

## 2.5 BUDGETED EXPENSES AND PERFORMANCE FOR OUTCOME 5

### 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

### 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**

### Linked Programs

#### Other Commonwealth entities that contribute to Outcome 5

##### Australian Radiation Protection and Nuclear Safety Agency<sup>1</sup>

###### 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 through implementation of activities under the *Biosecurity Act 2015*, such as the ongoing monitoring of mosquito vectors at ports and airports (5.2).

##### Australian Competition and Consumer Commission

###### Program 1.1: Australian Competition and Consumer Commission

The Australian Competition and Consumer Commission contributes to the health and safety of the Australian community through the consideration and management of unacceptable safety risks posed by consumer goods (5.1).

##### Department of Education and Training

###### Program 1.2: 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).

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<sup>1</sup> Refer to the Australian Radiation Protection and Nuclear Safety Agency chapter in these Portfolio Budget Statements for further information on the work of this entity.

<p><b>Department of the Environment and Energy</b> <b>Program 1.6: Management of Hazardous Wastes, Substances and Pollutants</b> The Department of the Environment and Energy contributes to this Outcome through the effective management of risks associated with industrial chemicals by undertaking environmental risk assessments for the National Industrial Chemicals Notification and Assessment Scheme (5.1).</p>
<p><b>Department of Immigration and Border Protection</b> <b>Program 1.2: Border Management</b> The Department of Immigration and Border Protection facilitates access to health and support services of the Australian community through effective:</p> <ul style="list-style-type: none"><li>- Management of the risks associated with industrial chemicals by maintaining records on the importation of these products (5.1)</li><li>- Management of the regulations for the import and export of controlled substances at the border (5.1).</li></ul>
<p><b>Department of Human Services</b> <b>Program 1.2: Services to the Community</b> 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 Immunisation Register on behalf of the Department of Health (5.3).</p>
<p><b>Department of Social Services</b> <b>Program 1.1: Family Tax Benefit</b> 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 the supplements is linked to satisfying the requirements of age-related immunisation (5.3).</p>
<p><b>Safe Work Australia</b> <b>Program 1: Reform of and improvements to Australian work health and safety and workers' compensation arrangements</b> 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).</p>
<p><b>The Treasury</b> <b>Program 1.9: National Partnership Payments to the States</b> The Treasury makes National Partnership Payments to the State and Territory Governments as part of the Federal Financial Relations Framework.<sup>2</sup> Activities funded through the following National Partnership Agreements contribute to the Government's objectives within this Outcome:</p> <ul style="list-style-type: none"><li>- Royal Darwin Hospital – equipped, prepared and ready (5.2)</li><li>- OzFoodNet Program (5.2)</li><li>- Addressing Blood Borne Viruses (BBV) and Sexually Transmissible Infections (STI) in the Torres Strait (5.2)</li><li>- Mosquito Control and Cross Border Liaison in the Torres Strait (5.2)</li><li>- Management of Torres Strait/Papua New Guinea Cross-Border Health Issues (5.2)</li><li>- Vaccine-preventable diseases surveillance (5.2)</li><li>- Essential vaccines (5.3).</li></ul>

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<sup>2</sup> 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**

Table 2.5.1 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.

	<b>2016-17 Estimated actual \$'000</b>	<b>2017-18 Budget \$'000</b>	<b>2018-19 Forward Year 1 \$'000</b>	<b>2019-20 Forward Year 2 \$'000</b>	<b>2020-21 Forward Year 3 \$'000</b>
<b>Program 5.1: Protect the Health and Safety of the Community Through Regulation</b>					
Administered expenses					
Ordinary annual services <sup>(a)</sup>	-	-	-	-	-
Departmental expenses					
Departmental appropriation <sup>(b)</sup>	16,081	15,821	13,799	13,725	14,131
to Special Accounts	(10,522)	(10,254)	(8,302)	(8,312)	(8,357)
Expenses not requiring appropriation in the Budget year <sup>(c)</sup>	88	85	106	90	90
Special Accounts					
OGTR Special Accounts <sup>(d)</sup>	7,773	7,878	7,635	7,643	7,682
NICNAS Special Accounts <sup>(e)</sup>	19,676	19,710	14,456	14,356	14,418
TGA Special Accounts <sup>(f)</sup>	153,535	153,474	146,168	147,627	150,232
Expense adjustment <sup>(g)</sup>	(8,566)	(7,029)	4,197	5,007	4,578
<b>Total for Program 5.1</b>	<b>178,065</b>	<b>179,685</b>	<b>178,059</b>	<b>180,136</b>	<b>182,774</b>

**Table 2.5.1: Budgeted Expenses for Outcome 5 (continued)**

	2016-17 Estimated actual \$'000	2017-18 Budget \$'000	2018-19 Forward Year 1 \$'000	2019-20 Forward Year 2 \$'000	2020-21 Forward Year 3 \$'000
<b>Program 5.2: Health Protection and Emergency Response <sup>(h)</sup></b>					
Administered expenses					
Ordinary annual services <sup>(a)</sup>	88,699	89,269	91,167	90,771	87,968
Non cash expenses <sup>(i)</sup>	21,515	29,926	24,661	12,788	2,525
Special Accounts					
Human Pituitary Hormones Special Account	160	160	170	170	170
Departmental expenses					
Departmental appropriation <sup>(b)</sup>	15,799	15,036	15,016	14,858	14,829
Expenses not requiring appropriation in the Budget year <sup>(c)</sup>	1,221	379	474	401	401
<b>Total for Program 5.2</b>	<b>127,394</b>	<b>134,770</b>	<b>131,488</b>	<b>118,988</b>	<b>105,893</b>
<b>Program 5.3: Immunisation <sup>(h)</sup></b>					
Administered expenses					
Ordinary annual services <sup>(a)</sup> to Australian Childhood Immunisation Special Account	36,352 (5,913)	30,714 (5,966)	26,194 (5,966)	26,157 (5,966)	24,966 (5,966)
Special Accounts					
Australian Immunisation Register Special Account	9,650	9,820	9,820	9,820	9,820
Special appropriations <i>National Health Act 1953</i> - essential vaccines	302,619	284,930	284,928	284,855	284,855
Departmental expenses					
Departmental appropriation <sup>(b)</sup>	7,923	7,300	7,232	7,153	7,138
Expenses not requiring appropriation in the Budget year <sup>(c)</sup>	555	137	171	145	145
<b>Total for Program 5.3</b>	<b>351,186</b>	<b>326,935</b>	<b>322,379</b>	<b>322,164</b>	<b>320,958</b>

**Table 2.5.1: Budgeted Expenses for Outcome 5 (continued)**

	2016-17 Estimated actual \$'000	2017-18 Budget \$'000	2018-19 Forward Year 1 \$'000	2019-20 Forward Year 2 \$'000	2020-21 Forward Year 3 \$'000
<b>Outcome 5 totals by appropriation type</b>					
Administered expenses					
Ordinary annual services <sup>(a)</sup>	125,051	119,983	117,361	116,928	112,934
to Special accounts	(5,913)	(5,966)	(5,966)	(5,966)	(5,966)
Non cash expenses <sup>(i)</sup>	21,515	29,926	24,661	12,788	2,525
Special Accounts	9,810	9,980	9,990	9,990	9,990
Special appropriations	302,619	284,930	284,928	284,855	284,855
Departmental expenses					
Departmental appropriation <sup>(b)</sup>	39,803	38,157	36,047	35,736	36,098
to Special accounts	(10,522)	(10,254)	(8,302)	(8,312)	(8,357)
Expenses not requiring appropriation in the Budget year <sup>(c)</sup>	1,864	601	751	636	636
Special Accounts	172,418	174,033	172,456	174,633	176,910
<b>Total expenses for Outcome 5</b>	<b>656,645</b>	<b>641,390</b>	<b>631,926</b>	<b>621,288</b>	<b>609,625</b>

	2016-17	2017-18
<b>Average staffing level (number)</b>	895	882

<sup>(a)</sup> Appropriation (Bill No. 1) 2017-18.

<sup>(b)</sup> Departmental appropriation combines 'Ordinary annual services (Appropriation Bill No. 1)' and 'Revenue from independent sources (s74)'.

<sup>(c)</sup> Expenses not requiring appropriation in the Budget year are made up of depreciation expense, amortisation expense, makegood expense and audit fees.

<sup>(d)</sup> Office of the Gene Technology Regulator Special Account.

<sup>(e)</sup> National Industrial Chemicals Notification and Assessment Scheme Special Account.

<sup>(f)</sup> Therapeutic Goods Administration (TGA) Special Account.

<sup>(g)</sup> 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.

<sup>(h)</sup> 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, refer to Budget Paper No. 3 or Program 1.9 of the Treasury's Portfolio Budget Statements.

<sup>(i)</sup> 'Non cash expenses' relate to the write down of drug stockpile inventory due to expiration, consumption and distribution.

### Movement of Funds

There were no movements of administered funds between years for Outcome 5.

## Planned Performance for Outcome 5

Tables 2.5.2 – 2.5.4 below detail the performance criteria for each program associated with Outcome 5. These tables also summarise how each program is delivered and where 2017-18 Budget measures have materially changed existing programs.

**Table 2.5.2: Performance Criteria for Program 5.1**

<b>Purpose</b>
Lead and shape Australia's health and aged care system and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation.
<b>Outcome 5: Regulation, Safety and Protection</b>
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
<b>Program 5.1: Protect the Health and Safety of the Community Through Regulation</b>
<p>The Government, through the Therapeutic Goods Administration (TGA), protects the health and safety of the community by regulating therapeutic goods for safety, effectiveness/performance and quality. The TGA aims to deliver efficient, best practice regulatory outcomes through international collaboration and reform.</p> <p>The TGA will continue to monitor therapeutic goods which are manufactured, used, imported into or exported from Australia, and undertake compliance and enforcement activities.</p> <p>Through the Office of Drug Control, 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 regulate the cultivation and manufacture of medicinal cannabis products in Australia.</p> <p>The Government aims to protect the health and safety of people and the environment by identifying and managing risks through regulating activities with genetically modified organisms (GMOs). In 2017-18, the Office of the Gene Technology Regulator will continue to ensure that all risk assessments of GMOs are based on current scientific evidence and represent international best practice by keeping pace with advances in scientific knowledge and regulatory practice.</p> <p>The Government also aims to protect human health and the environment by assessing the risks posed by the introduction and 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.</p> <p>In the 2017-18 Budget, the Government will spend \$2.1 million over two years to implement its 2016 election commitment to introduce a ban on cosmetic testing on animals from 1 July 2017.</p>

Delivery
<p><b>A. Regulating therapeutic goods for safety, effectiveness/performance and quality while promoting best practice</b></p> <ul style="list-style-type: none"> <li>• Publish performance statistics reports and a key performance indicator report in compliance with the Regulator Performance Framework.</li> <li>• Participate in international engagement and work sharing activities with comparable international regulators.</li> <li>• Monitor regulatory compliance and take appropriate action.</li> <li>• Improve access to therapeutic goods for consumers and streamline regulatory processes for industry by implementing the Australian Government’s reforms arising from the Review of Medicines and Medical Devices Regulation.</li> </ul> <p><b>B. Regulating the import, export, and manufacture of controlled drugs, and cultivation of medicinal cannabis</b></p> <ul style="list-style-type: none"> <li>• Continue to administer the 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.</li> <li>• Provide timely and quality advice to meet Australia’s reporting obligations under the International Drug Conventions.</li> <li>• Administer the licensing and permit regime for the cultivation and production of medicinal cannabis, including supporting the development of a new industry while working with law enforcement agencies to control diversion risks.<sup>3</sup></li> </ul> <p><b>C. Protecting people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use</b></p> <ul style="list-style-type: none"> <li>• Make recommendations to Commonwealth, State and Territory risk management agencies on the safe use of industrial chemicals.</li> <li>• Make information on the safe use of industrial chemicals publicly available.</li> <li>• Implement reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to achieve an appropriate balance between regulatory effort and risks posed by industrial chemicals.</li> </ul> <p><b>D. Protecting the health and safety of people and the environment by regulating activities with genetically modified organisms (GMOs)</b></p> <ul style="list-style-type: none"> <li>• Administer the national scheme for the regulation of gene technology to protect the health and safety of people and the environment through the Gene Technology Regulator.</li> <li>• Conduct cooperative compliance activity with regulated communities for managing any risk to people and the environment. These include routine inspection of certified facilities and licensed activities with GMOs in contained facilities and field trials.</li> </ul> <p><b>E. Protecting the health of people and the environment through effective regulation</b></p> <ul style="list-style-type: none"> <li>• Amend the National Health and Medical Research Council (NHMRC), <i>Australian code for the care and use of animals for scientific purposes 8<sup>th</sup> edition (2013)</i> to exclude the use of animals for testing cosmetic products and ingredients.</li> <li>• Undertake procurement to develop an Industry Code of Practice and a product information and communication package to ensure industry and the general public are aware of the details of the ban of the testing of cosmetics on animals.</li> </ul>

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<sup>3</sup> Diversion refers to the transfer of legally prescribed substances from the person for whom it was intended to another person for illicit use.

<b>Performance criteria</b>				
<b>A. Regulating therapeutic goods for safety, effectiveness/performance and quality while promoting best practice</b>				
Regulate therapeutic goods for safety, effectiveness/performance and quality. <sup>4</sup>				
a. Percentage of applications lodged under prescription medicines registration (Category 1 applications) processed within 255 working days.				
b. Percentage of quality related evaluations of prescription medicines (Category 3 applications) processed within 45 working days.				
c. Percentage of conformity assessments for medical devices processed within 255 working days.				
d. Percentage of licensing and surveillance inspections completed within target timeframes.				
2016-17 Estimated result	2017-18 Target	2018-19 Target	2019-20 Target	2020-21 Target
a. 100%	100%	100%	100%	100%
b. 100%	100%	100%	100%	100%
c. 100%	100%	100%	100%	100%
d. 85%	85%	85%	85%	85%
<b>Contribute to the evolving international environment to help support the quality and safety of medicines and medical devices in Australia.<sup>5</sup></b>				
2016-17 Estimated result	2017-18 Target	2018-19 (& beyond) Target		
Engaged in activities to reduce duplication in pre and post-market regulation of therapeutic goods and enable consistent regulatory decision making about the safety, quality and effectiveness of therapeutic goods available in Australia. Engaged in international forums and collaboration with other national regulatory authorities to facilitate the harmonisation of requirements, strengthening of regulatory partnerships, and monitoring of global regulatory priorities.	Increase engagement with overseas regulators in comparable health systems, and with regional and international organisations, such as the World Health Organization, to improve public health and safety. Increase use of overseas assessments by comparable regulators, while maintaining sovereignty of regulatory decisions.	As per 2017-18.		

<sup>4</sup> Further information available at: [www.tga.gov.au/half-yearly-performance-reports](http://www.tga.gov.au/half-yearly-performance-reports); [www.tga.gov.au/tga-key-performance-indicators-july-2015-june-2016](http://www.tga.gov.au/tga-key-performance-indicators-july-2015-june-2016); [www.tga.gov.au/performance-statistics-reports](http://www.tga.gov.au/performance-statistics-reports)

<sup>5</sup> Further information available at: [www.tga.gov.au/publication/tga-international-engagement-strategy-2016-2020](http://www.tga.gov.au/publication/tga-international-engagement-strategy-2016-2020)



<b>Improve intelligence, monitoring and compliance functions to ensure compliance with the <i>Therapeutic Goods Act 1989</i>.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>Developed a Compliance and Enforcement Plan to provide a targeted approach to investigation and compliance activities.</p> <p>Developed more effective inter-agency partnerships to enable greater monitoring and use intelligence to target non-compliance.</p> <p>Removed illegal and/or non-compliant products that pose an unacceptable risk from the Australian market.</p>	<p>Implement the Compliance and Enforcement Plan.</p> <p>Strengthen inter-agency partnerships to enable greater monitoring and use intelligence to target non-compliance.</p> <p>Remove illegal and/or non-compliant products that pose an unacceptable risk from the Australian market.</p>	<p>Review the Compliance and Enforcement Plan to ensure ongoing improvement in targeting compliance activities.</p> <p>Through effective inter-agency partnerships, monitor and use intelligence to target non-compliance.</p> <p>Remove illegal and/or non-compliant products that pose an unacceptable risk from the Australian market.</p>
<b>Improve access to therapeutic goods for consumers whilst maintaining the safety of therapeutic goods in Australia.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>Commenced implementation of the Australian Government's reforms arising from the Review of Medicines and Medical Devices Regulation (the Review),<sup>6</sup> including initial changes to the <i>Therapeutic Goods Act 1989</i> through the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.</p> <p>Further review of the regulatory framework applying to low risk therapeutic goods as part of the Medicines and Medical Devices program of reforms.</p>	<p>Implementation of the Australian Government's reforms arising from the Review progressed through:</p> <ul style="list-style-type: none"> <li>– Developing and implementing new regulatory pathways for prescription and complementary medicines and medical devices.</li> <li>– A risk-based approach to variations to registered medicines.</li> <li>– Improving patient-specific access to unapproved therapeutic goods.</li> <li>– More effective regulation of therapeutic goods advertising.</li> </ul>	<p>Full implementation of the Australian Government's reforms arising from the Review.</p>
<b>Maintain the Poisons Standard in accordance with the requirements of the <i>Therapeutic Goods Regulations 1990</i> to support protection of the community.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>Considered advice from the Advisory Committee on Medicines or Chemicals Scheduling to inform updates to the Poisons Standard.</p> <p>Further review of the Scheduling Policy Framework as part of the Medicines and Medical Devices program of reforms.</p>	<p>Consider advice from the Advisory Committee on Medicines or Chemicals Scheduling to inform updates to the Poisons Standard.</p> <p>Implement scheduling policy reforms.</p>	<p>Consider advice from the Advisory Committee on Medicines or Chemicals Scheduling to inform updates to the Poisons Standard.</p>

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<sup>6</sup> Further information available at: [www.tga.gov.au/mmdr](http://www.tga.gov.au/mmdr)

<b>B. Regulating the import, export, and manufacture of controlled drugs, and cultivation of medicinal cannabis</b>				
<b>Applications for the import, export, and manufacture of controlled substances are assessed and processed within appropriate timeframes to support Australian industry to engage in international trade, and ensure that medicinal products are available to Australian patients.</b>				
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>		
Applications have been processed within agreed timeframes.	Applications are processed within agreed timeframes.	As per 2017-18.		
<b>Ensure that licence applications for the cultivation and production of medicinal cannabis are subject to fit and proper person and security tests through engagement with law enforcement and State and Territory regulatory authorities.</b>				
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>		
All applications received have been subject to the relevant tests and assessment of diversion risk. <sup>7</sup> Response rates from States and Territories are improving.	Improve response rates from law enforcement agencies through the formalisation of Memoranda of Understanding. Build internal intelligence holdings supporting repeat and new applications.	As per 2017-18.		
<b>C. Protecting people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use</b>				
<b>Increased proportion of NICNAS risk management recommendations considered by Commonwealth and State and Territory risk management agencies and accepted to promote safer use of industrial chemicals.</b>				
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 Target</b>	<b>2019-20 Target</b>	<b>2020-21 Target</b>
80%	≥80%	≥80%	≥85%	≥85%
<b>Increased proportion of known importers and manufacturers of industrial chemicals registered with NICNAS, to promote awareness among the regulated community of their legal obligations.</b>				
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 Target</b>	<b>2019-20 Target</b>	<b>2020-21 Target</b>
90%	≥90%	≥90%	≥95%	≥95%
<b>Maintain proportion of NICNAS risk assessments completed within statutory timeframes to minimise regulatory burden on businesses.</b>				
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 Target</b>	<b>2019-20 Target</b>	<b>2020-21 Target</b>
95%	≥95%	≥95%	≥95%	≥95%

<sup>7</sup> Diversion refers to the transfer of legally prescribed substances from the person for whom it was intended to another person for illicit use.

<b>D. Protecting the health and safety of people and the environment by regulating activities with genetically modified organisms (GMOs)</b>		
<b>Protect people and the environment through open, effective and transparent regulation of genetically modified organisms (GMOs).</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>Prepared risk assessments and risk management plans for 100% of licence applications for release of GMOs into the environment. Consulted stakeholders, including the public, on assessments of licence applications. The Regulator made all licence decisions within the statutory timeframes.</p> <p>The regulated communities maintained a high level of compliance with the gene technology legislation. No adverse effects on human health or the environment from authorised GMOs were found.</p>	<p>Risk assessments and risk management plans prepared for 100% of applications for licensed dealings.</p> <p>100% of licence decisions made within statutory timeframes.</p> <p>High level of compliance with gene technology legislation and no adverse effect on human health or environment from authorised GMOs.</p> <p>Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment.</p>	As per 2017-18.
<b>Enhance harmonisation in the regulation of genetically modified organisms (GMOs) and genetically modified products.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>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. Continued cooperative arrangements with relevant national regulators to enhance coordinated decision making and avoid duplication in the regulation of GMOs and genetically modified products.</p>	<p>Maintained best practice regulation through participation in international harmonisation activities and collaboration with relevant national regulators.</p>	As per 2017-18.

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<b>E. Protecting the health of people and the environment through effective regulation</b>		
<b>Strengthen existing frameworks to ban cosmetic testing on animals.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
Stakeholder consultation on the approach to the delivery of the ban on cosmetic testing on animals occurred in late 2016 and March 2017.	Amend the National Health and Medical Research Council (NHMRC) <i>Australian Code for the care and use of animals for scientific purposes</i> (Animal Ethics Code) to ban cosmetic testing on animals. Undertake procurement and commence work program to develop a voluntary Industry Code of Practice and a product information and communication package. Legislate Animal Cosmetic Testing Ban as part of the new Industrial Chemicals Bill 2017.	Work with States and Territories to incorporate a cosmetic testing ban through State and Territory legislation in line with the NHMRC Animal Ethics Code. Implement the Industry Code of Practice. The Animal Cosmetic Testing Ban in the Industrial Chemicals Bill takes effect from 1 July 2018.
<b>Material changes to Program 5.1 resulting from the following measures:</b>		
<ul style="list-style-type: none"> <li>• There are no material changes to Program 5.1 resulting from measures.</li> </ul>		

**Table 2.5.3: Performance Criteria for Program 5.2**

<b>Program 5.2: Health Protection and Emergency Response</b>
<p>The Government aims to protect the health of the Australian community through effective national leadership and coordination, and through building 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.</p> <p>In the 2017-18 Budget, the Government will continue to fund the production and supply of Australian antivenoms, Q fever vaccine and test kits, and will maintain Australia's ability to domestically manufacture priority pandemic vaccines to respond to an influenza pandemic. In addition, the Government will provide \$85.4 million over three years to support the replenishment of the National Medical Stockpile.</p>
<b>Delivery</b>
<p><b>A. Reducing the incidence of blood borne viruses and sexually transmissible infections</b></p> <ul style="list-style-type: none"> <li>• Continue to provide national leadership and coordination of the implementation of the National Blood Borne Viruses (BBV) and Sexually Transmissible Infections (STI) Strategies 2014–2017.</li> <li>• Develop and implement a new <i>National Strategy for BBV and STI 2018–2022</i> which provides a national framework for responding to HIV, hepatitis B, hepatitis C and STIs.</li> <li>• Continue to work with State and Territory Governments, and community and professional organisations, to encourage increased uptake of testing and treatment among priority populations, including Aboriginal and Torres Strait Islander peoples, and to implement the Australian Government priority actions to respond to HIV, hepatitis B, hepatitis C and STIs.</li> <li>• Continue to support activities through the Health Protection Program to ensure the quality and safety of the Australian blood supply.</li> </ul> <p><b>B. Providing an effective response to national health emergencies, improving biosecurity and minimising the risks posed by communicable diseases</b></p> <ul style="list-style-type: none"> <li>• Continue to strengthen preparedness to respond to public health threats and health emergencies by reviewing key emergency response plans, the National Health Emergency Response Arrangements and ongoing monitoring of health threats through the National Focal Point.<sup>8</sup></li> <li>• Continue to improve Australia's ability to prevent, detect and rapidly respond to public health threats through improved compliance with the World Health Organization's <i>International Health Regulations (2005)</i> core capacities.</li> <li>• Maintain Australia's capacity to respond to health emergencies through ensuring that a strategic reserve of essential pharmaceuticals and protective equipment is available in the National Medical Stockpile.</li> </ul>

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<sup>8</sup> National Focal Point is the area or areas within the Department of Health, designated under the *National Health Security Act 2007*, as the International Health Regulations National Focal Point to liaise with and facilitate actions by national and international bodies to prevent, protect against, control and respond to a Public Health Event of National Significance or a Public Health Emergency of International Concern.

<b>Performance criteria</b>		
<b>A. Reducing the incidence of blood borne viruses and sexually transmissible infections</b>		
<b>National direction supports a coordinated response to reducing the spread of blood borne viruses (BBV) and sexually transmissible infections (STI).</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
Reporting on progress of programs that support the <i>National BBV and STI Strategies 2014–2017</i> <sup>9</sup> was successfully undertaken in accordance with the Implementation Plan. States and Territories, clinicians, researchers and community and professional organisations were supported in addressing the rising rates of BBV and STI in the community.	All partners, including States and Territories, clinicians, researchers, and community and professional organisations are supported to address rising rates of BBV and STI in the community through development and publication of the new <i>National BBV and STI Strategy 2018–2022</i> , incorporating HIV, hepatitis B, hepatitis C, and STI, with a focus on Aboriginal and Torres Strait Islander BBV and STI.	All partners including States and Territories, clinicians, researchers and community and professional organisations are supported to address rising rates of BBV and STI in the community with a focus on Aboriginal and Torres Strait Islander BBV and STI through: <ul style="list-style-type: none"> <li>– Monitoring progress against the programs that support the new <i>National BBV and STI Strategy 2018–2022</i>, in accordance with any implementation plans.</li> <li>– Surveillance and monitoring of progress against targets and goals including estimates of incidence and prevalence.</li> </ul>
<b>B. Providing an effective response to national health emergencies, improving biosecurity and minimising the risks posed by communicable diseases</b>		
<b>Manage and respond to national health emergencies and emerging health protection issues through effective preparation and mitigation measures.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
National Notifiable Diseases Surveillance System data is publicly available. Data quality is monitored in accordance with the <i>National Health Security Act 2007</i> . The Department continued to manage the national response to the global Zika virus outbreak.	National responses to health emergencies are successfully managed through the timely engagement of national health coordination mechanisms and response plans. Collect and disseminate data in the National Notifiable Diseases Surveillance System, including publishing on the Department's website. <sup>10</sup> Complete World Health Organization <i>International Health Regulations (2005)</i> Joint External Evaluation of core capacities.	As per 2017-18. Maintain/improve compliance with the World Health Organization <i>International Health Regulations (2005)</i> core capacities.

<sup>9</sup> Further information available at: [www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies)

<sup>10</sup> Further information available at: [www.health.gov.au/internet/main/publishing.nsf/content/cda-surveil-ndss-nndssintro.htm](http://www.health.gov.au/internet/main/publishing.nsf/content/cda-surveil-ndss-nndssintro.htm)

<b>Provide national direction to minimise the spread of antimicrobial resistance (AMR).</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>The Implementation Plan to support the <i>National AMR Strategy 2015–19</i> was signed by the Minister for Health and the Minister for Agriculture and Water Resources in November 2016.</p> <p>An AMR One Health website is under development with an anticipated completion date of 30 June 2017.</p>	<p>Action against the spread of AMR is supported by implementation of programs that support the <i>National AMR Strategy 2015–2019</i>.<sup>11</sup></p>	<p>Action against the spread of AMR is supported through:</p> <ul style="list-style-type: none"> <li>– Implementation of programs that support the <i>National AMR Strategy 2015–2019</i>.</li> <li>– In 2019-20, development of National AMR Strategy 2019–2023 in partnership with the Department of Agriculture and Water Resources.</li> <li>– In 2020-21, action against the spread of AMR is supported by implementation of Department of Health programs that support the National AMR Strategy 2019–2023.</li> </ul>
<b>Support Australia’s defences against the potential spread of mosquito-borne diseases on mainland Australia and in the Torres Strait.</b>		
<b>2016-17 Estimated result</b>	<b>2017-18 Target</b>	<b>2018-19 (&amp; beyond) Target</b>
<p>A Public Library of Science Neglected Tropical Diseases Report published in February 2017<sup>12</sup> indicates the program has successfully reduced <i>Aedes albopictus</i> populations on Thursday Island and Horn Island to levels where it is undetectable in up to 90% of surveys, which has reduced the risk of mainland establishment via that route.</p>	<p>Undertake targeted vector surveillance and control programs in the Torres Strait.<sup>13</sup></p> <p>Work closely with the Department of Agriculture and Water Resources and States and Territories, on exotic vector surveillance and control at Australia’s international airports and seaports.</p>	<p>As per 2017-18.</p>
<p><b>Material changes to Program 5.2 resulting from the following measures:</b></p> <ul style="list-style-type: none"> <li>• There are no material changes to Program 5.2 resulting from measures.</li> </ul>		

**Outcome 5**

<sup>11</sup> Further information available at: [www.health.gov.au/internet/main/publishing.nsf/Content/ohp-amr.htm#tocstrategy](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-amr.htm#tocstrategy)

<sup>12</sup> Public Library of Science Neglected Tropical Diseases; DOI:10.1371/journal.pntd.0005286 February 13, 2017 available at: [www.journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005286](http://www.journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005286)

<sup>13</sup> Vector control and surveillance aims to manage and eradicate disease carrying mosquito populations.

**Table 2.5.4: Performance Criteria for Program 5.3**

<b>Program 5.3: Immunisation</b>				
<p>The Australian Government aims to reduce the incidence of vaccine preventable diseases to protect individuals and the Australian community through the National Immunisation Program and associated immunisation initiatives.</p> <p>Supporting No Job, No Pay, the Government will commit \$14.1 million over four years through the National Immunisation Program to provide ongoing Catch-Up vaccines for almost 375,000 Australians aged 10 to 19 years, and more than 8,000 adult refugees and humanitarian entrants. In addition, the Government will launch a \$5.5 million awareness campaign over three years to improve awareness and uptake of immunisation for children less than five years of age.</p>				
<b>Delivery</b>				
<p><b>A. Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program</b></p> <ul style="list-style-type: none"> <li>Promote the safety and effectiveness of the National Immunisation Program, including the need to remain vigilant against vaccine preventable diseases.</li> <li>Address low vaccine uptake in at risk populations (for example, geographic areas of low coverage) through the Australian Immunisation Register and incentive payments to vaccination providers.</li> <li>Partner with States and Territories, and other key stakeholders to deliver vaccine initiatives through the National Immunisation Program.</li> </ul>				
<b>Performance criteria</b>				
<p><b>A. Increasing national immunisation coverage rates and improving the effectiveness of the National Immunisation Program</b></p>				
<p><b>Increase the immunisation coverage rates in children at 5 years of age.<sup>14</sup></b></p>				
2016-17 Estimated result	2017-18 Target	2018-19 Target	2019-20 Target	2020-21 Target
92.2%	≥92.5%	≥93.0%	≥93.5%	≥94.0%
<p><b>Increase the immunisation coverage rates among 12-15 months of age Aboriginal and Torres Strait Islander children.<sup>15</sup></b></p>				
2016-17 Estimated result	2017-18 Target	2018-19 Target	2019-20 Target	2020-21 Target
89.8%	≥89.0%	≥90.0%	≥90.5%	≥91.0%
<p><b>Material changes to Program 5.3 resulting from the following measures:</b></p> <ul style="list-style-type: none"> <li><i>Supporting No Job No Pay – National Immunisation Program – expansion</i></li> </ul>				

<sup>14</sup> Further information available at: [www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/acir-curr-data.htm](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/acir-curr-data.htm)

<sup>15</sup> Ibid.