The Pharmaceutical Benefits Scheme: a quick guide

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Summary
This quick guide provides an introduction to the Pharmaceutical Benefits Scheme (PBS), the Australian Government program which subsidises the cost of medicines. The quick guide briefly introduces and provides links to further information on the PBS. It highlights the cost of the PBS to the Australian Government, the price of medicines for patients, medicines available on the PBS and the approval process that pharmaceutical companies undertake to have their medicines subsidised. It also outlines agreements between the Australian Government and external stakeholders that are relevant to the PBS, and suggests some possible future developments.

Introduction
The Australian Government subsidises the cost of many medicines for Australians through the Pharmaceutical Benefits Scheme (PBS). The first attempt to legislate for a scheme to provide approved prescription medicines, such as antibiotics, free of charge to Australian residents was made by the Curtin Labor Government in 1944 but the legislation was struck down by the High Court. A limited version of the PBS began in 1948, offering free medicines for pensioners and 139 ‘life saving and disease preventing’ medicines free of charge to the general public. The PBS became a comprehensive scheme offering access to a wide range of medicines in 1960.

The PBS is now regarded as a key component of the National Medicines Policy (NMP) which ‘aims to improve positive health outcomes for all Australians through their access to and wise use of medicines’. The PBS is established under the National Health Act 1953 (the NHA).

According to the 2014–15 Department of Health (DoH) Annual Report, the PBS cost the Australian Government $9.1 billion in 2014–15 with more than 211 million prescriptions subsidised (p. 49). This represents 21 per cent of the $43.3 billion in funds administered by the DoH in 2014–15. (p. 14). By way of comparison, medical services (including Medicare benefits) accounted for 47 per cent of the administered funds, and private health insurance rebates for 13 per cent.

Expenditure on the PBS is uncapped, and can therefore increase as new drugs are added and demand grows. Total PBS expenditure grew at an average annual rate of 4.9 per cent from 2005–06 to 2013–14, although growth was slower towards the end of this period, and PBS expenditure actually contracted by 2.2 per cent in 2012–13. More recently, PBS expenditure fell slightly from $9.15 billion in 2013–14 (p. 55) to $9.1 billion in 2014–15 (p.49).

Parliamentary Budget Office analysis shows that although moderate growth in PBS spending to 2018–19 was forecast in the 2015–16 Budget, this was subsequently revised downwards to a relatively flat level of spending (Figure 37, p. 20). This downwards revision is due to the 2015 PBS Access and Sustainability Package of reforms, which is lowering the price the Government pays for many medicines. It also reflects the ongoing impact of price...
disclosure policies, which are designed to move the PBS price paid by the Government closer to the market price of off-patent medicines (which may be heavily discounted).

**Consumer co-payments and safety nets**

Patients pay a co-payment towards the cost of each PBS medicine, with the Australian Government covering the remaining cost, which can vary from nil to thousands of dollars per prescription. This keeps otherwise expensive medicines affordable for consumers. Patient co-payments are currently set at $6.20 for concession card holders and up to $38.30 for those ineligible for a concession (known as general patients).

The PBS Safety Net scheme is intended to protect patients needing a large number of medicines in one year from excessive out-of-pocket costs. Individuals and families who spend an amount equal to their Safety Net threshold on co-payments in a calendar year receive further prescriptions for that year for free (concession card holders) or for the concessional co-payment of $6.20 (general patients). The 2016 thresholds are $372.00 for concession card holders and $1,457.70 for general patients.

Since 1 January 2016, pharmacists have been permitted to offer consumers a discount of up to $1 on each PBS co-payment, as long as the pharmacist absorbs the cost of the discount.

Under section 99G of the NHA, co-payments and Safety Net thresholds are adjusted in line with the Consumer Price Index (CPI) on 1 January each year. The PBS website provides a table outlining the history of PBS co-payments and Safety Net thresholds since 1960. The National Health Amendment (Pharmaceutical Benefits) Bill 2014 proposes to further increase co-payments and Safety Net thresholds. This Bill has been before the Senate since July 2014, but appears unlikely to pass.

**What medicines are subsidised under the PBS?**

According to the 2014–15 DoH Annual Report, as at June 2015, the PBS included 793 medicines in 2,066 forms and dosages, sold as more than 5,300 differently branded items (p.49).

Medicines that are subsidised under the PBS are listed on the Schedule of Pharmaceutical Benefits (the Schedule). The Schedule can be downloaded, browsed or searched via the ‘PBS Medicine Search’ box on the PBS website. Changes to the Schedule are made every month by amendment to the National Health (Listing of Pharmaceutical Benefits) Instrument 2012, which is made under the NHA.

**General Medicines**

Most PBS medicines are dispensed by community pharmacies and used by patients at home. These are known as ‘General Schedule’ or ‘section 85’ medicines because they are dispensed under section 85 of the NHA.

**Veterans’ Medicines**

Eligible veterans receive subsidised medicines through the Repatriation Pharmaceutical Benefits Scheme (RPBS), which is administered by the Department of Veterans’ Affairs (DVA) under the Veterans’ Entitlements Act 1986. This includes medicines listed on the PBS, as well as additional items such as wound care products which are listed on the Repatriation Schedule of Pharmaceutical Benefits.

According to the 2014–15 DVA Annual Report, expenditure under the RPBS was $355.3 million in 2014–15 (p. 79).

**Medicines with special arrangements**

Under section 100 of the NHA some PBS medicines are supplied through special arrangements where normal supply through community pharmacies is not suitable. For example, some medicines may require special storage or dispensing, specialist monitoring during treatment, or administration in a hospital outpatient setting. Such medicines are subsidised on the PBS under a number of ‘Section 100’ programs, including:

- the Highly Specialised Drugs Program for PBS medicines which must be prescribed by or under the guidance of a treating specialist, and dispensed by a hospital pharmacy (with some exceptions)

- Efficient Funding of Chemotherapy arrangements for PBS cancer medicines that are administered through infusion or injection

- programs for PBS subsidised supply of Botulinum Toxin, Human Growth Hormone and In Vitro Fertilisation (IVF) medicines and
• the Opiate Dependence Treatment Program which funds the cost of methadone and other medicines for the treatment of opioid addiction.

In addition to the above programs for specific medicines, section 100 also allows for the supply of many PBS medicines to remote area Aboriginal Health Services (AHSs). Under these arrangements, clients of approved AHSs can receive medicines free of charge directly from the AHS, without the need for a normal PBS prescription form.

Statistics on PBS medicines

PBS statistics are available in a number of forms. The annual PBS Expenditure and Prescriptions reports are particularly useful as they include information on the most frequently prescribed medicines and the highest cost medicines. These reports focus mainly on general (section 85) medicines, but also include some statistics on RPBS and section 100 medicines.

Statistics on the number of prescriptions and cost of subsidies paid for individual PBS and RPBS medicines are available via PBS Item Reports on the Department of Human Services website. The item number(s) or codes for an individual medicine can be located by entering the name of the medicine in ‘PBS Medicine Search’ box on the PBS website. The relevant item number(s) can then be entered into the ‘item numbers’ box on the PBS Item Reports to generate a custom report on the number or cost of PBS prescriptions dispensed in the selected timeframe. Caution should be used when generating these reports as the same medicine may have more than one item number, and item numbers can change over time.

Life saving drugs supplied outside the PBS

The Australian Government provides subsidised access, outside of the PBS, to ten expensive ‘life saving drugs’ for very rare conditions through the Life Saving Drugs Programme (LSDP). In 2014–15, 278 patients received free drugs under the LSDP (p. 52).

The listing process for PBS medicines

Therapeutic Good Administration (TGA) approval process

Before a medicine can be listed on the PBS, it must first be approved for use in Australia by the Therapeutic Goods Administration (TGA). The sponsor of the medicine, usually a pharmaceutical company, applies to the TGA to have the medicine entered in the Australian Register of Therapeutic Goods (ARTG) so that it can be sold in Australia. The sponsor must provide evidence (such as from clinical trials) that the medicine meets the required standards of quality, safety and effectiveness for the intended use.

Pharmaceutical Benefits Scheme (PBS) approval process

A medicine that is listed on the ARTG can be marketed in Australia. However, the medicine will not attract an Australian Government subsidy unless the sponsor is also successful in listing the medicine on the PBS. Without the subsidy, patients have to pay the full cost of the medicine.

Applications for PBS listing are considered by the Pharmaceutical Benefits Advisory Committee (PBAC), which is an independent expert body appointed by the Australian Government. A new medicine cannot be listed on the PBS unless the PBAC makes a positive recommendation for its listing. Under section 101 of the NHA, the PBAC must take into account both the cost and clinical effectiveness of the medicine when compared with other treatments for the same condition.

The PBAC Guidelines set out in detail the information that the sponsor needs to include in their application. This includes information about the new medicine and the medicine or treatment it is being compared to, evidence from clinical trials, an economic evaluation and an estimate of the impact on the Budget. A review of the PBAC Guidelines is currently underway, with an expected completion date of August 2016.

The PBAC has 17 weeks to assess and decide on the application, based on the cost-effectiveness or ‘value for money’ of the new medicine when compared to existing treatments. The PBAC uses a Health Technology Assessment (HTA) methodology to evaluate applications. The HTA methodology allows the PBAC to assess new medicines against existing treatments in order to ensure the medicines subsidised on the PBS achieve the greatest health improvement at the lowest cost. The PBAC can consider other factors in addition to cost-effectiveness, for example whether the new medicine is less toxic than existing treatments, or fills a treatment gap for a particular medical condition.
Consideration of a new medicine by the PBAC can result in one of three outcomes: a recommendation to Government that the medicine be listed on the PBS, a decision not to recommend listing on the PBS, or the deferral of a decision pending additional information. Since 2005, the PBAC has published Public Summary Documents giving reasons for its decision on each medicine considered for listing.

If a medicine does not receive a positive recommendation from the PBAC, the sponsor may prepare and resubmit a new application for PBS listing, or they may choose not to reapply and only to sell the medicine in Australia via private prescription.

If a positive recommendation is given by the PBAC, the sponsor must still negotiate the final arrangements for listing on the PBS, including pricing with the DoH. Final approval can be granted by the Minister for Health, unless the net cost of the medicine to the PBS is more than $20 million per year, in which case Cabinet approval is required for PBS listing.

The PBAC regularly reviews the list of PBS items, and can recommend that a medicine be removed from the Schedule if there are safety or efficacy concerns, or if better medicines have become available. Medicines may also be removed from the Schedule as a result of changes in Government policy, or at the request of the sponsor.

**Agreements**

The Australian Government maintains agreements with external stakeholders who have a direct interest in the operation of the PBS.

**Community Pharmacy Agreements**

Pharmacists need approval under the NHA to dispense PBS medicines from a particular pharmacy. The pharmacist charges the patient the relevant co-payment, and claims the remainder of the PBS-dispensed price for the medicine from the Australian Government. The PBS-dispensed price is made up of the cost of the medicine to the pharmacist, plus handling, dispensing and other fees.

These remuneration arrangements for pharmacists are agreed between the Australian Government and the Pharmacy Guild of Australia, the national peak body representing community pharmacies, and are set out in a succession of five year agreements. The most recent agreement, the Sixth Community Pharmacy Agreement (6CPA), commenced on 1 July 2015. In addition to pharmacist remuneration and wholesaler payments, the 6CPA also encompasses funding for community pharmacy programmes, Pharmacy Location Rules which regulate where approved pharmacies can operate, a review of pharmacy remuneration and regulation, and other matters.

**Pharmaceutical Industry agreements**

PBS policy and price settings have a significant impact on pharmaceutical companies, who in turn lobby and negotiate with the Government, in particular through their peak representative bodies.

**Medicines Australia** (MA) represents the innovative (patented) medicines industry. In 2010, MA entered into a Memorandum of Understanding (MoU) with the Government agreeing the direction of PBS reforms over 4 years. However, MA and the Government could not reach agreement regarding the 2015 round of reforms.

The **Generic and Biosimilar Medicines Association** (GMBA) represents generic and biosimilar (off patent) medicine suppliers in Australia. In 2015, GMBA signed its first Strategic Agreement with the Government (under its previous name of the Generic Medicines Industry Association), containing measures to promote the increased usage of cheaper generic and biosimilar medicines on the PBS. The Strategic Agreement acknowledges that such medicines increase price competition leading to significant savings for the Government.

**Future developments**

It is likely the Government will continue to seek savings from existing PBS listed medicines, through further price reforms or higher patient co-payments, or both, in order to accommodate future PBS listings. Competition in the pharmacy and pharmaceutical sectors may also come under renewed scrutiny, driven by factors such as the review of pharmacy regulation and the emergence of cheaper biosimilar alternatives to expensive medicines. The PBAC guidelines review is likely to stimulate the ongoing debate about how best to ensure the timely and cost effective listing of new medicines on the PBS.