

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, aims to provide reliable, timely and affordable access to cost-effective, sustainable and high quality pharmaceutical services and medicines. The Australian Government is committed to achieving this outcome by subsidising the cost of medicines through the Pharmaceutical Benefits Scheme (PBS), providing free access to expensive and ‘life saving’ drugs, and the provision of aids and appliances. The Government provides advice to health professionals and consumers on the quality use of medicines, including ongoing and enhanced funding of the National Prescribing Service and works with the pharmaceutical industry to ensure the supply of medicines under the PBS.

The Government will collaborate with community pharmacy and peak bodies, such as the Pharmacy Guild of Australia, to implement the Fifth Community Pharmacy Agreement (the Agreement). The Agreement provides \$15.4 billion in remuneration over five years for around 5,000 pharmacies for dispensing of PBS medicines, the provision of pharmacy programs and services, and the Community Service Obligation arrangements with pharmaceutical wholesalers. The Agreement also provides for a commitment to maintaining the location rules for approved pharmacies. The Agreement will result in gross savings of \$1 billion against the Australian Government’s forward estimates (and net savings of \$0.6 billion) over five years.

A number of significant reforms will be implemented in support of the long-term sustainability of the PBS. Over \$1.9 billion in savings will be delivered over the next five years through a range of statutory price reductions and the expansion and acceleration of the existing price disclosure program from 162 to over 1600 brands of medicines. The net outcome of the Agreement and further pricing reforms is a saving of \$2.5 billion over 5 years.

The savings are reflected in a four-year Memorandum of Understanding signed with Medicines Australia, the peak body representing the major patent and off patent pharmaceutical companies in Australia. The savings will ensure that the Australian community has ongoing access to existing, new and innovative medicines, now and into the future, whilst also providing a period of stability in PBS pricing policy for the medicines industry. A number of innovations designed to improve the operations of the PBS listing process and reduce delays in making new and innovative medicines widely available to patients through the PBS will also be introduced as part of the Memorandum of Understanding.

There will be immediate improvements to the quality of life of many people, including those with debilitating and life threatening illnesses and conditions, such as cancer, through the new listing of Revlimid[®].¹

The National Medicines Policy provides an overarching framework for Outcome 2. The policy seeks to produce better health outcomes through improved access to, and quality use of, medicines. There are four central objectives of the policy. These are timely access to medicines at an affordable cost to individuals and the community; that medicines should meet quality, safety and efficacy standards; quality use of medicines; and maintaining a responsible and viable medicines industry.

In 2010-11, the Department and Medicines Australia will report to the Minister for Health and Ageing, through the Access to Medicines Working Group, on more effective supply of medicines through the PBS.²

Outcome 2 is the responsibility of the 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

¹ For further discussion regarding cancer care, please refer to Outcomes 1 and 10 in these Portfolio Budget Statements.

² For further discussion on the Access to Medicines Working Group, please refer to Program 2.2 in these Portfolio Budget Statements.

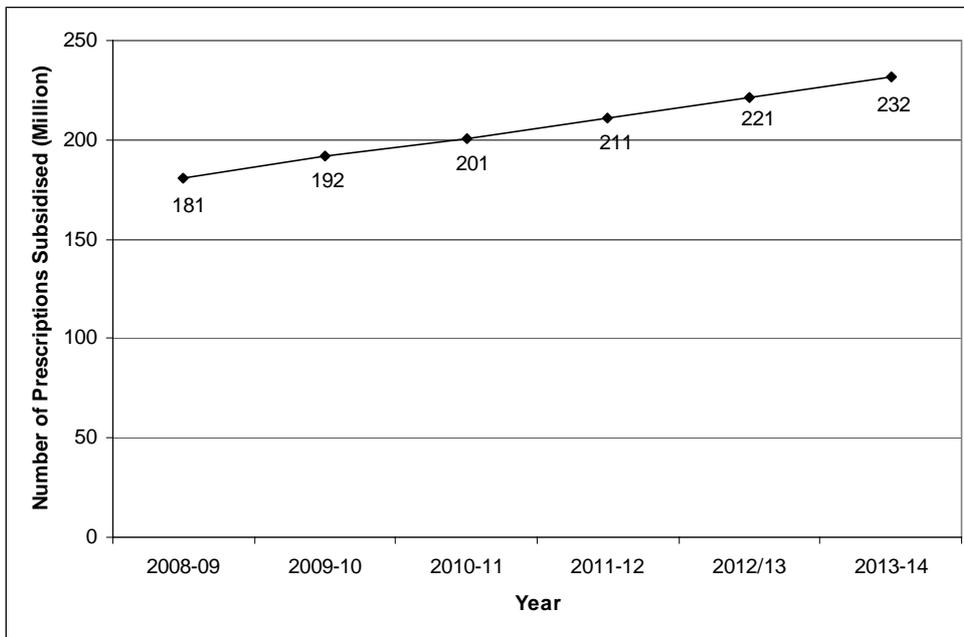
Outcome 2 Trend

Trend Projection 2.1: Working towards improving eligible Australians' access to pharmaceuticals, through subsidising PBS prescriptions for general and concessional patients.

The Government's report, *Australia to 2050: future challenges*³ (the 2010 intergenerational report), forecasts that Australian Government health spending will grow, as percentage of Gross Domestic Profit, from 4 per cent in 2009-10 to 7.1 per cent in 2049-50. Per capita expenditure on the PBS is expected to grow in real terms over the forecast period. Pharmaceutical spending remains a significant share of the health budget throughout the projection period, growing from \$443 real per capita in 2012-13 to \$534 real per capita in 2022-23.

Prescription volumes are also predicted to grow from an estimated 192 million in 2009-10 to a predicted 232 million by 2013-14.

Figure 1: Estimated number of prescriptions subsidised through the PBS



Source: Department of Health and Ageing internal modelling based on PBS prescription volume data from Medicare Australia (2009).

³ Accessible at: www.treasury.gov.au/igr/igr2010/report/pdf/IGR_2010.pdf

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

	2009-10	2010-11
	Estimated	Estimated
	actual	expenses
	\$'000	\$'000
Program 2.1: Community pharmacy and pharmaceutical awareness		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	371,823	261,695
Departmental expenses		
Ordinary annual services (Appropriation Bill No. 1)	13,493	13,608
Revenues from other sources (s31)	205	214
Unfunded depreciation expense	-	375
Total for Program 2.1	385,521	275,892
Program 2.2: Pharmaceuticals and pharmaceutical services		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	187,792	192,974
Special appropriations		
<i>National Health Act 1953</i> - pharmaceutical benefits	8,486,519	9,038,627
Departmental expenses		
Ordinary annual services (Appropriation Bill No. 1)	34,332	34,624
Revenues from other sources (s31)	523	544
Unfunded depreciation expense	-	954
Total for Program 2.2	8,709,166	9,267,723
Program 2.3: Targeted assistance - pharmaceuticals		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	76,152	119,326
Departmental expenses		
Ordinary annual services (Appropriation Bill No. 1)	1,301	1,312
Revenues from other sources (s31)	20	21
Unfunded depreciation expense	-	36
Total for Program 2.3	77,473	120,695
Program 2.4: Targeted assistance - aids and appliances		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	617	1,521
Special appropriations		
<i>National Health Act 1953</i> - aids and appliances	230,098	248,579
Departmental expenses		
Ordinary annual services (Appropriation Bill No. 1)	2,362	2,382
Revenues from other sources (s31)	36	37
Unfunded depreciation expense	-	66
Total for Program 2.4	233,113	252,585

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

	2009-10	2010-11
	Estimated actual	Estimated expenses
	\$'000	\$'000
Outcome 2 totals by appropriation type		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	636,384	575,516
Special appropriations	8,716,617	9,287,206
Departmental expenses		
Ordinary annual services (Appropriation Bill No. 1)	51,488	51,926
Revenues from other sources (s31)	784	816
Unfunded depreciation expense	-	1,431
Total expenses for Outcome 2	9,405,273	9,916,895
	2009-10	2010-11
Average staffing level (number)	267	259

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Contributions to Outcome 2

Program 2.1: Community pharmacy and pharmaceutical awareness

Program Objective

The Australian Government, through this program, aims to:

- support timely access to medicines and professional pharmacy services through the implementation of the Fifth Community Pharmacy Agreement; and
- support quality use of medicines for Aboriginal and Torres Strait Islander peoples, through education and targeted support for consumers and health professionals.

Major Activities

Fifth Community Pharmacy Agreement

The Australian Government will work to ensure all eligible Australians have timely access to PBS medicines and other professional services through the Fifth Community Pharmacy Agreement (the Agreement). The Agreement will provide funding of more than \$15.4 billion over the next five years (2010-11 to 2014-15) which represents a gross saving of \$1 billion against the Australian Government's forward estimates. This funding will remunerate pharmacists for dispensing PBS medicines and will provide pharmacists with a range of professional programs and services, including services to support medication management, programs to assist the pharmacy workforce, and activities to support improved service quality.

In 2010-11, the Australian Government will fund both new and continuing pharmacy programs. The Programs Reference Group will provide advice to the Minister for Health and Ageing on the design, implementation and evaluation of these programs. The Department will work closely with consumers, the Pharmacy Guild of Australia, and other peak pharmacy and key accreditation and standards agencies to enhance the provision of services to assist people to take their medicines more consistently, improve health literacy, and decrease the risk of medicine-related harm.

A number of existing services, such as Home Medicines Reviews and Residential Medication Management Reviews, will be refined to improve both access to medicines and the quality of services provided. In 2011-12, the Department will work towards the introduction of a new Medicines Use Review program. This will involve working with key stakeholders to design a pilot program for the reviews, including evaluation requirements. This program will allow for comprehensive in-pharmacy consultation and agreement on a medication action plan between the pharmacist and patient. These services will improve access to professional pharmacist advice and support.

Rural Pharmacy Programs will be an important element of the Agreement, offering a number of incentives and support for the pharmacy workforce. This will promote equitable access and availability of services for people who live in areas with limited access to health infrastructure. The Rural Pharmacy Workforce program will continue to support the training and development of pharmacists in rural areas. Under the Rural Pharmacy Maintenance program, annual payments are made to pharmacies in rural and remote areas in recognition of the additional costs and difficulties of maintaining a pharmacy in these areas. This will assist rural communities to have better access to PBS medicines.

The pharmacy accreditation program will be amended to include a requirement for pharmacies to display and comply with a Patient Service Charter. The charter will inform patients about the services they should receive from a pharmacy, as part of the process of dispensing PBS medicines.

The accreditation program will determine the ability of pharmacies to access a new range of payments under the Pharmacy Practice Incentive Program. From 2011-12, payments will be made annually to accredited community pharmacies that demonstrate delivery of defined services to patients to improve their quality use of medicines.

A new fee of \$0.15 per transaction will be paid to pharmacists for dispensing PBS, Repatriation Pharmaceutical Benefits Scheme and under copayment prescriptions that are generated electronically by prescribers, equating to \$75.5 million over the life of the Agreement. The fee will offset some of the costs charged to pharmacists by prescription exchange service providers, which is currently approximately \$0.25 per electronic prescription.

Improve access to PBS for Aboriginal and Torres Strait Islander peoples

As part of the Australian Government's contribution to the Council of Australian Governments' Indigenous Health National Partnership Agreement, the Department is implementing fourteen measures, which comprise the Indigenous Chronic Disease Package. Under this package, the Department has responsibility for Measure B1 – Subsidising PBS Medicine Co-payments. Despite two to three times higher levels of illness, PBS expenditure for Aboriginal and Torres Strait Islander peoples is about half of the non-Indigenous average. Cost has been identified as a significant barrier for access to medicines by Aboriginal and Torres Strait Islander peoples.

From 1 July 2010, this measure aims to provide assistance to Aboriginal and Torres Strait Islander patients who are assessed as having, or being at risk of developing, chronic disease; and whose adherence or access to medication may otherwise not be assured. Co-payments for these patients' PBS prescriptions will be reduced, so general patients will only pay the concessional co-payment (currently \$5.40), and concession card holders will receive medicines free-of-charge. Only PBS prescriptions annotated as 'Closing the Gap'⁴ prescriptions will be subsidised under this measure.

This work complements other activity under the Agreement, such as the targeted support under the rural programs. In addition, a number of financial incentives are available to pharmacists who visit remote area Aboriginal Health Services to provide assistance in improving the quality use of medicines by clients. This maximises the benefits that clients of these services receive from their medication.

Program 2.1 is linked as follows:

- Medicare Australia (Department of Human Services) to administer Indigenous access to the PBS, under the Delivery of Pharmaceutical Benefits and Services (Program 1.2).

⁴ Under the National Partnership Agreement on Closing the Gap in Indigenous Health Outcomes.

Program 2.1: Expenses

Table 2.2: Program expenses

	2009-10 Estimated actual \$'000	2010-11 Budget \$'000	2011-12 Forward year 1 \$'000	2012-13 Forward year 2 \$'000	2013-14 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	371,823	261,695	316,574	308,867	329,746
Program support	13,698	14,197	13,263	13,135	13,239
Total Program expenses	385,521	275,892	329,837	322,002	342,985

Program 2.1: Deliverables

The Department will produce the following ‘Deliverables’ to achieve the Program Objective.

Table 2.3: Qualitative Deliverables for Program 2.1

Qualitative Deliverables	2010-11 Reference Point or Target
Produce relevant and timely evidence-based policy research	Relevant evidence-based policy research produced in a timely manner
Stakeholders participate in program development through a range of avenues	Stakeholders participated in program development through avenues such as regular consultative committees, conferences, stakeholder engagement forums, surveys, submissions on departmental discussion papers and meetings
Fifth Community Pharmacy Agreement	
Implement revisions to professional programs and services under the Fifth Community Pharmacy Agreement	Establish the Programs Reference Group and agreement on revisions for new and existing programs and services
Develop and implement a Patient Service Charter framework	In consultation with key stakeholders, develop a Patient Service Charter that is agreed for use by community pharmacies
Provide funding to community pharmacies to support the delivery of professional programs and services	Community pharmacies in rural and remote areas access funding to support the delivery of medication management services

Qualitative Deliverables	2010-11 Reference Point or Target
Map Pharmacy Accessibility and Remoteness Index to new Australian Standard Geographic Classifications to support shift to new funding model for rural pharmacy programs	Mapping to new geographical classifications completed by 30 June 2011

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Table 2.4: Quantitative Deliverables for Program 2.1⁵

Quantitative Deliverables	2009-10 Revised Budget	2010-11 Budget	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Percentage of variance between actual and budgeted expenses	≤0.5%	≤0.5%	≤0.5%	≤0.5%	≤0.5%
Fifth Community Pharmacy Agreement					
Number of medication management services provided under the Fifth Agreement ⁶	N/A	60,000	61,500	63,000	64,500
Improve access to PBS for Aboriginal and Torres Strait Islander peoples					
Number of patients issued a Closing the Gap prescription through the PBS co-payment measure under the Indigenous Chronic Disease Package ⁷	N/A	20,000	40,000	70,000	75,000

⁵ Fourth Community Pharmacy Agreement reached completion on 30 June 2010, and the Fifth Agreement commenced in 2010-11. Deliverables have been modified accordingly. The 2009-10 deliverable relating to the NPS News has been removed. New deliverables have been provided which focus on Medication Management Services which is a more appropriate trend to measure, given it includes key programs under the Fifth Agreement such as Home Medicines Reviews and Residential Medication Management Reviews. The new deliverables reflect services delivered to individuals in the community, opposed to professional programs and services.

⁶ Fifth Community Pharmacy Agreement commenced in 2010-11.

⁷ Package commences 1 July 2010.

Program 2.1: Key Performance Indicators

The following ‘Key Performance Indicators’ measure the impact of the Program.

Table 2.5: Qualitative Key Performance Indicators for Program 2.1

Qualitative Indicators	2010-11 Reference Point or Target
Improve access to PBS for Aboriginal and Torres Strait Islander peoples	
Successful implementation and uptake of the Subsidising PBS Medicine Co-payments Measure by community pharmacies	Uptake of claims from 1 July 2010, and stakeholder satisfaction with the Measure
Improved management of medicines for Aboriginal and Torres Strait Islander patients	Overall evaluation of the Indigenous Chronic Disease Package indicates that the Subsidising PBS Medicine Co-payments Measure has contributed to these outcomes

Table 2.6: Quantitative Key Performance Indicators for Program 2.1⁸

Quantitative Indicators	2009-10 Revised Budget	2010-11 Budget Target	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Fifth Community Pharmacy Agreement					
Percentage of rural community pharmacies accessing targeted programs to ensure accessibility of community pharmacy in rural and remote Australia	60%	60%	65%	70%	75%
Improve access to PBS for Aboriginal and Torres Strait Islander peoples					
Percentage of Aboriginal Community Controlled Health Services participating in the Subsidising PBS Medicine Co-payments Measure ⁹	N/A	80%	85%	90%	100%

⁸ The key performance indicator ‘Number of general doctors participating in education initiatives’ has been deleted due to changes to program arrangements under the Fifth Community Pharmacy Agreement.

⁹ Measure commenced in 2010-11.

Program 2.2: Pharmaceuticals and pharmaceutical services

Program Objective

The Australian Government, through this program, aims to:

- manage the PBS including gaining better value from competition between brands of medicines listed on the PBS;
- improve health outcomes and sustainability of the PBS by improving the evidence base for prescribing decisions and the assessment of effectiveness of listed PBS medicines;
- list cost-effective new, innovative, clinically effective medicines on the PBS; and
- improve access to a range of pharmaceutical benefits by the community when prescribed by appropriately trained and certified nurse practitioners and midwives.

Major Activities

Pharmaceutical Benefits Scheme

In 2010-11, the Australian Government will implement a major PBS sustainability package. This package, along with the Fifth Community Pharmacy Agreement, will provide the Government with net total savings of \$2.5 billion from 2010-11 to 2014-15. The package is being implemented under a Memorandum of Understanding agreed in April 2010 with Medicines Australia, the peak body for the medicines industry in Australia. The Government and the medicines industry recognise the need to work together to enable the Australian community to have ongoing access to existing, new and innovative medicines, now and into the future.

The package follows on from PBS reforms initiated in 2007, providing savings through price reductions for medicines on the F2 formulary of the PBS (the medicines most subject to competition). Most importantly, price disclosure arrangements will be significantly strengthened. The prices paid by pharmacists to suppliers for medicines are often less than are paid by the PBS to pharmacists. Price disclosure requires suppliers of medicines to advise the prices they charge to pharmacies. Prices paid under the PBS are being revised to reflect weighted average prices actually being charged in the market. Price disclosure presently applies to 162 brands of medicines. Under the new arrangements, price disclosure will apply to more than 1,600 brands of medicines. Furthermore, Medicines Australia has agreed to an arrangement whereby a minimum level of savings under price disclosure is assured. No prices will rise for consumers as a result of this policy. In fact, in some cases it will result in lower prices for consumers as some medicines fall under the co-payment level, particularly for non-concessional consumers.

A further measure will provide information to consumers to increase their understanding that generic medicines are of equivalent quality, safety and efficacy to popular brand medicines. Through this measure, funding will be provided to the National Prescribing Service to assist the sustainability of the PBS.

The Australian Government's funding arrangements for the provision of chemotherapy medicines announced in the 2008-09 Budget was deferred from 1 September 2009, to allow consideration of the measure in the context of the negotiations with the Pharmacy Guild of Australia for the Fifth Community Pharmacy Agreement. The measure has been revised in line with a proposal received from community pharmacy and other stakeholders. It will eliminate wastage caused by excess dispensing of whole vials, and requires individual patient doses to be dispensed in combinations of vial sizes that will produce the least cost to

the taxpayer. The measure includes new fees for pharmacists which recognise the specialist activities undertaken to prepare cancer chemotherapy infusions. The measure will now save \$75.4m over the forward estimates period.

In 2010-11, the Australian Government will continue to work with Medicines Australia through the Access to Medicines Working Group. The group, established as part of 2007 PBS reforms, meets at least three times a year and reports to the Minister for Health and Ageing on how medicines can be supplied more effectively through the PBS. The group provides strategic oversight of joint activities undertaken by the Department and Medicines Australia to enhance the PBS processes, and considers issues relating to timely and appropriate access to effective new medicines on the PBS.

The listing of medicines on the PBS is based on the advice of the Pharmaceutical Benefits Advisory Committee (PBAC). The committee assesses the therapeutic benefits and cost-effectiveness of medicines, including comparisons with other treatments. The PBAC is an independent advisory body of medical specialists, general practitioners, other health professionals, and includes consumer representation.

The Department and peak consumer organisations meet regularly to discuss consumer literacy on health and increased consumer involvement in the PBAC process. Consumers and other interested stakeholders have the opportunity to comment on medicines to be considered by the PBAC. The PBAC meets three times a year in March, July and November, and the agenda is published on the Department's website¹⁰ six weeks prior to each meeting. This mechanism has improved the transparency of processes for listing medicines on the PBS. The Department is working with consumer groups to develop consultation strategies on the drugs being considered for subsidy. The Access to Medicines Working Group will continue to liaise with the PBAC to evaluate the benefits of this initiative.

In 2010-11, the PBAC will consider and recommend medicines for listing on the PBS. New listings on the PBS must be both clinically and cost effective. In 2009-10, the PBAC considered 214 submissions, of which 73 were major submissions requiring cost-effectiveness analysis. A similar number of submissions are expected to be considered in 2010-11.

The Australian Government subsidises the cost of prescription medicines through the PBS for all eligible general or concessional patients. Patients contribute to the cost of their PBS prescription medicines by paying a co-payment. The co-payment rate in 2010 is \$5.40 for a concessional patient and up to \$33.30 for a general patient, with the Government paying the remaining cost of the medicine. The PBS safety net is designed to assist families and individuals who require a large number of medicines in a calendar year. In 2010, the PBS safety net threshold for general patients is \$1,281.30, while the concessional patient threshold is \$324.00. After reaching the threshold, general patients usually pay for PBS prescriptions at the concessional co-payment rate of \$5.40, and concessional patients are usually supplied with PBS prescriptions without charge for the remainder of the calendar year.

The National Medicines Policy advisory structure engages individual experts, related organisations and committees, Government representatives and stakeholders. Timely and responsive advice is provided to the Government on medicines policy issues. In 2010-11,

¹⁰ Accessible at: www.health.gov.au

the five key priorities are: integrating the medicines policy framework into health system reform; better informed and active consumers; translating evidence into practice and policy; monitoring medicines in use; and informing the research agenda. Sustainability and cost-effectiveness will be a theme across these priority areas.

Increase sustainability of the Pharmaceutical Benefits Scheme

In 2008-09 PBS growth was 9.2 per cent, and in 2009-10 PBS growth was estimated at 10.6 per cent. This growth takes into account the impact of PBS reform measures implemented in 2007.

PBS growth is influenced by a number of factors, including the prices of existing PBS medicines and changes in price over time. The factors also include the number and cost of new medicines added to the PBS, population growth, the level of coverage by concession cards, the number of prescriptions dispensed, and the amount that patients contribute towards the cost of prescriptions.

Biological disease-modifying antirheumatic drugs (bDMARDs) are listed on the PBS for the treatment of patients with severe active rheumatoid arthritis, severe active psoriatic arthritis and active ankylosing spondylitis. In 2009, PBAC initiated a cost-effectiveness review of the bDMARDs for the rheumatoid arthritis indication. The review was conducted in consultation with the sponsors of the bDMARDs and the Australian Rheumatology Association. The PBAC recommended changes to the current restrictions and recommended that the Government seek a price reduction, to ensure that these medicines are cost-effective and affordable for consumers.

In 2010-11, the Department will implement the recommended price reductions and new restrictions for these drugs.

New medicine listings

The Government listed lenalidomide (Revlimid®) on the PBS and Repatriation Pharmaceutical Benefits Scheme from 1 November 2009, at an estimated cost of \$104 million over four years. Lenalidomide is used for the treatment of multiple myeloma, a cancer of the bone marrow. This medicine is expected to benefit more than 1,000 people over four years.

Since 1 November 2009, there have been over 90 new listings or alterations to current listings of medicines, at a cost of \$135 million over four years.

Nurse practitioners and midwives

On 1 November 2010, the Australian Government will extend access to PBS medicines prescribed by appropriately trained and certified nurse practitioners and midwives within the scope of their practice. This will help improve access to PBS medicines for consumers, while increasing the efficiency and effectiveness of the health workforce. Nurse practitioners and midwives play a significant role in responding to increasing demand for health services, particularly in rural and remote areas and in primary care settings.¹¹

The prescribing rights of health professionals, including nurse practitioners and midwives, are underpinned by specific state and territory legislation. In September and October 2009, the Department established two technical advisory groups comprising representatives from

¹¹ For further discussion on workforce, rural and primary health care, please refer to Outcomes 3, 5, 6, 8 and 12 located later in these Portfolio Budget Statements.

midwifery, nursing, medical, pharmaceutical and consumer groups, to provide advice on PBS medicines lists for midwives and nurse practitioners. Following consideration of the advice, the Department provided submissions to the PBAC. The PBAC then provided advice to the Minister for Health and Ageing, in April and May 2010, on the PBS medicines list for midwives and nurse practitioners respectively.

Once the medicines lists are approved, they will be incorporated into the *Schedule of Pharmaceutical Benefits* effective from 1 November 2010. A PBS subsidy will then apply for certain medicines prescribed by these authorised nurse practitioners and midwives.

Program 2.1 is linked as follows:

- Medicare Australia (Department of Human Services) to administer the PBS, including payment of script benefits, authority approvals, new and other PBS items under the Delivery of Pharmaceutical Benefits and Services (Program 1.2).

Program 2.2: Expenses

Table 2.7: Program expenses

	2009-10 Estimated actual \$'000	2010-11 Budget \$'000	2011-12 Forward year 1 \$'000	2012-13 Forward year 2 \$'000	2013-14 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	187,792	192,974	200,099	208,807	212,604
Special appropriations					
<i>National Health Act 1953</i> - pharmaceutical benefits	8,486,519	9,038,627	9,515,604	9,870,522	10,521,710
Program support	34,855	36,122	33,747	33,423	33,685
Total Program expenses	8,709,166	9,267,723	9,749,450	10,112,752	10,767,999

Program 2.2: Deliverables

The Department will produce the following 'Deliverables' to achieve the Program Objective.

Table 2.8: Qualitative Deliverables for Program 2.2

Qualitative Deliverables	2010-11 Reference Point or Target
Produce relevant and timely evidence-based policy research	Relevant evidence-based policy research produced in a timely manner
Stakeholders participate in program development through a range of avenues	Stakeholders participated in program development through avenues such as regular consultative committees, conferences, stakeholder engagement forums, surveys, submissions on departmental discussion papers and meetings

Qualitative Deliverables	2010-11 Reference Point or Target
Pharmaceutical Benefits Scheme	
Provide advice to Minister for Health and Ageing on streamlining PBS processes	Advice provided to the Minister in a timely manner
Increase sustainability of the Pharmaceutical Benefits Scheme	
Provide advice to affected sponsors of outcomes from price disclosure, three times a year, based on calculations from data collection	Data collection and calculations completed in a timely manner to allow determination and notification to be made in accordance with regulations
Put in place a dispute resolution framework for PBS price disclosure by 2010-11	Dispute resolution framework implemented in a timely manner
New medicine listings	
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 the 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
Nurse practitioners and midwives	
Implement PBS Prescribing for nurse practitioners and midwives	Implementation from 1 November 2010
PBS medicines list for nurse practitioners and midwives in place by November 2010	Medicines list in place by November 2010

Table 2.9: Quantitative Deliverables for Program 2.2

Quantitative Deliverables	2009-10 Revised Budget	2010-11 Budget	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Percentage of variance between actual and budgeted expenses	≤0.5%	≤0.5%	≤0.5%	≤0.5%	≤0.5%

Budget Statements – Department of Health and Ageing

Quantitative Deliverables	2009-10 Revised Budget	2010-11 Budget	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Pharmaceutical Benefits Scheme					
Percentage of Public Summary Documents, including recommendations, released 16 weeks after each Pharmaceutical Benefits Advisory Committee meeting ¹²	100%	100%	100%	100%	100%
Percentage of applications for consideration at next Pharmaceutical Benefits Advisory Committee meeting published on the Department's website to allow for public comment	100%	100%	100%	100%	100%
Increase sustainability of the Pharmaceutical Benefits Scheme					
Percentage of notification to affected sponsors of outcomes from price disclosure calculations	100%	100%	100%	100%	100%
New medicine listings					
Percentage of submissions to the Pharmaceutical Benefits Advisory Committee for PBS listings that are considered within 17 weeks of lodgement	100%	100%	100%	100%	100%

¹² The deliverable in the 2009-10 Portfolio Budget Statements has been revised.

Program 2.2: Key Performance Indicators

The following 'Key Performance Indicators' measure the impact of the Program.

Table 2.10: Qualitative Key Performance Indicators for Program 2.2

Qualitative Indicators	2010-11 Reference Point or Target
Pharmaceutical Benefits Scheme	
Develop strategies with consumer groups to encourage consumers to participate in the consideration of PBAC submissions	Strategies developed in a timely manner
Achieve better value from medicines that are subject to price competition by applying price disclosure processes	Accurate and timely price disclosure calculations and notification to affected sponsors

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Table 2.11: Quantitative Key Performance Indicators for Program 2.2

Quantitative Indicators	2009-10 Revised Budget	2010-11 Budget Target	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Pharmaceutical Benefits Scheme					
Percentage of prescriptions listed on the <i>Schedule of Pharmaceutical Benefits</i> subsidised under the PBS	80%	80%	80%	80%	80%
Number of prescriptions subsidised through the PBS	192m	201m	211m	221m	232m
Revenue received from the cost recovery of the PBS listing process	\$4.6m	\$14.0m	\$14.1m	\$14.1m	\$14.1m
Increase sustainability of the Pharmaceutical Benefits Scheme					
Estimated savings to Government from the price disclosure program ¹³	N/A	\$9.0m	\$38.0m	\$62.0m	\$121.0m

¹³ 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.

Quantitative Indicators	2009-10 Revised Budget	2010-11 Budget Target	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Nurse practitioners and midwives					
Number of PBS prescriptions written by midwives	N/A	9,535	17,218	34,667	53,319
Number of PBS prescriptions written by nurse practitioners	N/A	133,742	231,063	232,940	234,904

Program 2.3: Targeted assistance – pharmaceuticals

Program Objective

The Australian Government, through this Program, aims to:

- improve access to new and existing medicines for patients with life threatening conditions.

Major Activities

Access to life saving medicines

The Australian Government will continue to provide free access to expensive and life saving medicines for eligible Australians through its Life Saving Drugs program. The program provides patients with financial assistance to access expensive and ‘life saving’ drugs for serious and very rare medical conditions. Eight drugs are currently funded through the program. Each drug has separate eligibility guidelines, developed and administered with the advice of an expert Advisory Committee. Currently there are 173 patients being assisted through the program.

Following a positive recommendation from the PBAC in March 2008, the Government agreed to fund Zavesca[®] (miglustat) as part of the 2009-10 Budget (subject to appropriate financial arrangements being put in place). As a result, from 1 September 2009, the Department, in consultation with the Gaucher Disease Advisory Committee, arranged for the subsidy for ordering and delivery of Zavesca[®] to eligible patients. These patients suffer from Gaucher disease with poor venous access, severe needle phobia and hypersensitivity.

In the 2009-10 Budget, the Government also agreed to fund Myozyme[®] (alglucosidase alfa) following a positive recommendation from the PBAC in July 2008. As a result, from 1 February 2010, the Department has arranged for the subsidy, ordering and delivery of Myozyme[®] for eligible patients with infantile onset Pompe disease, in consultation with the Infantile-onset Pompe Disease Advisory Committee.

The Department will administer the program to support the needs of eligible patients. In 2010-11, to further improve efficiency and sustainability, the Department will implement the outcome of the program review completed in 2009.

Program 2.3: Expenses

Table 2.12: Program expenses

	2009-10 Estimated actual \$'000	2010-11 Budget \$'000	2011-12 Forward year 1 \$'000	2012-13 Forward year 2 \$'000	2013-14 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	76,152	119,326	123,985	119,582	120,846
Program support	1,321	1,369	1,279	1,266	1,276
Total Program expenses	77,473	120,695	125,264	120,848	122,122

Program 2.3: Deliverables

The Department will produce the following ‘Deliverables’ to achieve the Program Objective.

Table 2.13: Qualitative Deliverables for Program 2.3

Qualitative Deliverables	2010-11 Reference Point or Target
Produce relevant and timely evidence-based policy research	Relevant evidence-based policy research produced in a timely manner
Stakeholders participate in program development through a range of avenues	Stakeholders participated in program development through avenues such as regular consultative committees, conferences, stakeholder engagement forums, surveys, submissions on departmental discussion papers and meetings
Access to life saving medicines	
Provide funding to facilitate the treatment of eligible patients through the Life Saving Drugs program	Timely allocation and expenditure of funding

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Table 2.14: Quantitative Deliverables for Program 2.3¹⁴

Quantitative Deliverables	2009-10 Revised Budget	2010-11 Budget	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Percentage of variance between actual and budgeted expenses	≤0.5%	≤0.5%	≤0.5%	≤0.5%	≤0.5%
Access to life saving medicines					
Number of patients assisted through the Life Saving Drugs program	159	191	208	225	242
Number of patients assisted to receive Zavesca [®] through the Life Saving Drugs program	2	9	11	12	13
Number of patients assisted to receive Myozyme [®] through the Life Saving Drugs program	2	6	8	11	12

Program 2.3: Key Performance Indicators

The following ‘Key Performance Indicators’ measure the impact of the Program.

Table 2.15: Qualitative Key Performance Indicators for Program 2.3

Qualitative Indicator	2010-11 Reference Point or Target
Access to life saving medicines	
Eligible patients have timely access to the Life Saving Drugs program	Patient applications processed within 30 calendar days of receipt

¹⁴ The 2009-10 deliverable relating to Herceptin has been removed. While Herceptin is still available through the Life Saving Drugs Program, an alternative drug, Tykerb, is also available.

Table 2.16: Quantitative Key Performance Indicators for Program 2.3

Quantitative Indicators	2009-10 Revised Budget	2010-11 Budget Target	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Access to life saving medicines					
Percentage of eligible patients with access to fully subsidised medicines through the Life Saving Drugs program	100%	100%	100%	100%	100%
Percentage of eligible patients with access to fully subsidised Zavesca [®] through the Life Saving Drugs program	100%	100%	100%	100%	100%
Percentage of eligible patients with access to fully subsidised Myozyme [®] through the Life Saving Drugs program	100%	100%	100%	100%	100%

Program 2.4: Targeted assistance – aids and appliances**Program Objective**

The Australian Government, through this Program, aims to:

- increase the affordability of insulin pumps and associated consumables for children under 18 years of age with type 1 diabetes;
- continue to assist people with a stoma by providing free stoma related products; and
- ensure continued access to necessary and clinically appropriate dressings, and improve the quality of life for people with Epidermolysis Bullosa.

Major Activities**Type 1 diabetes insulin pump program**

The Australian Government aims to increase the affordability of insulin pumps by subsidising up to 80 per cent of the cost of insulin pumps for young Australians under 18 years of age with type 1 diabetes. The type 1 diabetes insulin pump program is administered by the Juvenile Diabetes Research Foundation, on behalf of the Australian Government. The subsidies available under the program were increased in February 2010. The program now provides a means-tested subsidy of up to 80% of the cost of a clinically recommended insulin pump (capped at \$6,400) for young people with type 1 diabetes. The maximum subsidy is available for successful applicants who have an annual family income of up to \$64,240 (indexed each year). The level of subsidy operates on a sliding

scale, gradually reducing to 10 per cent of the pump cost, or \$500 (whichever is greater), for families with an income of \$101,045 (also indexed each year). In addition to the subsidy boost, eligible families with two or more children with type 1 diabetes are entitled to the calculated subsidy for the first child and the maximum subsidy available for subsequent children. This increased subsidy extends the choices available for young people seeking to purchase an insulin pump.

In 2010-11, the Australian Government will monitor the delivery of the program to ensure it continues to provide appropriate assistance to children with type 1 diabetes. Program participation rates and clinical information provided by the Foundation will be regularly analysed to confirm the program is assisting this target group. The Department will continue to liaise with the Foundation to ensure eligible children have access to information about the program's subsidy levels and eligibility criteria. The Foundation will also conduct a communication campaign to provide relevant health care professionals with information about the program.

Stoma Appliance Scheme

The Australian Government aims to assist eligible people with stomas¹⁵ by providing a range of stoma related products. The Department supports stoma associations across Australia to help people better manage their condition by providing access to stoma related products. These products include pouches, skin protectors, flow filters and creams listed on the Stoma Appliance Scheme's Schedule. The Department advises stoma associations of new product listings and variations to current product listings, through regular updates, and manages ongoing administration of the scheme.

To ensure the sustainability of the scheme, the Department will continue to monitor the implementation of a number of changes, including a new pricing and listing mechanism for stoma products, as recommended by a review conducted in 2009-10. In 2010-11, the Department will work closely with stakeholders to enhance the operation of the scheme and improve access to stoma products for eligible people.

National Epidermolysis Bullosa Dressing Scheme

The Australian Government aims to improve the quality of life for people with Epidermolysis Bullosa¹⁶ by subsidising clinically appropriate dressings and bandages. The Department consults with a Clinical Advisory Committee consisting of experts in the treatment of Epidermolysis Bullosa from across Australia, to ensure dressing treatment practices are consistent with international best practice. Patient education will ensure the subsidised dressings will be applied according to best practice.

In 2010-11, a review of the administrative arrangements and pricing of dressings under the National Epidermolysis Bullosa Dressing Scheme will be conducted.

¹⁵ An opening in the abdomen for evacuation of products from the bowel or bladder.

¹⁶ An illness that causes skin to be fragile and easily injured causing blisters.

Program 2.4: Expenses**Table 2.17: Program expenses**

	2009-10 Estimated actual \$'000	2010-11 Budget \$'000	2011-12 Forward year 1 \$'000	2012-13 Forward year 2 \$'000	2013-14 Forward year 3 \$'000
Annual administered expenses					
Ordinary annual services	617	1,521	802	528	522
Special appropriations					
<i>National Health Act 1953 -</i>					
aids and appliances	230,098	248,579	267,478	281,812	297,099
Program support	2,398	2,485	2,322	2,300	2,318
Total Program expenses	233,113	252,585	270,602	284,640	299,939

Program 2.4: Deliverables

The Department will produce the following 'Deliverables' to achieve the Program Objective.

Table 2.18: Qualitative Deliverables for Program 2.4

Qualitative Deliverables	2010-11 Reference Point or Target
Produce relevant and timely evidence-based policy research	Relevant evidence-based policy research produced in a timely manner
Stakeholders participate in program development through a range of avenues	Stakeholders participated in program development through such avenues as regular consultative committees, conferences, stakeholder engagement forums, surveys, submissions on departmental discussion papers and meetings
Type 1 diabetes insulin pump program	
Information about the type 1 diabetes insulin pump program is communicated to healthcare professionals and families of children with type 1 diabetes	Program communications activities are delivered in a timely and effective manner
Stoma Appliance Scheme	
Eligible people with stomas are provided access to new and innovative stoma products appropriate for their conditions	New stoma products are approved and listed in a timely and effective manner

Table 2.19: Quantitative Deliverables for Program 2.4

Quantitative Deliverables	2009-10 Revised Budget	2010-11 Budget	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Percentage of variance between actual and budgeted expenses	≤0.5%	≤0.5%	≤0.5%	≤0.5%	≤0.5%
Type 1 diabetes insulin pump program					
Number of people under 18 years of age with type 1 diabetes receiving a subsidised insulin pump	92	233	108	62	59
Stoma Appliance Scheme					
Number of people receiving stoma related products	37,750	38,500	39,250	41,000	41,750
National Epidermolysis Bullosa Dressing Scheme					
Number of people with Epidermolysis Bullosa receiving subsidised dressings ¹⁷	98	164	166	168	171

Program 2.4: Key Performance Indicators

The following ‘Key Performance Indicators’ measure the impact of the Program.

Table 2.20: Qualitative Key Performance Indicators for Program 2.4

Qualitative Indicators	2010-11 Reference Point or Target
Type 1 diabetes insulin pump program	
Monitor the impact of changes to the type 1 diabetes insulin pump program	Monitoring concludes that program meets its intended aim of assisting families with children under 18 with type 1 diabetes with the cost of purchasing insulin pumps

¹⁷ The 2009-10 Key Performance Indicator, “Average amount of Australian Government expenditure on Epidermolysis Bullosa dressings per patient who accesses the program” has been deleted, as the number of patients accessing the program is more indicative than the expenditure of the program.

Qualitative Indicators	2010-11 Reference Point or Target
Stoma Appliance Scheme	
Evaluate the implementation of a sustainable listing and pricing process for the Stoma Appliance Scheme	Evaluation concludes that approved new listings have been added to the Stoma Appliance Scheme's Schedule in a sustainable manner
National Epidermolysis Bullosa Dressing Scheme	
Evaluate the National Epidermolysis Bullosa Dressing Scheme	The financial burden of eligible people with Epidermolysis Bullosa accessing dressings is reduced

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Table 2.21: Quantitative Key Performance Indicators for Program 2.4

Quantitative Indicators	2009-10 Revised Budget	2010-11 Budget Target	2011-12 Forward Year 1	2012-13 Forward Year 2	2013-14 Forward Year 3
Type 1 diabetes insulin pump program					
Percentage of eligible applicants receiving subsidised insulin pumps	100%	100%	100%	100%	100%
Stoma Appliance Scheme					
Percentage of new product listings completed in accordance with the new pricing and listing process	100%	100%	100%	100%	100%
National Epidermolysis Bullosa Dressing Scheme					
Percentage of eligible applicants receiving subsidised dressings	100%	100%	100%	100%	100%

