for bringing forward the benefits of the My Health Record nationally.

The Department has engaged an independent evaluator to assess the outcomes of the trials. The independent evaluator's findings, which will be presented in a final report at the end of November 2016, will inform the Department's report to the Government. The Department's report will inform the Government's decisions on the future direction for the My Health Record system.

Provide national eHealth leadership

System availability.
Source: 2015-16 Health Portfolio Budget Statements, p. 120

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
99% of the time (excluding planned outages)	99.38% of the time (excluding planned outages) **Result: Met** ✓	99.86% (excluding planned outages)	N/A	N/A	N/A

The Department worked with its partner organisation to improve My Health Record system availability. This work included continued improvements to system monitoring tools for early detection of technical issues, and implementation of infrastructure failover capability, to ensure system availability in the event of equipment failure.

New eHealth governance arrangements are implemented, including establishment of the Australian Commission for eHealth.[56]
Source: 2015-16 Health Portfolio Budget Statements, p. 119

2015-16 Target	2015-16 Result
The Commission is operational from 1 July 2016.	The Australian Digital Health Agency was established in law on 30 January 2016 and commenced operations on 1 July 2016. **Result: Met** ✓

The Australian Digital Health Agency commenced operating on 1 July 2016 and will lead the ongoing development and delivery of the national digital health capability, which will allow health care providers, professionals and patients to seamlessly share health information.

The Intergovernmental Agreement which commits funding to the Australian Digital Health Agency was approved and executed by the COAG Health Council on 8 April 2016.

The Minister for Health appointed the Chair and Board members on 20 April 2016, after agreement from State and Territory health ministers. An acting CEO was appointed on 4 May 2016 pending the appointment of a permanent CEO.

[56] The Australian Commission for eHealth was renamed the Australian Digital Health Agency in November 2015 by the Minister for Health, to better address the long term digital transformation of health care and provide a simple title for the health consumer.

Analysis of performance – Program 7.2: Health Information

The Department met all the performance targets for Program 7.2: Health Information. In 2015-16, the Department continued to work with the States and Territories through the Council of Australian Governments' (COAG) Health Council to improve health outcomes of all Australians, through a coordinated and collaborative approach to health policy development. Health services are delivered more efficiently through a coordinated approach, which in turn contributes to the sustainability of the health system.[57]

The Department also continued to seek advice from peak and advisory bodies. This advice is considered as part of the development of policies and programs that directly improve health outcomes.

Provide support to the COAG Health Council and AHMAC

Australian Government initiated activities undertaken by AHMAC and its Principal Committees support the COAG Health Council in providing leadership on national health issues.
Source: 2015-16 Health Portfolio Budget Statements, p. 121

2015-16 Target	2015-16 Result
Relevant Australian Government priorities are highlighted and progressed in the activities of the COAG Health Council.	Priorities were agreed and progressed by Australian Health Ministers' Advisory Council (AHMAC) and endorsed by the COAG Health Council. **Result: Met** ✓

The Commonwealth, State and Territory Governments have a shared intention to work in partnership to improve health outcomes for all Australians and ensure the sustainability of the Australian health system.[58]

The COAG Health Council, supported by AHMAC, focussed on a broad range of issues in 2015-16 including: long term future of the health system; hospital and health service delivery; establishment and integration of primary care networks; coordination of care for people with chronic and complex conditions; Aboriginal and Torres Strait Islander Health; digital health; health workforce; mental health; safety and quality; aged care; and health promotion and prevention.

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

Advice obtained from national peak and advisory bodies informs policy and programme development.
Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 75

2015-16 Target	2015-16 Result
Funding agreements with a range of national peak and advisory bodies commencing from 1 January 2016.	Funding agreements commenced from 1 January 2016. **Result: Met** ✓

An approach to market was undertaken and finalised prior to 31 December 2015. Funding agreements commenced from 1 January 2016.

[57] Sustainability of the health system refers to the ability of the Government to continue to fund services over the longer term given increasing demand for and costs of services.

[58] Ibid.

Analysis of performance – Program 7.3: International Policy Engagement

The Department met all the performance targets for Program 7.3: International Policy Engagement. Responding to global health security threats, building effective health systems, and preventing and treating disease, including non-communicable disease, are global challenges that require global solutions.

In 2015-16, the Department continued to provide leadership in international health fora, promoting international best practice and sharing its technical and policy expertise, focussing on regional and global health priorities.

The Department also continued to host overseas delegations to share information and experiences in different aspects of health systems. The learnings from these delegations continue to assist the Department in the ongoing development of a more affordable, accessible, efficient, and high quality health system.

Facilitate international engagement on global health issues

Number of international health delegation visits facilitated by the Department.
Source: 2015-16 Health Portfolio Budget Statements, p. 123

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
15-20	16 **Result: Met** ✓	20	20	25	35

Incoming visits from overseas delegations that are interested in learning more about various parts of Australia's health system, are an important means of engaging with other countries: to build networks and professional linkages between individuals and organisations; exchange ideas and experience; and facilitate international discussions on health issues.

Australia's interests secured at relevant meetings of key international health bodies and organisations.

Source: 2015-16 Health Portfolio Budget Statements, p. 123 & 2015-16 Corporate Plan, p. 15

2015-16 Target	2015-16 Result
Departmental representatives will have actively engaged in meetings of the WHO governing bodies, OECD Health Committee, APEC Health Working Group and other international fora.	The Department provided leadership in international health fora, promoting and learning from international best practice and sharing its technical and policy expertise focussing on domestic regional and global health priorities. **Result: Met** ✓

The Department pursued meaningful governance reform of the World Health Organization (WHO), and was active at the World Health Assembly, where countries achieved positive outcomes including reaching agreement on: the WHO's new health emergency program and global health security issues more broadly; the first ever Global Strategy and Plan of Action on Ageing and Health; access to medicines; and new global health sector strategies on HIV, viral hepatitis and sexually transmitted infections. The Department also represented Australia at the 66th Session of the WHO's Western Pacific Regional Committee Meeting securing critical outcomes on regional action plans and frameworks on viral hepatitis, tuberculosis, universal health coverage and urban health.

The Department actively engaged with the OECD Health Committee and participated in a number of expert group meetings and committee projects, including supporting a comprehensive review of Australia's health system.

Through the Asia-Pacific Economic Cooperation (APEC) Health Working Group, the Department worked to improve health security preparedness through improved capacity and better cooperation across sectors. The Department led Australia's delegations to the Pacific Heads of Health Meeting, contributing to strategic policy objectives for Pacific health ministries, in particular in the area of non-communicable diseases.

Analysis of performance – Program 7.4: Research Capacity and Quality

The Department met the majority of the performance targets for Program 7.4: Research Capacity and Quality. There were some challenges in achieving all performance targets, which are discussed in the performance criteria below.

Health and medical research over the medium to longer term is vital to the future of the health system. All Australians stand to benefit from ongoing investments in research through the Medical Research Future Fund (MRFF), either directly through improved health, or indirectly by supporting improved system productivity and economic growth.

The first disbursements from the MRFF were scheduled to be made during 2015-16. The legislation that underlies the MRFF requires the Australian Medical Research Advisory Board to undertake consultation prior to determining the Australian Medical Research and Innovation Strategy and related Priorities. Consultations commenced in May 2016. First disbursements from the MRFF are expected to be made in early 2017.

Improve research capacity

Stakeholders are engaged in developing strategies to improve clinical trials processes.
Source: 2015-16 Health Portfolio Budget Statements, p. 125

2015-16 Target	2015-16 Result
Agreement reached by jurisdictions on strategies to improve clinical trials processes.	Jurisdictions and key stakeholder representatives endorsed a *Clinical Trials Framework for Action*. Key stakeholders engaged in investigation into recruitment and retention barriers in Australian clinical trials. **Result: Met** ✓

The endorsed *Clinical Trials Framework for Action* will ensure a cohesive and strategic national approach and improve the clinical trials environment in Australia.

The Department funded a systematic review of barriers and enablers to clinical trials recruitment in Australia, to inform future strategies for improvement. Project consultations included jurisdictional representatives and key stakeholders from across the clinical trials sector, as well as consumers.

Clinical trials reform continues to deliver improved processes and drive further investment.
Source: 2015-16 Health Portfolio Budget Statements, p. 126

2015-16 Target	2015-16 Result
Adoption of national metrics system by all jurisdictions as a mechanism for quality improvement.	*Framework for National Aggregate Statistics for Clinical Trials* was implemented by jurisdictions. Work in 2015-16 ensured that the first activity report was provided to Australian Health Ministers' Advisory Council (AHMAC) in May 2016. **Result: Met** ✓

Health Ministers endorsed a *Framework for National Aggregate Statistics for Clinical Trials* in April 2015. In 2015-16, jurisdictions reported data for initial metrics and delivered the *First Activity Report on Commercially Sponsored Clinical Trials in Australian Public Health Organisations* to AHMAC in May 2016.

The report (which will be refined over time) provides a national picture of number, phase and timelines for clinical trials in Australia, to evaluate the success of efforts to improve the clinical trials environment, and to inform future quality and performance improvement.

Investment in medical research supports sustainability for the health system and drives innovation.

Source: 2015-16 Health Portfolio Budget Statements, p. 126 & 2015-16 Corporate Plan, p. 15

2015-16 Target	2015-16 Result
Strategic investment of total available funding in 2015-16.	First disbursements under the Medical Research Future Fund will be made in 2016-17. **Result: Not met**

The *Medical Research Future Fund Act 2015* (MRFF Act) was passed by Parliament in August 2015, with the Australian Medical Research Advisory Board (Advisory Board) established in April 2016.

The MRFF Act requires the Advisory Board to consult and develop the Australian Medical Research and Innovation Strategy and related Priorities to be considered by Government in making decisions on fund disbursements. The MRFF Act requires that stakeholder consultation and engagement occurs before the Advisory Board determines the Strategy and Priorities. A public consultation process, including a public call for submissions finished on 31 August 2016.

The passage of the enabling MRFF legislation (an interdepartmental effort led by the Department of Finance) and subsequent appointment of the Advisory Board, impacted on the ability to make disbursements in 2015-16.

It is anticipated the delivery of Strategy and Priorities will now occur in October 2016, allowing the first disbursements to be made in early 2017.

The movement of 2015-16 funds to 2016-17 has been agreed by Government and is published in the 2016-17 Budget.

The Biomedical Translation Fund (BTF) was announced as part of the National Innovation and Science Agenda in December 2015. The BTF will provide funding to private fund managers for investment into biomedical discoveries. Funds intended for the capital base of the MRFF have been diverted to form the BTF, which will allow for the fast tracking of investments into biomedical start-ups. A BTF Committee was established under Innovation Australia to guide the appointment of fund managers. The Committee's first meeting was held in June 2016. The call for fund managers closed on 14 September 2016 and it is expected that fund managers will be appointed in late 2016. Fund managers are expected to identify investees and commence the drawdown of matched funds in early 2017.

Monitor the use of diagnostics, therapeutics and pathology

Information regarding quality use of medicines newly listed on the PBS is provided to health professionals where appropriate.

Source: 2015-16 Health Portfolio Budget Statements, p. 125

2015-16 Target	2015-16 Result
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.	The Department supported NPS MedicineWise to produce its scheduled publications which provide evidence-based information on therapeutics, including new and revised listings of medicines on the PBS, for health professionals and consumers. **Result: Met**

NPS MedicineWise publications include the *Rational Assessment of Drugs and Research (RADAR)*, *Australian Prescriber* and an annual evaluation report of all NPS MedicineWise programs.

The Department also continued to support NPS MedicineWise through the Quality Use of Diagnostics, Therapeutics and Pathology Flexible Fund, to provide information and support to consumers and health professionals on quality use of medicines and medical testing.

Education was provided to health professionals in the form of one-on-one education visits, clinical e-Audits, peer group sessions, online modules and publications. Information was provided to health consumers through targeted campaigns (including on the appropriate use of antibiotics) and through various therapeutic topics accessible through the NPS MedicineWise website.[59]

Improve safety and quality in health care

Relevant evidence-based resources are available to help reduce unwarranted healthcare variation by changing clinical practice.
Source: 2015-16 Health Portfolio Budget Statements, p. 126

2015-16 Target	2015-16 Result
Tools are available to consumers, clinicians and health services to promote adoption of clinical best practice.	Information is available to reduce variation in 36 health care interventions. **Result: Met** ✓

The first Australian Atlas of Healthcare Variation (the Atlas) points to actions clinicians and health services can take to address health care variation.

Identification of potential unwarranted healthcare variation.
Source: 2015-16 Health Portfolio Budget Statements, p. 126

2015-16 Target	2015-16 Result
Agreement with relevant stakeholders on unwarranted healthcare variation for further investigation.	Agreement pending. Stakeholders currently considering the incidence of healthcare variation revealed in the Atlas. **Result: Not met**

The Atlas contains 67 recommendations directed to multiple stakeholders across the health care system. The suggested actions are designed to improve equity and efficiency, as well as the safety and quality of health care. Twelve recommendations are directed to the Department and have been considered in the context of broader health reform.

[59] Available at: www.nps.org.au

Analysis of performance – Program 7.5: Health Infrastructure

The Department substantially met two of the three performance targets for Program 7.5: Health Infrastructure.

Investment in health infrastructure will improve access to essential health services for people living in rural, remote and very remote communities. The Department continues to monitor the progress of infrastructure projects, taking remedial action where required.

The Department has not achieved the target of providing 75 Rural and Regional Teaching Infrastructure Grants (RRTIGs). RRTIGs work in partnership to stimulate the bringing forward of capital expenditure for upgrades of private health infrastructure in rural and regional Australia.

While the Department made 74 offers to successful applicants, not all RRTIGs offers were accepted. In seeking feedback, the Department understood offers were declined due to the amount of the grant offered and the limitations on how grant money could be spent by applicants. The Department has worked to reduce the administration burden on applicants as a result of this feedback.

Invest in other major health infrastructure

Funding arrangements in place for all successful projects under the 2010 and 2011 Regional Priority Round of Health and Hospitals Fund (HHF) grants.
Source: 2015-16 Health Portfolio Budget Statements, p. 127

2015-16 Target	2015-16 Result
Remaining six funding agreements signed by 31 December 2015.	One of the funding agreements was signed by 31 December 2015 and a further four funding agreements were signed by 18 February 2016. The remaining funding agreement is expected to be finalised by 30 September 2016. **Result: Not met**

The outstanding funding agreements all involved complex negotiations to ensure the agreed outputs for the projects would be achieved within the approved scope and budget.

Effective monitoring of HHF projects for compliance with agreed outputs.
Source: 2015-16 Health Portfolio Budget Statements, p. 128

2015-16 Target	2015-16 Result
Reports are received for all projects in the required timeframe and remedial action taken as required.	357 reports were due during the period. 304 reports were submitted in the required timeframe, remedial action was taken for the 53 reports which have now been submitted. **Result: Substantially met**

The majority of HHF funding recipients were compliant in providing project reports and achieving agreed project outputs within the required timeframes. Where projects were found to be non-compliant, the Department undertook remedial action in a timely manner.

This performance result of 'substantially met' is based on meeting 85% of the target.

Improve primary health care infrastructure

Number of grants to support the provision of additional space for teaching and training to strengthen the rural workforce.
Source: 2015-16 Health Portfolio Budget Statements, p. 128

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
75	43 **Result: Not met**	10	N/A	N/A	N/A

The Department has 43 RRTIGs funding agreements in place.

The Department made 74 grant funding offers to applicants, of which 20 applicants decided to withdraw from contract negotiations. The main reasons cited for withdrawal were the amount of the grant to be awarded and limitations in how the grant funds could be utilised. The Department is continuing negotiations to finalise the remaining offers.

The RRTIGs program has been streamlined to reduce administrative burden on applicants.

Analysis of performance – Program 7.6: Blood and Organ Donation

The Department met all performance targets for Program 7.6: Blood and Organ Donation.

In 2015-16, the Department continued to ensure there was sufficient blood and blood products available to support Australian patients. Governments endorsed the 2016–18 Jurisdictional Blood Committee Strategic Plan which incorporates a range of activities to improve the efficiency of the national blood arrangements and ensure its financial sustainability. Embedded within the Strategic Plan are eight policy priority areas for action over the life of the Plan, covering topics such as appropriateness of use and sustainability of Immunoglobulin; blood product use and wastage within the private sector; and harmonising the provisions of the National Blood Agreement with that of the broader health sector.

The Department continued to support the Organ and Tissue Authority in implementing, coordinating and monitoring a national approach to organ and tissue donation, with the aim of increasing Australians' access to life-saving and life-transforming transplants. This included activities in relation to the implementation of the 2014-15 Budget measure – *Accelerating Growth in Organ and Tissue Donation for Transplantation.*

On 1 July 2015, the Department assumed responsibility for the administration of the Supporting Leave for Living Organ Donors (SLLOD) Program, for which funding is provided until 30 June 2017. The SLLOD Program provides a financial contribution, via the donor's employer, to alleviate the financial burden for leave taken during the living donation process and recovery period. The Department also continued to provide policy oversight and support to the Department of Human Services in administering the Australian Organ Donor Register which enables Australians to register their decision about becoming an organ and/or tissue donor for transplantation after death.

The Department continued to ensure Australian patients are able to access Australian donors/cord blood units, or matched international donors/cord blood units, for stem cell transplant purposes, as part of life-saving treatment for cancer and other serious conditions.

Improve Australians' access to organ and tissue transplants

Support the Australian Bone Marrow Donor Registry and the National Cord Blood Collection Network to identify matched donors and stem cells for transplant.
Source: 2015-16 Health Portfolio Budget Statements, p. 130

2015-16 Target	2015-16 Result
Increased diversity of tissue types of donors and cord blood units available for transplant.	Diversity of donors and cord blood units available for transplant has increased. **Result: Met** ✓

The Australian Bone Marrow Donor Registry and the National Cord Blood Collection Network have been supported, and continue to identify matched donors and cord blood units for patients requiring them for transplantation. Donors from ethnically diverse backgrounds are required to increase the chance of a match being found in the Australian registry, as the Australian population profile is ethnically diverse. While the diversity of cord blood units has increased, a new donor recruitment strategy is being assessed to substantially improve the diversity of the stem cell donor pool. At present the donor pool is ageing and predominantly of north-west European descent, and needs younger donors from other backgrounds. This issue is being considered in the context of meeting the needs of Australian patients into the future.

Number of banked cord blood units.
• Total • Indigenous
Source: 2015-16 Health Portfolio Budget Statements, p. 130

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
Total 1,600 Indigenous 50	Total 1,700 Indigenous 60 **Result: Met** ✓	1,765 119	1,957 101	523 64	810 94

Cord blood units continue to be collected and banked in the three public cord blood banks in Australia, which now have more units per head of population banked than most other countries. A review of cord blood banking in Australia has recently been completed and will inform the future direction of the cord blood banking sector in Australia.

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.
Source: 2015-16 Health Portfolio Budget Statements, p. 131

2015-16 Target	2015-16 Result
Funding is provided to meet the Commonwealth's agreement with the Australian Bone Marrow Donor Registry.	Funding was provided as agreed. **Result: Met** ✓

The Australian Bone Marrow Donor Registry has been fully funded as per the Agreement, and stem cells from matched international donors have been transported for transplantation for Australian patients.

Demand for stem cell transplants continues to increase and international currency fluctuations impact on the cost of sourcing and transporting matched cells donated internationally.

Support access to blood and blood products

Effective planning of the annual blood supply through the National Supply Plan and Budget.
Source: 2015-16 Health Portfolio Budget Statements, p. 130

2015-16 Target	2015-16 Result
Implementation of the 2015-16 National Supply Plan and Budget that was agreed by all Health Ministers in 2014-15.	The 2015-16 National Supply Plan and Budget was agreed by all Health Ministers on 17 April 2015 and has been implemented. **Result: Met** ✓

The Commonwealth's contribution in 2015-16, based on the national cost-sharing arrangements, was expected to be up to $721.3 million.[60]

The supply of blood and essential blood products are effectively supported in order to meet Australia's clinical need.
Source: 2015-16 Health Portfolio Budget Statements, p. 131

2015-16 Target	2015-16 Result
Funding is provided to meet the Commonwealth's contribution under the National Blood Agreement.	Funding has been provided as agreed. **Result: Met** ✓

The supply of blood and essential blood products have been fully-funded as per the National Blood Agreement to ensure that there is a sufficient supply of blood and blood products and services in all the States and covered Territories.

This funding ensured Australians had access to blood and blood products required for treatment of numerous medical conditions in 2015-16. Conditions include cancer, heart, stomach, bowel, liver and kidney diseases. Blood and/or blood products are predominantly provided during and after surgery, for treatment of traumatic injury or burns, and for chronic conditions including blood disorders (e.g. haemophilia) and immunodeficiency conditions.

[60] The Commonwealth's contribution in 2015-16 will be reconciled approximately in December 2016 to reflect actual expenditure.

Analysis of performance – Program 7.7: Regulatory Policy

The Department met, or substantially met, the majority of performance targets for Program 7.7: Regulatory Policy.

The Department has continued to contribute significantly to the Government's regulatory reform agenda with the aim to reduce the red tape burden on businesses, community organisations and individuals. The focus of the reforms has been on ensuring delivery of appropriate and effective regulation which maintains desired health outcomes, upholds public health and safety protections, and implements effective compliance regimes while reducing unnecessary regulatory and red tape burden.

The Department has been at the forefront of implementing regulatory reform initiatives such as the Regulator Performance Framework (RPF) and the adoption of international standards and risk assessment under the Government's Industry Innovation and Competitiveness Agenda. In 2015-16, the first year of RPF implementation, departmental and portfolio regulators worked closely to develop and publish evidence metrics under the RPF. These will be used to assess regulators' performance through annual self-assessments.

In 2015-16, to protect the health, safety and wellbeing of the Australian community, the Department continued to provide national leadership in regulatory policy in the areas of therapeutic goods, industrial chemicals and gene technology.

The Department has contributed to the achievement of significant reductions in red tape burden. The Portfolio has reported red tape reduction savings worth $249 million since September 2013.

Continue the quality improvement and regulatory reform process

Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to reduce red tape.
Source: 2015-16 Health Portfolio Budget Statements, p. 133

2015-16 Target	2015-16 Result
Opportunities to reduce regulatory and red tape burden are identified and contribute to the Government's $1 billion per annum regulation reduction target.	In 2015, the Department made 40 regulatory savings decisions worth a combined total net saving of $96.8 million. **Result: Met** ✓

The Government's red tape reduction outcomes are reported on a calendar year basis. For 2015, the Department reported gross savings decisions of $100.4 million and net savings decisions worth $96.8 million, contributing to the whole-of-government net outcome of $2.5 billion for that year. Details of specific regulatory reform activities undertaken by the Department are published in the *2015 Annual Red Tape Reduction Report*.[61]

Further opportunities for regulatory reform have been identified, and the Department and wider portfolio will continue to promote regulatory reform, encouraging best practice in regulation and minimising unnecessary compliance burden in 2016-17 and beyond.

[61] Available at: www.cuttingredtape.gov.au/annual-red-tape-reduction-report-2015

The Department is currently putting in place a detailed regulatory framework, enabling applications for licences and permits for the cultivation, production and manufacture of medicinal cannabis products.

Medicinal cannabis scheme to ease pain of suffering Australians

Amendments to the *Narcotic Drugs Act 1967*, passed by Parliament in February 2016, will allow the domestic cultivation and manufacture of medicinal cannabis products and related research purposes after 30 October 2016. The medicinal cannabis scheme will allow medical professionals to prescribe medicinal cannabis products where appropriate and aims to help Australians who suffer from illnesses including nausea associated with cancer treatment, childhood epilepsy, multiple sclerosis and to assist those in end of life palliative care.

The Department has been working closely with State and Territory Governments to form relevant regulations and guidelines, as well as holding public consultations around the country.

The medicinal cannabis scheme has been met with enthusiasm by many who attended the information and consultation sessions with a number of attendees believing this has been a long time coming. The scheme will not only help Australians who suffer from a range of illnesses that might benefit from medicinal cannabis, but potentially give those who have turned to illegal sources in a desperate attempt to find relief an alternative, legal option.

The medicinal cannabis scheme is expected to start accepting and reviewing licence and permit applications to cultivate and manufacture after 30 October 2016, with the aim of having domestically grown products available for patients by mid-2017.

The Department, through the Therapeutic Goods Administration (TGA), continued to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods, while ensuring that the goods available in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

Further to publication on 24 June 2015 of the 32 recommendations in the first report of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review), on 20 November 2015 the second and final report was published. This report looked at the regulatory framework for complementary medicines and the advertising of therapeutic goods and made a further 26 recommendations.

Advice to the Government in response to the recommendations of the Review was provided. Work is currently underway on implementation of the 2016-17 Budget measure – *Improving the Regulation of Therapeutic Goods in Australia*.

The National Industrial Chemicals Notification Assessment Scheme (NICNAS), administered by the Department, continued to aid in the protection of the Australian people and the environment. In 2015-16, NICNAS continued to disseminate high quality assessment reports that inform workers, governments, industry and community about the risks and safe use of new and existing industrial chemicals. Reports cover chemicals used in solvents, adhesives, plastics, paints, inks, fuels, or laboratory reagents, as well as in refrigeration, cosmetics and household cleaning. The Department also commenced work on the implementation of the reforms to NICNAS that had been announced by the Government in the context of the 2015-16 Budget. The Department published a series of consultation papers and convened a series of workshops to better understand and (to the extent possible within the policy parameters decided by the Government) accommodate the divergent views of different stakeholder groups in preparing advice for the Government on the practical details of a reformed scheme.

The Gene Technology Regulator, supported by the Department, administers the national gene technology regulatory scheme. In 2015-16, the Regulator continued to protect the health and safety of people, and to protect the environment, by identifying risk posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

There have been significant technological advances in recent years, including the development of a range of novel techniques for making precise changes to genes. Regulatory frameworks across the world were developed prior to the existence of these new technologies. The Gene Technology Regulator is working to address the challenges of keeping pace with the new techniques and their regulation.

Therapeutic goods

Regulate therapeutic goods for safety, effectiveness/performance and quality

Continue to regulate therapeutic goods for safety, effectiveness/performance and quality.
Source: 2015-16 Health Portfolio Budget Statements, p. 133

2015-16 Target	2015-16 Result
Effective pre-market evaluation and post-market monitoring and assessment of therapeutic goods, as required under the *Therapeutic Goods Act 1989* and associated regulations.	The TGA continued to undertake pre-market and post-market monitoring and assessment of therapeutic goods as required under the *Therapeutic Goods Act 1989* and associated regulations. **Result: Substantially met** ✓

Through the TGA, the Department demonstrates regulatory performance through its reporting framework. The framework consists of various reports that focus on its performance as a regulator and engagement with stakeholders, as well as more detailed information about regulatory and corporate activities.

Performance measures surrounding pre-market application processing and post-market activities are reported below.

In addition, detailed information regarding pre and post-market statistics are reported in the TGA's Performance Statistics Report and published on the TGA website annually.

Performance result of 'substantially met' is based on meeting 99.1% of the targeted 100% of Category 3 applications for prescription medicines processed within legislated timeframes.

Update and maintain the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for medicines.
Source: 2015-16 Health Portfolio Budget Statements, p. 133

2015-16 Target	2015-16 Result
SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the *Therapeutic Goods Regulations 1990*.	The SUSMP was amended as soon as practicable after the Secretary's delegate's final decision. In all, there were 6 updates to the SUSMP during 2015-16. **Result: Met** ✓

All required SUSMP legislative instruments were amended as soon as practicable after the Secretary's delegate's final decision during 2015-16 and all are available on the Federal Register of Legislation (FRL) website for June 2015, July 2015, October 2015, February 2016, March 2016 and June 2016. This result represents an increase in SUSMP publication of 100% during the financial year to meet demand.

Percentage of applications for the import, export, and manufacture of controlled substances that are assessed and processed within agreed timeframes.
Source: 2015-16 Health Portfolio Budget Statements, p. 134

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
95%	99% **Result: Met** ✓	N/A	N/A	N/A	N/A

During 2015-16, 99% of applications were completed within the requisite timeframe due to improvements to internal workflow processes.

In 2015-16, the Office of Drug Control (ODC) issued a total of 7,002 licences and permits authorising the import, export and manufacture of controlled drugs. This represents a decrease of 6% compared to 2014-15.

The ODC also provided 230 basic checks and statements to law enforcement.

Percentage of evaluations/assessments completed within legislated timeframes:[62]
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; and
c) Conformity assessments for medical devices processed within 255 working days.
Source: 2015-16 Health Portfolio Budget Statements, p. 135

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	a) 100% b) 99.1% c) 100% **Result:** **a) Met** ✓ **b) Substantially met** ✓ **c) Met** ✓	a) 99.7% b) 98% c) 100%	a) 99.8% b) 100% c) N/A	a) 99.7% b) 100% c) N/A	a) 99.5% b) 99.4% c) N/A

Category 1 applications are for new medicines, presentations and indications. Category 3 applications are initiated by sponsors for manufacturing and quality changes and are usually to an existing, marketed medicine.

380 of 380 (100%) Category 1 evaluations for prescription medicines, 1,390 of 1,403 (99.1%) Category 3 evaluations and 186 of 186 (100%) of conformity assessment applications for medical devices were processed within legislated timeframes.

As a result of business improvement processes, all conformity assessments for medical devices have been processed in less than 200 working days throughout the reporting period.

[62] Once an application has been accepted by the TGA, the approval time is defined as the number of TGA working days until a decision is made. This timeframe is underpinned by legislation and excludes public holidays, weekends, the time allocated to the applicant to provide responses to requests for information and 'mutual clock stop' periods agreed with the applicant. In accordance with the *Therapeutic Goods Regulations 1990*, a 'submission' may include a number of applications submitted at the one time. The data presented relate to submissions as this best reflects the evaluation and decision-making processes.

Percentage of alleged breaches of the *Therapeutic Goods Act 1989* received that are assessed within 10 working days and an appropriate response initiated.
Source: 2015-16 Health Portfolio Budget Statements, p. 135

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	100% **Result: Met** ✓	100%	100%	100%	100%

Complaints are triaged in a risk-based regulatory compliance framework and against the scope of jurisdictional reach of Commonwealth law to determine the appropriate response in relation to risks posed by breaches of the TGA's regulatory scheme.

Percentage of licensing and surveillance inspections closed out within target timeframes.
Source: 2015-16 Health Portfolio Budget Statements, p. 135

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
85%	87% **Result: Met** ✓	N/A	N/A	N/A	N/A

The Department reviewed the process for conducting post-inspection activities to allow a more efficient resolution of deficiencies and close-out of inspections and to align with international practice. Following a trial of the modified process, in addition to consultation with the Technical Industry Working Group on Good Manufacturing Practice, changes have been made to:

- deficiencies reported to manufacturers after the inspection in place of the inspection report;
- requirements for objective evidence required under certain circumstances e.g. critical deficiencies, initial inspection or recurring deficiencies;
- the inspection report issued to the manufacturer after the responses to the deficiencies have been addressed and closed; and
- the format and content of the inspection report.

External guidance material is available on the TGA website and continues to be updated.

Participate in international regulatory convergence and work sharing activities

Implement international harmonisation and work sharing activities with comparable international regulators.
Source: 2015-16 Health Portfolio Budget Statements, p. 133

2015-16 Target	2015-16 Result
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.*	The Department successfully continued collaboration activities with comparable international regulators through international fora as outlined in the TGA's *International Engagement Strategy 2013–15*. **Result: Met** ✓

The Department promoted enhanced cooperation and work sharing, and influenced international regulatory policy, in relation to therapeutic goods, through its continued participation in fora such as the International Coalition of Medicines Regulatory Authorities and the International Medical Devices Regulators' Forum.

Percentage of good manufacturing practice clearances of overseas manufacturers that take into account approvals by equivalent international regulators.
Source: 2015-16 Health Portfolio Budget Statements, p. 134

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
85%	95% **Result: Met** ✓	N/A	N/A	N/A	N/A

New processes have led to improvements in the TGA's ability to issue Good Manufacturing Practice clearances in a shorter timeframe.

Continue the quality improvement and regulatory reform process

Implement reforms that enhance TGA's current regulatory processes and are consistent with the Government's deregulation and red tape reduction agenda.
Source: 2015-16 Health Portfolio Budget Statements, p. 133

2015-16 Target	2015-16 Result
Begin implementation of the Government's response to the Review of Medicines and Medical Devices Regulation.	Changes to the Medicines and Medical Devices Regulation in response to the Review were funded in the 2016-17 Budget and are in the process of being implemented. **Result: Met** ✓

These reforms, when fully implemented, are estimated to save around $75 million annually through removing unnecessary duplication, cutting red tape and easing the regulatory burden on the pharmaceutical and medical device industries.

Number of reforms implemented to enhance TGA's regulatory processes.
Source: 2015-16 Health Portfolio Budget Statements, p. 134

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
9[63]	2 **Result: Not met**	1	9	28	N/A

In December 2011, the Government released its response, *TGA Reforms: a blueprint for the TGA's future* (the Blueprint), to a number of reviews undertaken of therapeutic goods regulation. It was agreed that the reforms and recommendations contained in the Blueprint would be implemented over a four year period.

To date, 40 of 48 Blueprint reference targets have been met. Implementation of a small number of recommendations was put on hold pending the Expert Panel Review of Medicines and Medical Devices Regulation. A plan to ensure information on the TGA website is current, accurate, relevant and up to date and meets the needs of its audiences has been developed.

Chemical safety

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

Scientifically robust assessments of new and existing industrial chemicals.
Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
Peer review and stakeholder feedback support assessment outcomes.	Peer review and stakeholder feedback supported assessment outcomes. **Result: Met**

In 2015-16, NICNAS published assessment reports for 196 new chemicals, one Priority Existing Chemical, and published three reports following secondary notifications of previously assessed chemicals and one secondary notification of a new chemical. All of these reports were peer reviewed, and stakeholder feedback was considered prior to finalising the reports. No reviews of NICNAS's chemical assessments were conducted by the Administrative Appeals Tribunal.

NICNAS aids in the protection of the Australian people and the environment by disseminating high quality assessment reports that inform workers, governments, industry and community about the risks and safe use of new and existing industrial chemicals.

[63] This target does not include one uncompleted reform from 2014-15. As at 30 June 2016, eight reforms are still to be implemented.

High quality assessment outcomes are produced through effective use of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.
Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
The IMAP framework will be reviewed to inform future assessment approaches for industrial chemicals already in use.	The IMAP framework was internally reviewed and found to be a suitable basis for future assessment approaches under reformed chemical assessment arrangements. **Result: Met** ✓

The IMAP framework was established in 2012 and is being implemented in a staged manner to accelerate the assessment of previously unassessed chemicals listed on the Australian Inventory of Chemical Substances (AICS).

By the end of the four years of Stage One of the application of the IMAP framework (30 June 2016), NICNAS had made 2,705 recommendations to manage newly identified risks associated with the industrial use of 2,135 unique chemicals assessed under the IMAP framework.

This includes 194 recommendations made during 2015-16. In all cases, interested parties were given the opportunity to comment on those recommendations. NICNAS staff engaged with stakeholders, and met with key Australian risk management agencies to promote the uptake of recommendations.

NICNAS staff, in consultation with Australian and international stakeholders, undertook a review of Stage One of the implementation of the IMAP program, which found that the IMAP framework is very effective overall in accelerating high quality assessment outputs for chemicals. The review found that recommendations contained in IMAP assessment reports have been taken up by relevant regulatory agencies to improve the safe use of chemicals already in use in Australia, and that more effective management of risks associated with the use of these chemicals will further aid in the protection of the Australian people and the environment. The review concluded that the tools and approaches used in the IMAP framework were aligned with international best practice and were fit for purpose.

Following this review, the Assistant Minister for Health and Aged Care approved the commencement of the second stage of implementing the IMAP framework.

Contribution to the international harmonisation of regulatory approaches and methodologies for assessing industrial chemicals by reviewing Australian processes.
Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
Regulatory approaches are reviewed and methodologies developed by the Organisation for Economic Co-operation and Development (OECD) Chemicals Committee and its key sub-committees for their application to NICNAS assessments of industrial chemicals.	Continued collaborative activities through the reviewing and consulting on international methodologies, guidance and regulation for their application to NICNAS assessments of industrial chemicals. **Result: Met** ✓

In 2015-16, NICNAS participated in the OECD Chemicals Committee and its key subsidiary committees (the Task Force on Hazard Assessment; Clearing House on New Chemicals; Working Party on Manufactured Nanomaterials) and presented a Metals Risk Assessment workshop at the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue forum in the Philippines.

NICNAS also engaged with other regulators on a bilateral and multilateral basis to further facilitate international harmonisation of NICNAS assessment methods.

Increased international harmonisation of chemical regulation reduces the regulatory burden on industry, which facilitates the availability of newer and safer chemicals in Australia.

All introducers of industrial chemicals are aware of their legal obligations.
Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
Identified introducers are registered and provided with regular information updates.	NICNAS uses a variety of means to identify chemical importers and manufacturers to promote their awareness of legal obligations, and to provide relevant information updates. **Result: Met** ✓

At the end of 2015-16, there were 6,144 companies registered with NICNAS, which is 99.7% of identified introducers. Thirteen information sessions were delivered to over 600 attendees in major capital cities and regional areas, with positive feedback received. An online questionnaire was developed to prioritise companies for further assessment of their compliance with new chemical obligations.

Update and maintain the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for chemical poisons.
Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the *Therapeutic Goods Regulations 1990.*	The SUSMP was amended as soon as practicable after the Secretary's delegate's final decision. In all, there were 6 updates to the SUSMP during 2015-16. **Result: Met** ✓

All required SUSMP legislative instruments were amended as soon as practicable after the Secretary's delegate's final decision during the 2015-16 financial year and all are available on the Federal Register of Legislation (FRL) website for June 2015, July 2015, October 2015, February 2016, March 2016 and June 2016. This result represents an increase in SUSMP publication of 100% during this financial year to meet demand.

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.

Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
Reforms to NICNAS more efficiently and effectively achieve the objects of the *Industrial Chemicals (Notification and Assessment) Act 1989*.	NICNAS published three consultation papers on the implementation of the NICNAS reforms, and sought input from stakeholders including international regulators and technical experts. **Result: Met** ✓

119 submissions were received in response to the three consultation papers published in 2015-16. In addition, a total of 301 people attended six stakeholder workshops to discuss the reform proposals.

Stakeholder views obtained through written submissions and workshops will be taken into account in finalising the regulatory model for industrial chemicals submitted to Government for agreement.

The NICNAS reforms will reduce regulatory burden on industry and promote the availability of safer chemicals by streamlining assessment approaches and refocussing regulatory effort on higher risk industrial chemicals, while ensuring Australia's robust safety standards are maintained.

Effective use of international information.

Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
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.	Continued collaborative activities with trusted international regulators to harmonise assessment approaches. **Result: Met** ✓

Departmental regulatory scientists continued to use information on the hazards of chemicals obtained from a range of international sources in conducting assessments of the risks of the use of these chemicals in Australia. Departmental scientists engaged with their counterparts in comparable international regulatory agencies and global industry associations to obtain and review relevant information, and received ongoing professional development in a range of assessment-focussed areas. In addition, internal databases were updated with new internationally validated testing guidelines and assessment methods, to enable assessors to effectively interpret the latest information. Nineteen assessments from comparable international agencies were incorporated in NICNAS new chemicals assessments.

Effective use of international information reduces regulatory duplication, and considers relevant information in the Australian context. This reduces the regulatory burden on industry and promotes the availability of safer chemicals for use in Australia.

Human health risk assessments for agricultural and veterinary chemicals are performed in a timely manner.

Source: 2015-16 Health Portfolio Budget Statements, p. 137

2015-16 Target	2015-16 Result
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).	Human health risk assessments for agricultural and veterinary chemicals were performed in accordance with the service level agreement. **Result: Met** ✓

Human health risk assessments for agricultural and veterinary chemicals are performed by the Department in accordance with the service level agreement between the Department and the APVMA. The service level agreement specified the timeframes and cost recovery arrangements and quality assurance criteria for the various assessment categories.

In 2015-16, the Department continued to undertake human health risk assessments for the APVMA. The Department completed 114 assessments and the overall timeframe compliance increased to 76.3%, which is the highest timeframe compliance rate since 2009-10.

The Department recommended against granting some applications based on the potential for these chemicals to cause adverse health impacts.

Percentage of new industrial chemical assessments completed within legislated timeframes.

Source: 2015-16 Health Portfolio Budget Statements, p. 138 & 2015-16 Corporate Plan, p. 15

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
96%	99% **Result: Met** ✓	98%	96%	95%	95%

NICNAS completed 292 certificate and permit assessments for new industrial chemicals, with 289 of these completed within legislated timeframes.

Timely assessment of new chemicals ensures timely access to safer and innovative chemical products for the Australian community. New chemical assessment reports, certificate and permit details are published on the NICNAS website to increase public confidence on the chemicals introduced into the country.

Cumulative percentage of Stage One industrial chemicals assessed through effective application of IMAP framework.
Source: 2015-16 Health Portfolio Budget Statements, p. 138

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
95%	97.3%[64] **Result: Met** ✓	93%	56%	24%	N/A

By the end of Stage One (30 June 2016) of implementation of the IMAP Framework, NICNAS completed 5,114 human health and/or environment assessments for 3,419 unique chemicals in 2015-16 for chemicals that may already be in use in Australia. This includes 909 assessments completed in 2015-16.

Percentage of Level C and D introducers of industrial chemicals assessed for compliance with their new chemicals obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989*.
Source: 2015-16 Health Portfolio Budget Statements, p. 138

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
45%	45% **Result: Met** ✓	40%	35%	30%	25%

During 2015-16, 45% of registrants that had introduced relevant industrial chemicals with a value above $500,000 were screened for evidence of compliance with new chemicals obligations. This resulted in 103 organisations being selected for further risk assessment. Fifty-five of these registrants were required to provide NICNAS with further information with regard to their new chemicals obligations via an online questionnaire.

Ongoing compliance monitoring raises awareness among the regulated community of their obligations under the Act and identifies non-compliance.

Gene technology regulation

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

Commence technical review of the *Gene Technology Regulations 2001*.
Source: 2015-16 Health Portfolio Budget Statements, p. 139

2015-16 Target	2015-16 Result
Review undertaken in consultation with relevant stakeholders.	A technical review of the *Gene Technology Regulations 2001* commenced. **Result: Substantially met** ✓

In 2015-16, a technical review of the *Gene Technology Regulations 2001* commenced. Due to complexity of the new technologies, a discussion paper was prepared on options for a review of the regulations. During this period, the Department through the OGTR liaised with other regulatory agency stakeholders. A full consultation with all stakeholders will commence in 2016-17.

[64] This total included 515 chemicals that were not on the Stage One list, that were able to be efficiently assessed due to their close similarity to chemicals already being assessed.

Provide open, effective and transparent regulation of GMOs.
Source: 2015-16 Health Portfolio Budget Statements, p. 139

2015-16 Target	2015-16 Result
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.	Risk assessments and risk management plans prepared for 100% of licence applications for release of GMOs into the environment. Stakeholders, including the public, consulted on all assessments of these applications. Record of GMO dealings and maps of all field trial sites maintained and made publicly available on the OGTR website. **Result: Met** ✓

The Gene Technology Regulator prepared comprehensive risk assessments and risk management plans and consulted with stakeholders, including the public, on nine GMO licence applications for intentional release into the environment (three field trials, two clinical trials, two commercial GM canola, one commercial GM cut flower and a commercial GM cancer treatment). The Regulator also prepared risk assessments and risk management plans for six licence applications for work in contained facilities. The Regulator maintained a record of approved GMOs and maps of all field trial sites, and made them available on the OGTR website.

Percentage of field trial sites and higher level containment facilities inspected.
Source: 2015-16 Health Portfolio Budget Statements, p. 139

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
≥20%	46% of field trial sites 21% of higher level containment facilities **Result: Met** ✓	44% 29%	40% 25%	42% 25%	44% 33%

In 2015-16, 46% of GM field trial sites across the country were inspected to monitor compliance with licence conditions ensuring risks to human health and the environment were minimised. Sites were inspected in New South Wales, Northern Territory, Queensland, Victoria and Western Australia. Inspections included GM banana, barley, canola, cotton, safflower, sugarcane and wheat.

The Department through the OGTR also inspected 21% of higher level containment facilities to ensure compliance with certification conditions. These inspections focussed on the integrity of the physical structure of the facility and on the general laboratory practices followed.

Protect people and environment through identification and management of risks from GMOs.
Source: 2015-16 Health Portfolio Budget Statements, p. 140

2015-16 Target	2015-16 Result
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.	No adverse effect on human health or environment from authorised GMOs. **Result: Met** ✓

Routine monitoring of the regulated community found a high level of compliance with the gene technology legislation.

Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and /or genetically modified products.
Source: 2015-16 Health Portfolio Budget Statements, p. 140

2015-16 Target	2015-16 Result
High degree of cooperation with relevant regulatory agencies and provision of timely advice.	Maintained high degree of cooperation with relevant regulatory agencies. **Result: Met** ✓

In 2015-16, the Regulator continued cooperative arrangements with other Australian Government regulators to enhance coordinated decision-making and avoid duplication in regulation of GMOs and genetically modified products.

The Department through the OGTR engaged in international fora relevant to GMO regulation including the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. Regulators from other countries continued to seek input from the OGTR because the Australian scheme is considered a model for robust, practical and efficient regulation of GMOs. The OGTR also provided technical support to Australian engagement for meetings under the United Nations Convention on Biological Diversity and Cartagena Protocol on Biosafety.

Percentage of licence decisions made within statutory timeframes.
Source: 2015-16 Health Portfolio Budget Statements, p. 140

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	100% **Result: Met** ✓	95%	100%	100%	100%

Fifteen licence decisions were made, all within the applicable statutory timeframes.

Outcome 7 – Budgeted expenses and resources

	Budget Estimate[1] 2015-16 $'000 (A)	Actual 2015-16 $'000 (B)	Variation $'000 (B) - (A)
Program 7.1: eHealth[2]			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	129,182	116,697	(12,485)
Non cash expenses[3]	21,662	19,420	(2,242)
Departmental expenses			
Departmental appropriation[4]	17,488	18,361	873
Expenses not requiring appropriation in the current year[5]	289	964	675
Total for Program 7.1	**168,621**	**155,442**	**(13,179)**
Program 7.2: Health Information			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	18,296	19,428	1,132
Departmental expenses			
Departmental appropriation[4]	4,040	4,060	20
Expenses not requiring appropriation in the current year[5]	105	264	159
Total for Program 7.2	**22,441**	**23,752**	**1,311**
Program 7.3: International Policy Engagement			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	14,412	14,412	-
Departmental expenses			
Departmental appropriation[4]	6,021	6,529	508
Expenses not requiring appropriation in the current year[5]	151	366	215
Total for Program 7.3	**20,584**	**21,307**	**723**
Program 7.4: Research Capacity and Quality[2]			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	79,217	78,543	(674)
Special accounts			
Medical Research Future Fund	-	-	-
Departmental expenses			
Departmental appropriation[4]	10,957	9,698	(1,259)
Expenses not requiring appropriation in the current year[5]	250	630	380
Total for Program 7.4	**90,424**	**88,871**	**(1,553)**

	Budget Estimate[1] 2015-16 $'000 (A)	Actual 2015-16 $'000 (B)	Variation $'000 (B) - (A)
Program 7.5: Health Infrastructure[2]			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	11,380	9,590	(1,790)
Special appropriations	54,984	24,787	(30,197)
Special accounts			
Health and Hospital Fund Health Portfolio Special Account	33,197	52,484	19,287
Departmental expenses			
Departmental appropriation[4]	5,261	5,061	(200)
Expenses not requiring appropriation in the current year[5]	133	320	187
Total for Program 7.5	**104,955**	**92,242**	**(12,713)**
Program 7.6: Blood and Organ Donation[2]			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	23,084	19,509	(3,575)
Special appropriations			
National Health Act 1953 - Blood Fractionation, Products and Blood Related Products - to National Blood Authority	645,262	718,382	73,120
Departmental expenses			
Departmental appropriation[4]	4,345	4,221	(124)
Expenses not requiring appropriation in the current year[5]	118	277	159
Total for Program 7.6	**672,809**	**742,389**	**69,580**

	Budget Estimate[1] 2015-16 $'000 (A)	Actual 2015-16 $'000 (B)	Variation $'000 (B) - (A)
Program 7.7: Regulatory Policy			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	256	39	(217)
Departmental expenses			
Departmental appropriation[4]	13,089	14,119	1,030
to Special accounts	(11,612)	(11,247)	365
Expenses not requiring appropriation in the current year[5]	-	191	191
Special accounts			
OGTR Special Account[6]	7,882	7,599	(283)
NICNAS Special Account[7]	18,532	15,873	(2,659)
TGA Special Account[8]	138,876	133,749	(5,127)
Expense adjustment[9]	(5,215)	(6,288)	(1,073)
Expenses not requiring appropriation in the current year[5]	-	5	5
Total for Program 7.7	**161,808**	**154,040**	**(7,768)**
Outcome 7 Totals by appropriation type			
Administered expenses			
Ordinary annual services (Appropriation Act No. 1)	275,827	258,218	(17,609)
Non cash expenses[3]	21,662	19,420	(2,242)
Special accounts	33,197	52,484	19,287
Special appropriations	700,246	743,169	42,923
Departmental expenses			
Departmental appropriation[4]	61,201	62,049	848
to Special accounts	(11,612)	(11,247)	365
Expenses not requiring appropriation in the current year[5]	1,046	3,012	1,966
Special accounts	160,075	150,938	(9,137)
Total expenses for Outcome 7	**1,241,642**	**1,278,043**	**36,401**
Average staffing level (number)	**1,049**	**1,039**	**(10)**

1 Budgeted appropriation taken from the *2016-17 Health Portfolio Budget Statements* and re-aligned to the 2015-16 outcome structure.
2 This Program excludes National Partnership payments to State and Territory Governments by the Treasury as part of the Federal Financial Relations Framework.
3 'Non cash expenses' relates to the depreciation of computer software.
4 Departmental appropriation combines 'Ordinary annual services (Appropriation Act No. 1)' and 'Revenue from independent sources (s74)'.
5 'Expenses not requiring appropriation in the budget year' is made up of depreciation expense, amortisation, make good expense, operating losses and audit fees.
6 Office of the Gene Technology Regulator Special Account.
7 National Industrial Chemicals Notification and Assessment Scheme Special Account.
8 Therapeutic Goods Administration Special Account.
9 Special accounts are reported on a cash basis. The adjustment reflects the difference between cash and expenses.