Outcome 5:
Regulation, Safety and Protection

Protection of the health and safety of the Australian community and preparedness to respond to national health emergencies and risks, including through immunisation, initiatives, and regulation of therapeutic goods, chemicals, gene technology, and blood and organ products

Analysis of performance

In 2016-17, the Department continued to deliver world-class regulation of therapeutic goods, contributing to better health outcomes for Australians. Work continued to aid in the protection of the Australian people and the environment by disseminating high quality assessments about risks from the use of new and existing industrial chemicals. Legislative changes have allowed for the legal cultivation, production and manufacturing of medicinal cannabis products in Australia. The expansion to the whole-of-life Australian Immunisation Register has enabled increased reporting for immunisation coverage data for additional population groups and a range of private vaccines.

These activities have contributed to the Department's achievements of objectives under Outcome 5 and our Purpose.

Highlights

Medicinal cannabis cultivation gets the green light

New laws allowed the Department to grant 15 licences to cultivate, produce and manufacture cannabis for medicinal purposes in Australia.
Refer *Program 5.1*

Renewed funding for OzFoodNet

Through OzFoodNet, the Department will continue to work with State and Territory health authorities on enhanced foodborne disease surveillance to help rapid identification and response to outbreaks of foodborne illnesses.
Refer *Program 5.2*

Support for world leading AusVaxSafety initiative

Investment in the world-leading AusVaxSafety, a new national collaborative active vaccine safety initiative, has ensured continued safety and public confidence in immunisation.
Refer *Program 5.3*

Looking ahead

- The Department, through the Therapeutic Goods Administration, will reduce regulatory burden on business through the roll out of a manufacturer compliance framework, an electronic Conformity Assessment application form, and a new notifications process for low risk changes to registered medicines.
- The Government will provide early access to certain new medicines that address unmet clinical needs for serious conditions, supported by a strengthened post-market monitoring and vigilance system.
- The next iteration of the National Blood Borne Viruses (BBV) and Sexually Transmissible Infections (STI) Strategies (2018–22) will be developed to set the direction for a coordinated national response to HIV, hepatitis B, hepatitis C, STI, and with a dedicated strategy to specifically address BBV and STI in the Aboriginal and Torres Strait Islander population.
- 10–19 year olds and newly arrived refugees and humanitarian entrants will now have access to essential vaccines under the expansion of the National Immunisation Program.
- Australia's first national immunisation campaign in 20 years will be implemented, aiming to improve vaccination coverage rates, timely completion of schedule points and confidence in the program.
- Reforms to the National Industrial Chemicals Notification and Assessment Scheme will reduce regulatory burden on Australian importers and manufacturers of industrial chemicals, and remove unnecessary barriers to the introduction of safer chemicals, whilst continuing to protect the public and environment.

Purpose, programs and program objectives contributing to Outcome 5

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.
Program 5.1: Protect the Health and Safety of the Community Through Regulation
Therapeutic Goods
Regulating therapeutic goods for safety, effectiveness/performance and quality
Participating in international regulatory convergence and work sharing activities
Promoting best practice regulation of therapeutic goods
Drug Regulation
Regulating the import, export, and manufacture of controlled drugs
Regulating the cultivation and manufacture of medicinal cannabis
Chemical Safety
Aiding 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
Protecting the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)
Performance criteria from the 2016-17 Corporate Plan
Program 5.2: Health Protection and Emergency Response
Reducing the incidence of blood borne viruses and sexually transmissible infections
Providing a comprehensive and effective response to national health emergencies
Improving biosecurity and minimising the risks posed by communicable diseases
Supporting the development of policies and implementation activities relating to health protection issues of national significance
Program 5.3: Immunisation
Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program
Performance criteria from the 2016-17 Corporate Plan

Program 5.1: Protect the Health and Safety of the Community Through Regulation

The Department met the majority of performance targets related to Program 5.1: Protect the Health and Safety of the Community Through Regulation.

In 2016-17, the Department continued to participate in international fora that aim to promote enhanced information sharing and cooperation, and regulatory convergence in relation to therapeutic goods. Collaborating with international regulators continues to enable the Department to make more informed and consistent regulatory decisions about the safety, quality and effectiveness of therapeutic goods in Australia.

In 2016-17, the Department, through the Therapeutic Goods Administration (TGA), began implementing the response to the Review of Medicines and Medical Devices Regulation, announced in the 2016-17 Budget. The first legislative changes to implement the reforms were enacted in June 2017. A key challenge faced by the TGA was commencing the implementation of regulatory reform, while maintaining core activities associated with providing high quality regulation of therapeutic goods in Australia. This challenge is expected to continue in 2017-18 as implementation of regulatory reform continues.

The Office of Drug Control (ODC) is facilitating access to medicinal cannabis products for patients that have medical conditions where there is evidence to support its use. To fully achieve this, a number of legislative and regulatory changes were required. On 30 October 2016, ODC implemented amendments to the *Narcotic Drugs Act 1967* that have allowed for the cultivation, production and manufacturing of cannabis to commence, as well as enabled access to medicinal cannabis under prescription for suitable patients. In November 2016, initial applications were received by ODC with a total of 15 licences being granted by 30 June 2017.

ODC faced a number of challenges in 2016-17, mostly around unknown factors in relation to the size of the medicinal cannabis industry, the anticipated numbers of licence applications, and the implementation of regulations designed in the absence of a functioning industry. In addition, ODC was increasingly involved in detailed stakeholder discussions and consultation in response to substantial political and public interest in the medicinal cannabis industry. These challenges affected other core business around licensing for prohibited substance imports and manufacture oversight for other narcotic drugs, and resulted in reduced ability to meet priority targets and delayed processing times.

In 2016-17, through its administration of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Department continued to provide high quality assessment reports that inform the public, workers, the Government and industry of risks from the introduction and use of industrial chemicals, thereby promoting their safe use. The Department also continued the implementation of significant reforms to NICNAS that were announced in the 2015-16 Budget. The details of the implementation were developed through extensive stakeholder consultation, within the policy framework agreed by Government. The proposed changes have caused some challenges to staff administering NICNAS. This is due to the need to develop and consult on the technical details of the reforms while continuing to operate under the current scheme.

The launch of the NICNAS Business Services web portal increased the efficiency of annual registration processes for both industrial chemical introducers and the regulator by moving from paper-based to online processes.

The Department through the Office of the Gene Technology Regulator (OGTR) continued to ensure that the community can have confidence that Genetically Modified Organisms approved in Australia have followed a robust risk assessment process and any identified risks have been managed effectively. In 2016-17, the OGTR continued to progress the technical review of the Gene Technology Regulations 2001 with significant community and stakeholder consultation. The proposed amendments would provide greater regulatory clarity to stakeholders, reduce burden and promote innovation.

Therapeutic Goods

Regulating therapeutic goods for safety, effectiveness/performance and quality

Continue to regulate therapeutic goods for safety, effectiveness/performance and quality.
Source: 2016-17 Health Portfolio Budget Statements, p. 117

2016-17 Target	2016-17 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 Therapeutic Goods Administration (TGA) continued to undertake effective pre-market evaluation and post-market monitoring and assessment of therapeutic goods, as required under the *Therapeutic Goods Act 1989* and associated regulations. **Result: Substantially met**

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

Detailed information regarding pre and post-market statistics and information about the TGA's performance against the Regulator Performance Framework is available on the TGA website.[45] The outcomes of laboratory testing and compliance and enforcement actions by the TGA are published on the TGA website.[46]

A performance result of 'substantially met' is based on meeting 99.8% 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).
Source: 2016-17 Health Portfolio Budget Statements, p. 117

2016-17 Target	2016-17 Result
SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the Therapeutic Goods Regulations 1990.	There were five updates to the SUSMP during 2016-17. Each update was made as soon as practicable after a final decision was made. **Result: Met**

All required SUSMP legislative instruments were amended as soon as practicable after the Secretary's delegate's final decision during 2016-17. All amendments were made available on the Federal Register of Legislation website[47] for July 2016, October 2016, November 2016, February 2017 and June 2017.

[45] Available at: www.tga.gov.au/publication/performance-reports

[46] Available at: www.tga.gov.au/ws-labs-index

[47] Available at: www.legislation.gov.au/Details/F2017L00605

Percentage of evaluations/assessments completed within legislated timeframes:
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.
Source: 2016-17 Health Portfolio Budget Statements, p. 118

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
100%	a) 100% b) 99.8% c) 100% **Result:** **a) Met** **b) Substantially met** **c) Met**	a) 100% b) 99.1% c) 100%	a) 99.7% b) 98% c) 100%	a) 99.8% b) 100% c) N/A	a) 99.7% b) 100% c) N/A

Category 1 applications are for new medicines, presentations and indications. All Category 1 applications (332) were processed within the legislated timeframe.

Category 3 applications are initiated by sponsors for manufacturing and quality changes, and are usually to an existing registered medicine. Majority of Category 3 applications (1,372 of 1,375) were processed within the legislated timeframe. Internal processing delays associated with provision of data contributed to failing to meet the timeframes for three applications.

All conformity assessments for medical devices (204) were processed in under 200 working days.

Performance result relating to b) of 'substantially met' is based on meeting 99.8% of the target.

Percentage of alleged breaches of the *Therapeutic Goods Act 1989* received that are assessed within 10 working days and an appropriate response initiated.
Source: 2016-17 Health Portfolio Budget Statements, p. 118

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
100%	100% **Result: Met**	100%	100%	100%	100%

During 2016-17, 3,702 alleged breaches and/or referrals were assessed against the Therapeutic Goods Administration regulatory scheme and triaged using a risk-based regulatory compliance framework. Responses to alleged breaches may include investigation and prosecution, or referral for investigation to another State, Territory or Commonwealth agency.

Percentage of licensing and surveillance inspections closed out within target timeframes.
Source: 2016-17 Health Portfolio Budget Statements, p. 118

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
85%	87% **Result: Met**	87%	N/A	N/A	N/A

The Department has maintained an improved process for conducting post-inspection activities introduced in the previous reporting period, which has enabled more efficient resolution of deficiencies and close-out of inspections, and alignment with international practice.

Participating in international regulatory convergence and work sharing activities

Implement international harmonisation and work sharing activities with comparable international regulators.
Source: 2016-17 Health Portfolio Budget Statements, p. 118

2016-17 Target	2016-17 Result
Enhanced cooperation and work sharing, including increased reliance on medicines evaluation and facilities inspection information from international regulators, as outlined in the Therapeutic Goods Administration's *International Engagement Strategy 2016–2018*.	The Department contributed to public health and safety through active engagement in international regulatory initiatives alongside comparable international regulators, as outlined in the TGA's *International Engagement Strategy 2016–2020* (released December 2016). **Result: Met**

In 2016-17, the Department continued to participate in international fora that aim to promote enhanced information sharing, cooperation and regulatory convergence in relation to therapeutic goods. This includes international initiatives such as the vice-chairmanship of the International Coalition of Medicines Regulatory Authorities; the International Medical Devices Regulators' Forum (including the Medical Devices Single Audit Program); the Australia, Canada, Singapore and Switzerland consortium; as well as bilateral collaboration with like-minded regulators.

Percentage of good manufacturing practice clearances of overseas manufacturers that take into account approvals by equivalent international regulators.
Source: 2016-17 Health Portfolio Budget Statements, p. 119

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
85%	92% **Result: Met**	95%	N/A	N/A	N/A

The Therapeutic Goods Administration maintained its ability to issue Good Manufacturing Practice clearances in a shorter timeframe.

Promoting best practice regulation of therapeutic goods

Implement reforms that enhance the Therapeutic Goods Administration's current regulatory processes and are consistent with the Government's regulatory reform agenda.

Source: 2016-17 Health Portfolio Budget Statements, p. 119

2016-17 Target	2016-17 Result
Begin implementation of the Government's response to the Review of Medicines and Medical Devices Regulation.	Implementation of the Government's response to the Review of Medicines and Medical Devices Regulation (the Review) began in a staged approach to allow continuity of routine regulatory business. **Result: Met**

The Government's response to the Review was released in September 2016, initiating a significant program of work, including stakeholder consultation, legislative changes and business improvement projects. Consultation was undertaken to inform implementation of the recommendations, which included 13 public consultations.

The first tranche of legislative changes to implement the reforms, the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*, was enacted in June 2017. The supporting regulations, the Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017, were endorsed by the Governor-General in June 2017.

To support the reforms, a number of IT projects have been initiated such as an online catalogue of approved ingredients for use in complementary medicines, an e-form for variation of prescription medicines, and enhanced adverse event reporting analytics and database capability. A new priority review pathway that will enable faster access to important new medicines for Australian patients, as well as enhanced post-market monitoring and vigilance, will also be supported by new e-forms. A new workflow system for the approval of applications for access to unapproved goods and reduction in requirements for authorised prescribers under the Special Access Scheme, were also implemented.

The Small and Medium Enterprise Assist service, designed to help small and medium enterprises and research institutions to better understand and navigate Australia's therapeutic goods regulation and legislation, was launched in June 2017.

Streamlining regulation for listed complementary medicines

In September 2016, the Government released its response to the Review of Medicines and Medical Devices Regulation (the Review), accepting the majority of the Review recommendations that will significantly benefit consumers, the therapeutic goods industry and health professionals.

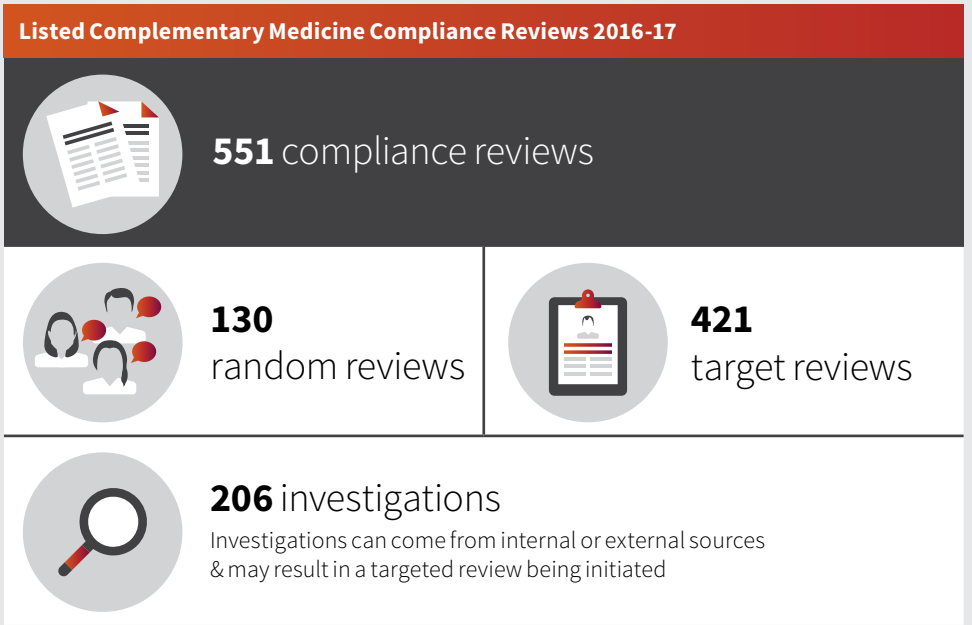
The Review identified ways we can streamline our existing regulatory framework, further enhance our post-market compliance framework and improve consumers' access to new therapeutic goods, while still ensuring their safety and effectiveness.

In Australia, therapeutic goods include medicines which contain ingredients such as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations. These are referred to as 'complementary medicines'. Complementary medicines are either listed (low-risk) or registered (higher-risk) on the Australia Register of Therapeutic Goods. Most complementary medicines are listed on the Register based on their low-risk ingredients and low-level indications.

Currently there are more than 11,000 listed products on the Register.

Each year, consumers benefit from extensive post-market compliance and monitoring processes, where a proportion of listed medicines undergo random or targeted review. In 2016-17 the TGA completed 551 reviews, more than double the amount completed in 2014-15.

To support the reform proposals, changes such as – only allowing sponsors to select therapeutic claims from a prescribed list – will strike a balance between supporting consumer choice, providing flexibility for industry and ensuring the safe and effective use of therapeutic products. In addition, TGA have adopted a 'co-design' approach to strengthen relationships with key stakeholders and to encourage greater rates of compliance with the regulatory requirements.



Drug Regulation

Regulating the import, export, and manufacture of controlled drugs

Provide timely and quality advice to meet Australia's reporting obligations under the International Narcotic Drugs Conventions.
Source: 2016-17 Health Portfolio Budget Statements, p. 119

2016-17 Target	2016-17 Result
Timely response to requests for data and completion of quarterly and annual reports.	16 of the 49 reports were completed within the deadlines. However, as of 28 September 2017, all reports have been completed. **Result: Not met**

Australia is required to provide reports and estimates of drugs imported, exported, manufactured, consumed and stock levels under the *Single Convention on Narcotic Drugs of 1961* and the *Convention on Psychotropic Substances of 1971*. The controlling body, the International Narcotic Control Board, sets deadlines for all parties on reporting.

Increasing resource pressures have affected international drug reporting, as during this period resources have been prioritised to maintain client service levels and implement the Government's reforms on medicinal cannabis.

An updated drug reporting system has been procured from the United Nations Office on Drugs and Crime. Implementation of this system is anticipated in 2017-18. This system aims to improve client self-reporting and process efficiencies.

Percentage of applications for the import, export, and manufacture of controlled substances that are assessed and processed within agreed timeframes.
Source: 2016-17 Health Portfolio Budget Statements, p. 119

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
95%	98% **Result: Met**	99%	N/A	N/A	N/A

During 2016-17, 98% of applications were completed within the required timeframe, 3% above the target. The Department issued a total of 7,549 licences and permits authorising the import, export and manufacture of controlled drugs, which represents a 7% increase compared to 2015-16. The Department also provided 158 basic checks and statements to law enforcement.

Regulating the cultivation and manufacture of medicinal cannabis

Implement amendments to the *Narcotic Drugs Act 1967* to regulate and provide access to medicinal cannabis, in accordance with the International Narcotic Drugs Conventions.
Source: 2016-17 Health Portfolio Budget Statements, p. 120

2016-17 Target	2016-17 Result
Development of supporting regulations, a cost recovery model, licensing and permit procedures, a compliance and enforcement plan and a communications strategy by November 2016.	All documentation listed was completed and published online by November 2016. **Result: Met**

The necessary regulations, cost recovery model and procedures were developed and content published online to support the 30 October 2016 amendments to the *Narcotic Drugs Act 1967*. Following amendments, individuals and businesses were able to apply for cannabis licences and permits.

Percentage of applications for the production of medicinal cannabis processed within agreed timeframes.
Source: 2016-17 Health Portfolio Budget Statements, p. 120

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
90%	85% **Result: Substantially met**	N/A	N/A	N/A	N/A

A total of 111 licence applications for the production of medicinal cannabis were received. Licence applications began to arrive in the second quarter of 2016-17, with the rate of applications increasing in 2017, leading to some delays in processing and assessing applications.

The performance result of 'substantially met' is based on meeting 94% of the target.

Chemical Safety

Aiding 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: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result
Peer review and stakeholder feedback support assessment outcomes.	Peer review and stakeholder feedback supported assessment outcomes. **Result: Met**

In 2016-17, under the *Industrial Chemicals (Notification and Assessment) Act 1989*, the Department published assessment reports for 163 new chemicals, 4,367 existing chemicals, and one secondary notification assessment of a previously assessed chemical. All reports were peer reviewed, and stakeholder feedback was sought and considered prior to finalising the reports. No applications for review of regulatory outcomes were made to the Administrative Appeals Tribunal.

Contribution to the international harmonisation of regulatory approaches and methodologies for assessing industrial chemicals by reviewing Australian processes.
Source: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result
Regulatory approaches and methodologies developed by the Organisation for Economic Co-operation and Development (OECD) Chemicals Committee and its key sub-committees are reviewed for their application to NICNAS assessments of industrial chemicals.	The Department's technical experts reviewed and contributed to the development of OECD methodologies and guidance materials to promote international harmonisation of the regulation of industrial chemicals. **Result: Met**

Through active participation in the OECD Chemicals Committee and its key sub-committees, the Department worked to ensure that risk assessment approaches and methodologies developed by these international bodies would satisfy Australia's national interest and facilitate international harmonisation, where appropriate. The Department's technical experts reviewed and contributed to documents prepared by these bodies in relation to nanomaterials, hazard and exposure assessment.

The Department also contributed to the work of the Global Perfluorinated Chemicals (PFC) Group, established jointly by the OECD and the United Nations Environment Program.

All introducers of industrial chemicals are aware of their legal obligations.
Source: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result
Identified introducers are registered and provided with regular information updates.	98% of identified introducers were registered and provided with regular updates including upcoming information sessions, registration renewal information, opportunities for consultation on the NICNAS reforms and advice on the development of the new Industrial Chemicals Bill. Over 300 registrants attended NICNAS information sessions conducted in major capital cities, which were designed to inform introducers of their obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989*. **Result: Substantially met**

A total of 6,676 introducers of relevant industrial chemicals were registered with NICNAS in 2016-17, representing the highest number of registrants in the history of the scheme. During 2016-17, as a direct result of compliance monitoring activities, over 500 introducers registered with NICNAS for the first time.

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: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result
Reforms to NICNAS more efficiently and effectively achieve the objects of the *Industrial Chemicals (Notification and Assessment) Act 1989*.	The Department published two consultation papers in 2016-17 to obtain stakeholder feedback on the proposed approach to the implementation of the NICNAS reforms, and a paper on the proposed Cost Recovery Model for the reformed scheme. The reforms aim to deliver a more efficient and effective regulatory scheme by making regulatory effort more proportionate to risk, removing unnecessary barriers to the introduction of safer industrial chemicals and using international assessment materials where possible and appropriate. Enhanced monitoring and compliance powers will maintain the integrity of the scheme in protecting human health and the environment. **Result: Met**

Stakeholder input to the NICNAS reforms process through workshops and written submissions has informed the development of new primary legislation. This included the establishment of an ad-hoc working group to obtain expert input on technical aspects of the reforms. Consultation on delegated legislation and guidance materials is ongoing.

New legislation was introduced into Parliament on 1 June 2017.

Effective use of international information.
Source: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result
Criteria approved by the Health Minister for accepting international standards and risk assessment materials will be applied by NICNAS.	The Department has applied the criteria approved by the Health Minister for accepting international standards and risk assessment materials to the development of reform proposals and to the administration of NICNAS. **Result: Met**

In 2016-17, 12 comparable international agency assessments were used to undertake new chemical assessments. Use of comparable international agency assessments delivers efficiencies in the assessment process by reducing regulatory duplication and creating cost savings for industry. All NICNAS existing chemical assessments considered international standards and risk assessment material in accordance with criteria approved by the Health Minister.

The new legislation introduced into Parliament on 1 June 2017 allows chemicals that would otherwise require assessment under the new scheme (but have already been subject to an assessment by a comparable regulator that meets the criteria approved by the Health Minister), to be introduced without further assessment in Australia.

Percentage of new industrial chemical assessments completed within legislated timeframes.
Source: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
96%	99.6% **Result: Met**	99%	98%	98%[48]	95%

Under NICNAS, the Department completed 257 pre-market assessments of new chemicals with 256 of these completed within legislated timeframes. Timely completion of assessments provides certainty for industry and promotes the availability of new industrial chemicals to the community.

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: 2016-17 Health Portfolio Budget Statements, p. 121

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
45%	50% **Result: Met**	45%	40%	35%	30%

The Department, through NICNAS, monitored the introduction of industrial chemicals and identified 10 introducers who were non-compliant with obligations associated with new industrial chemicals in 2016-17. These introducers are being case-managed to ensure adequate resolution of issues involving reporting and notification of new chemicals.

An additional 39 companies were found to be at risk of non-compliance due to inadequate record keeping. These introducers were provided guidance and the opportunity to meet with Department staff to discuss their obligations under the Act.

[48] This figure was published incorrectly in the Department of Health Annual Report 2015-16 and has now been updated to reflect the correct result.

Gene Technology Regulation

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

Progress technical review of the Gene Technology Regulations 2001.
Source: 2016-17 Health Portfolio Budget Statements, p. 122

2016-17 Target	2016-17 Result
Draft amendment regulations, informed by stakeholder submissions, will be prepared in 2016. Consultation on proposed amendments will be undertaken in 2016-17.	Stakeholder consultation on proposed amendments will commence in 2017-18. **Result: Not met**

The Department, through the Office of the Gene Technology Regulator (OGTR), consulted with a wide range of stakeholders on regulatory options to address new technologies, outlined in a discussion paper. The OGTR received 741 submissions in response to the two month public submission period. Due to the complexity of the topic and significant community and stakeholder interest, the OGTR held follow-up discussions with a broad range of submitters.

Provide open, effective and transparent regulation of GMOs.
Source: 2016-17 Health Portfolio Budget Statements, p. 122

2016-17 Target	2016-17 Result
Risk assessments and risk management plans prepared for 100% of applications for licensed dealings. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment.	Risk assessments and risk management plans were prepared for 100% of applications for release of GMOs into the environment. Stakeholders, including the public, were consulted on the assessments of these applications. **Result: Met**

In 2016-17, stakeholders, including the public, were consulted on 11 risk assessment and risk management plans in response to licence applications for field trials of GM banana, cotton, Indian mustard, potato, wheat, barley, sorghum, and a vaccine for chickens, and commercial releases of two types of GM cotton and a dengue vaccine.

Protect people and environment through identification and management of risks from GMOs.
Source: 2016-17 Health Portfolio Budget Statements, p. 122

2016-17 Target	2016-17 Result
Scientifically robust risk assessment and effective 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.	Scientifically robust risk assessments were prepared and all the risks identified for GMOs were effectively managed. The regulated entities reported high levels of compliance with the gene technology legislation and no adverse effects on Australian people or the environment from the approved GMOs. **Result: Met**

In 2016-17, there were no adverse effects on human health or the environment from authorised GMOs. High level of compliance with the gene technology legislation continued with no enforcement action required. Risk assessment and risk management plans for the release of GMOs are available online.[49]

[49] Available at: www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1

Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and/or genetically modified products.

Source: 2016-17 Health Portfolio Budget Statements, p. 122

2016-17 Target	2016-17 Result
High degree of cooperation with relevant regulatory agencies and timely provision of advice, including supporting engagement in international fora.	A high degree of cooperation was maintained with relevant regulatory agencies with timely advice provided, as required. **Result: Met**

The Department, through the OGTR engaged with international fora relevant to GMO regulation including the Organisation for Economic Co-operation and Development 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 in meetings supporting the United Nations Convention on Biological Diversity and Cartagena Protocol on Biosafety.

Percentage of field trial sites and higher level containment facilities inspected.

Source: 2016-17 Health Portfolio Budget Statements, p. 123

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
≥20%	43% of field trial sites 26% of higher level containment facilities **Result: Met**	46% 21%	44% 26%	40% 25%	42% 25%

In 2016-17, the Department, through the OGTR inspectors, exceeded operational targets by inspecting 43% of field trial sites to monitor compliance with licence conditions. Sites were inspected in New South Wales, Queensland, Victoria and Western Australia. Crops inspected included GM canola, wheat, barley, cotton, sugarcane, white clover and safflower.

The Department, through the OGTR also inspected 26% of higher level containment facilities to ensure compliance with certification conditions. These inspections focused on the integrity of the physical structure of the facility and on the general laboratory practices followed.

Percentage of licence decisions made within statutory timeframes.

Source: 2016-17 Health Portfolio Budget Statements, p. 123

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
100%	100% **Result: Met**	100%	95%	100%	100%

In 2016-17, 100% of the licence decisions were made within the statutory timeframes. From these:

- six licences were issued for field trials of GM banana, cotton, Indian mustard, potato, wheat and a clinical trial of influenza vaccine;
- three commercial release licences were issued for two types of GM cotton, and a dengue vaccine; and
- ten licences were issued for work with GMOs in high level contained laboratory facilities.

Performance criteria from the 2016-17 Corporate Plan

Effective pre-market evaluation and post-market monitoring and assessment of therapeutic goods, as legislated.

Source: 2016-17 Department of Health Corporate Plan, p. 26

Refer p. 146 for performance criterion addressing pre-market evaluation, post-market monitoring and assessment of therapeutic goods.

Program 5.2: Health Protection and Emergency Response

The Department met the majority of performance targets related to Program 5.2: Health Protection and Emergency Response.

In 2016-17, specific priority populations most affected by blood borne viruses (BBV) and sexually transmissible infections (STI) as identified in the National BBV and STI Strategies 2014–2017, were supported through priority actions designed to increase prevention, testing and treatment related to BBV and STI. Priority actions undertaken included improving health professionals and affected populations' knowledge of the new hepatitis C treatments; supporting the capacity of community organisations to provide prevention education on HIV, and continuing to support activities to increase uptake of hepatitis B vaccinations in children.

The *Emergency Response Plan for Communicable Disease Incidents of National Significance* was completed and endorsed in May 2017. The plan provides a framework for escalating arrangements to ensure effective response to communicable disease, protecting the health of Australians. Greater effectiveness in managing the response will support minimising the impact on the community should an emergency occur.

Rapid responses to outbreaks of foodborne illnesses continue to be supported by the Commonwealth and State and Territory Governments through the signing of the Schedule for the OzFoodNet Program, which sits under the National Partnership Agreement (NPA) on Specified Projects. The NPA supports the delivery of OzFoodNet, a national system of enhanced foodborne disease surveillance that provides comprehensive information on foodborne disease and the capacity to rapidly identify and respond to outbreaks of foodborne disease.

In 2016-17, the Department continued to effectively respond to national health emergencies such as the ongoing Zika virus outbreak, limiting the morbidity and mortality from such events, which is essential in protecting the health of Australians.

The Government funds the Northern Territory Government through a bilateral Project Agreement to maintain the national Australian Medical Assistance Team (AUSMAT) capability.

The AUSMAT capability was deployed in February 2016 to Fiji for approximately three weeks to provide assistance after tropical cyclone Winston. The initial AUSMAT team of six personnel were deployed to Rakiraki, one of the most severely affected areas, and worked alongside local Fijian health personnel in mobile teams that were equipped to visit and assist people in remote communities. During the deployment, AUSMAT personnel provided medical assistance to more than 1,700 people across Fiji and supported the Fijian health authorities to establish enhanced surveillance and emergency management systems.

As Australia's National Focal Point under the International Health Regulations (2005), the Department's National Incident Room (NIR) responds to approximately 12 incidents a month. On a larger scale, the NIR provides the capability to coordinate a national response to health emergencies and health aspects of other emergencies. In 2016-17, responses were carried out for the international Zika virus outbreak and for the rise in invasive meningococcal disease cases due to serogroup W. In April 2017, the NIR facilitated communications from other areas of the health sector to Queensland Health during the response to Tropical Cyclone Debbie.

In order to reduce the risk of transmissible disease, in 2016-17 the Department continued to fund a mosquito control program that manages and successfully controls exotic mosquito populations with particular focus on the strategic transport hubs of Horn Island and Thursday Island.

The Department progressed a range of activities to support minimising the development and spread of antimicrobial resistance (AMR). Limiting the development and spread of AMR continues to protect the health of the Australian community by helping to ensure that antimicrobial treatments remain a viable and effective method of treating common infections.

As of November 2016, the new Health Protection Program came into effect, consolidating a number of activities that were previously funded separately. These activities are an important part of the Department's public health protection framework that supports an innovative and efficient health sector that contributes to improved health and safety outcomes for the Australian public.

Reducing the incidence of blood borne viruses and sexually transmissible infections

Support programs which are effective in reducing the spread of communicable disease and work towards the targets contained in the National BBV and STI Strategies 2014–2017.

Source: 2016-17 Health Portfolio Budget Statements, p. 124

2016-17 Target	2016-17 Result
Reporting on progress of programs that support the National BBV and STI Strategies 2014–2017 is undertaken according to the evaluation framework in the Implementation and Evaluation Plan.	Reporting on progress of programs that support the National BBV and STI Strategies 2014–2017 was undertaken according to the evaluation framework. **Result: Met**

The reporting, presented to the Blood Borne Viruses and Sexually Transmissible Infections Standing Committee, identified that all priority action areas contained in the National BBV and STI Strategies 2014–2017 were supported through programs and policy work undertaken by the Commonwealth, State and Territory Governments and community partners.

Providing a comprehensive and effective response to national health emergencies

Develop, exercise and refine national health emergency policy under the National Health Emergency Response Arrangements.

Source: 2016-17 Health Portfolio Budget Statements, p. 124

2016-17 Target	2016-17 Result
National Health Emergency Response Arrangements will be exercised and revised and an emergency response plan for communicable disease incidents of national significance will be developed.	The National Health Emergency Response Arrangements were exercised and revised through specific plans, and the Emergency Response Plan for Communicable Disease Incidents of National Significance (CDPlan) was completed and endorsed by the Australian Health Protection Principal Committee on 11 August 2016, with national arrangements endorsed in May 2017. **Result: Met**

The CDPlan provides a framework for identifying, monitoring and responding to emerging and nationally significant communicable diseases. The processes documented in the CDPlan have been tested during the recent response to invasive meningococcal disease due to serogroup W. Lessons learnt from this response will inform the review of the CDPlan.

The Domestic Health Response Plan for Chemical, Radiological, Biological and Nuclear Incidents of National Significance, a sub-plan to the National Health Emergency Response Arrangements, has been revised and is currently circulating with stakeholders for consultation. To refine the processes undertaken to implement the National Health Emergency Response Arrangements, the Department's staff undertook 34 training exercises.

Containment of national health emergencies through the timely engagement of national health coordination mechanisms and response plans.
Source: 2016-17 Health Portfolio Budget Statements, p. 124

2016-17 Target	2016-17 Result
National responses to health emergencies are successfully managed.	Effective responses were carried out for the international Zika virus outbreak, the rise in meningococcal W cases in Australia, Tropical Cyclone Winston in Fiji, and Tropical Cyclone Debbie in Queensland. **Result: Met**

An Australian National Audit Office audit report tabled on 22 June 2017 assessed the effectiveness of the Department's strategies for managing a communicable disease emergency (refer page 227 for audit recommendations). The report found that the Department responded effectively to the three communicable disease incidents examined, has developed strategies to manage its coordination role for communicable disease emergencies, and collects sufficient information to identify communicable disease incidents.

Improving biosecurity and minimising the risks posed by communicable diseases

Collect and disseminate data in the National Notifiable Diseases Surveillance System and monitor data quality in accordance with the *National Health Security Act 2007*.
Source: 2016-17 Health Portfolio Budget Statements, p. 125

2016-17 Target	2016-17 Result
Data is collected and available for regular reporting by the Commonwealth and ad hoc requests by stakeholders, including publishing in the Department's journal *Communicable Diseases Intelligence*.	Data was provided electronically, daily to the National Notifiable Diseases Surveillance System from States and Territories, and was available on request. **Result: Met**

Throughout 2016-17, data was made available to stakeholders upon request and published in the *Communicable Diseases Intelligence* journal.[50] Data sets for invasive pneumococcal disease, influenza, salmonella and invasive meningococcal disease are now publicly available.[51]

[50] Available at: www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-cdiintro.htm

[51] Available at: www9.health.gov.au/cda/source/cda-index.cfm

Manage and control exotic mosquito populations to reduce the risk of disease transmission in the Torres Strait and mainland Australia.

Source: 2016-17 Health Portfolio Budget Statements, p. 125

2016-17 Target	2016-17 Result
Regular mosquito surveillance to indicate whether the mosquito population has reduced in the target areas in the Torres Strait and not spread to the mainland.	Surveillance reports continue to confirm the suppression of exotic mosquito populations in the Torres Strait. There have been no detections of the targeted exotic mosquito on mainland Australia. **Result: Met**

The program to protect Australia by preventing expansion of areas infested with the exotic mosquito, *Aedes albopictus*, has remained successful during 2016-17. Focus has been maintained on suppression of the exotic mosquito on the strategic transport hubs of Horn Island and Thursday Island. The intensive control and monitoring activities on these islands in recent years have resulted in near elimination, such that the species has been undetectable in most of the surveys conducted.

Mosquito suppression strategies have effectively prevented growth or expansion of the residual population of exotic mosquitoes and consequently there have been no detections of the exotic mosquito in surveys conducted on the mainland of Australia.

The development and spread of antimicrobial resistance (AMR) is minimised as a result of the *National Antimicrobial Resistance (AMR) Strategy 2015–19*.

Source: 2016-17 Health Portfolio Budget Statements, p. 125

2016-17 Target	2016-17 Result
Progress reports indicate that actions to minimise the development and spread of AMR are being implemented in accordance with the National AMR Implementation Plan.	In 2016-17, progress reports indicated that a range of activities were undertaken to contribute to minimise the development and spread of AMR in accordance with the National AMR Implementation Plan. **Result: Met**

The National AMR Implementation Plan incorporates an extensive stocktake of AMR-related activities being undertaken in Australia. In 2016-17, substantial progress has been made to support the AMR Strategy and Implementation Plan. Activities included:

- development of the national AMR and antimicrobial usage surveillance report;
- continuing to review and enhance the national AMR surveillance system;
- development of a 'One Health' AMR website to better coordinate AMR-related activities, information and education resources both in Australia and internationally;
- commitment of funds for AMR research funding through the Medical Research Future Fund;
- a mail-out campaign for general practice to enhance awareness of AMR prescribing issues; and
- commencement of a pilot project to implement the National Antimicrobial Prescribing Survey in General Practice.

Additionally, the Australian Strategic and Technical Advisory Group on antimicrobial resistance met in December 2016 to conduct a gap analysis workshop for AMR, and work has commenced on the development of a progress report on the National Antimicrobial Resistance Strategy. The Commonwealth (including the Department) has also actively participated in international fora including the United Nations, World Health Organization, Organisation for Economic Co-operation and Development, G20 and various other alliances and interest groups, to progress AMR issues.

Percentage of designated points of entry into Australia capable of responding to public health events, as defined in the International Health Regulations (2005).

Source: 2016-17 Health Portfolio Budget Statements, p. 125

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
100%	100% **Result: Met**	100%	100%	100%	100%

With the speed of air travel, an outbreak of an infectious disease may occur on the other side of the world and an infected traveller may bring that disease into Australia within hours.

Under the *Biosecurity Act 2015*, all aircraft and vessels must enter Australian territory at designated Points of Entry (PoE) that meet a minimum number of standards as set by the Director of Biosecurity and Director of Human Biosecurity. There are 94 PoE in Australia, of which 14 are also designated as PoE under the International Health Regulations (IHR). To be a PoE under the IHR there are a number of capacities that must be maintained at all times including: access to medical services, good health and hygiene standards at airport and seaport terminals, vector control[52] programs, emergency plans which incorporate strategies to respond to health emergencies, and ready access to ambulance services.

An internal audit conducted in 2016 by the Department found that all 14 PoE were assessed as meeting the capacities under the IHR, and specifically that 100% of Australian PoE are capable of responding to public health events as defined in the IHR.

Supporting the development of policies and implementation activities relating to health protection issues of national significance

Establishment of the Health Protection Program to support the development of policies and activities relating to health issues of national significance comprising:

- **prevention;**
- **preparedness; and**
- **response.**

Source: 2016-17 Health Portfolio Budget Statements, p. 126

2016-17 Target	2016-17 Result
Implementation of the new Health Protection Program from 1 July 2016.	The Health Protection Program (HPP) commenced November 2016. **Result: Not met**

The HPP consolidates a number of activities that were previously funded under the Health Protection Fund, the Health Surveillance Fund and the Communicable Disease Prevention and Service Improvement Grants Fund.

The HPP was covered by the three existing guidelines until they were consolidated under the new HPP guidelines that were approved by the Minister for Finance on 1 February 2017. Due to the delays from the extensive approval processes required for legislative authority, the program was unable to commence from 1 July 2016.

The HPP will fund a small number of grants to organisations that due to their national role, World Health Organization accreditation or expertise may be required to provide ongoing surveillance and assistance in health protection.

[52] Vector control is any method to limit or eradicate the mammals, birds, insects or other arthropods which transmit disease pathogens.

Program 5.3: Immunisation

The Department either met or substantially met the majority of performance targets related to Program 5.3: Immunisation.

In 2016-17, advice was received which made the Department reconsider the need for a specific and expanded Australian Schools Vaccination Register, expanding on the existing National Human Papillomavirus Vaccination Register. As requested by Government, the Department is now looking at alternatives to the Australian Schools Vaccination Register that include options that may involve the whole-of-life Australian Immunisation Register.

As at September 2016, the whole-of-life Australian Immunisation Register came into full effect, expanding on the previous Australian Childhood Immunisation Register. This expansion has enabled increased reporting for additional population groups such as older Australians, enabling the capture of data for most privately purchased vaccines, in addition to these data provided through the National Immunisation Program (NIP).

Through the delivery of the NIP, childhood immunisation rates continue to be high, indicating a high level of protection in the Australian community. This high level of protection has continued to result in strengthening the protection for those medically unable to immunise.

Even though there has been an increase in immunisation coverage rates for Aboriginal and Torres Strait Islander children at 12–15 months of age, a significant gap still remains due to persistent adverse social and environmental barriers. Increased coverage rates ensure better protection against vaccine preventable diseases circulating within the community.

In order to provide assurance that all Australians are receiving safe vaccines, the Government invested in the AusVaxSafety National Surveillance System. This has provided access to a world-leading surveillance system, providing real-time feedback on NIP vaccines, enhancing the overall quality of vaccine safety in Australia.

In 2016-17, the Department completed a transition to a centralised procurement process for the supply of vaccines under the NIP. Centralised purchasing arrangements allow for the secure, ongoing supply of quality, safe and efficacious vaccines for the Australian population.

Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program

Key actions of the National Immunisation Strategy 2013-2018 (NIS) are implemented.
Source: 2016-17 Health Portfolio Budget Statements, p. 127

2016-17 Target	2016-17 Result
NIS actions to improve vaccination coverage rates are undertaken in accordance with the NIS Implementation Plan.	Actions to improve vaccination coverage rates were undertaken in accordance with the NIS Implementation Plan. **Result: Substantially met**

In 2016-17, three key actions were progressed.

- Improving immunisation data in order to increase vaccination coverage rates, especially in adolescents and adults.
- The expansion of the Australian Childhood Immunisation Register to become the whole-of-life Australian Immunisation Register, effective as of September 2016. This expansion will, over time enable reporting of whole-of-life immunisation coverage data for population groups such as older Australians.
- Implementing a new vaccination program from 1 November 2016 under the National Immunisation Program to provide a vaccine to protect 70 year olds against shingles, with a five year catch up program for people aged 71–79 years old.

New National Partnership Agreement on Essential Vaccines (NPEV) for 2017 onwards in place by 30 June 2017.

Source: 2016-17 Health Portfolio Budget Statements, p. 127

2016-17 Target	2016-17 Result
New NPEV agreed by First Ministers by 30 June 2017.	On 23 June 2017, the Prime Minister offered the new NPEV to all States and Territories. The new NPEV came into effect in July 2017. **Result: Not met**

The new NPEV strengthens governance of the National Immunisation Program and encourages continuous improvements in immunisation coverage rates, including amongst at risk cohorts, and sustainability by addressing wastage and leakage of vaccines.

Number of completed tenders under the NPEV (Essential Vaccines Procurement Strategy).

Source: 2016-17 Health Portfolio Budget Statements, p. 128

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
3	4 **Result: Met**	4	1	0	3

In 2009-10, the Department commenced the transition to centralised purchasing arrangements for essential vaccines funded under the National Immunisation Program (NIP). This transition was completed in 2016-17 with the procurement of five final vaccines for the NIP which supported the efficient and effective delivery of the program and ensured States and Territories were able to continue improving immunisation coverage rates. These vaccines were:

- Rotavirus vaccine for infants aged 2 and 4 months;
- hepatitis B (hepB) vaccine supplies for infants at birth;
- HepB-DTPa-Hib-IPV (hepatitis B, diphtheria, tetanus, acellular pertussis (whooping cough), Haemophilus influenzae type b, inactivated poliomyelitis (polio)) for infants aged 2, 4 and 6 months;
- DTPa-IPV (diphtheria, tetanus, acellular pertussis (whooping cough) and inactivated poliomyelitis (polio)) vaccine supplies for children aged 4 years; and
- adolescent booster dTpa (diphtheria, tetanus and acellular pertussis (whooping cough)) vaccine supplies for adolescents aged 10–15 years.

The Department also finalised procurement for the supply of the Herpes Zoster (Shingles) vaccines for older Australians.

Increase the immunisation coverage rates among children 12–15 months of age.

Source: 2016-17 Health Portfolio Budget Statements, p. 128

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
92.0%	93.8% **Result: Met**	93.0%	91.3%	90.4%	91.3%

Increase the immunisation coverage rates among children 24–27 months of age.

Source: 2016-17 Health Portfolio Budget Statements, p. 128

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
92.0%	90.9% **Result: Substantially met**	90.7%	89.2%	92.4%	92.4%

Increase the immunisation coverage rates among children 60–63 months of age.

Source: 2016-17 Health Portfolio Budget Statements, p. 128

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
92.5%	93.6% **Result: Met**	92.9%	92.3%	92.0%	91.5%

Increase the immunisation coverage rates among 12–15 months of age Aboriginal and Torres Strait Islander children.

Source: 2016-17 Health Portfolio Budget Statements, p. 128

2016-17 Target	2016-17 Result	2015-16	2014-15	2013-14	2012-13
88.5%	92.2% **Result: Met**	89.8%	N/A	N/A	N/A

Immunisation coverage rates have continued to increase in 2016-17. This trend is expected to continue towards the World Health Organization Western Pacific Region, Chief Medical Officer's and Chief Health Officers' aspirational target coverage rate of 95%. The Department will continue to work with States and Territories to achieve this target.

In 2016-17, there has been an impact on coverage rates amongst children 24–27 months of age due to the changes in the definition of 'fully immunised'. Additional antigens have been included in the 'fully immunised' calculations which have resulted in lower coverage rates. These changes usually resolve over time as the additional vaccines become routine. The performance result of 'substantially met' for the 24–27 months of age cohort is based on meeting 98.8% of the target.

Immunisation coverage rates among 12–15 months of age Aboriginal and Torres Strait Islander children continues to improve with the gap between non-Indigenous children in the same cohort decreasing from 3.2% in 2015-16 to 1.6% in 2016-17.

Performance criteria from the 2016-17 Corporate Plan

Reduction in the number of notified cases preventable via immunisation.
Source: 2016-17 Department of Health Corporate Plan, p. 23

This performance criterion is supported by data from the Australian Institute of Health and Welfare and the National Notifiable Diseases Surveillance System, which is reported each year but has a two year data lag. Data for 2016-17 will be available in 2019 in *Australia's Health 2018*.

Data for 2014 indicates that 37% of all disease notifications in 2014 were for vaccine preventable diseases. This was a 70% increase on vaccine preventable disease cases notified in 2013. This increase can be attributed to a rise in influenza notifications, which peaked higher in 2014 than in previous seasons.

Outcome 5 – Budgeted expenses and resources

	Budget estimate 2016-17 $'000 (A)	Actual 2016-17 $'000 (B)	Variation $'000 (B) - (A)
Program 5.1: Protect the Health and Safety of the Community through Regulation			
Administered expenses			
Ordinary annual services (*Appropriation Act No. 1*)	-	-	-
Departmental expenses			
Departmental appropriation[1]	16,081	15,587	(494)
to Special Accounts	(10,522)	(10,522)	-
Expenses not requiring appropriation in the budget year[2]	88	473	385
Special Accounts			
OGTR Special Account[3]	7,773	7,453	(320)
NICNAS Special Account[4]	19,676	18,192	(1,484)
TGA Special Account[5]	153,535	149,656	(3,879)
Expense adjustment[6]	(8,566)	(5,636)	2,930
Expenses not requiring appropriation in the budget year[2]	-	119	119
Total for Program 5.1	**178,065**	**175,322**	**(2,743)**
Program 5.2: Health Protection and Emergency Response[7]			
Administered expenses			
Ordinary annual services (*Appropriation Act No. 1*)	88,699	79,724	(8,975)
Non cash expenses[8]	21,515	21,539	24
Special Accounts			
Human Pituitary Hormones Special Account (s78 PGPA Act)	160	199	39
Departmental expenses			
Departmental appropriation[1]	15,799	15,694	(105)
Expenses not requiring appropriation in the budget year[2]	1,221	1,923	702
Total for Program 5.2	**127,394**	**119,079**	**(8,315)**
Program 5.3: Immunisation[7]			
Administered expenses			
Ordinary annual services (*Appropriation Act No. 1*)	36,352	34,023	(2,329)
to Australian Childhood Immunisation Special Account	(5,913)	(6,971)	(1,058)
Special Accounts			
Australian Childhood Immunisation Register Special Account (s78 PGPA Act)	9,650	9,955	305
Special appropriations			
National Health Act 1953 – essential vaccines	302,619	294,505	(8,114)
Departmental expenses			
Departmental appropriation[1]	7,923	7,816	(107)
Expenses not requiring appropriation in the budget year[2]	555	909	354
Total for Program 5.3	**351,186**	**340,237**	**(10,949)**

Outcome 5 – Budgeted expenses and resources (continued)

	Budget estimate 2016-17 $'000 (A)	Actual 2016-17 $'000 (B)	Variation $'000 (B) - (A)
Outcome 5 totals by appropriation type			
Administered expenses			
Ordinary annual services (*Appropriation Act No. 1*)	125,051	113,747	(11,304)
to Special Accounts	(5,913)	(6,971)	(1,058)
Non cash expenses[8]	21,515	21,539	24
Special Accounts	9,810	10,154	344
Special appropriations	302,619	294,505	(8,114)
Departmental expenses			
Departmental appropriation[1]	39,803	39,097	(706)
to Special Accounts	(10,522)	(10,522)	-
Expenses not requiring appropriation in the budget year[2]	1,864	3,305	1,441
Special Accounts	172,418	169,784	(2,634)
Total expenses for Outcome 5	**656,645**	**634,638**	**(22,007)**
Average staffing level (number)	**895**	**887**	**(8)**

Note: Budget estimate represents estimated actual from 2017-18 Health Portfolio Budget Statements.

[1] Departmental appropriation combines 'Ordinary annual services (*Appropriation Act No. 1*)' and 'Revenue from independent sources (s74)'.

[2] Expenses not requiring appropriation in the budget year are made up of depreciation expense, amortisation, make good expense, operating losses and audit fees.

[3] Office of the Gene Technology Regulator Special Account.

[4] National Industrial Chemicals Notification and Assessment Scheme Special Account.

[5] Therapeutic Goods Administration Special Account.

[6] Special accounts are reported on a cash basis. The adjustment reflects the difference between expense and cash, and eliminates inter-entity transactions between the core Department and TGA.

[7] This program excludes National Partnership payments to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework.

[8] Non cash expenses relate to the write down of drug stockpile inventory due to expiration, consumption and distribution.