GLI GLOBAL LEGAL INSIGHTS

Pricing & Reimbursement

2021

Fourth Edition

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glg global legal group

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Australia

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Abstract

The primary mechanism governing the pricing and reimbursement of prescription pharmaceutical products in Australia is the Pharmaceutical Benefits Scheme (**PBS**). The PBS is a scheme by which the Commonwealth (Federal) Government subsidises access to medicines. Because of the impact on the Commonwealth budget, funding of the PBS is often a politically charged issue, and the subject of regular attention by Parliament and among pharmaceutical sponsors.

Market introduction/overview

Australia is a nation with a population of approximately 25.7 million people.[1] It is a generally healthy nation, with life expectancies in the top 10 of OECD nations. Australians have access to a Government-subsidised system of universal healthcare, which includes subsidised access to many medicines through the PBS.

Like many western countries, Australia is experiencing an ageing population. The median age of the Australian population, as at June 2021, is approximately 38 years, compared to approximately 35 years in June 1999. The Australian population is also growing – the annual population growth rate as at September 2020 was 0.9% (down from 1.5% in the year ending 30 June 2019), in part due to a substantial decline in net overseas migration. Typically, roughly two-thirds of Australia's population growth is attributable to immigration and one-third to natural increases.

While Australia is a generally healthy nation, it faces many of the problems typical of western countries in which life expectancy has been extended and diet and lifestyle factors play a significant role in affecting health. The following snapshot of Australian health is taken from the Australian Institute for Health and Welfare's reporting on Australia's Health for 2020:[2]

- the life expectancy of a person born in 2016–2018 is 80.7 years for a male and 84.9 years for a female (which has been rising steadily over time);
- in 2016–2018, the leading cause of death in Australia varied by age, with chronic diseases featuring more prominently for people aged 45 years and over, and external causes (e.g. accidents and suicides) being the leading causes for people aged 1–44. Coronary heart disease was Australia's leading single cause of death in 2018, with dementia being the second leading cause of death;
- chronic disease is becoming increasingly common. Based on 2017–18 estimates, almost half (47% or more than 11 million people) have at least one of 10 selected chronic conditions, with one in five having multiple chronic conditions (e.g. heart disease, cancer, stroke, diabetes, arthritis and asthma). Many chronic conditions share risk factors that

are modifiable, including tobacco smoking, high blood pressure, insufficient physical activity, poor diet and overweight and obesity. In 2017, Australia had the fifth highest obesity rate (out of 23 countries in the OECD) for people aged 15 and over. In 2017–18, 67% of Australian adults were estimated to be overweight or obese; and

- often, people living in rural and remote and/or lower socioeconomic areas of Australia, people with disability and Aboriginal and Torres Strait Islander people experience high rates of illness, hospitalisation and death than other Australians. Indigenous Australians also have a lower life expectancy at birth (around nine to 10 years).

Australia is a federation comprising six states and two territories. The Australian Constitution defines the powers of the Federal Government (called the "Commonwealth"). In particular, section 51(xxiiiA) of the Constitution provides that the Commonwealth Parliament may make laws with respect to:

> "*the provision of maternity allowances, widows' pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances.*"

The Commonwealth has used this power to establish the PBS, which will be the main subject of this chapter.

However, in reality, the funding of the health system in Australia is much more complicated and relies on a combination of Commonwealth, State and private funding. The essential elements of the system are:

- the Commonwealth has established the Medicare system pursuant to which Australian citizens and permanent residents receive access to universal healthcare. Any eligible person may be admitted to a public hospital and receive care free of charge, prioritised on the basis of need. Furthermore, outside the public hospital system the cost of services listed on the Medicare Benefits Schedule, which are provided by doctors, is subsidised by the Commonwealth. In practice, this means that most eligible persons pay little or nothing for routine visits to the doctor;
- the public hospital system is, with very limited exceptions, operated by the State and Territory Governments, who receive funding from the Commonwealth in exchange for agreeing to provide the care required by the Medicare system;
- the cost of prescription medicines is subsidised by the Commonwealth pursuant to the PBS; although prescription medicines that are not available on the PBS can also be supplied by private script (without Government subsidy); and
- there is a private hospital system which runs alongside the public hospital system. Private hospitals are used by patients for elective surgery, or who wish to choose their doctors or avoid waiting lists in public hospitals. Private health insurance is available to meet the hospital costs of private hospitals. However, fees charged by doctors for services provided in a private hospital setting are still subsidised by Medicare. Any gap between the subsidised amount and the doctor's fee must generally be paid by the patient (although health insurers are now permitted to make arrangements with individual doctors to make gap payments).

The total Commonwealth Budget for the Department of Health for 2021–2022 aims to deliver AU$121.4 billion in 2021–2022 and AU$503 billion of overall investment over four years. Of particular note, the Government has invested over AU$25 billion as part of the emergency health response to the global COVID-19 pandemic since March 2020. The reported investment in this Budget includes AU$1.1 billion to extend the COVID-19 health response, AU$1.9 billion to drive the COVID-19 vaccine rollout, Medicare investment

including a AU$204.6 million telehealth extension and AU$43 billion to support the PBS over four years (including AU$878.7 million for new and amended listings).[3] However, it should be noted that the budget allocation for the PBS overstates net expenditure on the Scheme because it does not take into account the significant rebates paid to the Commonwealth by sponsors of high-cost prescription pharmaceuticals. In 2018–2019, those rebates, which are discussed in greater detail in section "Policy issues that affect pricing and reimbursement" below, were estimated to be worth AU$3 billion.[4]

Pharmaceutical pricing and reimbursement

Regulatory classification

In Australia, therapeutic goods (including prescription medicines, over-the-counter medicines, complementary medicines, medical devices, and certain blood and blood products) are regulated by the Commonwealth regulator, the Therapeutic Goods Administration (**TGA**), in accordance with the Therapeutic Goods Act 1989 (Cth) and its delegated legislation. The TGA is responsible for evaluating, assessing and monitoring goods that are manufactured or supplied in, exported from or imported into Australia.

The PBS is established by Part VII of the National Health Act 1953 (Cth). It is an extremely long-lived scheme, having begun in 1948 as a Government-subsidised scheme to provide free medicines for pensioners and a list of 139 life-saving and disease-preventing medicines free of charge for others.[5] It has evolved over time, with changes in recent years designed to manage the cost of the scheme for the Government and, in conjunction with industry (in particular, arising from agreement between the Department of Health and the industry body for prescription medicine sponsors, Medicines Australia, in 2010 (memorandum of understanding) and 2017 (strategic agreement)).

The PBS subsidises drugs or medicinal products. A medicine is a therapeutic good that is represented to achieve, or is likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.[6]

The regime under the National Health Act requires (except under very limited circumstances) that a pharmaceutical benefit may only be supplied by an approved pharmacist on presentation of and in accordance with a prescription written by a PBS prescriber as permitted by the legislation. Depending on the particular item in question, a PBS prescriber may be a medical practitioner, a participating dental practitioner, an authorised optometrist, an authorised midwife or an authorised nurse practitioner.[7]

As such, the Government does not subsidise medical devices, animal health products, blood or blood products, over-the-counter or complementary medicines via the PBS.

It is also worth mentioning that the Australian Repatriation System provides defined benefits for eligible veterans and their dependants, which include subsidising certain medications and dressings via the Repatriation Pharmaceutical Benefits Scheme (**RPBS**). This chapter focuses on the general PBS.

A further separate programme is the Life Saving Drugs Program (**LSDP**), which is a programme through which the Government subsidises high-cost transformational therapies for rare diseases which do not meet the usual expectations of the PBS for cost-effectiveness. The LSDP sits outside the PBS and is managed through individual agreements between the sponsors of such products and the Commonwealth. There are currently 15 medicines available to eligible patients for the treatment of 10 rare conditions.[8]

In January 2018, the Commonwealth released the report of a review in relation to the LSDP which proposed certain changes to the criteria for inclusion in that programme and the

way it is managed. The Australian Government and Medicines Australia (on behalf of sponsors of medicines on the LSDP) entered into an agreement on 8 May 2018, which operates from 1 July 2018 to 30 June 2022 in respect of the commitments of each party to implement reforms outlined therein. These include the establishment of an Expert Panel to provide advice and assistance to the Commonwealth Chief Medical Officer in assessing rare disease medicines seeking listing on the LSDP, and Medicines Australia's support for reviews of LSDP medicines, including assessment of usage, financial costs and other relevant information associated with a medicine's listing.[9]

A medicine must first be considered by the Pharmaceutical Benefits Advisory Committee (PBAC; see further below) for subsidisation on the PBS, before it can be considered for funding on the LSDP. There are eight criteria which must be satisfied in order for a medicine to be listed on the LSDP which relate to the characteristics of the disease being treated, the availability of therapies and the cost of the medicine in question.[10]

Who is/who are the payer(s)?

Under the PBS, the Commonwealth Government subsidises the cost of medicines listed on the Schedule of Pharmaceutical Benefits (**Schedule**).

All Australian residents holding a current Medicare card, and certain overseas visitors with which Australia has a Reciprocal Health Care Agreement[11] are eligible to access the PBS. The National Health Act provides that an eligible person receiving applicable treatment is entitled to receive pharmaceutical benefits without paying money or any other consideration[12] except as follows:

- A patient co-payment which, from 1 January 2021, is up to AU$41.30 or AU$6.60 if the patient has a concession card for most PBS medicines. Pharmacists may (voluntarily) choose to discount the PBS patient co-payment by up to AU$1.00 for some medicines. The amount of the co-payment is adjusted annually on 1 January in accordance with the Consumer Price Index (**CPI**).[13]
- Two other fees may be payable by a general (not concessional) patient if the cost of the medicine is less than the current co-payment: an allowable additional patient charge (currently AU$4.42); and an additional fee for ready-prepared items (currently AU$1.29). Neither of these fees can be added to increase the amount payable by the patient above the co-payment amount.
- Some brands of medicines have a price premium or brand premium. This is an additional amount which represents the difference between the price at which the sponsor is prepared to sell and the price which the Government is prepared to subsidise. Government policy is to only permit such arrangements in limited circumstances, typically where an innovator medicine and one or more generic brands of the same drug are listed on the Schedule.

The legislation also provides for a "Safety Net". If a patient's prescriptions exceed the relevant Safety Net Threshold for a calendar year, general patients pay for further PBS prescriptions at the concessional co-payment rate, and concessional patients will receive PBS prescriptions at no additional charge for the remainder of the year. The current Safety Net thresholds (as at 1 January 2021) are AU$316.80 for concession card holders and AU$1,497.20 for general patients.

What is the process for securing reimbursement for a new pharmaceutical product?

Registration/listing and decision-making

Unless a medicine is proceeding along a parallel TGA and PBS track, it must be approved for supply in Australia before it can be listed on the Schedule. For prescription medicines, this requires registration on the Australian Register of Therapeutic Goods (**ARTG**).

The Commonwealth Minister for Health is empowered by the National Health Act to list medicines as pharmaceutical benefits on the Schedule.[14] The Commonwealth Minister will make a determination, set out in a legislative instrument, that a particular drug, in a particular brand, form and manner of administration, is to be listed on the Schedule.

The Pharmaceutical Benefits Advisory Committee (**PBAC**) is established by the National Health Act to act as an advisor to the Department of Health and Minister for Health in relation to the listing and pricing of pharmaceutical items on the PBS. The PBAC's functions include making recommendations to the Minister as to the drugs which it considers should be made available as pharmaceutical benefits on the PBS, as well as providing advice on issues relating to the administration of the PBS more generally.[15] The Minister may not list a pharmaceutical item on the Schedule unless the PBAC has recommended that the Minister do so.

In deciding whether to recommend to the Minister that a particular drug or medicinal preparation (or class of drugs or preparations) be available as a pharmaceutical benefit on the PBS, the National Health Act requires the PBAC to give consideration to the effectiveness and cost of the therapy involving use of the drug, preparation or class, including by comparing this with alternative therapies.[16] Furthermore, if a medicine is substantially more costly than alternative therapies, the PBAC may not recommend its listing unless the PBAC is satisfied that, for some patients, the medicine provides a significant improvement in efficacy or reduction in toxicity of the alternative therapies.[17]

The PBAC publishes a detailed set of guidelines (current version 5.0, September 2016) which are the "Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee" (**PBAC Guidelines**).[18] The PBAC Guidelines identify five quantitative factors which influence PBAC decision-making:[19]

(a) comparative health gain – including magnitude and clinical importance of effect;
(b) comparative cost-effectiveness – including on a cost-effectiveness or cost-minimisation basis; as well as a consideration of comparative costs including healthcare resources not limited to cost of the drug;
(c) patient affordability in the absence of PBS subsidy;
(d) predicted use in practice and financial implications for the PBS (projected annual net cost); and
(e) predicted use in practice and financial implications for the Australian Government health budget (projected annual net cost).

The Department of Health has also published a "Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme" (version 2.0, December 2020),[20] which provides further detailed information about the processes, procedures, timelines and documents required. This procedure guidance also provides information about consideration of vaccines for the National Immunisation Program.

In practice, at a high level, for listing a new medicine on the PBS, the process involves: the making of a detailed submission to the PBAC; consideration by two subcommittees – the Drug Utilisation Sub-Committee (**DUSC**) and the Economic Sub-Committee (**ESC**); consideration by the PBAC itself; recommendation by the PBAC to make or not make the requested listing and (if positive), negotiation and agreement on the price between the sponsor and the Department; and formalisation of the listing by the Minister signing the relevant legislative instrument.

Formulary placement

Amendments to the legislation in 2007 introduced two formularies called F1 and F2. The Minister may determine that a particular listed drug is on F1 or F2.[21] There is no requirement

(including as to timing) as to when this must occur; however, in practice, it is proximate to the initial listing (or change of circumstances necessitating a move between formularies), since the formulary also influences the pricing mechanisms which may apply.

The Minister may only determine that a drug is on F2 if it does not satisfy one or more of the criteria for F1. The criteria for F1 require that there are no brands of pharmaceutical items that have the drug and are bioequivalent or biosimilar and which are listed on the PBS, or that there are no brands of pharmaceutical items having another listed drug in the same therapeutic group. Generally speaking, F1 drugs are "innovator" or "single brand" drugs, which are still on patent and for which there is no suitable alternative for patients. Drugs on F2 are drugs for which there are multiple brands; that is, drugs that are off patent and operating in a competitive market with generic or biosimilar brands available.

Appeals

The powers of the PBAC and the Minister (intentionally) give wide scope for judgment and for rejection. This has also been confirmed in legal proceedings: *Pfizer Pty Ltd v Birkett* (2001) 112 FCR 305 at [36] – the purpose of the words in section 101(3) of the National Health Act is to give the PBAC "the widest scope for judgment and indeed for rejection".

There are no statutory rights to appeal or review decisions for the listing or pricing of items on the PBS. The alternatives open to an applicant who wishes to challenge such a decision include:

(a) resubmission to the PBAC (where a sponsor intends to challenge a decision made by the PBAC);
(b) independent review (a form of merits review); or
(c) judicial review.

The timing and likelihood of success will depend on which option is taken, what decision is subject to challenge, and the facts of the particular case.

Independent review may be an option where a submission to PBAC has not resulted in a recommendation to list a drug on the PBS or where PBAC has declined to recommend an extension of the listing of an already listed drug. Independent review involves an independent reviewer looking at all the evidence that was before the PBAC to determine whether the correct decision was made, and making a recommendation accordingly.[22]

The reviewer's findings are not binding on the PBAC.

Judicial review is the review of Government decision-making by a Court, under the *Administrative Decisions (Judicial Review) Act* 1977 (Cth) or sections 39B(1) and 39B(1A) of the *Judiciary Act* 1903 (Cth). Judicial review looks at the way in which a decision was made (which may include acts or steps preparatory to the decision). Relevant factors may include procedural impropriety (e.g. lack of procedural fairness), irrationality (e.g. failure to take into account a relevant consideration or taking into account irrelevant considerations), or illegality (decision-maker acting beyond power).

How is the reimbursement amount set? What methodology is used?

Once a pharmaceutical benefit is listed on the PBS, a set of quite complex arrangements set out the way in which the reimbursement is paid. In general terms, the Schedule specifies the price which may be charged by the sponsor for the medicine (the Approved Ex-Manufacturer Price, or **AEMP**). However, the Commonwealth subsidy is paid to the pharmacist who dispenses the medicine. The subsidy (called the Commonwealth price) is therefore the AEMP plus mark-ups and associated fees charged by the wholesaler and pharmacist. Those mark-ups and fees are controlled. For community pharmacy, the Seventh Community Pharmacy Agreement between the Commonwealth, the Pharmacy Guild of Australia

and the Pharmaceutical Society of Australia (commencing 1 July 2020) sets out how the Commonwealth price is set.[23] For private hospitals, the *National Health (Pharmaceutical benefits supplied by private hospitals) Determination* 2010 (Cth) applies. For public hospitals, *National Health (Commonwealth Price – Pharmaceutical Benefits Supplied By Public Hospitals) Determination* 2017 (Cth) applies.

How are drug prices set? What is the relationship between pricing and reimbursement?

A positive recommendation by the PBAC to list a drug on the PBS will trigger further steps to be taken by the Department of Health and the drug sponsor. Importantly, the Minister and the drug sponsor seek to negotiate the price for the new listing, having regard to the PBAC's advice to the Minister. The parties should seek to agree the appropriate maximum price of the brand for the pharmaceutical item, by reference to the pricing quantity of the brand of the pharmaceutical item.[24] Once negotiated, the sponsor provides the Department with a completed "PB11a" form – a request for an approved ex-manufacturer price.

The Government adopts a reference pricing policy whereby it will subsidise medicines that are therapeutically equivalent up to the lowest-priced such medicine.

For the first listing of a new drug, the economic evaluation to be adopted will depend on the clinical performance and cost-effectiveness of the new medicine compared with the main comparator. A cost-effectiveness analysis is appropriate where the proposed medicine is therapeutically superior to the main comparator but likely to result in additional costs to the healthcare system, or therapeutically inferior but likely to result in lower costs. If such a submission demonstrates therapeutic superiority, the sponsor will be able to negotiate a premium price over alternatives. A cost-minimisation approach is used where there is a therapeutic claim of non-inferiority (or superiority), the safety profile is equivalent or superior (nature and magnitude), and use of the proposed medicine is anticipated to result in equivalent or lesser costs to the health system.[25] In such circumstances, the sponsor will only be able to obtain a price equivalent to or lower than relevant comparators.

If there are no comparators for a medicine, the PBAC will examine the economic analysis provided by the sponsor and reach a view as to whether the economic analysis (which must assume a cost to Government and therefore a price) justifies a recommendation for listing. The tool used by the PBAC to do this is typically the incremental cost-effectiveness ratio (**ICER**) which measures the cost to the Commonwealth of each quality-adjusted life year the medicine generates. The PBAC does not have any formal policy as to what represents an acceptable ICER. However, it is widely assumed that the PBAC does apply informal standards about the ICERs it regards as acceptable (which vary depending on the therapeutic area).

It is quite common for high-cost drugs to be subject to a risk-sharing deed pursuant to which the sponsor agrees to rebate some part of the Commonwealth price to the government.[26] The formula is sometimes a simple percentage of the Commonwealth price and in other cases may involve a rebate applying once the Commonwealth payment moves above a certain level. There are also examples of differential rebates being paid for different uses of a medicine. These arrangements all create a difference between the AEMP and the effective price of the medicine.

The relationship between the price agreed between Minister and sponsor and reimbursement is described in section "How is the reimbursement amount set? What methodology is used?" above.

The legislation includes three types of mechanisms which operate to reduce the AEMP agreed between Minister and sponsor. They are as follows:

- automatic price reductions which apply on the fifth, 10th and 15th anniversary of listing for drugs on the F1 formulary (5%, 10% and 5%, respectively),[27] subject to exercise of a Ministerial discretion in appropriate cases;

- statutory price reductions on the first listing of a bioequivalent or biosimilar brand of a pharmaceutical item (currently 25%, in place during the term of the Strategic Agreement with Medicines Australia, until June 2022), subject to exercise of Ministerial discretion, as well as certain exemptions for new pharmaceutical items that are new presentations of existing medicines;[28] and
- for medicines on F2, price-disclosure-driven price reductions. These require sponsors to provide the Commonwealth with periodic data about the discounts and other benefits which they provide in association with the supply of the medicine. The Commonwealth then uses a formula set out in regulations[29] to calculate the weighted average effective price for a medicine and the AEMP for each brand of that medicine is reduced accordingly. As a result, once a medicine is on F2, its AEMP reduces over time to the minimum price at which sponsors are prepared to sell it.

Issues that affect pricing

In addition to the issues flagged in the sections above, an interesting issue in this space in recent years has been the Government's approach to biosimilar medicines and interchangeability of those medicines at a pharmacy level.

In Australia, there is no mandatory substitution of generic or biosimilar medicines (or "cheaper" medicines) instead of the innovator product. In fact, under the National Health Act, it is an offence for a pharmacist to supply anything other than the pharmaceutical benefit specified in a prescription, except under certain prescribed circumstances.[30]

A pharmacist may supply another substitute benefit if:

(a) the prescriber did not indicate that only that benefit was to be supplied (in practice, by checking a box or writing "substitution not permitted" on the script);
(b) the Schedule of Pharmaceutical Benefits states that the specified benefit and the substitute benefit are equivalent;
(c) the substitute benefit is a listed brand of a pharmaceutical item; and
(d) the supply of the substitute benefit is not otherwise prohibited by State or Territory law.[31]

Products which the Department has determined as "Schedule equivalent" are marked on the Schedule of Pharmaceutical Benefits with what is colloquially known as an "a" flag. The "a" flag has been relatively uncontroversial in the context of generic (bioequivalent) medicines. However, in the newer area of biological (biosimilar) medicines, the use of the "a" flag has been a cause for some concern within the medical community and industry, particularly in certain therapeutic areas. This concern led to the Department's Biosimilar Awareness Initiative, directed at prescribers, pharmacists and consumers. That Initiative (introduced in 2015) aims to support awareness of and confidence in the use of biosimilar medicines. In certain therapeutic areas, this has also been supported by changing the administrative steps required to prescribe a particular medicine, to encourage biosimilar uptake.[32]

The Department continues to look for new ways to encourage biosimilar uptake. For example, when biosimilar versions of Adalimumab were listed on the PBS on 1 April 2021, the Department has specified that biosimilar brands of Adalimumab, but not the originator brand, are substitutable for ongoing treatment.

Policy issues that affect pricing and reimbursement

Most policy issues in relation to pricing and reimbursement arise from the tension between the desire to list new medicines on the PBS and the need to manage the Government's health budget.

The underlying philosophy of the PBS is not to choose particular products or brands for preferential treatment for reimbursement, but rather to allow any product which can

demonstrate appropriate clinical efficacy and safety to be listed. Cost to Government is then managed in two ways:

- the role played by the PBAC as a gateway to the listing of new products unless they are either cost-effective or cost-minimised to existing therapeutically equivalent products. The way in which the PBAC discharges its role as an independent Health Technology Assessment body, its composition and its relationship with both Government and industry is a constant issue of interest to stakeholders; and
- a legislative and policy measure described above designed to ensure that the Government pays the same price for all products which have similar clinical effectiveness (and that price always moves to the lowest price available for a therapeutically equivalent product).

This approach has, in general, made the PBS a successful and cost-effective Government programme. However, it faces constant policy challenges as a result of a desire on the part of the Government to limit the growth of the PBS budget.

Within that framework, three policy issues that are currently of interest and importance are as follows:

Statutory price reductions and Strategic Agreements

Since 2007, the Commonwealth has sought to manage the PBS budget by legislation and policy which seeks to reduce the AEMP for products on the Schedule over time. This occurs through the use of the reference pricing policy and the statutory price reduction mechanisms described in section "Pharmaceutical pricing and reimbursement", "How are drug prices set? What is the relationship between pricing and reimbursement?" above.

There has been a consistent level of concern within the industry about the tendency of the Commonwealth to introduce new price-reduction policies (including new interpretations of the reference pricing policy) and new legislation without sufficient warning, thereby eroding the ability of the industry to predict and manage the future prices of their products.

The response from the industry and the Commonwealth has been to enter into agreements whereby industry agrees to certain price-control measures being introduced in exchange for the Commonwealth promising a degree of policy certainty and consultation and due process in relation to any future policy changes.

These agreements are reflected in agreements between the Commonwealth and industry representative bodies, in particular, Medicines Australia representing the innovative medicines industry, and the Generic Medicines Industry Association for the generic medicines industry.

The first such agreement was a Memorandum of Understanding entered into between Medicines Australia and the Commonwealth in 2010 with a four-year term.[33] The Memorandum of Understanding was generally thought to have been effective in achieving cost control on PBS expenditure,[34] but questions were raised about whether it had been effective in providing industry with policy certainty.

In 2015, the Generic Medicines Industry Association entered into a Strategic Agreement with the Commonwealth with an initial five-year term,[35] an extension until 30 June 2020 and a further extension to 30 June 2022.[36] This Agreement provided for certain changes to the price disclosure regime to accelerate the speed with which price disclosure reduced generic prices. In exchange, the Commonwealth promised not to introduce further price-related saving policies for medicines on the F2 Formulary and agreed to introduce policy measures to encourage increased use of biosimilars.

In 2017, Medicines Australia entered into a Strategic Agreement with the Commonwealth with a five-year term.[37] This Strategic Agreement provided for a substantial change to the way

in which the statutory price reduction regime operates (including increased price reductions). However, it also introduced for the first time Ministerial discretions not to apply statutory price reductions to medicines which have already been subject to significant reference-pricing-driven price reductions. In this agreement, the innovative medicine industry also agreed to a range of policy measures, including more expansive biosimilar uptake drivers.

Many of these changes were reflected in amendments to the Act which were passed into law in January and October 2018. Views on the effectiveness of these two Strategic Agreements (and the Health Technology Assessment system itself) in maintaining the balance required for a sustainable medicines policy differ substantially.

As at the time of writing, the Commonwealth and Medicines Australia are involved in negotiations for a new Strategic Agreement to replace the existing agreement when it expires on 30 June 2022.

Rebates

The last 20 years have seen dramatic growth in the use of risk-sharing agreements (described in section "Pharmaceutical pricing and reimbursement", "How are drug prices set? What is the relationship between pricing and reimbursement?" above) to create a difference between the published price of a medicine (the AEMP) and the effective price paid by the Commonwealth for that medicine. Under these deeds, the difference between published price and effective price represents rebates paid by the sponsor to the Commonwealth. Almost all high-cost drugs are now listed on the Schedule with a confidential risk-sharing arrangement in place.

This has resulted in a dramatic growth in rebates over the last 15 years (see section "Market introduction/overview" above) to the extent that the size of the rebates is about 25% of the total PBS budget and close to half of the amount of that budget attributable to the price charged by sponsors for their products.

For sponsors, this creates a problem because the perceived cost of their products to the Government is much greater than the actual cost. Medicines Australia has made submissions to the Commonwealth seeking explicit recognition of rebates in the way the PBS budget is presented.

For the Commonwealth, it has created an accounting problem because rebates are often paid months and sometimes more than a year after the supply has occurred.

For these reasons, the Commonwealth has proposed restructuring the PBS payments system so that for high-cost drugs a net subsidy amount (the "effective price") would be paid directly to the sponsor rather than to the pharmacist.

This apparent simple change gives rise to numerous complex legal, accounting and practical issues which are currently the subject of discussions between the Commonwealth and industry. It remains to be seen how those issues are resolved.

To that end, a Project Advisory Board (comprising representatives from the Department of Health and various industry associations) was established on 9 August 2018 to support, advise and assist the project, keep members and stakeholders informed, assist in resolving conflicts and disputes and make recommendations to the Department, as necessary. Technical working groups have also been established.[38]

The Department initially proposed to implement the first phase of the new payment arrangements from 1 July 2019 involving a subset of medicines with special pricing arrangements, and to progressively roll out new payment arrangements to all medicines with special pricing arrangements from 1 July 2020. The significant uncertainty relating to the legal and practical difficulties associated with such arrangements have seen this be

further delayed. There is still no agreement as to which of proposed models (if any) for a reformed payment system should be pursued and it seems unlikely that these changes will ever be brought into effect.

More recently, the Government took on the task of seeking amendments to all current Deeds of Agreement, which reflect the special pricing arrangements, to move to a monthly (rather than quarterly) rebating system (as well as other changes to the evidence supporting the monthly rebate invoices to streamline the process).[39]

The Government's approach to special pricing arrangements more generally appear to remain under consideration; however, reports of new criteria and, potentially, a substantial conceptual change to the circumstances in which the Government may agree to such an arrangement have not yet come to fruition. Any narrowing of the circumstances in which a special pricing arrangement may be agreed may have significant implications for decisions of innovator companies to list their drugs on the Australian PBS.

Timely access to medicines

The PBS is a very effective system in delivering access to subsidised medicines quickly once they are listed on the Schedule. However, there has been criticism of the speed with which medicines are able to be listed on the PBAC.

In the Fifth Edition of its *Facts Book* (June 2021), Medicines Australia reported that for the period 2010–2019, most therapeutic areas took over seven months on average to achieve a successful listing on the PBS once a positive recommendation was received from the PBAC. The average number of days across therapeutic areas to gain PBS listing was 285 days (or 9.4 months). Having regard to the PBAC's recommendation, rejection and deferral rates from 2010 to 2020, Medicines Australia reported that the highest proportion of positive recommendations was in 2019 (75% of submissions), compared with a low of 61% in 2020. Annual recommendations and rejections show a decline over time and the deferral rate shows an increase over time.[40] The PBAC's rigid meeting schedule exacerbates the problem with timely access of reimbursed medicines because it means that if a submission is rejected or deferred by the PBAC it is usually a minimum of four months – and more commonly, eight months – before the medicine can return to the PBAC.

There are a number of policy reforms which have been made or are under consideration to address this issue, including the introduction of a parallel processing model whereby it is possible to lodge a submission for PBS listing before final TGA approval is obtained.

In the interests of transparency of the PBS listing process, the Medicine Status Website was launched in February 2020 and aims to enable the public to track the process of a medicine from PBAC application to listing.[41] In addition, though not without controversy, the Department of Health published a "Procedure Guidance for standardised redactions to Public Summary Documents" in April 2020, which seeks to minimise negotiation between the Department and sponsors of the redactions to confidential or sensitive information set out in Public Summary Documents.[42]

Emerging trends

As described in "Policy issues that affect pricing and reimbursement", "Statutory price reductions and Strategic Agreements" above, a Strategic Agreement was signed by Medicines Australia and the Commonwealth, with a five-year term. The purpose of that Strategic Agreement was to give some certainty to the prescription medicines industry and the Government. Since the pricing mechanisms were (necessarily) introduced into legislation,

there have been some instances where expectations of the industry have not aligned with understanding of the role of the Strategic Agreement and the agreement reached with the Government. This means that there is still some uncertainty around the application of pricing policy and the interface with legislation. Of course, a change in the Government always has the potential to impact these arrangements. It is also clear that the general trend and focus for the Government is to control budgetary pressure and to appropriately manage the cost of the PBS in the future.

In addition, as described in "Policy issues that affect pricing and reimbursement", "Rebates" above, the widespread use of rebates and a potential new structure for the reimbursement of (at least) high-cost medicines continues to be a current focus for the Government, both in the context of the PBS and the LSDP.

The Government has recently introduced a cost recovery approach to the fees associated with listing a medicine on the PBS, by reference to a detailed schedule of fees. That cost recovery scheme has resulted in a significant increase in those fees for sponsors. At the same time it has sought to decrease the times for PBS listing of priority medicines by introducing a system of the prioritisation of listing applications according to need. This system is in its early stages and it remains to be seen whether it will have any effect on time to reimbursement in Australia.

Finally, as with the rest of the world, we note that the COVID-19 pandemic has had a significant impact on sponsors of medicines, prescribers, dispensers and patients. The Government in Australia has acted promptly to address a range of matters in this space, including a shift to telehealth, introducing limits to discourage or prevent stockpiling, permitting remote dispensing of PBS medicines and relaxing restrictions which would otherwise require face-to-face attendance of vulnerable people at hospitals, health centres or pharmacies. We will be interested to see which of these initiatives will remain available in the future.

Successful market access

Critical to successful market access for an innovator prescription medicine sponsor is co-ordination between the company's clinical and pricing teams and a thorough knowledge of the competitive market for a particular drug and disease state. It is worth noting that the Government does not tend to be persuaded by comparative pricing in other international markets, although that may be a key driver for a particular sponsor. The Minister has broad discretion in relation to particular pricing decisions and those decisions may be difficult (and costly) to challenge.

New entrants to Australia sometimes underestimate the importance given to the role and independence of the PBAC and the principal Health Technology Assessment body. While the PBAC will be acutely aware of the broader political and market environment in which an application for listing is made, its approach is fundamentally data-driven. The PBAC will not recommend a product for listing unless the available data support its clinical efficacy and justify the price sought by the sponsor relative to the alternatives and in accordance with what the PBAC regards as acceptable cost-effectiveness.

A well-planned pricing strategy must give consideration to both the clinical needs of patients and the Government's budgetary pressures (and desire to focus upon lowest-cost comparators). If a sponsor wishes to seek a higher price for a medicine seeking listing, this must be justifiable by reference to the available alternatives and the advantages (whether clinical or economic) of the new product seeking listing compared to alternative therapies.

Endnotes

1. Unless otherwise indicated, data presented in this introduction and overview are sourced from the Australian Bureau of Statistics (https://www.abs.gov.au).
2. https://www.aihw.gov.au/reports-data/australias-health. "Australia's health 2020" is described on the AIHW website as the 17th biennial report on the health of Australians, presented as a set of data insights, health snapshots and a brief, visual report.
3. Budget 2021–22, Portfolio Budget Statements 2021–2022, Budget Related Paper No 1.7 – Health Portfolio, 2021; https://www.health.gov.au/sites/default/files/documents/2021/05/budget-2021-22-portfolio-budget-statements-budget-2021-22-health-portfolio-budget-statements.pdf. See also 'Guaranteeing the essential services', https://budget.gov.au/2021-22/content/essentials.htm#one.
4. 2018–2019 Medicines Australia Federal Budget Submission (https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/2018-2019-MA-Federal-Budget-Submission.pdf). This figure has not been updated in the 2019–2020 Medicines Australia Federal Budget Submission (https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2020/02/Medicines-Australia-Pre-Budget-Submission.pdf nor the Medicines Australia Pre-Budget Submission 2021-22 (https://www.medicinesaustralia.com.au/wp-content/uploads/2021/03/MA-Pre-Budget-Submission-2021-22.pdf).
5. http://www.pbs.gov.au/info/about-the-pbs.
6. Section 3, Therapeutic Goods Act 1989 (Cth) – "Medicine".
7. Sections 84 "PBS prescriber", 88–90 of the National Health Act. The Schedule of Pharmaceutical Benefits identifies which items are able to be prescribed by which type of PBS prescriber (e.g. dentists and optometrists cannot prescribe general PBS items but have access to a separate Dental Schedule or Optometrical Schedule (respectively)).
8. https://www.health.gov.au/initiatives-and-programs/life-saving-drugs-program.
9. https://www.health.gov.au/sites/default/files/documents/2020/10/ensuring-the-future-sustainability-of-the-life-saving-drugs-program.pdf.
10. https://www.health.gov.au/sites/default/files/documents/2020/10/procedure-guidance-for-medicines-funded-through-the-life-saving-drugs-program-lsdp.pdf (section 3 – "Funding criteria").
11. Currently, Belgium, Finland, Ireland, Italy, Malta, the Netherlands, New Zealand, Norway, Slovenia, Sweden and the United Kingdom.
12. Includes medical treatment by a medical practitioner, dental treatment by a participating dental practitioner, optometrical treatment by an authorised optometrist, midwifery treatment by an authorised midwife or nurse practitioner treatment by an authorised nurse practitioner (section 86 of the National Health Act).
13. http://www.pbs.gov.au/info/about-the-pbs#What_are_the_current_patient_fees_and_charges.
14. Section 85 of the National Health Act.
15. Section 101 of the National Health Act sets out the functions of the PBAC.
16. Section 101(3A) of the National Health Act.
17. Section 101(3B) of the National Health Act. Section 100 of the National Health Act also empowers the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons living in isolated areas, who are receiving treatment in circumstances where pharmaceutical benefits are inadequate for that treatment or if the pharmaceutical benefits can be more conveniently or efficiently supplied under those arrangements. Examples include the Efficient Funding of Chemotherapy programme, Highly Specialised Drugs Program and IVF Program (https://www.pbs.gov.au/browse/section100).

18. https://pbac.pbs.gov.au/content/information/files/pbac-guidelines-version-5.pdf.
19. Page 4, PBAC Guidelines.
20. https://www.pbs.gov.au/industry/listing/procedure-guidance/files/Procedure-guidance-for-listing-medicines-on-the-Pharmaceutical-Benefits-Scheme-v2.0.pdf.
21. Section 85AB of the National Health Act.
22. http://www.pbs.gov.au/info/general/independent-review/independent-review-pbs-info-for-applicants.
23. https://www.pbs.gov.au/info/general/seventh-community-pharmacy-agreement.
24. Section 85AD of the National Health Act.
25. Page 60, PBAC Guidelines.
26. Section 85E of the National Health Act empowers the Minister to enter into such deeds on behalf of the Commonwealth.
27. Sections 99ACF, 99ACHA, 99ACJ, 99ACK of the National Health Act.
28. Section 99ACB of the National Health Act.
29. Part 7, Division 2 – Subdivision B (sections 71–81) of the National Health (Pharmaceutical Benefits) Regulations 2017 (Cth).
30. Section 103(2)(a) of the National Health Act.
31. Section 103(2A) of the National Health Act.
32. http://www.pbs.gov.au/info/general/biosimilars.
33. http://www.pbs.gov.au/info/industry/useful-resources/memorandum.
34. See, for example, https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf.
35. https://www.gbma.com.au/wp-content/uploads/2015/09/GMiA_StrategicAgreement_SignedCommonwealthandGMiA_-150524_FINAL.pdf.
36. https://www.gbma.com.au/wp-content/uploads/2016/01/GBMA-agreement.pdf.
37. https://medicinesaustralia.com.au/policy/strategic-agreement/.
38. http://www.pbs.gov.au/info/industry/pricing/improving-access-to-medicines-improved-payment-administration.
39. The Government's Guidelines for Deeds of Agreement (version 1.5 dated 7 October 2020), including a template Deed, can be found here: https://www.pbs.gov.au/pbs/industry/listing/elements/deeds-agreement.
40. https://www.medicinesaustralia.com.au/wp-content/uploads/2021/06/Medicines-Australia-Facts-Book-2021.pdf.
41. https://www.pbs.gov.au/medicinestatus/home.html.
42. https://www.pbs.gov.au/info/news/2020/04/procedure-guidance-standardised-redactions-to-psds.

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