



Australian Government
Department of Health

EXECUTIVE MINUTE

on
JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT
REPORT No. 451
Community Pharmacy Agreements – Review of Auditor-General Report No. 25 (2014-15)

General comments

The Department of Health (Health) welcomes the Joint Committee of Public Accounts and Audit's (JCPAA) Report No. 451, *Community Pharmacy Agreements – Review of Auditor-General Report No. 25 (2014-15)* and supports the recommendations. Health notes the JCPAA's four themes of interest in the report, namely:

- value for money;
- record keeping;
- key performance indicators (KPIs); and
- conformity with relevant Commonwealth acts.

Value for money

Value for money consideration was a key factor in the development of the Sixth Community Pharmacy Agreement (6CPA). Key examples of this are the cost effectiveness assessments of 6CPA pharmacy programs, and the Review of Pharmacy Remuneration and Regulation. Other examples include changes to the National Diabetes Services Scheme (NDSS), changes to the Community Services Obligation (CSO) arrangements for distribution of pharmaceuticals by wholesalers, better targeting of the Premium Free Dispensing Fee (PFDI), and the provision for pharmacies to discount copayments.

6CPA pharmacy programs

The 6CPA outlines that funding for existing programs and new pharmacy programs will be subject to a cost-effectiveness assessment by an independent health technology assessment body. In effect, this will bring pharmacy programs more into line with other health care services that are assessed for clinical and cost effectiveness.

The Department has engaged with the independent Medical Services Advisory Committee (MSAC) to determine appropriate approaches to cost effectiveness assessments. For existing programs, the MSAC considered a high level evidence summary prepared by a consultant on behalf of the Department at a 30 March 2016 meeting. The MSAC has requested that more detailed work be undertaken to assess national and international evidence of cost-effectiveness in relation to each of the programs. This work is being progressively tendered. The first two evaluations are underway. As each evaluation is completed, the MSAC will make recommendations to Government about the design and funding of the programs, based on evidence of effectiveness.

The Pharmacy Trial Program (PTP) is providing \$50 million over the life of the 6CPA to trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers and extend the role of pharmacists in the delivery of primary healthcare services. The Department has been working with the MSAC and its Protocol Advisory Sub Committee (PASC) to inform trial design and assessment. PASC has a significant role in providing advice on the approach to developing scientifically rigorous trial protocols under the PTP, ensuring that the clinical and cost-effectiveness of each trial can be assessed.

Health has undertaken a range of stakeholder engagement activities for the PTP, including a Stakeholder Consultation Forum in October 2015, bilateral meetings with key stakeholder groups from March to April 2016, and the release of a discussion paper *Supporting pharmacist delivery of primary health care services through the Pharmacy Trial Program* which included a 'call for ideas' through the Department's PTP consultation website. The discussion paper, in addition to outlining the PTP and providing contextual information, invited stakeholders to provide ideas on programs and services that could be funded through the PTP. Health received 108 ideas in response to the discussion paper. These ideas covered a broad range of themes including: medication adherence and management; primary care services; pharmacists in general practice; and Aboriginal and Torres Strait Islander Health.

The PTP will be implemented across a number of tranches. Tranche one trials, announced by the Minister for Health on 17 March 2016 will include:

- Pharmacy-based screening and referral for diabetes;
- Improved medication management for Aboriginal and Torres Strait Islanders through pharmacist advice and culturally appropriate services; and
- Improved continuity in the management of patients' medications when they are discharged from hospital.

The Minister has agreed to a number of priorities that will form the basis of Tranche two of the PTP, which will include an approach to the market later this year inviting applications from organisations to implement trials in the priority areas, informed by the consultation activities outlined above.

6CPA Review of Pharmacy Remuneration and Regulation

The Review of Pharmacy Remuneration and Regulation (the Review) is a key plank in the 6CPA to achieve value for money and ensure reliable and affordable access to medicines. The Review provides the opportunity to examine approaches to ensuring supply of and access to medicines for all Australians. The review is well advanced and is expected to report in March 2017.

Other initiatives flowing from 6CPA that significantly contribute to value for money considerations

- Under 6CPA, NDSS products will be supplied through the CSO pharmacy distribution arrangements. This provides a more efficient supply chain for NDSS products by utilising a proven mainstream delivery system for pharmaceuticals and related products.
- There are efficiencies being gained in the CSO distribution arrangements under 6CPA through the market testing of its administration and through the encouragement of better stock management practise by pharmacies.
- The PFDI is a fee paid to pharmacists when they dispense a brand of medicine that does not have a price premium associated with its brand, thereby encouraging the dispensing of cheaper brands to consumers. Under 6CPA the PFDI is better targeted to help meet the policy intent of increasing the use of generic medicines by only being applicable when brand substitution is available.

- The Copayment Discount initiative enables competition between pharmacies and drives value for consumers through an optional \$1 reduction of patient copayments, at a cost to the pharmacy.

Record keeping

Health has taken a number of steps to significantly strengthen its record keeping under 6CPA. This has included:

- documenting all 6CPA negotiation meetings;
- ensuring Government was appropriately updated on the 6CPA negotiation process and subsequent implementation issues;
- having an independent review of its record keeping practises for community pharmacy agreements, which resulted in a number of recommendations that Health has accepted and is currently implementing;
- undertaking a range of activities to embed appropriate record keeping practices, including staff training, information sessions, development of record keeping guidelines, and a specific record keeping workshop; and
- implementing better electronic document and record management systems to assist with record management practises.

KPIs

As discussed in Health's response to recommendation 2 below, revised KPIs were introduced in Health's 2015-16 Portfolio Additional Estimates Statement for Outcome 2, Access to Pharmaceutical Services as listed at [Attachment A](#). In developing these KPIs, Health took into consideration the manner in which the 6CPA supports the National Medicines Policy, as reflected in the Background section of the 6CPA (refer pages 3 and 4 of 6CPA):

The Package¹ is intended to support the National Medicines Policy and appropriately balance the need to:

- *ensure consumers can continue to have access to new and innovative PBS subsidised medicines at an affordable price that are necessary to maintain the health of the community;*
- *promote and improve the quality use of medicines (QUM); and*
- *ensure a cost-effective and sustainable PBS.*

There are now KPIs in the Portfolio Budget Statement that:

- directly measure access (both to pharmacies, medication review programs, and to new medicines);
- monitor affordability and quality of medicines through Pharmaceutical Benefits Advisory Committee (PBAC) and post market related processes;
- promote QUM through such things as measuring access to medication management services; and
- ensure a cost-effective and sustainable PBS through such activities as measuring the average cost to the PBS of a script and the average cost to the patient of a script.

An extract of the relevant part of Health's 2015-16 Annual Report is at [Attachment B](#). It shows the results for 2015-16 for the KPIs discussed above.

Health will prepare KPIs for pharmacy programs that continue after cost effectiveness review. This will ensure that the KPIs developed appropriately reflect the cost-effectiveness framework required by the 6CPA for both ongoing and new programs.

¹ The PBS Access and Sustainability Package, of which 6CPA is a key element.

Health, in response to recommendation 7 from the Australian National Audit Office's (ANAO) performance audit of the Fifth Community Pharmacy Agreement (5CPA), now publishes an annual breakdown of key expenses related to the community pharmacy agreements. This is to assist with greater transparency and provide greater confidence about performance and delivery under the community pharmacy agreements. The [2014-15 Expenses Report](#) for the community pharmacy agreement is contained in Supplement 4 of the 2015 PBS Expenditure and Prescriptions Report.

Conformity with relevant Commonwealth Acts

Health notes the concerns raised by the JCPAA and the ANAO with respect to the compliance of section 12 of the *Financial Management and Accountability Act 1997* (FMA) under 5CPA, and the equivalent requirements under the *Public Governance, Performance, and Accountability Act 2013* (PGPA).

Health has strengthened its processes in this area, including through:

- awareness raising of PGPA requirements to staff;
- a central Health team to support line areas with PGPA requirements; and
- providing additional resources on Health's intranet site to assist with meeting PGPA requirements for procurement and grant processes.

Other comments

Health welcomed the ANAO conducting its follow-on audit of the 5CPA Performance Audit, as per recommendation 3 of the JCPAA report. This follow-on audit occurred from November 2015 to May 2016, and the related Auditor-General's Report² was tabled in Parliament on 31 August 2016. Of the eight recommendations from the original performance audit, the ANAO found that six have been fully implemented, with two partially implemented (recommendations 2 and 4).

Recommendation 2 relates to utilising the correct indexation factors during the development of costings related to the negotiation phase of 6CPA. The ANAO found through its follow-on audit that Health had not applied the correct forecast indexation factor to one of eleven savings measures when preparing the 6CPA. Health will be able to subsequently address this matter through an estimates update, and will implement an enhanced quality assurance process for any future community pharmacy agreement in relation to how indexation factors are applied to costing calculations.

Recommendation 4 relates to the provision of improved data to Health from the Department of Human Services (Human Services). The ANAO noted that this work is progressing well. Specifically, a Data Strategy Working Group has been formed that includes Health, the Department of Human Services, and the Department of Veterans' Affairs, and it is working on improving the reliability and content of data provided by Human Services to Health. One key item of work relates to a new data feed to Health from Human Services that will have additional data elements, with more timely completeness of data following a claim being made by a pharmacist. This new data feed is scheduled to commence in the last quarter of 2016, with the new data arrangements being backdated to 1 July 2016 to allow for a full year of similar data collection. In addition, from 1 July 2016 Health is now able to fully record the breakdown of costs related to the dispensing of chemotherapy medicines under the Efficient Funding of Chemotherapy measure.

² Auditor-General's ANAO Report No. 9 2016-17 *Community Pharmacy Agreement: Follow-on Audit*

Response to the recommendations

Recommendation No. 1

The Joint Committee of Public Accounts and Audit (JCPAA) recommends that the Department of Health report back to the JCPAA:

- within 6 months of tabling this report with an update on progress of the two year review of remuneration and regulation of the 6th Community Pharmacy Agreement, including considerations of 'value-for-money' spending; and
- a further report upon the completion of the two year review.

Health supports this recommendation.

Following is a progress report in response to the first dot point of Recommendation 1. Health will provide a further report to the JCPAA upon the completion of the Review.

Progress of the Review

- The Review of Pharmacy Remuneration and Regulation (the Review) commenced on 24 November 2015 with the release of the Review's Terms of Reference by the Minister for Health and announcement of the membership of the independent panel that will conduct the Review.
- The Terms of Reference note that the Review's recommendations will be directed toward achieving arrangements which are cost-effective for government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines.
- From December 2015 to April 2016 the Review Panel consulted with over 50 stakeholders, including consumer, pharmacy, wholesaler and health practitioner groups and has also visited a number of community pharmacies, a hospital pharmacy and a wholesaler distribution depot to build first-hand experience of a range of pharmacy and wholesaler models. These consultations have gone on to inform the Review Panel's Discussion Paper.
- Following a delay due to the recent federal election and caretaker period, Prof. Stephen King announced the release of the Review's Discussion Paper on 27 July 2016, inviting formal submissions to the Review.
- The Discussion Paper was made available from the Review's webpage and provided all interested parties an opportunity to comment on both the current arrangements for pharmacy remuneration and regulation, and how these arrangements may be improved in the interests of the Australian community. The closing date for written submissions was 23 September 2016.
- From 1 August to 7 September 2016, the Review Panel hosted a round of national consultations to support submissions to the Review. These consultations were extensive, with public forums in each state and territory (including metro and regional centres), stakeholder meetings and briefings at industry conferences.
- The national consultation process culminated with an interactive live national webcast, broadcasted from Canberra on 7 September 2016. The webcast drew together issues and discussions from the national consultations.

- An online questionnaire was released on 25 August 2016 to provide a further avenue for both pharmacists and members of the general public to respond in a convenient and structured way to core issues raised in the Discussion Paper. The questionnaire was also made available from the Review webpage. The questionnaire was open for responses until 30 September 2016.
- The Interim Report is due to be released in November 2016.
- The Panel will deliver its Final Report to the Australian Government by 1 March 2017.
- Further information and updates on the progress of the Review will be posted on the Review's webpage at: <http://www.health.gov.au/pharmacyreview>

Recommendation No. 2

The Joint Committee of Public Accounts and Audit (JCPAA) recommends that the Department of Health reports back to the JCPAA on the final Key Performance Indicators (KPIs) for components of the 6th Community Pharmacy Agreement. That report should include:

- the KPIs;
- how the KPIs will be achieved; and
- how outcomes to the KPIs will be monitored and measured and reported.

Health supports this recommendation.

The three key components of 6CPA are:

1. stable community pharmacy remuneration arrangements;
2. ongoing funding of the Community Services Obligation (CSO)³ – which ensures that all Australians have timely access to the PBS medicines they require regardless of the cost of the medicine or where they live; and
3. increased funding for community pharmacy programs⁴ – with a focus on assisting patients better manage their medications; reducing medication misadventure; and delivering better primary health care services.

Health undertook a review of the KPIs for the Portfolio Budget Statement in the last quarter of 2015. This addressed the key components of pharmacy remuneration arrangements, the CSO, and access to some pharmacy programs under 6CPA. The updated KPIs were included in Health's 2015-16 Portfolio Additional Estimates Statements (PAES) for Outcome 2 – Access to Pharmaceutical Services. The relevant extract of Outcome 2 from PAES is at Attachment A, and the results for 2015-16 are included at Attachment B which is an extract from Health's 2015-16 Annual Report.

The KPIs were designed with external expert support, utilising better practices for KPI design to ensure the indicators and targets are specific, measureable, relevant, achievable and targeted. They are part of a continuing program of improvement in this regard. They are also part of a broader set of objectives that Health is seeking to achieve with respect to individual health benefits.

The KPIs related directly to pharmacy in the Portfolio Budget Statement will be achieved through pharmacy activity and CSO distribution activity. They will be monitored, measured, and reported by Health as part of the regular Government annual reporting cycle.

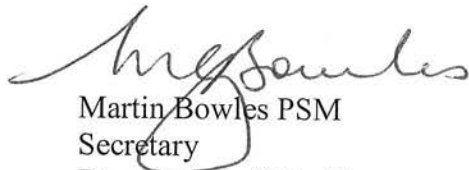
³ It should be noted that under 6CPA, to minimise additional delivery costs, pharmacies are required to better manage their inventory of commonly used medicines, resulting in more efficient ordering practise by pharmacies.

⁴ This includes programs under the Pharmacy Trial Program element of 6CPA. There is a focus on ensuring all programs are cost-effective.

All pharmacy programs are being reviewed for cost effectiveness. Once these reviews are complete, specific program KPIs will be developed for programs that continue. Consideration will be given to how the KPIs will be achieved and how the outcomes to the KPIs will be monitored, measured, and reported. The aim is to ensure the KPIs developed for the programs reflect, amongst other considerations, the enhanced approach to cost-effectiveness of pharmacy programs under the 6CPA, access to consumers most in need, and maximum health outcomes.

Health contact

Should you require any further information about Health's response, please contact Ms Julianne Quaine, Assistant Secretary of the Pharmaceutical Access Branch. Ms Quaine's phone number is 02 6289 8372 and email is julianne.quaine@health.gov.au.



Martin Bowles PSM
Secretary
Department of Health

7 October 2016

KPIs from Health's 2015-16 Portfolio Additional Estimates Statement

Outcome 2 - Access to Pharmaceutical Services, programs 2.1, 2.2, and 2.3⁵

Maintenance of pharmCIS and delivery of an increased suite of reporting and data related to pharmacy and PBS funded medicine access and cost made available to Parliament, consumers and business.

Percentage of urban centres/localities in Australia with a population in excess of 1,000 people with a resident community pharmacy or approved supplier of PBS medicines.

Percentage of urban centres/localities in Australia with a population in excess of 1,000 people with a resident service provider of, or recipient of, Medscheck, Home Medicines Review, Residential Medication Management Review or Clinical Intervention.

Percentage of subsidised PBS units delivered to community pharmacy within agreed requirements of the Community Service Obligation.

Average cost per subsidised script funded by the PBS.

Average cost per subsidised script paid by consumers for subsidised medicines.

Estimated savings to Government from price disclosure.

Percentage of submissions for new medicines for listing that are considered by PBAC within 17 weeks of lodgement.

Percentage of submissions for new medicines that are recommended for listing by PBAC, that are listed on the PBS within six months of agreement of budget impact and price.

Percentage of post-market reviews completed within scheduled timeframes.

Percentage of Government-accepted recommendations from post-market reviews that have been implemented within six months.

Number of patients assisted through the Life Saving Drugs Program (LSDP).

Percentage of Government-accepted recommendations from LSDP post-market reviews that are implemented.

Eligible patients have timely access to the LSDP.

Percentage of eligible patients with access to fully subsidised medicines through the LSDP.

⁵ Note, the above KPIs are the set of KPIs that were presented in the 2015-16 Portfolio Additional Estimates Statements under the 'old' program 2.1, 2.2, and 2.3 and reflected in program 4.3 of the 2016-17 Portfolio Budget Statement.



Our Purpose



Lead and shape Australia's health and aged care system and sporting outcomes through evidence-based policy, well targeted programs, and best practice regulation



In 2015-16, we undertook activities which contributed to achieving Our Purpose, including under Outcome 2

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

Analysis of performance – **Outcome 2** Access to Pharmaceutical Services

In 2015-16, the Department continued to support the Pharmaceutical Benefits Scheme (PBS), ensuring the efficiency and cost-effectiveness of the PBS, and supporting a viable effective community pharmacy sector. Access to a contemporary range of effective medicines is integral to improving health outcomes in Australia.

The Department managed the ongoing application of price disclosure policy which continues to reduce the price of many medicines for consumers and taxpayers.

The Department also continued to review medicines that are listed on the PBS to ensure that they remain clinically and cost effective. This helps to ensure that Australians have access to innovative and affordable medicines. In 2015-16, there were 370 new and amended PBS listings. This included high cost medicines for the treatment of cancers such as trastuzumab, pertuzumab and trastuzumab emtansine for the treatment of metastatic breast cancer, and pembrolizumab and trametinib for the treatment of melanoma.

The Department continued to support the integrity of the PBS by delivering on health provider compliance activities. Refer Program 3.1: Medicare Services and Appendix 3: *Health Provider Compliance Report*.

These activities have contributed to the Department's achievement of objectives under Outcome 2 and Our Purpose.

Key community benefits for **Outcome 2** in 2015-16



Ensured access to cost-effective, innovative and clinically effective medicines

The Department worked with the Pharmaceutical Benefits Advisory Committee and product sponsors to ensure the Australian community has access to contemporary, high quality and affordable medicines. 370 new and amended medications were listed on the PBS in a timely manner at a cost of \$2.1 billion (including revenue).



Provided access to expensive and lifesaving drugs for rare and life threatening medical conditions through the Life Saving Drugs Program

71 new patient applications to access medicines listed on the Life Saving Drugs Program were approved within 30 days, giving these patients access to critical medication.



PBS subsidy for break-through drugs to cure chronic hepatitis C from 1 March 2016

Over 230,000 Australians living with chronic hepatitis C will benefit from having access to new medicines that cure this potentially fatal disease.

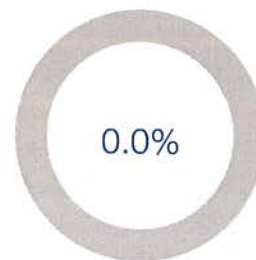
Summary of performance criteria results for **Outcome 2**



Met



Substantially met



Not met

Looking ahead

- The Department will implement the Pharmacy Trial Program during 2016-17. This program will test new approaches to providing primary care services to Australians through pharmacies.
- In 2016-17, the Australian Government will continue to consider new listings as recommended by the Pharmaceutical Benefits Advisory Committee.
- The Australian Government will continue to support the PBS by:
 - looking at ways to reduce the cost of medicines for taxpayers and consumers;
 - bringing new and innovative medicines on to the PBS in a timely way; and
 - ensuring efficiency in the pharmaceutical supply chain.
- The Department implemented the first phase of the Hospital Medication Chart on 1 July 2016, with electronic Hospital Medication Charts to be implemented by March 2017. The Hospital Medication Chart aims to improve the efficiency and safety of medication management in Australian hospitals, leading to improved quality use of medicines outcomes.

Programs and program objectives contributing to **Outcome 2**²²

Program 2.1: Community Pharmacy and Pharmaceutical Awareness

- Support timely access to medicines and pharmacy services

Program 2.2: Pharmaceuticals and Pharmaceutical Services

- Increase the sustainability of the PBS²³
- List cost-effective, innovative, clinically effective medicines on the PBS
- Post-market surveillance

Program 2.3: Targeted Assistance – Pharmaceuticals

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

Program 2.4: Targeted Assistance – Aids and Appliances

- To improve health outcomes for people with diabetes across Australia through the provision of subsidised products and self-management services
- Assist people with a stoma by providing stoma related products
- Improve the quality of life for people with Epidermolysis Bullosa
- Access to aids and appliances

²² Revised performance information for Outcome 2 was published in the *2015-16 Portfolio Additional Estimates Statements*, replacing the performance information published in the *2015-16 Health Portfolio Budget Statements* and the Department's *2015-16 Corporate Plan*.

²³ Sustainability of the PBS refers to the ability of the Government to continue to fund medicines over the longer term given increasing demand for and costs of medicines and related services, e.g. dispensing.

Analysis of performance – Program 2.1: Community Pharmacy and Pharmaceutical Awareness

The Department has met all performance targets for Program 2.1: Community Pharmacy and Pharmaceutical Awareness. Access to pharmacy services is key to improving the health of all Australians. The Department has worked with key stakeholders, including consumer organisations and industry groups, to ensure access to community pharmacies.

The Department implemented new and continuing measures such as the pharmacy Administration, Handling and Infrastructure fee, the Co-payment \$1 discount measure and the continuation of existing pharmacy programs. These have enhanced the timely and affordable access to PBS medicines and professional services, through community pharmacies, for all Australians.

In 2015-16, the Department also commenced developing a Pharmacy Trial Program which will trial new and expanded community pharmacy programs with the aim of improving clinical outcomes for consumers. This included work to develop trial protocols for three trials and a 'call for ideas' which generated 108 ideas for future trials.

The aim of the Community Services Obligation (CSO) Funding Pool is to ensure there are arrangements in place for all Australians to have timely access to PBS medicines, via their community pharmacy, regardless of where they live and usually within 24 hours. The CSO financially supports pharmaceutical wholesalers to supply the full range of PBS medicines and diabetes products under the National Diabetes Services Scheme to pharmacies across Australia, regardless of pharmacy location, within agreed timeframes.

Support timely access to medicines and pharmacy services

Maintenance of PharmCIS and delivery of an increased suite of reporting and data related to pharmacy and PBS funded medicine access and cost made available to Parliament, consumers, business.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 42

2015-16 Target	2015-16 Result
Periodically increase the volume and nature of data on the Department of Health website during the course of 2015-16.	The target was achieved with the ongoing publication of regular PBS schedules and data sets, and an increased range of data published. Result: Met ✓

In addition to the regular PBS data that is published and made available to the public, in 2015-16 there was an increase in the range and availability of data captured and the level of breakdown that is publicly available. For example, the Date of Supply and Under Co-payment PBS datasets are now updated and available monthly. This provides a complete picture of the PBS data to allow researchers and stakeholders the capability to perform more detailed analysis. The pbs.gov.au website was updated on 4 May 2016 to include additional data on Fifth Community Pharmacy Agreement expenses in 2014-15. This can be found in tables 21, 22, 23 and 24 of the publication *Expenditure and prescriptions twelve months to 30 June 2015*.²⁴

From 1 January 2016, under the Sixth Community Pharmacy Agreement, the Department commenced capturing point of sale data from community pharmacy and patient payments for medicines. Opportunities to publish this data will be available in PBS data releases as the data set grows.

The Department has a contract in place to maintain the PharmCIS application. The PharmCIS application is used to support the efficient management of the PBS listing process. The Department continues to manage a formal change control process to modify the PharmCIS application to accommodate policy, legislative and PBS listing changes as required.

²⁴ Available at: www.pbs.gov.au/statistics/2014-2015-files/exp-prs-book-01-2014-15.pdf

Providing transparency of PBS expenditure data provides the Australian community with an understanding of the costs to Government associated with the PBS supply chain, including pharmaceutical manufacturers, pharmaceutical distributors and community pharmacies, as a result of providing Australians with access to necessary medicines.

Percentage of urban centres/localities in Australia with a population in excess of 1,000 people with a resident community pharmacy or approved supplier of PBS medicines.²⁵

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 42

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
>90%	91.8%	N/A	N/A	N/A	N/A
Result: Met ✓					

91.8% of communities with a population of at least 1,000 people have timely access to PBS subsidised medicines from a community pharmacy or approved supplier when needed. Approved suppliers can be a pharmacy, a medical practitioner (in rural/remote locations where there is not access to a pharmacy) or an Aboriginal Health Service, approved to supply PBS medicines to the community.

Percentage of urban centres/localities in Australia with a population in excess of 1,000 people with a resident service provider of, or recipient of, Medscheck, Home Medicines Review, Residential Medication Management Review or Clinical Intervention.²⁶

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 42

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
>80%	97%	N/A	N/A	N/A	N/A
Result: Met ✓					

97% of communities with a population of at least 1,000 people, have access to advice and reviews when needed.

Medication Management Review services include the following programs:

- *Clinical Intervention* – the process of a pharmacist identifying, and making a recommendation to prevent or resolve a drug-related problem; for example, a change in the patient's medication therapy, means of administration or medication-taking behaviour;
- *Medscheck/Diabetes Medscheck* – a structured pharmacy service, which takes place in the pharmacy, involving face-to-face consultations between the pharmacist and consumer, with the aim to improve medicine use through education, self-management and medication adherence strategies;
- *Home Medicines Review* – a comprehensive clinical review of a patient's medicines in their home by an accredited pharmacist on referral from the patient's general practitioner (GP). An assessment is undertaken to identify, resolve and prevent medication-related problems and a report is provided to the patient's GP; and

²⁵ The 2015-16 Health Portfolio Additional Estimates Statements indicated that this performance criterion would report against urban centres/localities (UC/Ls) in Australia with a population in excess of 1,000 people. In determining the result for 2015-16 only Urban Centres (UCs) with a population in excess of 1,000 people were utilised, consistent with the Australian Bureau of Statistics definition of an urban centre.

²⁶ Ibid.

- *Residential Medication Management Review* – a service provided to a permanent resident of an Australian Government funded aged care facility. It is conducted by an accredited pharmacist when requested by a resident's GP. An assessment is undertaken to identify, resolve and prevent medication-related problems and a report is provided to the resident's GP.

Percentage of subsidised PBS units delivered to community pharmacy within agreed requirements of the Community Service Obligation.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 42

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
>95%	96%	N/A	N/A	N/A	N/A
Result: Met ✓					

Communities have timely access to subsidised medicines from community pharmacies within specified timeframes. The timely supply of PBS medicines is secured under the Community Services Obligations (CSO) Funding Pool. Wholesalers engaged under the CSO are contractually required to deliver medicines within the guaranteed supply period of 72 hours for medicines in the Top 1,000 Brands list and 24 hours for all other medicines.

Average cost per subsidised script funded by the PBS.²⁷

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 43

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
\$30.04	\$27.37	N/A	N/A	N/A	N/A
Result: Met ✓					

In 2015-16, the average cost of subsidised scripts under the PBS was \$27.37. This includes PBS prescriptions that are subsidised (cost above the patient co-payment) and unsubsidised (those below general patient co-payment).

Average cost per subsidised script paid by consumers for subsidised medicines.²⁸

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 43

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
\$9.76	\$9.27	N/A	N/A	N/A	N/A
Result: Met ✓					

In 2015-16, the average cost of subsidised scripts paid by consumers under the PBS was \$9.27. This includes PBS prescriptions that are subsidised (cost above the patient co-payment) and unsubsidised (those below general patient co-payment).

²⁷ This is the average across all PBS prescriptions, including under co-payment prescriptions.

²⁸ This is the average across all PBS prescriptions for the period 1 January 2016 – 30 June 2016 to allow for the inclusion of actual under co-payment patient payment amounts.

Analysis of performance – Program 2.2: Pharmaceuticals and Pharmaceutical Services

The Department has met majority of the performance targets for Program 2.2: Pharmaceuticals and Pharmaceutical Services. The PBS has continued to be managed in a fiscally responsible way which has ensured that all Australians have had access to new, innovative and affordable medicines, such as the new generation of hepatitis C medicines. Pressure is still expected to continue on the PBS growth rate due to factors such as an increase in the prevalence of chronic disease, the ageing population and the listing of specialised new and expensive medicines in Australia.

The Department has undertaken reviews of medicines to ensure the appropriateness and quality of medicines to help improve health outcomes for patients and to ensure value for money for taxpayers.

A new generation of hepatitis C medicines

HEP C TREATMENT patient journey



Hepatitis C is an infectious, blood-borne virus that attacks the liver, causing inflammation and in some cases leading to cirrhosis, end-stage liver disease, liver cancer or death. Approximately 230,000 Australians are living with this disease.

On 1 March 2016, a breakthrough of new generation hepatitis C medicines was listed on the Pharmaceutical Benefits Scheme (PBS), at a total cost to Government of over \$1 billion dollars.

So far, approximately 20,000 Australians have begun treatment to cure their hepatitis C. About 5,000 of these Australians have already completed their course of treatment. At this rate, Australia is on track to eliminate hepatitis C within a generation.

The new drugs cure hepatitis C in over 90% of patients, after just 12 weeks of treatment, making them significantly more effective than previous treatment options. They are also less complex to administer and have fewer side effects than other hepatitis C medications.

The new direct-acting antiviral medicines are available through the PBS for use by all Australians over the age of 18 who suffer from chronic hepatitis C. Eligible patients pay the normal PBS co-payment for a prescription – currently \$6.20 for concessional patients and \$38.30 for general patients for a treatment, which would otherwise cost more than \$20,000.

Increase the sustainability of the PBS²⁹

Estimated savings to Government from Price Disclosure.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 43

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
\$2,429.7m	\$2,258.4m	N/A	N/A	N/A	N/A
Result: Substantially met ✓					

The save in 2015-16, from all rounds, was \$2,258.4 million, which is \$171.3 million, or 7.1%, below the target. The savings are driven by market behaviour, and while the savings to Government are below estimates, price disclosure is still producing significant savings to consumers as the price of most medicines subject to price disclosure reductions are below the general co-payment of \$38.30.

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

Percentage of submissions for new medicines for listing that are considered by PBAC within 17 weeks of lodgement.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 44

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	100%	N/A	N/A	N/A	N/A
Result: Met ✓					

The Pharmaceutical Benefits Advisory Committee (PBAC) met on five occasions in 2015-16, including two special meetings in August 2015 and April 2016.³⁰

The PBAC consistently met to consider recommendations within the specified 17 week timeframe from lodgement of submissions. Approved medications were made publicly available in timeframes consistent with long standing arrangements agreed with the pharmaceutical industry.

All PBAC assessments are based on the clinical and cost effectiveness of the medicine.

Percentage of submissions for new medicines that are recommended for listing by PBAC, that are listed on the PBS within six months of agreement of Budget impact and price.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 44

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
80%	92%	N/A	N/A	N/A	N/A
Result: Met ✓					

Negotiations with product sponsors and listing activities for new listings of medicines on the PBS were completed in a timely manner, with 92% being listed on the PBS within six months of agreement on price, and the overall cost to Government (Budget impact), meeting the performance target.

²⁹ Sustainability of the PBS refers to the ability of the Government to continue to fund medicines over the longer term given increasing demand for and costs of medicines and related services e.g. dispensing.

³⁰ Refer Appendix 1: Processes Leading to PBAC Consideration – Annual Report for 2015-16 for more information.

Post-market surveillance

Percentage of post-market reviews completed within scheduled timeframes.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 44

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
90%	100%	N/A	N/A	N/A	N/A
Result: Met ✓					

Post-market reviews enable the systematic review of Government funded medicines against agreed objectives including improved patient safety, achievement of intended clinical benefits, ongoing viability of the PBS and improvements to the quality use of medicines and education for patients and prescribers.

The Post-market Review of the Life Saving Drugs Program, which sought to ensure Australians with very rare conditions continue to have subsidised access to much needed, expensive medicines, was completed and the report finalised.

The Post-market Review of Authority Required PBS Listings (Authority Review), which sought to reduce administrative burden on prescribers and dispensers of PBS listed medicines, has been completed.

Percentage of Government-accepted recommendations from post-market reviews that have been implemented within six months.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 44

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
80%	80%	N/A	N/A	N/A	N/A
Result: Met ✓					

All Government accepted recommendations arising from the Post-market Authority Review were implemented through core PBS listing processes. Implementation of the remaining Review recommendations continue to be processed.

To date, the Authority Review has produced total savings of approximately \$6,308,862, and an expected \$7 million per year in red tape reduction once implementation of Authority Review recommendations is completed. The following savings have been reported:

- 2014-15: savings of approximately \$935,612 (57 recommendations) in regulatory burden were reported;
- 1 September 2015: 30 recommendations were implemented saving approximately \$1,470,250 in regulatory burden; and
- 1 June 2016: a further 73 recommendations were implemented, saving approximately \$3,903,000 in regulatory burden.

Some recommendations required IT system changes, and/or further policy development work, which are being progressed.

Analysis of performance – Program 2.3: Targeted Assistance – Pharmaceuticals

The Department has met the majority of performance targets for Program 2.3: Targeted Assistance – Pharmaceuticals. The Department, through the Life Saving Drugs Program (LSDP), has continued to ensure access to expensive and life saving drugs to eligible patients, for rare and life threatening medical conditions.

During 2015-16, the Department undertook a review of the LSDP to ensure it continued to provide Australians with access to much needed and very expensive medications for rare conditions. The review has been completed.

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

Number of patients assisted through the LSDP.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 45

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
287	335	278	257	228	215

Result: Met ✓

The LSDP is a demand-driven program based on assessment of patients against set eligibility criteria.

Percentage of Government-accepted recommendations from LSDP post-market reviews that are implemented.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 45

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	N/A	N/A	N/A	N/A	N/A

There were no Government-accepted recommendations to implement in 2015-16.

Eligible patients have timely access to the LSDP.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 45

2015-16 Target	2015-16 Result
Patient applications are processed within 30 calendar days of receipt of the complete data package to support the application.	All patient applications were processed within 30 calendar days of receipt of the complete data package to support the application. Result: Met ✓

All 72 new patient applications received this financial year were processed within 30 calendar days of receipt of the complete data package to support the application, with 71 being approved.

Percentage of eligible patients with access to fully subsidised medicines through the LSDP.

Source: 2015-16 Health Portfolio Additional Estimates Statements, p. 45

2015-16 Target	2015-16 Result	2014-15	2013-14	2012-13	2011-12
100%	100%	100%	100%	100%	100%

Result: Met ✓

The Australian Government provides fully subsidised access for eligible patients to expensive drugs for rare and life threatening medical conditions through the LSDP.

Twelve drugs are currently funded through the program to treat eight serious and rare medical conditions. These conditions are: Fabry disease, Gaucher disease, Mucopolysaccharidosis Types I, II and VI, Pompe disease (Infantile-onset, Juvenile-onset or Adult Late-onset), Paroxysmal Nocturnal Haemoglobinuria, and Hereditary Tyrosinaemia Type I.

Analysis of performance – Program 2.4: Targeted Assistance – Aids and Appliances

The Department has met the majority of performance targets for Program 2.4: Targeted Assistance – Aids and Appliances. Diabetes is a serious complex condition that can have a significant impact on quality of life. Through the National Diabetes Services Scheme (NDSS), the Department ensures the provision of timely, reliable and affordable access to products and services to help people effectively self-manage their condition.

In 2015-16, the Department also continued to assist people with stomas by ensuring access to stoma-related products, with a greater choice of new improved products.

In addition, the Department continues to support access to clinically appropriate dressings and education on best treatment practices to improve the quality of life for people with Epidermolysis Bullosa.

The NDSS, Stoma Appliance Scheme, Insulin Pump Program and Epidermolysis Bullosa Dressing Scheme were established as a result of Government decisions to subsidise the supply of products. As the products supplied in these programs are aids and appliances and not medicines, they do not fit within the PBS.