

An introduction to the Pharmaceutical Benefits Scheme



Introduction

The use of medicines is the most common health intervention to combat illness and disease and promote good health and wellness. Of the more than 122.58 million general practice Medicare-claimed encounters in 2011–12, medicines were prescribed in 86% of these occasions.¹

The safe and effective use of medicines improves health outcomes and quality of life for individuals and improves the way health systems are used, optimising value for money spent on health. When suboptimal medicine use occurs, resources in healthcare and medicine budgets may be spent unnecessarily.

National Medicines Policy

In 2000, Australia's National Medicines Policy was released, providing the basis to bring about better health outcomes for Australians, focusing especially on people's access to, and safe and optimal use of medicines.² The central objectives of Australia's National Medicines Policy are:

- 1 Timely access to the medicines that Australians need, at a cost individuals and the community can afford
- 2 Medicines meeting appropriate standards of quality, safety and efficacy
- 3 Quality use of medicines (QUM)
- 4 Maintaining a responsible and viable medicines industry

What is the Pharmaceutical Benefits Scheme?

Consistent with Objective 1 of the National Medicines Policy, the Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to essential medicines, irrespective of where they live.

The PBS was first established in 1948 by the Chifley Government and has been in place, in various iterations, ever since. At its establishment the scheme provided the Australian public with basic access to a small number of essential medicines such as antibiotics and painkillers. The scheme has since evolved and grown due to many factors including the growing and ageing Australian population, changing cost burdens, and progress in medical and pharmaceutical technology giving rise to a much larger range of health treatment options.

The PBS is widely recognised both here and overseas as being one of the best systems in the world for patients and taxpayers. This judgement is based on the grounds of access, equity, structure and funding arrangements, and health outcomes. One of the major strengths of the PBS is that it is a national program, ensuring a consistent approach to evaluation, pricing and distribution of essential medicines.

Complementing the PBS is the Repatriation Schedule of Pharmaceutical Benefits (RPBS) which is managed by the Department of Veterans' Affairs (DVA) and supports eligible veterans, war widows/widowers and their dependants.³

1 General Practice Activity in Australia 2011–12, Family Medicine Research Centre, University of Sydney, page 37.

2 National Medicines Policy, www.health.gov.au

3 Department of Veterans' Affairs, www.dva.gov.au



An investment in health

In its 2013 Report, the Australian Institute of Health and Welfare (AIHW) identified that Australia's expenditure on health (by all governments and consumers) was estimated to be \$140.2 billion in 2011–12, or 9.5% of our gross domestic product (GDP).⁴ Of this, public hospital services accounted for \$42.0 billion (31.8%) of the recurrent health expenditure, medical services accounted for \$23.9 billion (18.1%) and medications accounted for \$18.8 billion (14.2%). While these costs are significant, the capacity for medicines to keep people healthy and out of hospitals with increased longevity and improved quality of life should be seen as an investment in health rather than simply a cost burden. Australia's ageing population reinforces the importance of continued investment in the PBS and quality use of medicines.

How does the PBS work?

The PBS works by subsidising the cost of prescribed medicines for Australian consumers to make them more affordable. Doctors prescribe PBS medicines from the general formulary for supply from a pharmacy at a subsidised price. There are also limited formularies for prescribing PBS medicines by dentists, optometrists and nurse practitioners.

Prescribers must have a PBS prescriber number in order to prescribe PBS medicines and pharmacists must have a PBS approval number to supply. In regions where a pharmacy is not available, a doctor may be approved to supply PBS medicines. There are strict requirements governing the approval process for pharmacists to supply PBS medicines and where pharmacies can be located. These requirements are set out in the Pharmacy Location Rules.⁵ As of 30 June 2013 there were 5351 pharmacies approved under Section 90 of the National Health Act supplying PBS medicines.

The majority of medicines subsidised under the PBS are provided under arrangements specified in Section 85 of the National Health Act. Approximately 10 per cent of the cost of the PBS is from special prescribing and supply arrangements contained in Section 100 of the Act. These medicines tend to be speciality, high cost medicines such as chemotherapy infusions or medicines to treat infertility or opiate dependence.

Medicines available on the PBS cover a range of health conditions, or therapeutic areas, demonstrating the breadth of support the scheme provides to the Australian community.

4 AIHW, Health Expenditure Australia 2011–12, page 6, www.aihw.gov.au

5 www.health.gov.au/acpa

The PBS supply chain

The PBS supply chain comprises three principal participants — manufacturers (pharmaceutical companies), wholesalers and pharmacists. Through negotiations with these sectors, the Australian Government sets an agreed subsidised price to cover the manufacture, distribution and dispensing of a subsidised medicine.

Manufacturers

Manufacturers are the pharmaceutical companies which discover, develop and manufacture the medicines for use by consumers. This includes the manufacturers of both originator and generic medicines. The manufacturer has the responsibility to ensure the medicine meets all the safety, quality and efficacy requirements associated with the supply of prescription medicines in Australia.

Wholesalers

Medicines are generally delivered to pharmacies throughout Australia by a pharmaceutical wholesaler distribution network. For the supply of PBS medicines, wholesalers operate under a Community Service Obligation (CSO) which was established to ensure the delivery of PBS medicines to the network of community pharmacies across Australia in a timely, affordable and secure way, ensuring Australians have access to the medicines they require regardless of the cost of the medicine or where they live.

The CSO also underpins Australia's preferred system of community pharmacy. It supports the role of the pharmacist in the front line of primary health care in Australia. With the CSO in place, pharmacists can depend on timely delivery of the medicines their patients need wherever in Australia they and the communities they serve are located.

More than one-quarter of all Australian pharmacies are located further than 100 kilometres from the nearest capital city. Without the CSO, patients in remote and regional communities may not be able to access essential medicine for days or weeks, with potentially serious health consequences.

Pharmacists

Pharmacists dispense prescribed medicines to their patients. This includes the clinical interpretation and professional evaluation of a prescription, correct labelling and safe supply of a medicine according to legal and professional requirements. Pharmacists also ensure patients understand how to use their medicines for optimal health outcomes and assist in managing any identified medicine-related issues or adverse outcomes. Pharmacists must keep adequate stock of PBS medicines to ensure availability for their patients. The Australian Government reimburses the pharmacist for the cost of the medicine, as well as paying a nominal mark-up and dispensing fee. The pharmacist in turn pays the wholesaler who distributes the medicine.

Listing a medicine on the PBS

In order to be added to the PBS formulary, medicines must go through an evaluation process and be approved for listing. The assessment process for listing a new medicine on the PBS is complex and can take some time.

New medicines submitted for listing on the PBS need to be evaluated by the Pharmaceutical Benefits Advisory Committee (PBAC). The National Health Act requires that the PBAC must make a positive recommendation to list a medicine before the Minister for Health can list that medicine on the PBS. The PBAC is a statutory committee that has been in place for many decades and is an independent, expert committee appointed by the Minister.

A submission to list a new medicine on the PBS is put forward by a 'sponsor', usually the pharmaceutical company that developed the medicine, but can be others such as doctors, specialist groups or patient groups. A summary of the process is as follows:

- Cost-effectiveness data is submitted by the applicant for assessment by a PBAC evaluator (a specialist in health technology assessment)
- PBAC evaluator prepares a first evaluation report
- The first evaluation report is reviewed by relevant PBAC sub-committees, including the Drug Utilisation Sub-Committee (DUSC) and the Economics Sub-Committee (ESC)
- Applicants are provided an opportunity to respond in writing to any issues identified by the PBAC evaluator, DUSC or ESC
- PBAC reviews all the information so far obtained and evaluates the evidence for listing
- If satisfied, PBAC makes a recommendation to the Minister for Health to list the medicine
- The sponsor negotiates pricing arrangements with the Department of Health
- Pricing arrangements are reviewed by the Pharmaceutical Benefits Pricing Authority (PBPA), a non-statutory committee comprising members appointed by the Minister for Health
- A final recommendation is made to the Minister for Health
- The Minister takes the recommendation for PBS listing to Federal Cabinet for approval, when that listing is expected to cost more than \$20 million in any one of the four years of the forward estimates period. This threshold was recently raised from the previous \$10 million anticipated cost in any year.

The time that this process takes varies over time, and depends on the category of medicine seeking listing. For example, the average time from TGA approval to final PBS listing for some forms of cancer medicines has markedly increased from 15 months to 31 months, over the past 10 years.⁶

There is often a lag between the time a medicine is first launched on the world market and when this medicine is finally listed on the PBS in Australia. A 2009 study found that since 1995 the median number of months from when a medicine was first launched on the market in the US to when it was subsidised on Australia's PBS was somewhere between 20 and 30 months, or between 1.5 and 2.5 years. Since 2006, however, this time had been increasing and by 2008 the median time between first launching a new medicines in the US and being finally subsidised in Australia was 43.9 months, or over 3.5 years.

6 Deloitte Access Economics. Access to Cancer Medicines in Australia, July 2013, page 55

Listing new brands on the PBS

When a medicine loses patent protection, other companies may bring new brands of the medicine to the market. These medicines are known as generic medicines. Generic medicines deliver the same effect in the body and deliver the same health benefit as the original brand. Generic medicines must also meet the same strict government regulatory standards as the original product.

Changes to the prices of PBS medicines can only occur at the beginning of April, August or December.⁷ Any new listing or change to an existing listing that results in a price change can only occur at these times. Applications for new brands that do not lead to a price change can be made at any time and listing occurs approximately ten weeks after the relevant deadline.

What do consumers pay?

While the Australian Government contributes the bulk of the cost of the scheme, consumers also make a contribution to the PBS. As at 1 January 2014, consumers pay a PBS co-payment of up to \$36.90 for a prescribed medicine, with the government paying for any additional cost over that. If the consumer holds a valid concession card, the co-payment is \$6.⁸ To be eligible for a concessional co-payment, a consumer needs to hold one of a Concessional Pensioner Card, a Commonwealth Seniors Health Card, a Health Care Card, or a Department of Veterans Affairs White, Gold or Orange Card. Co-payments are indexed annually with inflation, rising on 1 January each year.

In the case where a medicine has multiple brands, for example, where the patent on a medicine has expired and multiple companies are supplying the same medicine to the PBS, the PBS only reimburses an amount up to the lowest priced brand of that medicine. If a consumer chooses a brand that is priced higher than the lowest priced brand, the consumer pays the difference between the base level price and the higher price in what is called a 'brand premium'.

Consumers with chronic health conditions requiring a lot of medicines are protected by a PBS safety net system. Once a consumer reaches a certain level of expenditure on PBS medicines within a calendar year, they pay a lower co-payment. The general co-payment drops from \$36.90 per prescription to the concessional rate of \$6 for the remainder of the year. For concession card holders, once the safety net is reached, they no longer have to pay a co-payment for the remainder of the year. The safety nets for both general and concessional consumers re-commence at the beginning of the calendar year.

⁷ If a Bill to amend the National Health Act 1953 is passed by Parliament, from 1 October 2014 'simplified price disclosure' related reductions will occur on 1 April and 1 October each year with the possibility of 1 August and 1 December as further reduction days.

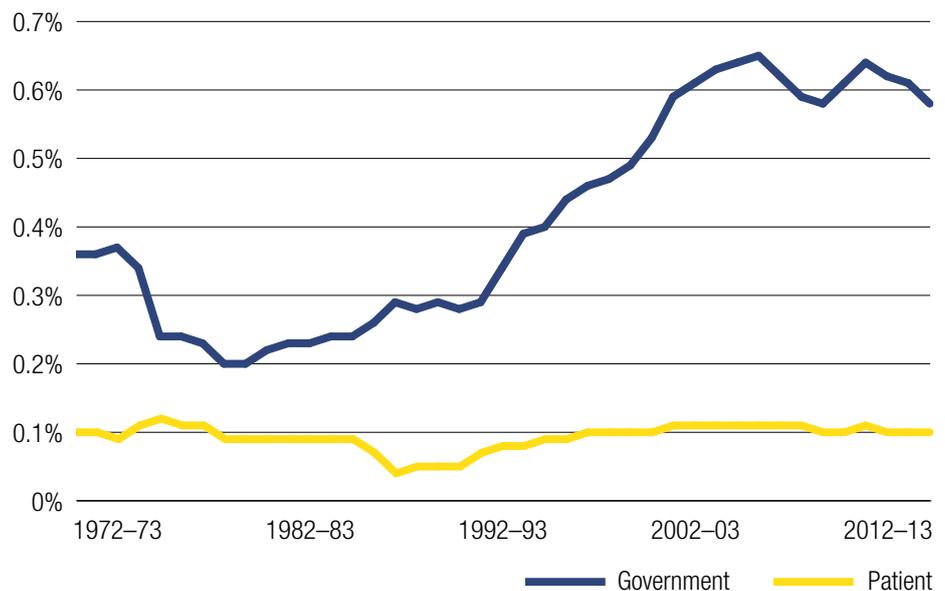
⁸ <http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>

How has the PBS changed over time?

Since its introduction over 60 years ago, the PBS has evolved as the size of the population has grown, the population has aged, medical technology has improved, and the range of therapies to treat or prevent health conditions has grown. This has generally led to an increase in the cost of the scheme over that time as well as an increase in the range of medicines the PBS subsidises. Notably, for the 2012–13 financial year, the cost of the PBS dropped by 3.49% to \$9.832 billion, due to a series of policy changes to put the Scheme on a more sustainable footing.⁹ These changes are detailed below.

The Australian Government funds the vast majority of the cost of the scheme (Figure 1), with the cost increasing to 0.65 per cent of GDP by 2003–04. The cost as a proportion of GDP then stabilised around that level, and is now forecast to drop over the forward estimates.¹⁰ In fact, since 2009–10, the PBS as a share of GDP has actually been falling. Moreover, the patient contribution to the cost of the scheme has remained relatively constant over the period since the early 1970s with increases in costs largely borne by the government.

Figure 1: PBS spending as a share of GDP



Source: Department of Health and Ageing, Prescriptions and expenditure twelve months to 30 June 2013, <http://www.pbs.gov.au/statistics/2012-2013-files/expenditure-and-prescriptions-12-months-to-30-06-2013.pdf>; ABS cat. 5206.0, Australia's National Accounts: National Income, Expenditure and Product, <http://www.abs.gov.au/AusStats/ABS@.nsf/MF/5206.0>.

⁹ 20102–13 Final Budget Outcome. www.budget.gov.au/2012-13

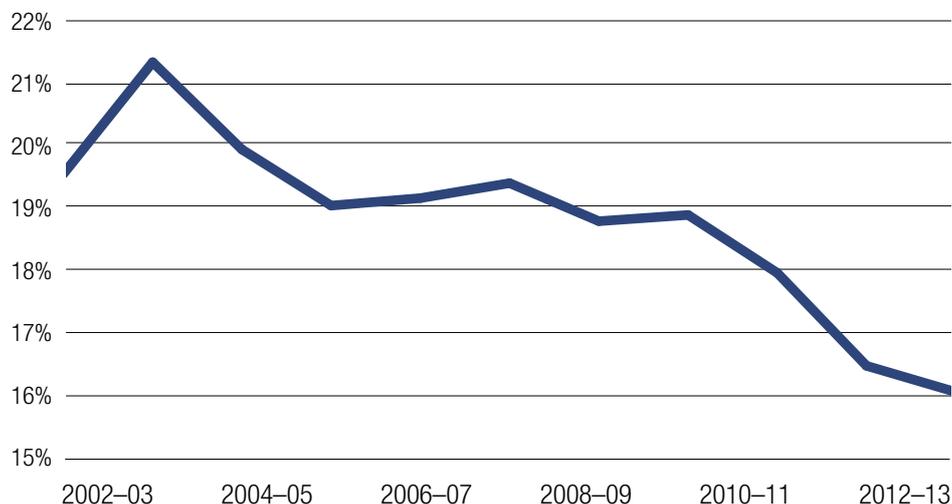
¹⁰ Analysis of 2011, 2012, 2013 Federal Budgets by Medicines Partnership of Australia, 17 May 2013. <http://medicinespartnership.com.au/category/pbs-scorecards>

¹¹ Parliamentary Budget Office, Australian Government spending, Part 1: Historical trends from 2002–03 to 2012–13, page 73

Similarly, since 2003–04 the cost of the PBS has fallen as a share of the Australian Government's total health budget (Figure 2). The relative stabilisation in growth over the last decade or so, together with larger increases in other areas of health spending such as hospitals, medical procedures and private health insurance, has meant that the PBS has become a smaller part of the total government's health spending. Today it accounts for 16 per cent of total Australian Government health spending, having fallen from 21.3 per cent in 2003–04.¹¹



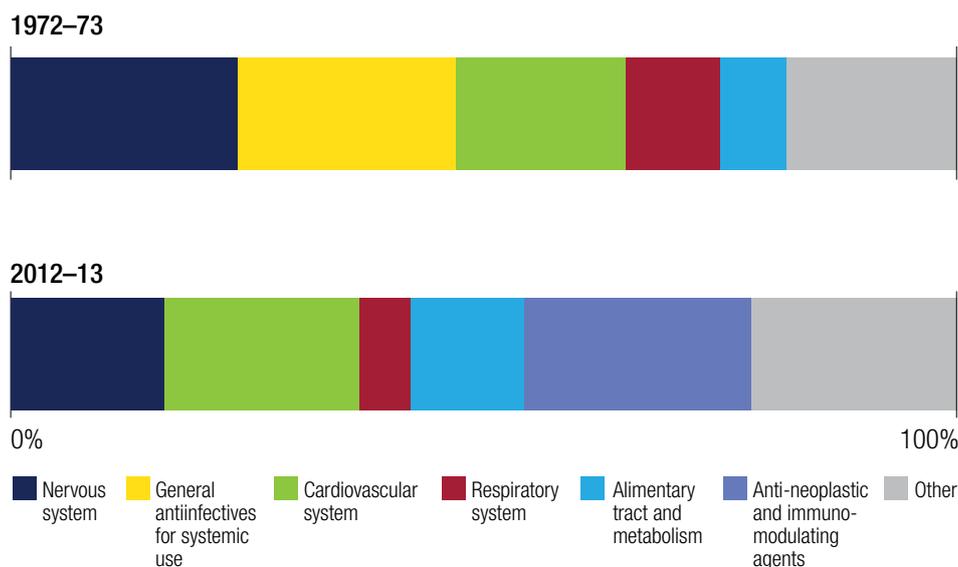
Figure 2: PBS as a share of total Commonwealth health funding



Source: Final Budget Outcomes Appendix A: Expenses by Function and Sub Function 2008-09, 2009-10, 2010-11, 2011-12, 2012-13.

The growing scale and cost of the PBS over the last 40 years has been driven in part by a growth in the range and convenience of prescription medicines available on the PBS. One of the major reasons the PBS costs more today is because there are many more medicines to treat a lot more health conditions. As an example, anti-neoplastic and immuno-modulating agents accounted for 24% of the total PBS cost in 2012-13 as compared to nil in 1971 (Figure 3).

Figure 3: PBS expenditure by therapeutic area, 1971 vs 2012-13



Source: Commonwealth Dept of Health, Annual report 1970-71, Pharmaceutical benefits, Drugs dispensed by chemist, table 46; Note: Figures for 1971 are financial year 1970-71. Therapeutic categories and their contributions to total Pharmaceutical benefits in 1970-71 were converted to ATC classification to enable comparison. Figures do not include public S100 medicines. Source Medicare Australia: Statistics, Pharmaceuticals Benefits Scheduled Groups Report. Note Figures are derived from July 2011 until June 2013.

Policy changes

Policy affecting the PBS, whether pricing policy affecting manufacturers, pharmacy and wholesaler remuneration, or co-payment policy affecting consumers, has also changed dramatically since the scheme's inception. Various policies to control the cost of the PBS have been introduced, such as referencing different medicines to the same price in a 'therapeutic group', brand premium policy, the use of cost-effectiveness for evaluating the listing of new medicines, mandatory price reductions upon patent expiry, the differential pricing of single- and multiple-brand medicines to allow the Australian Government to extract savings from competition in the off-patent market, and perhaps most significantly, the introduction of mandatory price disclosure.

Price disclosure

The aim of price disclosure is to ensure that Australian taxpayers benefit from discounts and incentives provided by manufacturers for medicines where there is more than one brand on the PBS. Once patent protection for an older medicine is lost, it can be sold under a number of brand names. Manufacturers may sell these new brands at prices lower than the Australian Government approved price to compete for market share. Over time, price disclosure brings the government price in line with the market price, benefiting taxpayers and consumers.

The introduction of price disclosure in 2007, followed by Expanded and Accelerated Price Disclosure in 2010, has created forecast savings of \$17.85 billion by 2017–18.¹² These figures do not include the estimated \$853 million in further savings over the forward estimates generated by a 'simplified price disclosure' process, announced in 2013 and currently in legislation before Parliament.

Community Pharmacy Agreements

Since 1990, the Australian Government and the Pharmacy Guild of Australia have entered into a series of agreements which set out the remuneration that pharmacists receive for dispensing PBS medicines and the arrangements regulating the location of pharmacies approved to supply PBS medicines. Over time these agreements have increased in scope to provide for professional pharmacy programs and services.

The Fourth Community Pharmacy Agreement (2005) announced the introduction of the Community Service Obligation to ensure timely, affordable and secure delivery of PBS medicines to community pharmacies across Australia. The Fifth Community Pharmacy Agreement commenced on 1 July 2010 and recognises the key role played by community pharmacy in primary healthcare through the delivery of the PBS and related services.¹³

Medicines Australia memorandum of understanding

More recently, the enhanced, predictable medicines industry pricing arrangements and process improvements have been framed under a memorandum of understanding (MOU) between Medicines Australia and the Australian Government.¹⁴ The MOU came into effect on 1 December 2010 and will be in effect until 30 June 2014. In exchange for further savings through price disclosure, the Australian Government agreed to process improvements such a six-month time limit between medicine pricing agreement and government consideration to list the medicine.

¹² Centre for Strategic Economic Studies, Impact of Further PBS Reform, May 2013, page 1

¹³ www.5cpa.com.au

¹⁴ <http://www.pbs.gov.au/info/industry/useful-resources/memorandum>

Patient co-payments

The co-payments that patients pay as part of the PBS have changed over time as well. Originally the scheme did not have any co-payments for patients. In 1960 the first co-payments were introduced costing 50 cents, but pensioners and concession card holders were exempt. In 1983 a \$2 co-payment was introduced for concession card holders excluding pensioners, then pensioners were included in the concession card co-payment in 1990. Since that time co-payments have generally increased with inflation. However, there have been instances where PBS co-payments have increased above the rate of inflation as a result of specific government policy decisions.

Cabinet threshold

Most recently, the Australian Government has increased the threshold at which federal Cabinet is required to approve the listing of a new medicine on the PBS. Since 2001, any medicine that cost more than \$10 million in any one of the next four years had to go to Cabinet for approval, with anything below that level able to be approved by the Minister for Health. In recent years, there has been variation around this with, at times, all medicines needing to be approved by Cabinet. The Abbott Government recently announced that it would increase the Cabinet threshold to \$20 million. This means that now any medicine costing more than \$20 million a year in any of the next four years requires Cabinet approval.



Future issues for the PBS

The PBS will continue to adapt to changing social, technological, economic and policy circumstances.

There are several key policy issues currently affecting the PBS, but the most immediately pressing is the ongoing need to balance financial sustainability with continuing to provide Australians affordable access to the latest and most effective prescription medicines. Often this debate is coloured by an overriding concern about the cost of the scheme, with less attention paid to the health, social, economic and productivity benefits the scheme has achieved. For example, it is likely that increased spending on the PBS over the years has delivered savings to other parts of the health system, such as hospital costs.

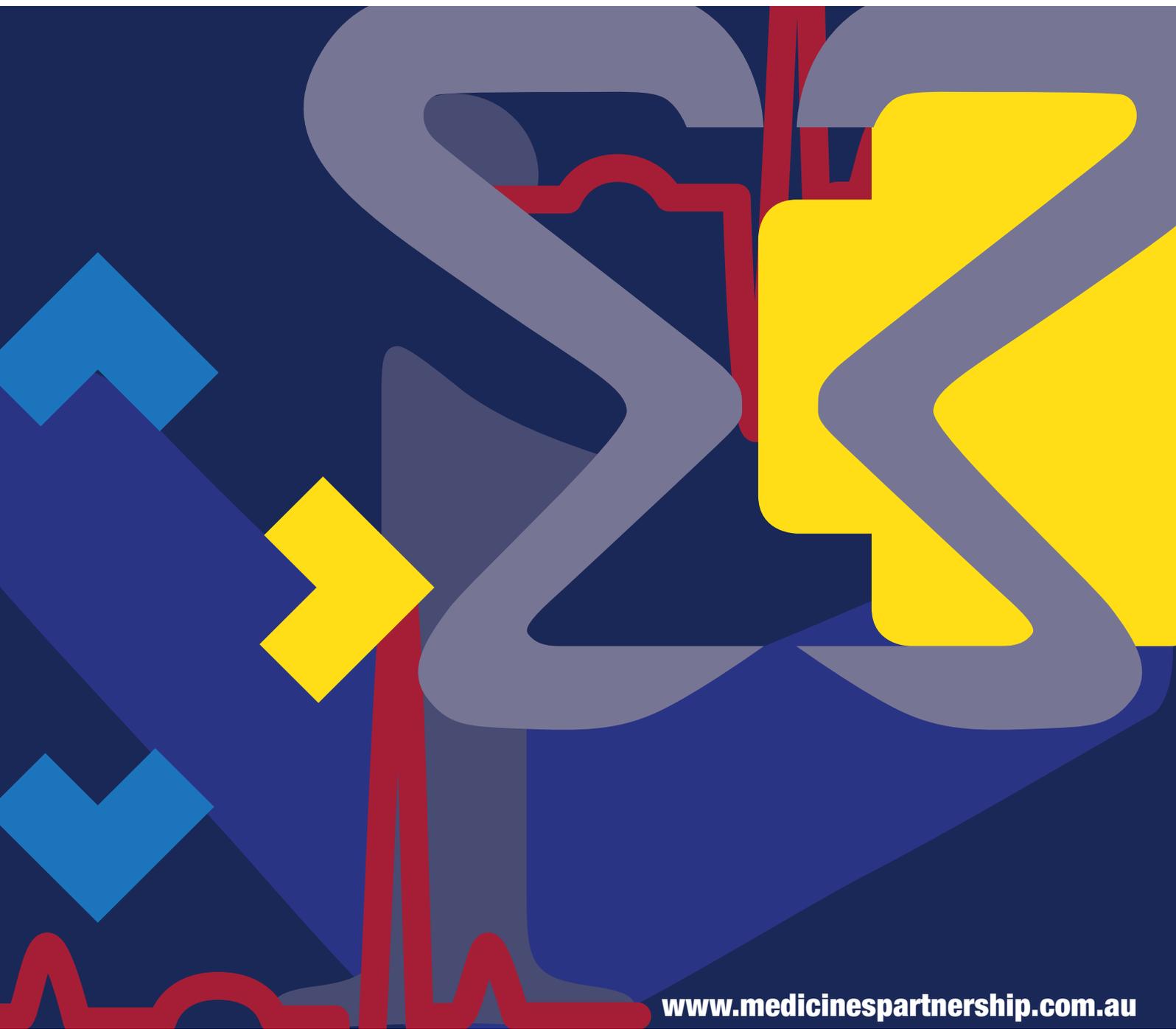
One of the important tasks in the future will be to recognise the benefits of the PBS in the face of ongoing pressures to curtail expenditure. While in the short term such cutbacks might make direct cost savings, the long term impact of excessive cut backs could result in higher costs elsewhere in the health system, reductions and delays for Australians in accessing treatments, poorer health outcomes and an increasingly unviable Australian medicines industry.

Policy will evolve to deal with issues like pricing, coverage, predictability, sustainability, efficiency of processes and dealing with new technologies such as co-dependent technologies (e.g. medicine-device combinations), biologic medicines which provide new treatments in new areas, and the increasing use of targeted therapies which target particular treatments to particular patients.

There is also the issue of ensuring predictable policy for all the stakeholders in the PBS system to avoid unintended consequences that could ultimately adversely affect the community. Examples like the Community Pharmacy Agreements and the Medicines Australia–Australian Government MOU show how constructive policy dialogue between stakeholders and government can deliver a robust and effective PBS now and into the future.

More information

- www.pbs.gov.au
- www.health.gov.au
- www.5cpa.com.au
- www.gmia.com.au
- www.medicinesaustralia.com.au



www.medicinespartnership.com.au