

10. Market Access in Australia

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10.1 Background

Australia became an independent nation on 1 January 1901, when the British Parliament allowed the six Australian colonies to govern in their own right as part of the Commonwealth of Australia. The Commonwealth of Australia was established as a constitutional monarchy, because it was established with a written constitution and because the head of state was Queen Victoria. The national language is English, but the most common other languages are Mandarin, Italian, Arabic, Cantonese, and Greek. The Australian estimated resident population in 2016 was 24.7 million, spread over 7,741,000 sq. km. Australia is divided into six states and two territories (Figure 1), the most populous states being New South Wales and Victoria.



Figure 1. Australian Administrative Division

The World Bank national account data indicated that Australia's is the world's thirteenth largest economy. In 2016 the Gross Domestic Product (GDP) was worth 1,129 trillion US dollars Purchasing Power Parity (PPP) while the GDP per capita was last recorded at 46,789 US dollars (PPP). This prosperity translates into a higher life expectancy, lower mortality, and better quality of life. Life expectancy has been continually increasing in Australia, as in other OECD (Organization for Economic Co-operation and Development) countries.

In 2014 the average life expectancy was 82.4. The average life expectancy for females increased from 73.9 years in 1960 to 84.4 in 2014. For males, it increased from 67.9 years to 80.3. Between 1970 and 2014, the percentage of Australians aged 65 and over increased from around 8.3% to around 14.7%.

However, as in other countries, the extent of the national health spending in Australia is determined by several factors, such as the structure of the healthcare system, the aging of the population, changing diseases, healthcare demand, macroeconomic level, etc. In nearly all the OECD countries, the public sector is the main source of healthcare financing, representing 72.9% of the total health expenditure. However, Australia shows a lower average share of public spending of the GDP (69.2% in 2015). In addition, Australia's per capita health spending was 4,420 US dollars (PPP) in 2015, and healthcare cost amounted to 9.3% of GDP, quite similar to the OECD average of 9% of GDP.

In terms of burden of disease, as in the other developing countries, chronic diseases such as cardiovascular diseases, cancers, COPD, and diabetes, are the leading cause of illness, disability, and death. In Australia in 2013 they accounted for 90% of all deaths. The disease groups contributing the most to the burden were cancer (19%), cardiovascular diseases (15%), mental disorders and drug abuse (12%), musculoskeletal conditions (12%) and injuries (9%). Together, they accounted for around two-thirds of the disease burden.

Due to the increasing prevalence of such non-communicable diseases (NCDs) after inpatient and outpatient care, the pharmaceutical expenditure represents the most important healthcare expenditure item in Australia.

Although the spending on pharmaceuticals is slightly lower than in some OECD countries, such as Germany, Switzerland, Canada, and Japan, the per capita pharmaceutical bill in Australia was around 656 US dollars (PPP) in 2015. In addition, the share of Over-the-Counter (OTC) drugs is relatively high, accounting for half of the pharmaceutical spending.

10.2 The Healthcare System

Compared with other countries, the Australian healthcare system is considered sufficient to bring full coverage and optimal outcomes for the whole population in terms of life expectancy, infant mortality and better life (according to the OECD Better Life Index).

As in other developed countries, the purchasers of healthcare services are separated from the providers. Such a structure led to expectations which increase the effective use of healthcare services through the competition among providers, but also reinforce primary care and the development of health outcomes.

Historically, until the middle of the twentieth century, individuals had to pay for their own healthcare, or take out an insurance. Private practitioners and hospitals provided health services, and some degree of free treatment was provided by the public hospitals handled by the States and by charitable institutions.

From the late nineteenth century to the mid-1940s, the friendly society movement was a driving force behind the healthcare system, offering members a range of benefits, including unemployment benefits and sick pay; furthermore, it purchased medical services from doctors on behalf of its members. Box 1 shows the major healthcare reforms and policy measures since 1946 (Box 1).

Currently the Australian healthcare system is based on an universal health coverage. The financing and delivering of the system are funded mainly by taxes, with the support of statutory insurance levy and private healthcare expenditures. In Australia, the Australian Government (or Commonwealth), and the state and territory governments are responsible for the provision and funding of healthcare services, as well as population health programs, community health services, health and medical research, and Aboriginal and Torres Strait Islander health services (Figure 2).

Box 1. Major healthcare reforms and policy measures in Australia [Healy, 2006]

- 1946: Hospital Benefits Act (Commonwealth subsidies for State-run public hospitals)
- 1950: Pharmaceutical Benefits Act (Commonwealth subsidies for pharmaceuticals)
- 1953: National Health Act (Commonwealth subsidies for medical services)
- 1975-1984: Health Legislation Amendment Act 1983 (Introduction of universal health insurance)
- 1985: Home and Community Care Act
- 1986: Disability Services Act
- 1989: Therapeutic Goods Act
- 1990s: Pay-for-performance element in primary care payments
- 1994: Health Legislation Amendment Act
- 1996: Medicare provider number legislation (Section 19AA of the Health Insurance Act 1973)
- 1997: Aged Care Act
- 1997: Private Health Insurance Incentives Act
- 1999: Introduction of the private health insurance rebate, and Lifetime Health Cover 2000
- 2004: Medicare Plus funding changes and safety net provisions for out-of-pocket

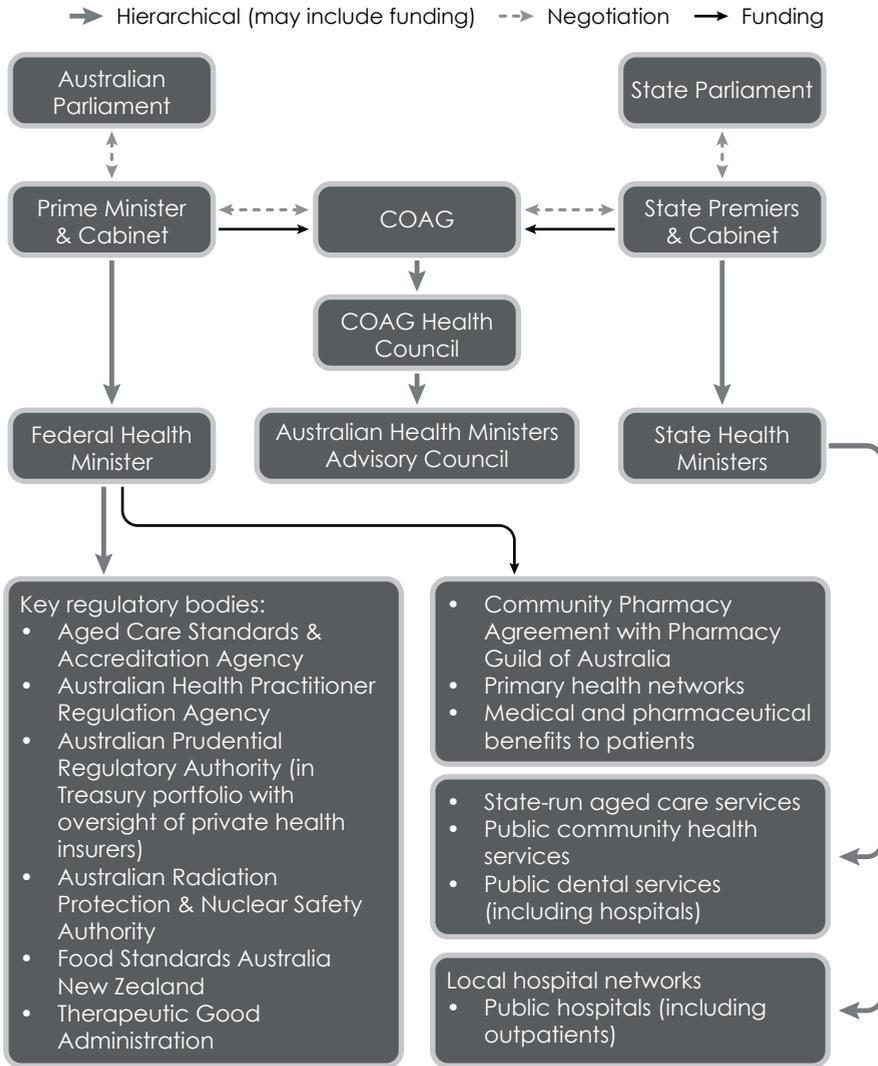


Figure 2. Organization of the healthcare system in Australia. Modified from [Mossialos, 2016]

COAG = Council of Australian Governments

The Australian Government funds three major schemes: Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS) and the private health insurance rebate. In addition, community (non-hospital) services are directly funded by the Australian Government on a fee-for-service basis. State and territory governments are responsible for

public hospital services (largely funded by the Australian government under a federal/state cost-sharing arrangement), community health services, and mental healthcare.

Australian taxpayers pay 2% of their income as Medicare levy. If their income exceeds AUS\$ 90,000 per year, and they do not have a private health insurance, there is an additional Medicare Levy Surcharge (MLS) of 1 to 1.5%. Therefore, a large proportion of the population takes out optional private health insurance for hospital and some ancillary services. MLS is designed to encourage individuals to take out private hospital cover and, where possible, to use the private hospital system to reduce the demand on the public Medicare system. To make the private health insurance more affordable, the Australian Government offers rebates for private health insurance premiums. Private Health Insurance provides access to the private hospital system or to the doctor of choice within public hospitals.

The Australian Government spends a relatively large amount on medical services provided by general practitioners (un-referred) and specialists (referred), and benefit-paid medications, with the balance coming from the non-government sector. On the other hand, community health services are funded by the state and territory governments, which share most of the expenditure on public hospital services, while non-government sources account for large portions of the expenditure on dental services, private hospitals, aids and appliances, all other medications (medications for which no government benefit has been paid) and other health practitioners' services.

Australia's 2016 health report shows that, during 2013-2014, the Australian Government and state and territory governments paid, respectively, 41% and 27% of the total healthcare expenditure. The remaining was shared among individuals, through out-of-pocket expenses (18%), private health insurers (8.1%) and through accident compensation schemes (5.9%). The contribution from the Australian Government, state and territory governments and the non-government sector varies, depending on the types of health goods and services being provided.

Despite the fact that both Australian Government and state and territory governments contribute much to the healthcare service, private health insurance is considered a parallel financing mechanism and therefore it is an important part of the Australian healthcare system. There are two types of private health insurance in Australia: hospital policies, that covers hospital expenses, and general treatment (also known as ancillary or extras cover), that covers dental, physiotherapy or ophthalmic treatments. They can be obtained separately or in combination.

According to a recent report of the Australian Prudential Regulation Authority, although private health insurance is optional, in 2017 55% of the population had general treatment cover, while about 46% had hospital treatment cover by private health insurances. Due to the popularity of the private health insurance, over the years the non-government expenditure including private health expenditure has been increasing.

In 2014-15, the share of private health insurance funds provided 8.7% of total expenditure. Between 2004-2014 private healthcare spending increased by 7.5%, while public health spending grew a little faster than the private (7.8%). These funds originate both from individuals who pay premiums to private health insurance funds and from subsi-

Box 2. Mechanisms for rebates on health insurance premiums

1. Insurers offer members a reduced premium and then insurers claim reimbursement from the Government.
 2. Members pay the full premium and claim the rebate through their income-tax return, at the end of the financial year.
- Both mechanisms of rebates are considered subsidies allocated by the Australian Government for the services that were partially funded through benefits paid by the health insurance funds.

dies allocated by the Australian Government. The Australian Government provides a rebate to reduce the burden of insurance costs for eligible people, and maintains the private health insurance cover (Box 2). To determine the rebate, a level income test is performed.

The Australian Government also sets the national healthcare policies. Figure 3 provides a picture of the main services, funding responsibilities and providers in Australia.

10.3 Medicare

Medicare is a universal public health insurance scheme funded by the Australian Government; it was introduced in 1984 to provide free or subsidized access to public hospital services and treatment by health professionals. The Medicare Benefits Schedule (MBS) is the list of Medicare services subsidized by the Australian Government.

The Medicare system has three parts: hospital, medical and pharmaceutical. Hospitals are an important component of the Australian healthcare system and have a significant share of healthcare expenditure. In 2016, in Australia there were 1,322 hospitals, of which 624 were private. Australian Government and the state and territory governments fund about 90% of the healthcare in public hospitals and 32% of that in private hospitals, while the remainder of the funding is provided by individuals, and the Department of Veterans' Affairs. Private hospitals are mainly funded by private health insurances and out-of-pocket payments by patients. Medicare offers fee-free treatment to a public patient in a public hospital, by a doctor appointed by the hospital, and it covers 75% of the MBS fee for the services and procedures for private patients in a public or private hospital.

10.4 Pathways of Market Access (Regulation, Pricing, and Reimbursement)

The growing demand for pharmaceuticals and medical devices in Australia resulted in an increase in the healthcare expenditure. Like other developed countries, Australia in-

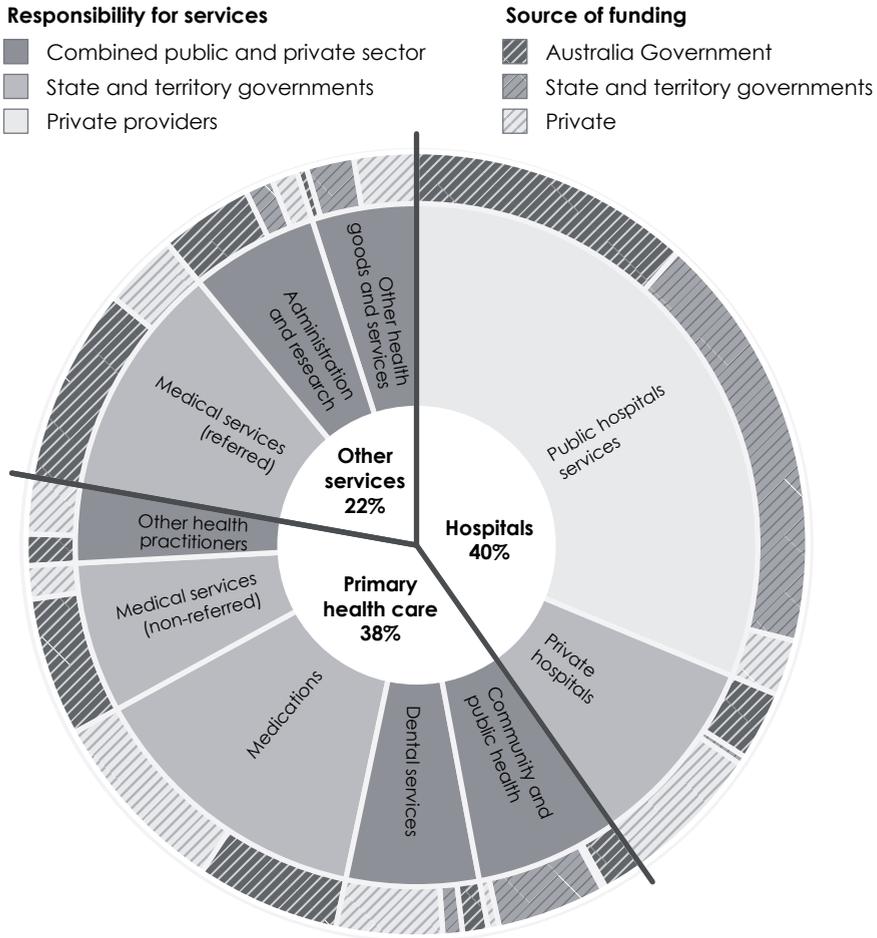


Figure 3. Health service funding and responsibilities (2013-2014). Modified from [Australia’s health series no. 15, 2016]

Note. The inner segments indicate the relative size of the expenditure in each of the three main sectors of the health system. The middle ring indicates the relative expenditure on each service in the sector, and who is responsible for providing the service. The outer ring indicates the relative amount of the funding and the funding source for the different services.

roduced price control mechanisms and pathways to manage the pharmaceutical expenditure.

The Australian regulatory framework of pharmaceuticals and medical devices mainly relies on four different agencies, that are responsible for conducting pharmaceutical regulation, pricing and reimbursement: the Therapeutic Goods Administration (TGA), the Pharmaceutical Benefits Advisory Committee (PBAC), and the Pharmaceutical Benefits

Scheme (PBS). The Australian National Medicines Policy is designed by these four agencies. Regulatory procedures have been established to ensure the quality, safety and efficacy of the therapeutic goods available in Australia. The supply of drugs is controlled through three main processes:

- Pre-market evaluation and approval of products to be supplied;
- Licensing of manufacturers;
- Post-market surveillance.

In this structure, PBS has undertaken a key role in the safe and timely access of Australians to medicines. The Australian Government funds pharmaceuticals through the PBS. Initially, the selection of the medicines to be listed within the PBS was based only on clinical needs, largely irrespectively of the cost. However, since 1988 medicines being considered for inclusion in the PBS are evaluated for comparative effectiveness and cost-effectiveness, with a mandatory economic evaluation since 1993.

Market Authorization

To be supplied in Australia, a new drug must gain an approval under the requirements of the Therapeutic Goods Act 1989, thereby proving its safety, quality, and effectiveness. Approval is also required to extend the indications of an established drug. Applications are managed by the TGA that has seven statutory expert committees it may call upon to obtain independent advice on scientific and technical matters. For prescription drugs, advice is sought from the Advisory Committee on Prescription Medicines (ACPM).

The TGA regulates therapeutic goods through pre-market assessments, post-market monitoring and enforcement of compliance with standards, and licensing of the Australian manufacturers and the assessment of the compliance by foreign manufacturers with the same standards of their Australian counterparts. The TGA adopts a risk management approach to regulate the therapeutic goods.

Coverage, Pricing and Reimbursement

Once a prescription drug is approved for marketing, the company usually applies to have the drug listed in the PBS. Once the PBAC has recommended a drug for listing in the PBS, the Department of Health negotiates the price with the company. After an agreement is reached, the Australian Government considers the advice of the PBAC and decides whether the drug will be listed in the PBS.

Drugs included in the PBS are listed in two formularies:

- Formulary One (F1) contains drugs that i) have only one brand for each form and strength listed in the PBS; and ii) are not interchangeable at the patient level with a drug that has multiple brands listed in the PBS.
- Formulary 2 (F2) contains all the drugs that do not meet the criteria for F1, excluding single-brand combination drugs (i.e. multi-branded pharmaceutical items, drugs included in therapeutic groups, because they are interchangeable with other drugs that have multiple brands).

Drugs in F1 are moved to F2 when the first additional brand is listed in the PBS. In 2016, although only 14.8% of the medications were in F1, the cost to the government was 53.1% of the total cost. Drugs in F2 account for 78.5% of the volume, and 33.5% of the cost. According to the 2014-15 Health Department Annual Report of the Australian Government, in June 2015, the PBS included 793 medicines in 2,066 forms and dosages, sold as over 5,300 differently branded items. In 2015-2016, there were 370 new and amended PBS listings, including the 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.

In addition to the drugs and medicinal products available under normal PBS arrangements, a number of drugs are also available as pharmaceutical benefits, but are distributed under alternative arrangements which are specified under “Section 100” of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way, and this section lists those drugs which are available under the highly specialized drugs program, the efficient funding of chemotherapy, the botulinum toxin program, the human growth hormone program, the IVF program, and the opiate dependence treatment program.

According to the PBS Expenditure and Prescriptions report 2015-2016, the total PBS government expenditure on an accrual accounting basis for the 2015-2016 financial year was AUD 10,838 million, compared with AUD 9072.1 million for the previous year. This is a 19.5% increase. Total PBS prescription volumes decreased by 1.9% to a total of 208 million for 2015-16, compared to 212.1 million for the previous year. Government expenditure amounted to AUD 7,964.9 million, which was 85.1% of the total cost of the PBS prescriptions. The remainder was patient contributions, that amounted to AUD 1,394.2 million, down from AUD 1,465.9 million in the previous twelve-month period.

The majority of the government expenditure on PBS prescriptions was directed towards concessional cardholders (75.9% of the total). On the other hand, the average dispensed price per prescription of PBS medicines increased to AUD 45.00 in 2015-16 from AUD 40.45 in the previous financial year. The average government cost of these prescriptions was AUD 38.29 for the same period (AUD 33.54 in 2014-15). The five drugs with the highest cost to the government were ledipasvir + sofosbuvir (AUD 357.9 million), adalimumab (AUD 334.7 million), ranibizumab (AUD 217.8 million), sofosbuvir (AUD 213 mil-

Box 3. Therapeutic Group Premium Policy

The Therapeutic Group Premium (TGP) Policy was introduced in 1998 and applies to specifically defined groups of drugs which have similar safety and health outcomes. Within these groups, the drugs can be interchanged at the patient level. The Government subsidizes all drugs within a group to the level of the lowest priced drug. The difference in price between the lowest priced drug and the highest priced drugs within the group is called TGP and is paid by the patient. The prices of the items in the therapeutic groups are reviewed annually.

lion) and aflibercept (AUD 213,1 million). The PBS drugs most frequently dispensed were atorvastatin, followed by esomeprazole and rosuvastatin.

In Australia, as in many other countries, to reduce unnecessary pharmaceutical demand consumers pay a co-payment against the cost of each PBS medicine. The amount of co-payment is adjusted on 1 January each year, in line with the Consumer Price Index (CPI). From 1 January 2017, the co-payment for people with eligible concession card (concessional beneficiaries) is AUD 6.30; for the rest of the population (general beneficiaries) is AUD 38.80. The Australian Government pays the remaining cost. From January

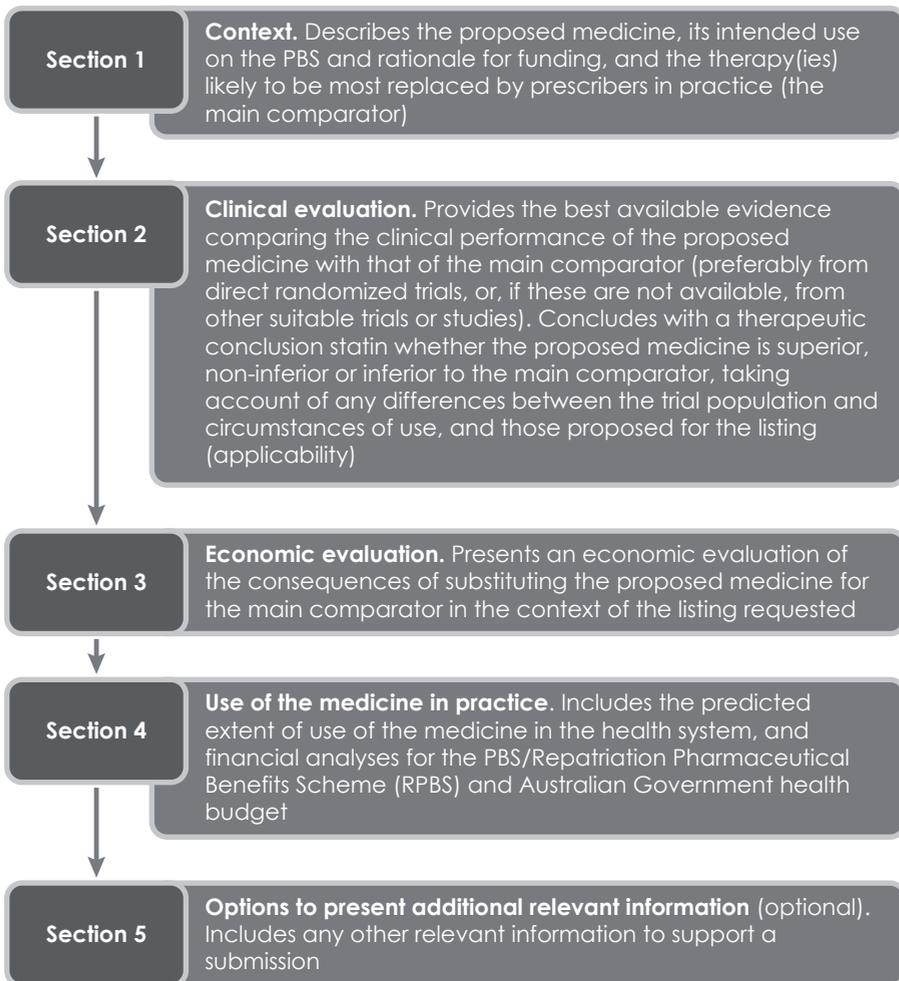


Figure 4. Structure of a major submission to the PBAC. Modified from [Guidelines for preparing submissions to the PBAC]

2016, pharmacists may discount the PBS patient co-payment by up to AUD 1.00; this is not mandatory and the pharmacist may choose whether or not to provide it (this option does not apply for prescriptions which are an early supply of a specified medicine). On the other hand, PBS provides a safety net for limiting the amount spent on medicines by individuals or families. On 1 June 2017, the safety net thresholds was AUD 378.00 for concession card holders, and AUD 1,494.90 for all other patients.

Apart from the assessment of new medicines, the PBAC is also responsible for the listing in PBS of the vaccines funded under the National Immunization Program (NIP), the already listed drugs, and the assessment of new medicinal products. During three annual meetings, the PBAC considers submissions from pharmaceutical companies, medical bodies, health professionals, and private individuals and their representatives. The PBAC has two sub-committees:

- The Economics Sub-Committee (ESC), that advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to the PBAC.
- The Drug Utilization Sub-Committee (DUSC), that monitors the patterns and trends of drug use and makes utilization data available publicly.

The PBAC has not a unique decision rule, but rather weighs a range of relevant factors in its considerations, such as the place in therapy, the overall effectiveness, cost, and cost-effectiveness of a proposed pharmaceutical compared with other pharmaceuticals listed for the same or similar indications, the potential cost to government health budgets, the “rule of rescue” listing in PBS. The submission procedure to the PBAC for a new medicine is shown in Figure 4. The PBAC differentiates submissions in “major submissions” and “minor submissions”. In the case of the listing of a new medicine or vaccine or substantial changes in a “restricted listing”, major submission should be made, including an economic evaluation. Minor submissions generally relate to requests to change existing listings that do not change the population or the cost-effectiveness ratio of the treatment.

10.5 Mapping and Structure of Decision Makers

The national drug policy in Australia is complex and undergoes periodic reforms, as can be seen in Box 1. These reforms mainly focus on price control, cost containment and management of the expenditure, while considering equality and quality. As discussed above, in Australia before a drug can be sold, it must be first approved for safety, quality and effectiveness by the TGA, and then deemed cost-effective by the PBAC for listing in the PBS. The final decision on whether and how pharmaceuticals should be listed in the PBS is made by Minister for Health (Figure 5).

In the Australian pharmaceutical pricing and reimbursement system, between the Australian Government and the beneficiaries there are many layers, including TGA, Australian Register of Therapeutic Goods (ARTG), PBAC, and PBS.

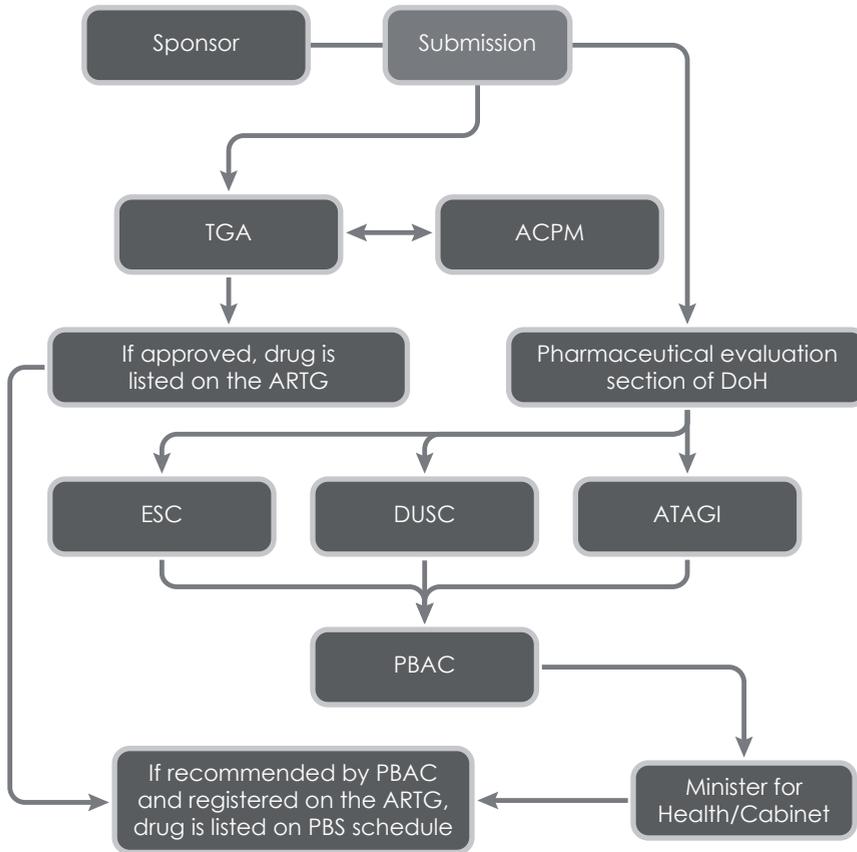


Figure 5. Decision-makers and the process of listing in PBS schedule in Australia. Modified from [CHERE, 2013]

ACPM = Advisory Committee on Prescription Medicines; ARTG = Australian Register of Therapeutic Goods; ATAGI = Australian Technical Advisory Group on Immunization; DoH = Department of Health; DUSC = Drug Utilization Sub-Committee; ESC = Economics Sub-Committee; PBAC = Pharmaceutical Benefits Advisory Committee; PBPA = Pharmaceutical Benefits Pricing Authority; PBS = Pharmaceutical Benefits Scheme; TGA = Therapeutic Goods Administration

Therapeutic Good Administration (TGA)

In Australia, before a medicine can be listed in the PBS, a pharmaceutical company must apply to the TGA to have the medicine included in the ARTG, so that it can be sold. For the marketing, the pharmaceutical company must provide evidence that the medicine meets the required standards of quality, safety, and effectiveness for the intended use.

Australian Register of Therapeutic Goods (ARTG)

In Australia, if a therapeutic good is not entered in the ARTG, it cannot be dispensed. Thus, the ARTG provides information on all therapeutic goods. In April 2016 there were approximately 86,896 products in the ARTG.

The Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC is a statutory committee established under the National Health Act of 1953. Committee members are general and specialist practitioners, pharmacists, and a representative of consumers. PBAC's evaluations and decisions are based on its two sub-committees: the Economics Sub-Committee (ESC) and the Drug Utilization Sub-Committee (DUSC). The ESC evaluates a drug based on a pharmacoeconomic perspective for major submission to the PBAC. The DUSC assesses the projected usage and financial cost of drugs. The additional collection of data on the actual use and its analysis are also provided by DUSC.

PBAC is tasked with making recommendations to the Minister for Health about which drugs and medicinal preparations should be listed for subsidy. The primary role of PBAC is to consider the value for money of new drugs. Besides regularly reviewing the list of PBS items since 2006, the PBAC also recommends vaccines for funding under the National Immunization Program (NIP). The PBAC meets three times a year, usually in March, July, and November.

The PBAC has 17 members who are appointed by the Minister for Health, including medical practitioners, pharmacists, consumers, and health economists. The PBAC considers submissions for new listings or changes to existing listings from industry sponsors, medical bodies, health professionals, private individuals, and their representatives. Since January 2010, the sponsor is also required to pay a cost-recovery fee to the PBS for the evaluation and listing of medicines and vaccines in the PBS and NIP. Each submission must comply with the PBAC guidelines that specify the clinical and economic data that must be submitted. All major submissions must provide an economic analysis undertaken by the sponsor, while submissions of new forms of previously listed products, or changes to the conditions of use, are considered as minor and they do not require the presentation of an economic evaluation.

Pharmaceutical Benefits Scheme (PBS)

The origin of PBS date back to 1919, when a program was established to provide subsidized medicines to World War I veterans and their families. Formally, in 1948 PBS was established to create lists for all the medicines. All the medicines in the PBS schedule are dispensed to patients at a Government-subsidized price. The cost of most prescription drugs is covered by PBS, which is available to all Australian residents who hold a current Medicare card. Foreign visitors from countries with which Australia has a Reciprocal Health Care Agreement (i.e. the UK, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium, and Slovenia) are also eligible to the PBS.

Medicines listed in the PBS schedule can fall into three broad categories:

- Unrestricted benefits, for medicines with no restrictions on therapeutic use;
- Restricted benefits, for medicines that can only be prescribed for specific therapeutic uses;
- Authority-approved benefits, for medicines that require prior approval from the Department of Health.

10.6 Challenges and Catalyzers for Market Access

The Australian government has maintained a strong focus on the regulatory and funding processes, in order to control expenditure as well as ensuring the safety, quality, and effectiveness of drugs. According to many analyses of the Australian pharmaceutical expenditure, drug prices are many times higher than in other developed countries. The prices of generic medicines in particular are too high compared to other countries.

Challenges

According to public discussion, the key challenges are the regulation of the pricing and reimbursement system as well as getting the value for money, funding innovative medicines and the treatment of rare diseases. Because of these reasons, there is growing concern about PBS expenditure, its budget affordability by the community, and the out-of-pocket costs for each individual patients. The National Commission of Audit stated that PBS spending is projected to grow by 5.4% per year from 2013-14 to 2023-24.

Despite recent cost containment policies aimed at keeping low the cost of medicines in the PBS schedule, there is growing evidence that many Australian patients are struggling to afford their prescribed medicines. According to a study by Kemp et al, Australian patients have faced increased prescription medicines costs over the recent years, and the expenditure on the part of patients is now in the mid to upper range versus the comparable countries.

On the other hand, Australia over the next decade will face serious challenges, that will strongly affect the pharmaceutical budget; in particular the increase in the demand for cancer drugs. According to Karikios et al., PBS expenditure on anticancer (anti-neoplastic) drugs and the average price paid by the PBS for anticancer drugs both increased significantly from 2000 to 2012, with an average annual increase in PBS expenditure on anticancer drugs of 19.1%, compared with 9.0% for all the other drugs combined. Furthermore, the average price paid by the PBS per anticancer drug prescription has increased by 133% between 2011-2012. Delayed funding decisions, or lack of funding for new cancer medicines in the PBS, have also been raised as a major concern by some consumer organizations and the pharmaceutical industry. For example, on 3 December 2014, the Australian Senate tasked the Senate Community Affairs References Committee to report on the availability of new, innovative and specialist cancer drugs in Australia.

In particular, the Committee was charged with focusing on issues related to the timing of access and affordability for patients; how the PBAC and PBS handles these medicines, and the impact of delays in approval on patients; and the impact of the quality of care on cancer patients.

The use of generic medicines in Australia is scarce by international standards, and the Australian generic price reductions are lower than those in many other countries. According to a report by the Grattan Institute, in 2013 Australian paid over \$ 1 billion too much per year for generic drugs. In this price scenario, generic drugs gained a lower market share than expected. Due to these high prices, generic drugs captured a smaller share of the market than expected. Nevertheless, the next expiry of a number of patents and the introduction of improved price disclosure arrangements are expected to increase the use of generics and reduce the pharmaceutical spending.

Catalyzers

Australia was the first country to introduce formal economic evidence-based funding of pharmaceuticals in 1993. Although most prescribed drugs are paid by the PBS through community pharmacies, some are distributed under alternative arrangements. A recent study conducted by Chim et al. shows the public preferences regarding the criteria for resource allocation decisions and that should be incorporate into PBCA decision-making processes (the severity of the disease, the diseases for which there is no alternative treatment available in the PBS – unmet need, the diseases that affect patients who are not economically wealthy and lifestyle-unrelated diseases). In line with these circumstances, under Section 100 of the National Health Act, 1953 several alternative programs have been arranged for the provision of some medicines. One of these is the Highly Specialized Drugs (HSDs) program.

HSDs are medicines for the treatment of chronic conditions such as cancer, HIV and organ transplantation. Because of their clinical use or other special features, their supply is commonly restricted through public and private hospitals having access to appropriate specialist facilities. Only the practitioners affiliated with these units can prescribe these drugs as pharmaceutical benefit items. Another arrangement is the “S100 Supply Arrangements for Remote Area Aboriginal Health Services” (AHSs), which improves the access to the PBS for patients in remote areas. Under these arrangements, the customers of

Box 4. PBCA criteria for Rule of Rescue (RoR)

When all four factors apply concurrently, RoR can be applied.

1. There are no pharmacological nor non-pharmacological alternatives
2. The medical condition is severe, progressive and expected to lead to premature death
3. The medical applies only to a very small number of patients
4. The proposed medicine provides a worthwhile clinical improvement sufficient to qualify as a rescue from the medical condition

participating AHSs are able to receive PBS medicines directly from the AHS upon consultation, without the need for a normal prescription form, and without charge.

In Australia, the PBAC is not obliged to accept some preferences or alternative opinions in its decision making, in some exceptional conditions such as a rare disease, or to take action for disadvantaged groups, i.e. reverse discrimination, it allows for the consideration of the Rule of Rescue (RoR) criteria as part of its decision-making process (Box 4).

Finally, the Australian Government provides subsidized access to expensive lifesaving drugs for very rare life-threatening conditions through the Life Saving Drugs Program (LSDP). The amount of funding for this program is limited, and determined on a yearly basis. The request for inclusion in the LSDP must be submitted in conjunction with the submission to the PBAC for PBS listing; the Chief Medical Officer can advise the Minister for Health on the drugs to be included in the LSDP.

10.7 Good Examples of Successful Market Access Strategies

In 2010, the Australian Government and the local pharmaceutical industries announced that they had reached an agreement on the establishment of a Managed Entry Scheme (MES) that would attempt to satisfy the needs of the key stakeholders. The basis of the scheme is that a product will be listed at a price commensurate with its cost-effectiveness, based on the evidence existing upon launch. Thereafter, the price of the product will be adjusted (upward or downward) on the basis of cost-effectiveness estimates arising from the generation of further RCT evidence (post-launch). Although MES could implement both non-outcome-based schemes and outcome-based schemes, according to Vitry et al. (2014) most of the managed entry agreements are non-outcome-based. Furthermore, the study of Vitry et al. showed that at February 2013, immune modulating agents (33.8%), nervous system (15.5%), alimentary tract and metabolism (9.8%) and cardiovascular system (7%) medicines were the drugs most represented in the MES. Furthermore, twenty-six (37%) pricing arrangements were applied to medicines restricted to supply through public and private hospitals (Section 100), and three products (abacavir, bosentan and efavirenz) have been listed with special bonus arrangements being agreed with the sponsor, rather than a rebate agreement.

10.8 Look-out for Near Future

The pharmaceutical pricing and reimbursement policy in Australia is quite complex and has been undergoing a series of reforms over many years. Despite the many challenges facing the pharmaceutical industry in Australia, there is an expected growth in this market, since it was valued at \$ 22.7 billion in 2013 and is projected to reach \$ 32 billion by 2020. In Australia, the PBS budget is uncapped and, although several overall policies

have been effective in decreasing drug prices and pharmaceutical expenditure, the current PBS expenditure and the potential for a high growth in the future, cause concerns for the long-term sustainability of the PBS. There are also increasing concern about the timely access to new medicines at affordable prices. The registration of novel chemical entities can be substantially delayed in Australia, where patients must wait several months to have access to some breakthrough medicines. In order to overcome such a challenge, the Government has recently taken steps to fast-track the registration of new drugs, generics, and biosimilars in the Australian market.

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