

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

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Outcome Strategy

The Australian Government, through Outcome 2, provides reliable, timely and affordable access to cost-effective, sustainable and high quality pharmaceutical services and medicines. The Government does this through subsidising the cost of medicines through the Pharmaceutical Benefits Scheme (PBS), by providing free access to expensive and 'life saving' drugs, and by supporting the provision of aids and appliances. The Government also offers advice to health professionals and consumers on the quality use of medicines, and works with the pharmaceutical industry to ensure the supply of medicines through the PBS.

The National Medicines Policy provides an overarching framework for the activities in Outcome 2. There are four central objectives of the policy: timely access to medicines at an affordable cost to individuals and the community; medicines should meet quality, safety and efficacy standards; quality use of medicines; and maintaining a responsible and viable medicines industry.

Under the National Medicines Policy, medicine reviews are conducted to improve the use of medicines in the community, improve health outcomes for patients and increase cost-effectiveness for Government.

Through the Fifth Community Pharmacy Agreement (the Fifth Agreement), the Government will provide funding and support to around 5,000 pharmacies to continue dispensing PBS medicines. The Government collaborates with community pharmacies, peak bodies and consumers to implement the Fifth Agreement.

Ensuring the sustainability of this system is of the utmost importance to the Government.

The Government will continue to implement and monitor pricing reforms and other initiatives agreed to under the Memorandum of Understanding (MoU) with Medicines Australia, such as the Managed Entry Scheme and Parallel Processing. Consumers and key stakeholder groups such as Medicines Australia, the Generics Medicines Industry Association and the Consumers Health Forum, will continue to be consulted through this process.

Together, the Fifth Agreement and the MoU are delivering net savings of \$2.5 billion over five years to support the ongoing sustainability of the PBS.

Outcome 2 is the responsibility of Pharmaceutical Benefits Division.

Programs Contributing to Outcome 2

Program 2.1: Community pharmacy and pharmaceutical awareness

Program 2.2: Pharmaceuticals and pharmaceutical services

Program 2.3: Targeted assistance – pharmaceuticals

Program 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 Program.

Table 2.1: Budgeted Expenses and Resources for Outcome 2

	2011-12 Estimated actual \$'000	2012-13 Estimated expenses \$'000
Program 2.1: Community pharmacy and pharmaceutical awareness		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	304,585	314,970
Departmental expenses		
Departmental appropriation ¹	12,363	11,169
Expenses not requiring appropriation in the budget year ²	467	325
Total for Program 2.1	317,415	326,464
Program 2.2: Pharmaceuticals and pharmaceutical services		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	186,435	189,929
Special appropriations		
<i>National Health Act 1953</i> - pharmaceutical benefits	9,413,587	9,734,204
Departmental expenses		
Departmental appropriation ¹	33,314	29,151
Expenses not requiring appropriation in the budget year ²	1,769	3,297
Total for Program 2.2	9,635,105	9,956,581
Program 2.3: Targeted assistance - pharmaceuticals		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	131,207	154,417
Departmental expenses		
Departmental appropriation ¹	2,262	2,043
Expenses not requiring appropriation in the budget year ²	85	59
Total for Program 2.3	133,554	156,519
Program 2.4: Targeted assistance - aids and appliances		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	802	745
Special appropriations		
<i>National Health Act 1953</i> - aids and appliances	265,761	284,682
Departmental expenses		
Departmental appropriation ¹	2,613	2,591
Expenses not requiring appropriation in the budget year ²	99	69
Total for Program 2.4	269,275	288,087

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

	2011-12 Estimated actual¹ \$'000	2012-13 Estimated expenses¹ \$'000
Outcome 2 totals by appropriation type		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	623,029	660,061
Special appropriations	9,679,348	10,018,886
Departmental expenses		
Departmental appropriation ¹	50,552	44,954
Expenses not requiring appropriation in the budget year ²	2,420	3,750
Total expenses for Outcome 2	10,355,349	10,727,651
	2011-12	2012-13
Average staffing level (number)	246	212

- 1 Departmental appropriation combines “Ordinary annual services (Appropriation Bill No 1)” and “Revenue from independent sources (s31)”.
- 2 “Expenses not requiring appropriation in the budget year” is made up of depreciation expense, amortisation expense, makegood expense and audit fees. This estimate also includes approved operating losses - please refer to the departmental financial statements in section 3 for further information.

Program 2.1: Community pharmacy and pharmaceutical awareness

Program Objectives

Support timely access to medicines and pharmacy services through the Fifth Community Pharmacy Agreement

The Australian Government will ensure all eligible Australians continue to have timely access to PBS medicines and other professional services through the Fifth Agreement. The Fifth Agreement provides funding over five years, from 2010-11 to 2014-15, to remunerate pharmacists for dispensing PBS medicines and provides pharmacists with a range of professional programs and services, including services to support medication management, programs to assist the pharmacy workforce, activities to support improved service quality, and ongoing research and development work.

The Programs Reference Group, established in 2010-11, will continue to provide advice on the design, implementation and evaluation of elements of the Fifth Agreement. In addition, the Department will continue to work with a range of stakeholders including consumers, pharmacists, peak pharmacy bodies, accreditation and standards setting organisations and Indigenous health organisations to enhance services and program delivery, improve health literacy and decrease the risk of medicine-related harm.

In 2012-13, the Department will continue over 20 programs to support the delivery of pharmaceutical services and quality use of medicines through community pharmacies. Six new initiatives will be introduced during 2012-13 including the Electronic Recording and Reporting of Controlled Drugs (which aims to collect and report data relating to controlled drugs to help address problems of forgery, abuse and doctor shopping) and Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities (which aims to improve medication safety for residents, and decrease the duplication of paperwork and administrative burden).

The Department will support the sustainability of community pharmacies in rural and remote Australia through a range of ongoing and revised targeted rural programs. These programs will address challenges specific to rural pharmacists including continuing professional education, locum services and undergraduate support. The Pharmacy Practice Incentives Program, which requires pharmacies to undergo national accreditation, will also contribute to raising the level of service a consumer can expect from their pharmacy through the requirement to display and adhere with the Community Pharmacy Service Charter.

Program 2.1 Expenses

Table 2.2: Program Expenses

	2011-12 Estimated actual \$'000	2012-13 Budget \$'000	2013-14 Forward year 1 \$'000	2014-15 Forward year 2 \$'000	2015-16 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	304,585	314,970	347,068	373,805	373,827
Program support	12,830	11,494	11,289	11,252	11,327
Total Program 2.1 expenses	317,415	326,464	358,357	385,057	385,154

Program 2.1: Deliverables¹

Table 2.3: Qualitative Deliverables for Program 2.1

Qualitative Deliverables	2012-13 Reference Point or Target
Support timely access to medicines and pharmacy services through the Fifth Community Pharmacy Agreement	
Phased roll out of measure: Electronic Recording and Reporting of Controlled Drugs Supply	Measure phased in during the first half of 2012-13, including working with jurisdictions to facilitate the delivery of this measure
Phased roll out of measure: Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities	Measure phased in during the first quarter of 2012-13, including testing the National Residential Medication Chart used in the aged care sector
Phased roll out of measure: Continued Dispensing of PBS medicines in Defined Circumstances	Measure phased in during the first quarter of 2012-13, including working with jurisdictions to facilitate the delivery of this measure

¹ In 2012-13, all deliverables and key performance indicators have been reviewed and updated to ensure targeted performance reporting.

Table 2.4: Quantitative Deliverables for Program 2.1

Quantitative Deliverables	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
Support timely access to medicines and pharmacy services through the Fifth Community Pharmacy Agreement					
Number of medication management services provided under the Fifth Agreement	61,500	63,000	64,500	66,000	67,500

Program 2.1: Key Performance Indicators

Table 2.5: Quantitative Key Performance Indicators for Program 2.1

Quantitative Indicators	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
Support timely access to medicines and pharmacy services through the Fifth Community Pharmacy Agreement					
Percentage of rural community pharmacies accessing targeted rural programs to support the sustainability of community pharmacy in rural and remote Australia	65%	70%	75%	75%	75%
Percentage of community pharmacies participating in the Pharmacy Practice Incentives Program	40%	45%	50%	55%	60%

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Program 2.2: Pharmaceuticals and pharmaceutical services

Program 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. In 2011-12, the PBS is expected to cost \$9.4 billion, increasing to \$9.8 billion in 2012-13.

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. Since the Mid Year Economic and Fiscal Outlook in November 2011, the Government has approved 44 new or amended PBS listings, at a cost of \$72.1 million over five years.

Increase the sustainability of the PBS

The Government ensures that the PBS is managed in a fiscally responsible and sustainable way, so that the Australian community will continue to be able to access affordable medicines into the future.

Price disclosure is one of the primary means through which the Government will reduce the costs of PBS subsidised drugs. It requires suppliers of medicines to disclose the prices they charge to pharmacies, allowing prices paid under the PBS to be revised to reflect the weighted average prices actually charged in the market. Price disclosure now applies to more than 2,700 brands of pharmaceutical items. Further price reductions are planned for 1 August 2012, 1 December 2012 and 1 April 2013.

The Department will also work with the pharmaceutical industry to balance the need to promote competition in the industry through the use of generic medicines without discouraging investment in pharmaceutical research and innovation.

Post Market Surveillance

In 2012-13, the Government will continue to progress several reviews of medicines in use, focusing on the appropriate and quality use of medicines, to help ensure ongoing cost-effectiveness.

National Medicines Policy

The National Medicines Policy provides the overarching guidelines for how the Government will ensure Australians have improved access to medicines and that those medicines are used safely and effectively. In 2012-13, the Department will continue to implement the National Medicines Policy through: collaboration with National Medicines Policy partners to improve the naming, labelling and packaging of medicines; develop revised *Guiding Principles for Medication Management in Residential Aged Care Facilities*; and the review of medicines in use.

Program 2.2 is linked as follows:

- Department of Human Services (Medicare Australia – Program 1.1) to administer the PBS, including payment of script benefits, authority approvals, new and other PBS items.

Program 2.2 Expenses

Table 2.6: Program Expenses

	2011-12 Estimated actual \$'000	2012-13 Budget \$'000	2013-14 Forward year 1 \$'000	2014-15 Forward year 2 \$'000	2015-16 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	186,435	189,929	192,806	196,468	200,199
Special appropriations					
<i>National Health Act 1953</i> - pharmaceutical benefits	9,413,587	9,734,204	10,421,715	11,155,373	11,927,896
Program support	35,083	32,448	32,397	32,301	32,496
Total Program 2.2 expenses	9,635,105	9,956,581	10,646,918	11,384,142	12,160,591

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Program 2.2: Deliverables²

Table 2.7: Qualitative Deliverables for Program 2.2

Qualitative Deliverables	2012-13 Reference Point or Target
List cost-effective, innovative, clinically effective medicines on the PBS	
The PBAC meets at least three times a year and provides recommendations to the Minister on new listings for the PBS	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
Price negotiations with sponsors and conditions for listing finalised, and quality and availability checks undertaken for new PBS listings	All negotiations and listing activity completed in a timely manner

² In 2012-13, all deliverables and key performance indicators have been reviewed and updated to ensure targeted performance reporting.

Table 2.8: Quantitative Deliverables for Program 2.2

Quantitative Deliverables	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
List cost-effective, innovative, clinically effective medicines on the PBS					
Percentage of the community's (public) comments included for consideration at each Pharmaceutical Benefits Advisory Committee meeting	100%	100%	100%	100%	100%

Program 2.2: Key Performance Indicators

Table 2.9: Quantitative Key Performance Indicators for Program 2.2

Quantitative Indicators	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
List cost-effective, innovative, clinically effective medicines on the PBS					
Number of prescriptions subsidised through the PBS ³	193m	199m	205m	211m	218m
Revenue received from the cost recovery of the PBS listing process	\$14.1m	\$14.1m	\$14.1m	\$14.1m	\$14.1m
Increase the sustainability of the PBS					
Estimated savings to Government from the price disclosure program per annum ⁴	\$62.0m	\$121.0m	\$296.0m	\$578.0m	\$855.0m

³ These prescription volume forecasts take into account lower than expected actual medicines usage in 2010-11. This was published at Additional Estimates 2011-12.

⁴ Figures in 2011-12 Portfolio Budget Statement were printed in error. The correct figures are presented here, as reported in PricewaterhouseCoopers, 2010. *The Impacts of Pharmaceutical Benefits Scheme Reform*, Report for the Department of Health and Ageing, page 91, Appendix A Table 3; Savings to Government by year.

Program 2.3: Targeted assistance – pharmaceuticals

Program Objective

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

The Australian Government will continue to provide free access to expensive and life saving medicines for eligible Australians through the Life Saving Drugs Program. The program provides patients with financial assistance to access expensive and 'life saving' drugs not available through the PBS.

Nine drugs are currently funded through the program to treat seven serious and very rare medical conditions. These conditions are: Fabry, Gaucher, Mucopolysaccharidosis Types I, II and VI, Infantile Pompe and Paroxysmal Nocturnal Haemoglobinuria. Each condition has separate eligibility guidelines, developed and administered using the advice of an expert disease advisory committee. Guidelines are reviewed regularly in consultation with the expert disease advisory committees and any amendments are submitted to the Pharmaceutical Benefits Advisory Committee for consideration.

In 2012-13, the Department will continue to facilitate and monitor access for new and continuing patients to these medicines. The Department will also continue to provide support to the five expert disease advisory committees.

Program 2.3 Expenses

Table 2.10: Program Expenses

	2011-12 Estimated actual \$'000	2012-13 Budget \$'000	2013-14 Forward year 1 \$'000	2014-15 Forward year 2 \$'000	2015-16 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	131,207	154,417	160,063	165,850	167,877
Program support	2,347	2,102	2,113	2,107	2,121
Total Program 2.3 expenses	133,554	156,519	162,176	167,957	169,998

Program 2.3: Deliverables⁵

Table 2.11: Qualitative Deliverables for Program 2.3

Qualitative Deliverables	2012-13 Reference Point or Target
Improve access to new and existing medicines for patients with life threatening conditions	
Review program guidelines to ensure they remain current and relevant	Program guidelines reviewed within agreed timeframes

Table 2.12: Quantitative Deliverables for Program 2.3

Quantitative Deliverables	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
Improve access to new and existing medicines for patients with life threatening conditions					
Number of patients assisted through the Life Saving Drugs Program	231	225	279	303	327

Program 2.3: Key Performance Indicators

Table 2.13: Qualitative Key Performance Indicators for Program 2.3

Qualitative Indicator	2012-13 Reference Point or Target
Improve access to new and existing medicines for patients with life threatening conditions	
Eligible patients have timely access to the Life Saving Drugs Program	Patient applications are processed within 30 calendar days of receipt

⁵ In 2012-13, all deliverables and key performance indicators have been reviewed and updated to ensure targeted performance reporting.

Program 2.4: Targeted assistance – aids and appliances

Program Objectives

Provide support for people with diabetes

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 NDSS is administered by Diabetes Australia through a funding agreement. In 2012-13, the Department, in conjunction with Diabetes Australia, will consider the outcomes of three reviews undertaken in 2011-12 to determine the future arrangements for product supply and delivery, the product schedule and registrant support services.

The Government also provides support to the families of children with type 1 diabetes through the Type 1 Diabetes Insulin Pump Program. This program 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 eligible people with stomas⁶ by providing them with stoma related appliances (such as pouches, products to assist irrigation, protective films and seals) through the Stoma Appliance Scheme.

In 2012-13, the clinical and cost effectiveness of all products listed on the scheme will be reviewed. This review will help ensure participants continue to have access to the most clinically suitable appliances to effectively manage their condition and will also assist in improving the sustainability of the scheme.

Improve the quality of life for people with Epidermolysis Bullosa

The Australian Government aims to improve the quality of life for people with Epidermolysis Bullosa⁷ through the National Epidermolysis Bullosa Dressing Scheme. The scheme, administered by Bright Sky Australia, subsidises clinically appropriate and necessary dressings. The Department works with clinical experts to ensure dressing treatment methods are consistent with best-practice. In 2012-13, there will be a review of the scheme to inform future directions beyond 30 June 2013.

⁶ An opening in the abdomen for evacuation of products from the bowel or bladder.

⁷ A genetic disease characterised by extremely fragile and blister prone skin.

Program 2.4 Expenses

Table 2.14: Program Expenses

	2011-12 Estimated actual \$'000	2012-13 Budget \$'000	2013-14 Forward year 1 \$'000	2014-15 Forward year 2 \$'000	2015-16 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	802	745	681	596	596
Special appropriations					
<i>National Health Act 1953 -</i>					
aids and appliances	265,761	284,682	305,292	327,040	345,659
Program support	2,712	2,660	2,672	2,486	2,503
Total Program 2.4 expenses	269,275	288,087	308,645	330,122	348,758

Program 2.4: Deliverables⁸

Table 2.15: Quantitative Deliverables for Program 2.4

Quantitative Deliverables	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
Provide support for people with diabetes					
Number of people with diabetes receiving benefit from the National Diabetes Services Scheme	1,080,000	1,180,000	1,280,000	1,400,000	1,526,000
Number of people under 18 years of age with type 1 diabetes receiving a subsidised insulin pump	108	62	59	59	59
Assist people with a stoma by providing stoma related products					
Number of people receiving stoma related products	39,250	41,000	41,750	43,500	44,250
Improve the quality of life for people with Epidermolysis Bullosa					
Number of people with Epidermolysis Bullosa receiving subsidised dressings ⁹	166	79	83	87	91

⁸ In 2012-13, all deliverables and key performance indicators have been reviewed and updated to ensure targeted performance reporting.

⁹ Numbers have been revised from the 2011-12 PB Statements to reflect lower than anticipated uptake of eligible patients under this demand driven scheme.

Program 2.4: Key Performance Indicators

Table 2.16: Qualitative Key Performance Indicators for Program 2.4

Qualitative Indicator	2012-13 Reference Point or Target
Improve the quality of life for people with Epidermolysis Bullosa	
The National Epidermolysis Bullosa Dressing Scheme is reviewed	Review completed by 30 June 2013

Table 2.17: Quantitative Key Performance Indicators for Program 2.4

Quantitative Indicators	2011-12 Revised Budget	2012-13 Budget Target	2013-14 Forward Year 1	2014-15 Forward Year 2	2015-16 Forward Year 3
Provide support for people with diabetes					
Percentage of eligible people with diabetes who are able to access clinically appropriate products	100%	100%	100%	100%	100%
Assist people with a stoma by providing stoma related products					
Percentage of eligible people with stomas who are able to access clinically appropriate products	100%	100%	100%	100%	100%

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