

Outcome 2

ACCESS TO PHARMACEUTICAL SERVICES

Access to cost-effective medicines, including through the Pharmaceutical Benefits Scheme and related subsidies, and assistance for medication management through industry partnerships

Outcome 1 02

Outcome Strategy

The Australian Government, through Outcome 2, aims to provide reliable, timely and affordable access to cost-effective, high quality medicines and sustainable pharmaceutical services. The Government does this through subsidising the cost of medicines through the Pharmaceutical Benefits Scheme (PBS) and Life Saving Drugs Programme and by supporting the provision of aids and appliances.

Supporting the National Medicines Policy, in 2015-16, the Government will work to ensure timely access to the medicines Australians need; at a cost individuals and the community can afford; that those medicines meet appropriate standards of quality, safety and efficacy; are underpinned by programmes that support the quality use of medicines; and help maintain a responsible and viable medicines industry.

There is an increasing pressure being placed on the PBS by new medicines which are becoming more specialised and carry a higher price tag.

From 1 July 2015, the Government expects to introduce a balanced range of measures to support the longer term access to, and sustainability of, the PBS. These have been developed through extensive consultation with a range of PBS stakeholders including consumers, the pharmacy and pharmaceutical sectors, and other health professional groups.

These measures have been designed to bring new and innovative medicines on to the PBS in a timelier manner, and ensure efficiency in the pharmaceutical supply chain. Negotiations relating to this package of measures are in their final stages.

Programmes Contributing to Outcome 2

Programme 2.1: Community Pharmacy and Pharmaceutical Awareness

Programme 2.2: Pharmaceuticals and Pharmaceutical Services

Programme 2.3: Targeted Assistance – Pharmaceuticals

Programme 2.4: Targeted Assistance – Aids and Appliances

Outcome 2 Budgeted Expenses and Resources

Table 2.1 provides an overview of the total expenses for Outcome 2 by programme.

Table 2.1: Budgeted Expenses and Resources for Outcome 2

	2014-15 Estimated actual expenses \$'000	2015-16 Estimated expenses \$'000
Programme 2.1: Community Pharmacy and Pharmaceutical Awareness		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	405,929	410,220
Departmental expenses		
Departmental appropriation ¹	10,199	9,525
Expenses not requiring appropriation in the budget year ²	419	207
Total for Programme 2.1	416,547	419,952
Programme 2.2: Pharmaceuticals and Pharmaceutical Services		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	197,488	199,624
Special appropriations		
<i>National Health Act 1953 - pharmaceutical benefits</i>	9,283,968	9,770,425
Departmental expenses		
Departmental appropriation ¹	44,430	40,384
Expenses not requiring appropriation in the budget year ²	3,099	1,769
Total for Programme 2.2	9,528,985	10,012,202
Programme 2.3: Targeted Assistance - Pharmaceuticals		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	151,230	116,223
Departmental expenses		
Departmental appropriation ¹	3,957	3,765
Expenses not requiring appropriation in the budget year ²	122	60
Total for Programme 2.3	155,309	120,048
Programme 2.4: Targeted Assistance - Aids and Appliances		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	596	596
Special appropriations		
<i>National Health Act 1953 - aids and appliances</i>	312,898	346,427
Departmental expenses		
Departmental appropriation ¹	2,402	2,256
Expenses not requiring appropriation in the budget year ²	94	46
Total for Programme 2.4	315,990	349,325

Table 2.1: Budgeted Expenses and Resources for Outcome 2 (continued)

	2014-15 Estimated actual expenses \$'000	2015-16 Estimated expenses \$'000
Outcome 2 totals by appropriation type		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	755,243	726,663
Special appropriations	9,596,866	10,116,852
Departmental expenses		
Departmental appropriation ¹	60,988	55,930
Expenses not requiring appropriation in the budget year ²	3,734	2,082
Total expenses for Outcome 2	10,416,831	10,901,527
	2014-15	2015-16
Average staffing level (number)	251	244

1 Departmental appropriation combines "Ordinary annual services (Appropriation Bill No. 1)" and "Revenue from independent sources (s74)".

2 "Expenses not requiring appropriation in the budget year" is made up of depreciation expense, amortisation expense, makegood expense and audit fees.

Programme 2.1: Community Pharmacy and Pharmaceutical Awareness

Programme Objectives

Support timely access to medicines and pharmacy services

The Fifth Community Pharmacy Agreement ceases on 30 June 2015. The Australian Government will work to ensure all eligible Australians continue to have timely access to PBS medicines and other professional services in 2015-16 and beyond.

Extensive consultations have been undertaken with PBS stakeholders including the pharmacy industry with a view to developing key policies relating to pharmacy remuneration, PBS supply chain arrangements and professional programmes and services, focused on improving the quality use of medicines in Australia. The package of measures supporting the long term sustainability of the PBS and access to medicines, including a future pharmacy agreement, are in the final stages of negotiation.

The Australian Government will promote timely access to PBS medicines and other professional services for all eligible Australians through the network of community pharmacies.

These policies will be designed to assist the pharmacy sector contribute to the health outcomes of all Australians.

Programme 2.1: Expenses

Table 2.2: Programme Expenses

	2014-15 Estimated actual \$'000	2015-16 Budget \$'000	2016-17 Forward Year 1 \$'000	2017-18 Forward Year 2 \$'000	2018-19 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	405,929	410,220	416,342	422,872	429,235
Programme support	10,618	9,732	8,845	8,833	8,622
Total Programme 2.1 expenses	416,547	419,952	425,187	431,705	437,857

Programme 2.1: Deliverables

Qualitative Deliverables for Programme 2.1

Support timely access to medicines and pharmacy services

Qualitative Deliverables	2015-16 Reference Point or Target
Phased roll out of measure: Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities and public and private hospitals.	Continue measure phase in, as the Government is working to expand the supply and claiming of PBS medicines dispensed from medication charts to include all public and private hospitals.
Funding provided for remuneration to ensure the sustainability of the pharmacy sector and access for patients to PBS medicines and pharmacy services.	Access to medicines and pharmacy services is maintained.

Programme 2.1: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 2.1

Support timely access to medicines and pharmacy services

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
The current pharmacy to population ratio remains stable.	N/A ¹	Within 5%	Within 5%	Within 5%	Within 5%

Programme 2.2: Pharmaceuticals and Pharmaceutical Services

Programme Objectives

List cost-effective, innovative, clinically effective medicines on the PBS

The PBS is the primary means through which the Australian Government ensures Australians have timely and affordable access to pharmaceuticals. The PBS is expected to cost \$9.77 billion² in 2015-16. Approximately 298 million PBS prescriptions will be dispensed in 2015-16.³

Since the 2014-15 Mid-Year Economic and Fiscal Outlook in December 2014, the Government has approved 169 new or amended PBS listings, and one listing on the Life Saving Drugs Programme (LSDP), at an overall cost of \$1.6 billion over five years, to treat a range of illnesses from rare forms of cancer to skin conditions.

¹ This is a new Key Performance Indicator for 2015-16, therefore there is no target for 2014-15.

² This excludes the outcomes of the negotiations on the Sixth Community Pharmacy Agreement and broader PBS Access and Sustainability Package of measures.

³ This includes subsidised prescriptions and those below the general co-payment.

The listing of medicines on the PBS is based on the advice of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body comprising doctors, other health professionals and a consumer representative. The PBAC assesses the safety, therapeutic benefits and cost-effectiveness of the medicine for the intended use, in comparison with other available treatments.

At its March 2015 meeting, the PBAC recommended a further \$2.5 billion in new listings for Government consideration in 2015-16. The PBAC will meet three times in 2015-16 to provide Government advice on requests for new listings on the PBS and National Immunisation Program.

Increase the sustainability of the PBS

The current fiscal environment, compounded by factors such as the increasing prevalence of chronic disease, the listing of specialised new and expensive medicines in Australia and population ageing, are expected to continue to put pressure on the PBS growth rate over the medium to long term. High cost medicines are a significant contributor to this growth. As more high cost medicines are listed and more patients require access to these treatments, the cost to Government will increase.

For example, while patients have been paying \$6.10 or \$37.70 (depending on patient status) per prescription, they can access PBS medicines such as:

- treatment for cystic fibrosis (ivacaftor) which costs up to \$300,000 a year;
- treatment for multiple sclerosis (alemtuzumab) which costs up to \$57,000 a year;
- treatment of diabetic macular oedema and retinal vein occlusion (aflibercept or ranibizumab) which costs over \$12,000 a year;
- treatment of malignant melanoma (trametinib) which costs over \$131,380 per course of treatment; or
- treatment of late stage metastatic breast cancer (trastuzumab, pertuzumab, trastuzumab emtansine) which costs \$82,700 a year.

The Government needs to ensure that the PBS is managed in a fiscally responsible way, so that the Australian community has access to new, innovative and affordable medicines now and into the future.

Post-market surveillance

In 2015-16, the Government will progress several reviews of medicines in use, focussing on the appropriate and quality use of medicines to help improve health outcomes for patients and ensure continued value for money for taxpayers. The review of all PBS authority required medicines commenced in 2014-15, and is expected to be completed in 2015-16. The review, which was undertaken in close collaboration with the Australian Medical Association, the Royal College of General Practitioners, and other key stakeholders, has removed unnecessary red tape and administrative burden for health practitioners. Approximately 60 recommendations from the first stage of the review were implemented on 1 May 2015, saving approximately \$355,722 in regulatory burden, and an expected

\$7 million per year in red tape reduction on completion of stage 2 and 3 of the review.

The PBAC Guidelines will be reviewed in 2015-2016. The PBAC Guidelines provide practical information for the pharmaceutical industry to make a submission to the PBAC for the listing of a medicine or medicinal product on the PBS. The review is consistent with the Government's focus on improving the PBS, and ensuring Australians have access to safe, clinically effective and cost-effective medicines, while safe-guarding the sustainability of the PBS.

The review of the PBAC Guidelines will ensure that the PBAC submission and assessment process remains consistent and transparent, while incorporating international best practice and removing any unnecessary regulatory burden on the pharmaceutical industry.

Programme 2.2 is linked as follows:

- The Department of Human Services (Services to the Community – Health Programme 1.2) to administer the PBS, including payment of script benefits, authority approvals, new and other PBS items.
- The Department of Veterans' Affairs (Veterans' Pharmaceuticals Benefits – Programme 2.3) to provide entitled beneficiaries access to a comprehensive array of pharmaceuticals and wound dressings for the treatment of their health care needs.

Programme 2.2: Expenses

Table 2.3: Programme Expenses

	2014-15 Estimated actual \$'000	2015-16 Budget \$'000	2016-17 Forward Year 1 \$'000	2017-18 Forward Year 2 \$'000	2018-19 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	197,488	199,624	202,742	204,801	208,069
Special appropriations					
<i>National Health Act 1953 - pharmaceutical benefits</i>	9,283,968	9,770,425	10,254,185	10,636,453	10,970,328
Programme support	47,529	42,153	39,186	38,403	38,844
Total Programme 2.2 expenses	9,528,985	10,012,202	10,496,113	10,879,657	11,217,241

Programme 2.2: Deliverables

Qualitative Deliverables for Programme 2.2

List cost-effective, innovative, clinically effective medicines on the PBS

Qualitative Deliverable	2015-16 Reference Point or Target
The PBAC provides recommendations to the Minister on new listings for the PBS, and the National Immunisation Program.	The PBAC recommendations for listing on the PBS are based on the clinical effectiveness and cost-effectiveness of new medicines, and provided in a timely manner.

Post-market surveillance

Qualitative Deliverable	2015-16 Reference Point or Target
Undertake reviews of medicines in use, focussing on the appropriate and quality use of medicines.	Complete reviews of medicines and implement phased outcomes from the PBS Authorities review, the Life Saving Drugs Programme and the PBAC Guidelines.

Programme 2.2: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 2.2

Increase the sustainability of the PBS

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Estimated savings to Government from Price Disclosure. ⁴	\$2,094.9m	\$2,429.7m	\$2,619.0m	\$2,830.1m	\$3,061.2m

⁴ This Key Performance Indicator has been amended to include impacts from Price Disclosure only.

Programme 2.3: Targeted Assistance – Pharmaceuticals

Programme Objectives

Provide access to new and existing medicines for patients with life threatening conditions

The Australian Government will provide fully subsidised access for eligible patients to expensive and ‘lifesaving’ drugs for rare and life threatening medical conditions through the Life Saving Drugs Programme (LSDP).

Ten drugs are currently funded through the LSDP to treat eight serious and very rare medical conditions. These conditions are: Fabry, Gaucher, Mucopolysaccharidosis Types I, II and VI, Infantile-onset and Juvenile late-onset Pompe disease and Paroxysmal Nocturnal Haemoglobinuria.

On 9 April 2014, the Government announced a post-market review of the LSDP to ensure it continues to provide Australians with very rare conditions with access to much needed but very expensive medicines. The review is examining issues such as access and equity, value for money and the future administration of the LSDP. The review is also examining the existing LSDP criteria and conditions for funding, identifying processes to facilitate data collection for rare diseases and looked at ways to better engage with consumers. The review is expected to be completed in late 2015.

Programme 2.3: Expenses

Table 2.4: Programme Expenses

	2014-15 Estimated actual \$'000	2015-16 Budget \$'000	2016-17 Forward Year 1 \$'000	2017-18 Forward Year 2 \$'000	2018-19 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	151,230	116,223	107,960	113,065	114,830
Programme support	4,079	3,825	3,614	3,609	3,643
Total Programme 2.3 expenses	155,309	120,048	111,574	116,674	118,473

Programme 2.3: Deliverables

Qualitative Deliverables for Programme 2.3

Provide access to new and existing medicines for patients with life threatening conditions

Qualitative Deliverable	2015-16 Reference Point or Target
Review LSDP Guidelines to ensure they remain current and relevant.	LSDP Guidelines reviewed within agreed timeframes.

Quantitative Deliverables for Programme 2.3

Provide access to new and existing medicines for patients with life threatening conditions

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of patients assisted through the LSDP.	260	287	302	317	332

Programme 2.3: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 2.3

Provide access to new and existing medicines for patients with life threatening conditions

Qualitative Indicator	2015-16 Reference Point or Target
Eligible patients have timely access to the LSDP.	Patient applications are processed within 30 calendar days of receipt of the complete data package to support the application.

Quantitative Key Performance Indicators for Programme 2.3

Provide access to new and existing medicines for patients with life threatening conditions

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Percentage of eligible patients with access to fully subsidised medicines through the LSDP.	100%	100%	100%	100%	100%

Programme 2.4: Targeted Assistance – Aids and Appliances

Programme Objectives

To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services

The Australian Government, through the National Diabetes Services Scheme (NDSS), aims to ensure that people with diabetes have timely, reliable and affordable access to products and services that help them effectively self-manage their condition.

The Government also provides support to the families of children with type 1 diabetes through the type 1 Diabetes Insulin Pump Programme. This programme subsidises the cost of insulin pump therapy for those families with children under the age of 18 who have type 1 diabetes and who meet the income limits.

Assist people with a stoma by providing stoma related products

The Australian Government assists over 40,000 people each year by providing them with stoma related appliances (such as pouches, products to assist irrigation, protective films and seals) through the Stoma Appliance Scheme (the Scheme).

From 1 July 2015, the Government will introduce two new product listings and 21 amended product listings onto the Scheme (to remove the price premium for 20 products and reduce the maximum quantity for one product). New products will continue to be considered for listing on the Scheme.

In 2015-16, the Government will support the sustainability of the Scheme by ensuring that prices paid by the Australian Government reflect the market cost of the products through a tender process. In 2013-14, the Scheme cost the Government \$85 million, and the Scheme has been growing by approximately 4.6 per cent per annum. The measure will maintain full entitlement and access to products on the Scheme and will not change patient payment arrangements.

Improve the quality of life for people with Epidermolysis Bullosa

The Australian Government aims to improve the quality of life for people with Epidermolysis Bullosa⁵ and to reduce unnecessary hospitalisation through the National Epidermolysis Bullosa Dressing Scheme. The Scheme provides access to subsidised clinically necessary dressings for eligible people and provides education on best treatment practices. The Department works with clinical experts to ensure dressing treatment methods are consistent with best practice.

In 2015-16, the Department will work with the administrator, BrightSky Australia, to conduct a tender for the products on the Schedule of Dressings to ensure that they are clinically effective and provide value of money to Government.

⁵ A genetic disease characterised by extremely fragile and blister prone skin.

Programme 2.4 is linked as follows:

- The Department of Human Services (Services to the Community – Health Programme 1.2) to administer payment of claims from Stoma Associations for stoma related appliances.

Programme 2.4: Expenses

Table 2.5: Programme Expenses

	2014-15 Estimated actual \$'000	2015-16 Budget \$'000	2016-17 Forward Year 1 \$'000	2017-18 Forward Year 2 \$'000	2018-19 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	596	596	596	596	596
Special appropriations					
<i>National Health Act 1953 -</i>					
aids and appliances	312,898	346,427	295,858	302,057	302,550
Programme support	2,496	2,302	2,140	2,136	2,161
Total Programme 2.4 expenses	315,990	349,325	298,594	304,789	305,307

Programme 2.4: Deliverables

Qualitative Deliverables for Programme 2.4

To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services

Qualitative Deliverable	2015-16 Reference Point or Target
Provide access to insulin pumps and associated consumables for children under 18 years of age with type 1 diabetes.	Arrangements for the administration of the programme are in place to ensure ongoing supply of insulin pumps to eligible recipients.

Quantitative Deliverables for Programme 2.4

To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services

Quantitative Deliverables	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of people with diabetes receiving benefit from the NDSS.	1,400,000	1,526,000	N/A ⁶	N/A	N/A

⁶ The current NDSS Agreement ends on 30 June 2016.

Quantitative Deliverables	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of people under 18 years of age with type 1 diabetes receiving a subsidised insulin pump.	68	68	68	68	68

Assist people with a stoma by providing stoma related products

Quantitative Deliverable	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
The number of stoma products supplied to eligible people on the Stoma Appliance Scheme.	35,500,000	37,500,000	39,500,000	41,500,000	43,500,000

Programme 2.4: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 2.4

To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services

Qualitative Indicator	2015-16 Reference Point or Target
The NDSS meets the needs of stakeholders.	Annual survey of registrants conducted by Diabetes Australia demonstrates that the needs of stakeholders are being met.

Quantitative Key Performance Indicators for Programme 2.4

To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of diabetes related products provided to eligible people through the NDSS.	5,598,785	6,060,008	N/A ⁷	N/A	N/A

⁷ The current NDSS Agreement ends on 30 June 2016.

Assist people with a stoma by providing stoma related products

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of people receiving stoma related products.	42,500	43,250	44,000	44,750	45,500

Improve the quality of life for people with Epidermolysis Bullosa

Quantitative Indicator	2014-15 Revised Budget	2015-16 Budget Target	2016-17 Forward Year 1	2017-18 Forward Year 2	2018-19 Forward Year 3
Number of people with Epidermolysis Bullosa receiving subsidised dressings. ⁸	115	135	145	155	165

⁸ Figures for 2015-16 and subsequent years have been increased to reflect current patient uptake of the National Epidermolysis Bullosa Dressing Scheme.