2.5 BUDGETED EXPENSES AND PERFORMANCE

OUTCOME 5 – REGULATION, SAFETY AND PROTECTION

Outcome 5:	**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**

Programs Contributing to Outcome 5

Program 5.1:	**Protect the Health and Safety of the Community Through Regulation**
Program 5.2:	**Health Protection and Emergency Response**
Program 5.3:	**Immunisation**

Outcome 5 is the responsibility of Health Systems Policy Division, Medical Devices and Product Quality Division, Medicines Regulation Division, National Industrial Chemicals Notification and Assessment Scheme, Office of the Gene Technology Regulator, Office of Drug Control, Office of Health Protection, and Regulatory Practice and Support Division.

Linked Programs

Commonwealth entity and linked program	Contribution to Outcome 5 made by linked programs
Australian Radiation Protection and Nuclear Safety Agency **Program 1.1**: Radiation Protection and Nuclear Safety	The Australian Radiation Protection and Nuclear Safety Agency contributes to the health and safety of the community by protecting the Australian people and environment from the harmful effects of radiation (5.1).
Department of Agriculture and Water Resources **Program 2.1:** Biosecurity and Export Services	The Department of Agriculture and Water Resources contributes to the protection of the health and safety of the Australian community, including through: - Looking for opportunities to harmonise regulatory requirements for Genetically Modified Organisms containment facilities (5.1) - Implementation of activities under the *Biosecurity Act 2015*, such as the ongoing monitoring of mosquito vectors at ports and airports (5.2).
Department of Education and Training **Program 1.7:** Child Care Benefit	The Department of Education and Training contributes to increasing immunisation coverage rates by including childhood immunisation requirements as part of the eligibility criteria for the Child Care Benefit. Eligibility for benefits is linked to satisfying the requirements for immunisation (5.3).

Employment Portfolio (Safe Work Australia) **Program 1:** Reform of and improvements to Australian work health and safety and workers' compensation arrangements	The Department of Employment contributes to the protection of the health and safety of the Australian community through effective management of risks arising from industrial chemicals through Australian work health and safety and workers' compensation arrangements (5.1).
Department of the Environment **Program 1.6:** Management of Hazardous Wastes, Substances and Pollutants	The Department of the Environment contributes to the achievement of this Outcome through the effective management of risks associated with industrial chemicals by undertaking environmental risk assessment for the National Industrial Chemicals Notification and Assessment Scheme (5.1).
Department of Immigration and Border Protection **Program 1.2:** Border Management	The Department of Immigration and Border Protection contributes to the protection of the health and safety of the Australian community through effective: - Management of the risks associated with industrial chemicals by maintaining records on the importation of these products (5.1) - Regulation of controlled drugs by enforcement at the border of the regulations for the import and export of controlled substances (5.1).
Department of Industry, Innovation and Science **Program 3:** Program Support	The Department of Industry, Innovation and Science contributes to the achievement of this Outcome through the effective management of the risks associated with industrial chemicals by reviewing the regulation of chemicals and plastics in Australia, which currently involves multiple entities across all levels of Government (5.1).
Department of Human Services **Program 1.2:** Services to the Community	The Department of Human Services contributes to increasing immunisation coverage rates, which protect the health and safety of the Australian community, by administering the Australian Childhood Immunisation Register on behalf of the Department of Health (5.3).
Department of Social Services **Program 1.1:** Family Tax Benefit	The Department of Social Services contributes to increasing immunisation coverage rates, which protect the health and safety of the Australian community, by administering the Family Tax Benefit A supplements to eligible parents. Eligibility for benefits is linked to satisfying the requirements of age-related immunisation (5.3).
The Treasury (Australian Competition and Consumer Commission) **Program 1.1:** Australian Competition and Consumer Commission	The Australian Competition and Consumer Commission contributes to the protection of the health and safety of the Australian community through management of risks arising from industrial chemicals by regulating consumer goods containing industrial chemicals (5.1).

The Treasury **Program 1.9:** National Partnership Payments to the States	The Treasury makes National Partnership Payments to the State and Territory Governments as part of the Federal Financial Relations Framework.[1] Activities funded through the following National Partnership Agreements contribute to the achievement of the Government's objectives within this Outcome: - Royal Darwin Hospital - equipped, prepared and ready (5.2) - OzFoodNet Program (5.2) - Addressing blood borne viruses and sexually transmissible infections in the Torres Strait (5.2) - Torres Strait Islander health protection strategy – mosquito control (5.2) - Health care grants for the Torres Strait/Papua New Guinea cross border health issues (5.2) - Vaccine preventable diseases surveillance (5.2) - Essential vaccines (5.3).

Table 2.5.1: Budgeted Expenses for Outcome 5

This table shows how much the entity intends to spend (on an accrual basis) on achieving the outcome, broken down by program, as well as by Administered and Departmental funding sources.

	2015-16 Estimated actual	2016-17 Budget	2017-18 Forward Year 1	2018-19 Forward Year 2	2019-20 Forward Year 3
	$'000	$'000	$'000	$'000	$'000
Program 5.1: Protect the Health and Safety of the Community through Regulation					
Administered expenses					
Ordinary annual services[1]	-	-	-	-	-
Departmental expenses					
Departmental appropriation[2]	11,612	11,328	9,354	9,398	9,465
to Special Accounts	(11,612)	(11,328)	(9,354)	(9,398)	(9,465)
Expenses not requiring appropriation in the budget year[3]	-	-	-	-	-
Special Accounts					
OGTR Special Accounts[4]	7,882	7,996	7,849	7,898	7,954
NICNAS Special Accounts[5]	18,532	19,676	15,337	14,456	14,356
TGA Special Accounts[6]	138,876	155,119	149,598	146,529	147,184
Expense adjustment[7]	(5,215)	(9,258)	(528)	6,251	5,836
Total for Program 5.1	**160,075**	**173,533**	**172,256**	**175,134**	**175,330**

[1] For Budget estimates relating to the National Partnership component of the program, refer to *Budget Paper No. 3* or Program 1.9 of the Treasury's Portfolio Budget Statements.

Table 2.5.1: Budgeted Expenses for Outcome 5 (continued)

	2015-16 Estimated actual $'000	2016-17 Budget $'000	2017-18 Forward Year 1 $'000	2018-19 Forward Year 2 $'000	2019-20 Forward Year 3 $'000
Program 5.2: Health Protection and Emergency Response[8]					
Administered expenses					
Ordinary annual services[1]	79,951	86,016	80,131	42,363	42,410
Non cash expenses[9]	105,379	17,577	28,276	20,796	20,796
Special Accounts					
Human Pituitary Hormones Special Account - s78 *PGPA Act*	160	160	170	170	170
Departmental expenses					
Departmental appropriation[2]	22,110	19,827	19,818	19,936	19,947
Expenses not requiring appropriation in the budget year[3]	694	615	620	660	559
Total for Program 5.2	**208,294**	**124,195**	**129,015**	**83,925**	**83,882**
Program 5.3: Immunisation[8]					
Administered expenses					
Ordinary annual services[1]	53,696	96,185	33,086	24,693	24,720
to Australian Childhood Immunisation Special Account	(5,858)	(5,913)	(5,966)	(5,966)	(5,966)
Special Accounts					
Australian Childhood Immunisation Register Special Account - s78 *PGPA Act*	9,563	9,650	9,820	9,820	9,820
Special appropriations					
National Health Act 1943 - essential vaccines	240,150	279,548	279,823	279,821	279,748
Departmental expenses					
Departmental appropriation[2]	9,960	8,688	8,441	8,433	8,438
Expenses not requiring appropriation in the budget year[3]	257	204	206	219	185
Total for Program 5.3	**307,768**	**388,362**	**325,410**	**317,020**	**316,945**

Table 2.5.1: Budgeted Expenses for Outcome 5 (continued)

	2015-16 Estimated actual $'000	2016-17 Budget $'000	2017-18 Forward Year 1 $'000	2018-19 Forward Year 2 $'000	2019-20 Forward Year 3 $'000
Outcome 5 totals by appropriation type					
Administered expenses					
Ordinary annual services[1]	133,647	182,201	113,217	67,056	67,130
to Special accounts	(5,858)	(5,913)	(5,966)	(5,966)	(5,966)
Non cash expenses[9]	105,379	17,577	28,276	20,796	20,796
Special Accounts	9,723	9,810	9,990	9,990	9,990
Special appropriations	240,150	279,548	279,823	279,821	279,748
Departmental expenses					
Departmental appropriation[2]	43,682	39,843	37,613	37,767	37,850
Expenses not requiring appropriation in the budget year[3]	951	819	826	879	744
Special Accounts	160,075	173,533	172,256	175,134	175,330
Total expenses for Outcome 5	**687,749**	**697,418**	**636,035**	**585,477**	**585,622**

	2015-16	2016-17
Average staffing level (number)	938	1,010

1 Appropriation (Bill No. 1) 2016-17.
2 Departmental appropriation combines "Ordinary annual services (Appropriation Bill No. 1)" and "Revenue from independent sources (s74)".
3 Expenses not requiring appropriation in the Budget year are made up of depreciation expense, amortisation expense, makegood expense and audit fees.
4 Office of the Gene Technology Regulator Special Account.
5 National Industrial Chemicals Notification and Assessment Scheme Special Account.
6 Therapeutic Goods Administration (TGA) Special Account.
7 Special accounts are reported on a cash basis. This adjustment reflects the differences between expense and cash, and eliminates inter-entity transactions between the Core department and TGA.
8 Budget estimates for this program exclude National Partnership funding paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework. National Partnerships are listed in this chapter under each program. For Budget estimates relating to the National Partnership component of this program, please refer to Budget Paper 3 or Program 1.9 of the Treasury's Portfolio Budget Statements.
9 "Non cash expenses" relate to the write down of drug stockpile inventory due to expiration, consumption and distribution.

Movement of Funds

	2015-16 Estimated actual $'000	2016-17 Budget $'000	2017-18 Forward Year 1 $'000	2018-19 Forward Year 2 $'000	2019-20 Forward Year 3 $'000
Movement of Administered funds between years for Outcome 5					
Programme 5.3: Immunisation					
No Jab No Pay	9,969	(9,969)			
Total movement of Funds	**9,969**	**(9,969)**	**-**	**-**	**-**

Planned Performance for Outcome 5

Tables 2.5.2 - 2.5.4 below detail the performance criteria for each program associated with Outcome 5.[2] These tables also summarise how each program is delivered and where 2016-17 Budget measures have created new programs or materially changed existing programs.

Table 2.5.2 – Performance Criteria for Program 5.1

Outcome	**5: 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**
Program	**5.1: Protect the Health and Safety of the Community Through Regulation** The Government aims to provide a world class, efficient and timely regulatory system for therapeutic goods. In 2016-17, the Therapeutic Goods Administration (TGA) will continue to promote best practice regulation through business improvement and regulatory reform, while abiding by the Australian Government's expectations under the Regulator Performance Framework. Through the newly established Office of Drug Control (ODC), the Department will continue to regulate and provide advice on the import, export, and manufacture of controlled drugs to support Australia's obligations under the International Narcotic Drugs Conventions, and implement the new regulatory framework for the cultivation and manufacture of medicinal cannabis in Australia. The Government aims to protect the health and safety of people and the environment by identifying and managing risks through regulating work with genetically modified organisms (GMOs). The Government also aims to protect human health and the environment by assessing the risks posed by the use of industrial chemicals. Consistent with the Government's regulatory reform agenda, regulation by the Department will be proportionate to risk, and safeguard the health and wellbeing of the community and the environment.
Purpose	Lead and shape Australia's health and aged care systems and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation.

[2] Progress against the performance criteria published in the *2015-16 Portfolio Budget Statements* will be reported in the 2015-16 Annual Report.

Delivery	Program activities, which are intended to benefit the Australian community, will be delivered under the following program objectives: **Therapeutic Goods:** A. Regulating therapeutic goods for safety, effectiveness/performance and quality B. Participating in international regulatory convergence and work sharing activities C. Promoting best practice regulation of therapeutic goods **Drug Regulation:** D. Regulating the import, export, and manufacture of controlled drugs E. Regulating the cultivation and manufacture of medicinal cannabis **Chemical Safety:** F. 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:** G. Protecting the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Program objective	
A. Regulating therapeutic goods for safety, effectiveness/performance and quality	
The TGA will continue to provide a world class, efficient and timely regulatory system for therapeutic goods, which involves and engages stakeholders to ensure the safe use of medicines, medical devices, cell and tissue products, blood and blood products.[3]	
Qualitative performance criteria	**2016-17 Reference point or target**
Continue to regulate therapeutic goods for safety, effectiveness/performance and quality.	Effective premarket evaluation and postmarket monitoring and assessment of therapeutic goods, as required under the *Therapeutic Goods Act 1989* and associated regulations.
Update and maintain the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).	SUSMP is amended as soon as practicable after the Secretary's delegate's final decision under the *Therapeutic Goods Regulations 1990*.

[3] For further information on access to blood and blood products and organ and tissue transplants, please refer to Program 1.1: *Health Policy Research and Analysis* of these Portfolio Budget Statements.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
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.	100%	100%	100%	100%	100%
Percentage of alleged breaches of the *Therapeutic Goods Act 1989* received that are assessed within 10 working days and an appropriate response initiated.	100%	100%	100%	100%	100%
Percentage of licensing and surveillance inspections closed out within target timeframes.	85%	85%	85%	85%	85%

Program objective

B. Participating in international regulatory convergence and work sharing activities

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

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

Qualitative performance criteria	2016-17 Reference point or target
Implement international harmonisation and work sharing activities with comparable international regulators.	Enhanced cooperation and work sharing, including increased reliance on medicines evaluation and facilities inspection information from international regulators, as outlined in TGA's *International Engagement Strategy 2016-2018*.[4]

[4] The target for this performance criterion has been updated to include reference to the TGA's most recent International Engagement Strategy.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of good manufacturing practice clearances of overseas manufacturers that take into account approvals by equivalent international regulators.	85%	85%	85%	85%	85%

Program objective

C. Promoting best practice regulation of therapeutic goods

In 2016-17, the TGA will continue implementation of a comprehensive reform agenda that will optimise a range of regulatory processes and improve the way the TGA communicates with the public about the benefits and risks of therapeutic goods.

The TGA will continue to identify opportunities and implement action to reduce regulatory burden on industry, consistent with the Government's regulatory reform agenda, while continuing to meet the objectives of safeguarding and enhancing the health of the Australian community.

Based on the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation, the Department will begin design and implementation of the agreed reforms.

Qualitative performance criteria	2016-17 Reference point or target
Implement reforms that enhance TGA's current regulatory processes and are consistent with the Government's regulatory reform agenda.[5]	*Begin implementation of the Government's response to the Review of Medicines and Medical Devices Regulation.*

Program objective

D. Regulating the import, export, and manufacture of controlled drugs

The Office of Drug Control (ODC) will administer a licensing and permit regime for import, export and manufacture of controlled drugs in line with Australian legislation and international conventions, to ensure access to essential medications while supporting Government policy on harm minimisation and harm reduction.

Qualitative performance criteria	2016-17 Reference point or target
Provide timely and quality advice to meet Australia's reporting obligations under the International Narcotic Drugs Conventions.	Timely response to requests for data and completion of quarterly and annual reports.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of applications for the import, export, and manufacture of controlled substances that are assessed and processed within agreed timeframes.[6]	95%	95%	95%	95%	95%

[5] The wording of this performance criterion has been revised to provide greater clarity.

[6] Previously reported under Therapeutic Goods.

Program objective
E. Regulating the cultivation and manufacture of medicinal cannabis
In 2016-17, the ODC will develop and implement regulations that will permit the legal cultivation of cannabis for medicinal and related scientific purposes. The legislation, the *Narcotic Drugs Amendment Act 2016*, was passed through Parliament in February 2016 and it is expected by 1 November 2016, at the latest, that enabling regulations and public guidance material will be enacted or made available. The ODC will then administer the legislation, including making decisions on applications to cultivate and manufacture medicinal cannabis products.

Qualitative performance criteria	2016-17 Reference point or target
Implement amendments to the Narcotic Drugs Act 1967 to regulate and provide access to medicinal cannabis, in accordance with the International Narcotic Drugs Conventions.	*Development of supporting regulations, a cost recovery model, licensing and permit procedures, a compliance and enforcement plan and a communications strategy by November 2016.*

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of applications for the production of medicinal cannabis processed within agreed timeframes.	*N/A*[7]	*90%*	*90%*	*90%*	*90%*

Program objective
F. Aiding the protection of the Australian people and the environment by assessing the risks of chemicals and providing information to promote their safe use
The Department manages the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which registers introducers of industrial chemicals, assesses industrial chemicals for their risks to human health and the environment, and makes recommendations to applicable regulatory authorities regarding risk mitigation. Consistent with the Government's Industry Innovation and Competitiveness Agenda, the Department will continue implementation of reforms announced in the 2015-16 Budget to improve the efficiency and effectiveness of the regulation of industrial chemicals, including the increased use of trusted international assessment materials. Consistent with the Government's broader regulatory reform agenda, the reforms will remove unnecessary regulatory burden while maintaining the protection of public health, worker safety and the environment. These reforms will make a contribution to the Government's red tape reduction target of $1 billion per annum.

[7] This is a new performance criterion for 2016-17, therefore there is no target for 2015-16.

Qualitative performance criteria	2016-17 Reference point or target
Scientifically robust assessments of new and existing industrial chemicals.	Peer review and stakeholder feedback support assessment outcomes.
Contribution to the international harmonisation of regulatory approaches and methodologies for assessing industrial chemicals by reviewing Australian processes.	Regulatory approaches and methodologies developed by the OECD Chemicals Committee and its key sub-committees are reviewed for their application to NICNAS assessments of industrial chemicals.[8]
All introducers of industrial chemicals are aware of their legal obligations.	Identified introducers are registered and provided with regular information updates.
The costs associated with the regulation of industrial chemicals are adequately balanced against the benefits to worker health and safety, public health and the environment.	Reforms to NICNAS more efficiently and effectively achieve the objects of the *Industrial Chemicals (Notification and Assessment) Act 1989.*
Effective use of international information.	Criteria approved by the Health Minister for accepting international standards and risk assessment materials will be applied by NICNAS.[9]

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of new industrial chemical assessments completed within legislated timeframes.	96%	96%	96%	96%	96%
Percentage of Level C and D introducers[10] of industrial chemicals assessed for compliance with their new chemicals obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989*.	45%	45%	45%	45%	45%

Program objective

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

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

In 2016-17, the Office of the Gene Technology Regulator (OGTR) will continue to ensure that all risk assessments of GMOs are based on current scientific evidence and represent international best practice by consulting with experts and key stakeholders, and by keeping pace with advances in scientific knowledge and regulatory practice. OGTR will continue to engage with other Australian Government regulators to enhance the reciprocal provision of

[8] The wording of the target for this performance criterion has been revised to provide greater clarity.
[9] Ibid.
[10] Level C and Level D introducers are those NICNAS registrants introducing at least $500,000 worth of relevant industrial chemicals annually.

advice on applications to support timely, scientifically robust assessment of GMOs and genetically modified products.

OGTR will continue to work with the Department of Agriculture and Water Resources to improve harmonisation of regulatory requirements for containment facilities, including closer alignment of guidelines where practical. OGTR will also engage in international harmonisation activities including collaborations in the region and provision of technical advice to other Australian Government entities to support engagement in international fora.

During 2016-17, OGTR will progress the technical review of the *Gene Technology Regulations 2001*. Consistent with the Government's regulatory reform agenda, the review will focus on ensuring that the regulation of GMOs to protect human health and the environment is commensurate with risk according to current science.

Qualitative performance criteria	2016-17 Reference point or target
Progress technical review of the *Gene Technology Regulations 2001.*	Draft amendment regulations, informed by stakeholder submissions, will be prepared in 2016. Consultation on proposed amendments will be undertaken in 2016-17.[11]
Provide open, effective and transparent regulation of GMOs.	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.[12]
Protect people and environment through identification and management of risks from GMOs.	Scientifically robust risk assessment and effective risk management of GMOs.[13] High level of compliance with the gene technology legislation and no adverse effect on human health or environment from authorised GMOs.
Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and /or genetically modified products.	High degree of cooperation with relevant regulatory agencies and timely provision of advice, including supporting engagement in international fora.[14]

11 The target for this performance criterion has been revised to identify activities to be undertaken in 2016-17. Finalisation of amendment regulations will require agreement of the States and Territories.

12 The target for this performance criterion has been revised to indicate openness and transparency of the regulation. Consultation documents, including all assessments for proposed release of GMOs into the environment, are available on the OGTR website: www.ogtr.gov.au

13 The wording of the target for this performance criterion has been revised to provide greater clarity.

14 The wording of the target for this performance criterion has been revised to include reference to engagement with international fora.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of field trial sites and higher level containment facilities inspected.	≥20%	≥20%	≥20%	≥20%	≥20%
Percentage of licence decisions made within statutory timeframes.	100%	100%	100%	100%	100%
Material changes to Program 5.1 resulting from the following measures:					
• *Improving the Regulation of Therapeutic Goods in Australia* • *Regulation of Medicinal Cannabis – charging arrangements*					

Table 2.5.3 – Performance Criteria for Program 5.2

Program	**5.2: Health Protection and Emergency Response** The Government aims to protect the health of the Australian community through effective national leadership and coordination and building of appropriate capacity and capability to detect, prevent and respond to threats to public health and safety arising from communicable diseases, natural disasters, acts of terrorism, and other incidents that may lead to mass casualties.
Purpose	Lead and shape Australia's health and aged care systems and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation.
Delivery	Program activities, which are intended to benefit the Australian community, will be delivered under the following program objectives: A. Reducing the incidence of blood borne viruses and sexually transmissible infections B. Providing a comprehensive and effective response to national health emergencies C. Improving biosecurity and minimising the risks posed by communicable diseases D. Supporting the development of policies and implementation activities relating to health protection issues of national significance
Program objective	
A. Reducing the incidence of blood borne viruses and sexually transmissible infections	
The Australian Government is committed to preventing the spread of blood borne viruses (BBV) and sexually transmissible infections (STI). In 2016-17, the Australian Government will continue to implement its contribution to the National Strategies 2014-2017 for HIV, hepatitis B, hepatitis C, STI, and Aboriginal and Torres Strait Islander BBV and STI. The National Strategies guide policies and programs related to the prevention, testing, management and treatment of BBV and STI. The Australian Government will continue to work with States and Territories to encourage increased testing and uptake of treatment for STI and BBV among priority populations. In 2016-17, the Department will also continue to support quality assurance programs for medical laboratories using in-vitro diagnostic devices, and the Australian Red Cross for the screening of fresh blood donations.	

Qualitative performance criteria	2016-17 Reference point or target
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.[15]	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.
Program objective	
B. Providing a comprehensive and effective response to national health emergencies	
The Department will continue to work with the relevant Commonwealth entities and States and Territories to plan, prepare for, and provide, a coordinated, comprehensive and effective response to public health or mass casualty incidents of national significance. Response arrangements include the maintenance of a deployable medical capability, coordinated through the National Critical Care and Trauma Response Centre in Darwin, which is supported by Commonwealth funding of $15.7 million in 2016-17. Australian Medical Assistance Teams (AUSMATs) can be deployed to respond to both domestic and international crises. The Australian Government will continue to ensure that the National Medical Stockpile holds a contingency reserve of essential pharmaceuticals and protective equipment to maintain Australia's capacity to respond to health emergencies. Funding of $25.5 million in 2016-17 will support the replenishment of expired or expiring stock. Reform activities to improve the efficiency and effectiveness of the operation and management of the National Medical Stockpile will continue. Engagement of a Prime Vendor, negotiation of a National Stockpiling Agreement with the States and Territories, and pre-deployment of inventory will continue in 2016-17.	
Qualitative performance criteria	**2016-17 Reference point or target**
Develop, exercise and refine national health emergency policy under the National Health Emergency Response Arrangements.	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.[16]
Containment of national health emergencies through the timely engagement of national health coordination mechanisms and response plans.	National responses to health emergencies are successfully managed.
Program objective	
C. Improving biosecurity and minimising the risks posed by communicable diseases	
In 2016-17, the Australian Government will continue to administer the Security Sensitive Biological Agent Regulatory Scheme to minimise the risk of access to biological agents that could be used in acts of terrorism or biocrime. The Government will continue to strengthen national laboratory capacity through funding support of $6 million over 2016-17 to the WHO Collaborating Centre for Reference and Research on Influenza, the National High Security Quarantine and Smallpox Laboratory,	

[15] The wording of this performance criterion has been revised to provide greater clarity.

[16] The target for this performance criterion has been revised to reflect a priority focus on finalising the emergency response plan for communicable disease incidents of national significance.

and the Proficiency Testing Program for biological agents for security concern by the Royal College of Pathology Australia.

The Australian Government is committed to strengthening Australia's defences against communicable diseases, including the spread of mosquito-borne diseases such as dengue fever. In 2016-17, this will include working closely with the Department of Agriculture and Water Resources on vector monitoring at ports and airports, and on the continuing implementation of the *Biosecurity Act 2015*.

The Government will continue to provide funding for an exotic mosquito detection, control and elimination program and support cross border communications between Queensland and Papua New Guinea to reduce communicable disease risk in the Torres Strait.

In addition, the Department will continue to maintain the National Notifiable Diseases Surveillance System. Under this scheme, notifications of more than 50 communicable diseases are made to State and Territory health authorities to ensure effective surveillance of communicable diseases.

The Department will also continue the OzFoodNet Program, a national system of enhanced foodborne disease surveillance, to provide comprehensive information on foodborne disease in Australia and the capacity to rapidly identify and respond to outbreaks, particularly those that cross state, territory and country borders.

The Government is providing national and international leadership to help prevent and contain the spread of antimicrobial resistance (AMR). In 2016-17, the Department will implement activities to respond to AMR under the *National Antimicrobial Resistance Strategy 2015-2019*, and coordinate Australia's efforts across human and animal health to reduce, monitor and respond to AMR.

Qualitative performance criteria	2016-17 Reference point or target
Collect and disseminate data in the National Notifiable Diseases Surveillance System and monitor data quality in accordance with the *National Health Security Act 2007.*	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*.
Manage and control exotic mosquito populations to reduce the risk of disease transmission in the Torres Strait and mainland Australia.	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.
The development and spread of antimicrobial resistance (AMR) is minimised as a result of the *National Antimicrobial Resistance (AMR) Strategy 2015-2019*.[17]	Progress reports indicate that actions to minimise the development and spread of AMR are being implemented in accordance with the National AMR Implementation Plan.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Percentage of designated points of entry into Australia capable of responding to public health events, as defined in the *International Health Regulations (2005).*	100%	100%	100%	100%	100%

[17] This performance criterion has been revised to reflect a combination of the two previous AMR criteria.

Program objective	
D. Supporting the development of policies and implementation activities relating to health protection issues of national significance	
The Health Protection Program funds prevention, preparedness and response activities that protect the health of all Australians from threats posed by communicable disease outbreaks, natural disasters, environmental hazards, acts of terrorism and other incidents that may lead to mass casualties.	
Qualitative performance criteria	**2016-17 Reference point or target**
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.	Implementation of the new Health Protection Program from 1 July 2016.
Material changes to Program 5.2 resulting from the following measures:	
• *Health Flexible Funds – pausing indexation and achieving efficiencies*	

Table 2.5.4 – Performance Criteria for Program 5.3

Program	**5.3: Immunisation** The Australian Government aims to protect the health of the community through immunisation initiatives. The Government recognises that immunisation is an effective way of protecting individuals and the Australian community, by reducing the spread of vaccine preventable disease. The Department implements the National Immunisation Program (NIP) which provides free vaccination programs in partnership with States and Territories.
Purpose	Lead and shape Australia's health and aged care systems and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation.
Delivery	Program activities, which are intended to benefit the Australian Community, will be delivered under the following program objective: A. Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program

Program objective	
A. Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program	
In 2016-17, the Department will work with States and Territories to develop a new National Partnership Agreement on Essential Vaccines (NPEV), to continue, and expand on, collaborative efforts to further improve immunisation coverage rates in Australia. The new agreement is expected to commence on 1 July 2017. The Department will also continue to monitor implementation of the strategic priorities of the National Immunisation Strategy 2013-2018 (NIS), which underpin the NIP. Improving immunisation data capture is a key NIS action being progressed in 2016-17 to increase vaccination coverage rates, especially in adolescents and adults. From September 2016, the Australian Childhood Immunisation Register will expand to become the Australian Immunisation Register, and will enable the reporting of coverage data for additional population groups such as older Australians. From January 2017, the new Australian School Vaccination Register will allow better follow-up of adolescents who have missed vaccine doses under the school based programs. The Department, in conjunction with States and Territories, will continue transitioning to a centralised procurement process for the supply of vaccines under the NIP. Centralised purchasing aims to streamline national purchasing arrangements and achieve administrative and financial efficiency. In addition, in 2016-17, the Department will undertake the procurement of vaccines for new cohorts, including a vaccine to protect against shingles which will be provided to 70 year olds, with a five year catch up program for people aged 71-79 years old. In 2016-17, the Government will continue to work closely with other Commonwealth entities, State and Territory Governments, academic institutions and non-government organisations on activities to improve vaccination rates. A key focus in 2016-17 will be enhancing communication efforts to ensure they best address parents' concerns and support uptake of vaccination.	
Qualitative performance criteria	**2016-17 Reference point or target**
Key actions of the National Immunisation Strategy 2013-2018 (NIS) are implemented.	NIS actions to improve vaccination coverage rates are undertaken in accordance with the NIS Implementation Plan.
New National Partnership Agreement on Essential Vaccines (NPEV) for 2017 onwards in place by 30 June 2017.	New NPEV agreed by First Ministers by 30 June 2017.

Quantitative performance criteria	2015-16 Target	2016-17 Target	2017-18 Target	2018-19 Target	2019-20 Target
Number of completed tenders under the NPEV (Essential Vaccines Procurement Strategy).	2	3[18]	1	1	1
Increase the immunisation coverage rates among children 12–15 months of age.	91.5%	92.0%	92.5%	93.0%	93.5%
Increase the immunisation coverage rates among children 24-27 months of age.	91.5%	92.0%	92.5%	93.0%	93.5%
Increase the immunisation coverage rates among children 60-63 months of age.	92.0%	92.5%	93.0%	93.5%	93.5%
Increase the immunisation coverage rates among 12-15 months of age Aboriginal and Torres Strait Islander children.	87.0%	88.5%	89.0%	90.0%	90.5%
Material changes to Program 5.3 resulting from the following measures:					
There are no material changes to Program 5.3 resulting from measures.					

[18] Number of procurements has increased to reflect new vaccines being added to the schedule and the transition of existing vaccines to Commonwealth Own Purpose Expenses.