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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 almost 27 million people.[1] It is a generally healthy nation, with a life expectancy of 83, two years above the OECD average of 81.[2] 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 30 June 2023, is recorded as 38.32 years, compared to approximately 32.7 years in June 1992. The median age is expected to increase to between 43 and 48 years over the next 50 years.[3]

In September 2023, Australia's population growth rate was recorded at 2.52%, with net overseas migration increasing by 60.3% since the previous year.

Typically, roughly two-thirds of Australia's population growth is attributable to immigration and one-third to natural increases. Compared with many other nations, Australia experienced relatively low mortality during the early years of the pandemic, although infection and mortality rates increased significantly during 2022. Unsurprisingly, international border restrictions in 2020 and 2021 had a significant impact on overseas migration, which in turn impacted Australia's population growth. The 2022–2023 growth rate represented a record high; however, the cycle of migration has not yet returned to the pattern seen before the COVID-19 pandemic.[4]

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 2022:[5]

- The life expectancy of a person born in 2018–2020 is 81.2 years for a male and 85.3 years for a female (which has been rising steadily over time).
- In 2020, the leading causes of death in Australia were coronary heart disease for males, and dementia, including Alzheimer's disease, for women.
- Today, more people are living longer with chronic conditions. Almost half of all Australians (approx. 47% in 2020–2021) were estimated to have one or more of the following conditions: arthritis; asthma; back problems; cancer; chronic kidney disease; chronic obstructive pulmonary disease; diabetes; mental and behavioural conditions (including mood disorders, alcohol and drug problems and dementia); osteoporosis; and selected heart, stroke and vascular diseases.
- There has also been an increase in recent years in the number of deaths of young people from suicide and external causes (e.g. drug misuse) affecting males more than females.
- Many chronic conditions share risk factors that are modifiable, including tobacco smoking, insufficient physical activity, poor diet, overweight and obesity, and other biomedical risk factors such as high blood pressure. In 2021, Australia had the ninth highest rate (out of 21 OECD countries with available data) for people aged 15 and over living with overweight or obesity. Sixty-five per cent of Australians aged 15 or over were estimated to be overweight or obese.
- 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 higher 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:

> "*[T]he 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.

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).
- There is a private hospital system that 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 Commonwealth Budget (released in May 2024) commits overall spending on health and aged care for 2024–2025 is AU$146.1 billion, with a five-year commitment to invest AU$10.7 billion, including AU$8.5 billion in health. In health, this includes investments to Medicare (AU$2.8 billion), delivery of cheaper medicines (AU$4.3 billion), mental health, including a AU$361.0 million commitment over four years to expand free mental health services, and women's health, committing AU$49.1 million for higher Medicare rebates for women to see a gynaecologist for complex conditions like endometriosis. The Commonwealth has described its commitments to maintaining access to cheaper medicines as including funding to support a freeze on the maximum patient co-payments for PBS prescriptions, a national "one-stop shop" for clinical trials and additional funding to support the Medical Research Future Fund.[6] 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 and reimbursement paid to the Commonwealth by sponsors of high-cost prescription pharmaceuticals. In 2022–2023, the Commonwealth reported recoveries relating to cost-sharing arrangements with pharmaceutical companies under the PBS totalled almost AU$4.7 billion. Further information about those rebates is discussed in greater detail in section "Policy issues that affect pricing and reimbursement" below.[7]

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.[8] 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 Commonwealth and the industry body

for prescription medicine sponsors, Medicines Australia, firstly, with a memorandum of understanding in 2010, and later with five-year strategic agreements from 2017–2022 and 2022–2027; and similar agreements between the Commonwealth and the Generic and Biosimilar Medicines Association).

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.[9]

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.[10]

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. 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 18 medicines available to eligible patients for the treatment of 11 rare conditions.[11]

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.[12]

In 2018, in response to the 2014 Post-Market Review of the LSDP, the LSDP Expert Review Panel commissioned eight disease-based reviews of existing LSDP medicines, to explore suitability of each medicine, appropriateness of eligibility or exclusion criteria and testing, and avenues to improve LSDP's overall value for money. On 24 March 2022, the LSDP Expert Review Panel published a report[13] that outlined 51 recommendations, including medicine-specific recommendations and recommendations on the programme. Recommendations proposed development and publication of a statement of rationale (including criteria for eligibility), review of data collection mechanisms and management, and considering adding criteria to set and adjust reasonable pricing criteria. There is also a 24-month review process by which newly listed medicines on the LSDP are considered, to assess "real-world" performance and use of the medicine as against recommendations and expectations at the time of listing.

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[14] 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,[15] except as follows:

- A patient co-payment which, from 1 January 2024, is AU$31.60, or AU$7.70 if the patient has a concession card, for most PBS medicines. The standard co-payment was substantially reduced on 1 January 2023, as part of Commonwealth Budget Measures designed to improve access to affordable medicines for eligible persons. Pharmacists may (voluntarily) choose to discount the PBS patient co-payment by up to AU$1 for some medicines (although this will be phased out, in accordance with Budget measures agreed in the context of negotiating the eighth Community Pharmacy Agreement (**8CPA**)).[16]
- 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$3.45); and an additional fee for ready-prepared items (currently AU$1.40). 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 2024) are AU$277.20 for concession card holders and AU$1,647.90 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.

The Commonwealth Minister for Health is empowered by the National Health Act to list medicines as pharmaceutical benefits on the Schedule.[17] 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 PBAC is established by the National Health Act to act as an advisor to the Department of Health and Aged Care and Minister for Health and Aged Care 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.[18] 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.[19] 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.[20]

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**).[21] The PBAC Guidelines identify five quantitative factors that influence PBAC decision-making:[22]

(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 and Aged Care has also published "Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme" (version 2.5, November 2022),[23] 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 and the Economic Sub-Committee; consideration by the PBAC itself; recommendation by the PBAC to make or not make the requested listing; (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

The Minister may determine that a particular listed drug is on one of the formularies, called F1 or F2.[24] 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. If a listed drug is in a combination item and there are no brands of combination items that have the drug, and are bioequivalent or biosimilar, it will be placed on the Combination Drugs List (section 85AB(5) National Health Act).

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.[25]

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 that 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 Eighth Community Pharmacy Agreement between the Commonwealth, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia (which commenced 1 July 2024) sets out how the Commonwealth price is set.[26]

For private hospitals, the *National Health (Commonwealth Price – Pharmaceutical benefits supplied by private hospitals) Determination* 2020 *(PB 99 of 2020)* (Cth) applies. For public

hospitals, *National Health (Commonwealth Price – Pharmaceutical Benefits Supplied By Public Hospitals) Determination* 2017 *(PB 25 of 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 Aged Care 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.[27] 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 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.[28] 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.[29] The formula is sometimes a simple percentage rebate of the Commonwealth price and in other cases may involve a reimbursement applying once the Commonwealth payment moves above a certain level. There are also examples of differential rebates being paid for different uses (indications) 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, including anniversary price reductions which apply on the fifth, 10th and 15th anniversary of listing for drugs on the F1 formulary and, as

well as certain "catch-up" price reductions (see section below titled "Statutory price reductions and strategic agreements"),[30] 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 – depending on the previous price reductions that have applied to the pharmaceutical item in question, and subject to exercise of Ministerial discretion. Exemptions may also be available from the statutory price reduction on the first listing of a new brand of a pharmaceutical item that is a new presentation of an existing medicine.[31]
- 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[32] 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, in practice, 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

An issue that has remained firmly on the agenda for the innovative medicines industry in recent years is the selection of the appropriate comparator therapy or therapies for the PBAC process and pricing decisions made in negotiation with the Minister or delegate. The National Health Act provides that the PBAC's task includes considering the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies. Industry participants often observe a focus on "lowest cost comparator" in deference to other features which might point to the appropriateness of an alternative, higher cost comparator (e.g. having regard to real-world experience and reflecting technological advances or patient-level benefits in usage).

In addition to the issues flagged in the sections above, the Commonwealth's approach to biosimilar medicines and the interchangeability of those medicines at a pharmacy level has continued to receive heightened interest within the sector.

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.[33]

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.[34]

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 in 2015, directed at prescribers, pharmacists and consumers, which 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.[35]

The Department continues to look for new ways to encourage biosimilar uptake. For example, the PBS Schedule includes administrative notes for some adalimumab listings, which state:

> *"**Biosimilar prescribing policy***
>
> *Prescribing of the biosimilar brand Abrilada, Adalicip, Amgevita, Hadlima, Hyrimoz, Idacio and Yuflyma is encouraged for treatment naïve patients.*
>
> *Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments…"*

Work is expected to continue in this space to encourage uptake at a prescribing and patient-level.

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 (**HTA**) 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 Government reference pricing policy and the statutory price reduction mechanisms described in sections "Pharmaceutical pricing and reimbursement" and "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 and Biosimilar Medicines 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.[36] The Memorandum of Understanding was generally thought to have been effective in achieving cost control on PBS expenditure, 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,[37] an extension until 30 June 2020 and a further extension to 30 June 2022.[38] 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.[39] 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 HTA system itself) in maintaining the balance required for a sustainable medicines policy differ substantially.

On 6 September 2021, the Commonwealth entered into a new Strategic Agreement with each of Medicines Australia[40] and the Generic and Biosimilar Medicines Association.[41] Each of the Strategic Agreements will expire on 30 June 2027. Many aspects of the Strategic Agreements are reflected in amendments to legislation which have commenced on a staged basis, with the first amendments taking effect on 1 July 2022 (*National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act* 2021 (Cth) and *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations* 2021). Relevantly, the amendments have modified the statutory price reduction regime, changing the anniversary price reductions and introducing certain "catch-up" price reductions, which started on 1 April 2023. The amendments also introduced a "floor price" and a minimum stockholding requirement for certain medicines on the PBS.

For innovative medical sectors, the Commonwealth has also committed to support and resource a HTA policy and method review. At the time of writing, the HTA Review Reference Committee is finalising its report and recommendations to the Commonwealth. The report and recommendations are expected by June 2024.[42]

In addition, the Commonwealth and Medicines Australia have agreed to work with patient groups to co-design a process to increase patient participation in the PBS medicine assessment process and have committed to establish an annual Horizon Scanning Forum with the industry to identify major therapeutic advances in future years.

Rebates

The last 20 years have seen dramatic growth in the use of risk-sharing agreements (described in sections "Pharmaceutical pricing and reimbursement" and "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, this historically created an accounting problem because rebates could be paid months and sometimes more than a year after the supply occurred.

As a result, the Government took on the task of seeking amendments to all (then) current Deeds of Agreement (reflecting 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).[43] The Government's guidelines for Deeds of Agreement were updated in July 2020.[44]

There has been some speculation about changes to the Government's approach to special pricing arrangements; however, reports of new criteria and, 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 showed a decline over time and the deferral rate shows an increase over time.[45]

A range of PBS process improvements, including parallel processing and the introduction of different pricing pathways (and related cost recovery measures), have recently been introduced. Metrics published by the Department of Health and Aged Care for the 2022–2023 financial year recorded the number of days from PBAC minutes to PBS listing for cost minimisation submissions recommended first time was an average of 182 days and a median of 187 days.[46]

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.

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.[47] In addition, though not without controversy, the Department of Health published "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.[48]

The Strategic Agreement between Medicines Australia and the Commonwealth states that Medicines Australia and the Commonwealth have shared goals to:

- reduce time to access for Australian patients so that they can access new health technologies as early as possible; and
- maintain the attractiveness of Australia as a first-launch country.

The Health Technology Assessment Policy and Methods Review (**HTA Review**) (which was a Strategic Agreement commitment, is currently underway and nearing completion (see the section "Emerging trends", below).

Emerging trends

One of the most pressing issues facing the sector at the moment is the HTA Review and its likely consequences. The HTA Review was the result of a commitment recorded in the Strategic Agreement with Medicines Australia. The focus for the HTA Review is the goals shared by the Commonwealth and Medicines Australia of:

- "reducing time to access for Australians so that they can access new health technologies as early as possible; and
- maintaining the attractiveness of Australia as a first-launch country to build on Australia's status as a world leader in providing access to affordable healthcare;

by ensuring that our assessment processes keep pace with rapidly advancing health technology and minimise barriers to access."[49]

The HTA Review extends to health technologies including all medicines and vaccines, highly specialised therapies such as cell and gene therapies, other related health

technologies that improve health outcomes with the aforementioned technologies, and foreseeable changes in health care that may influence the need, accessibility, effectiveness or cost-effectiveness of new health technologies. Recommendations may therefore be wide and varied. A final report and recommendations are due to be published imminently, and expected by June 2024. The Commonwealth's response, and proposals and timeline for any related implementation, will be matters being watched very closely by the industry.[50]

As described in the sections "Policy issues that affect pricing and reimbursement" and "Statutory price reductions and strategic agreements" above, the Strategic Agreements between the Government and each of Medicines Australia and the Generic and Biosimilar Medicines Association are each now into their third year of operation. Associated amending legislation has now commenced, with substantial impacts to pricing experienced across a large range of pharmaceutical items, with the introduction of a "catch-up" price reduction on 1 April 2023 (section 99ACN of the National Health Act). That catch-up brought the cumulative impact of statutory price reductions to each listed brand of a pharmaceutical item having a drug listed for more than 15 years to 36.82%. The application of this catch-up price reduction led to substantial controversy within the industry, with very large numbers of applications made to the Minister seeking to have the price reduction removed or reduced for specific medicines.

One of the other more controversial changes was the implementation of the minimum stockholding requirements for certain PBS-listed medicines, which took effect from 1 July 2023. This is likely to lead to significant impact for some sponsors in managing their inventory for Australia.

Because the Strategic Agreements reflect a negotiated position reached on behalf of industry, and each industry participant will have their own internal drivers, it is likely there have been, and will continue to be, instances where expectations of the industry do not align with understanding of the role of the agreements reached with the Government.

For single brand medicines there remains more room for price negotiation based on the application of pricing policy. This means that there is still some uncertainty around the application of pricing policy and the interface with legislation. 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.

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 (particularly to the extent that Australia represents a market for international reference pricing purposes). 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 as a key HTA 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. There has been significant discussion within the industry and wider stakeholder groups about what evidence, beyond traditional approaches, can be used to support PBAC submissions for listing, and how related uncertainty can be managed. Some of these issues may be dealt with following delivery of the HTA Review report and its recommendations.

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.oecdbetterlifeindex.org/topics/health/#:~:text=On%20average%2C%20life%20expectancy%20at,life%20expectancy%20of%2084%20years

3 https://www.abs.gov.au/statistics/people/population/population-projections-australia/2022-base-2071

4 https://www.abs.gov.au/statistics/people/population/overseas-migration/2022-23-financial-year

5 https://www.aihw.gov.au/reports-data/australias-health "Australia's health 2022" is described on the AIHW website as the 18th biennial report on the health of Australians, presented as a set of data insights, health snapshots and a brief, visual report.

6 Budget 2024–2025 Stakeholder Pack (https://www.health.gov.au/sites/default/files/2024-05/budget-2024-25-stakeholder-pack.pdf); Media release, the Hon. Mark Butler MP "Budget 2024–25: Cheaper medicines, new Medicare Urgent Care Clinics and more free mental health services in a stronger Medicare" (https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/budget-2024-25-cheaper-medicines-new-medicare-urgent-care-clinics-and-more-free-mental-health-services-in-a-stronger-medicare?language=en).

7 Department of Health and Aged Care Annual Report 2022–2023, pages 162 and 192. https://www.health.gov.au/sites/default/files/2023-10/department-of-health-and-aged-care-annual-report-2022-23_0.pdf

8 https://www.pbs.gov.au/info/about-the-pbs

9 Section 3, *Therapeutic Goods Act* 1989 (Cth) – "Medicine".

10 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)).

11 https://www.health.gov.au/our-work/life-saving-drugs-program/about-the-lsdp#lsdp-medicines

12 https://www.health.gov.au/sites/default/files/documents/2021/11/procedure-guidance-for-medicines-funded-through-the-life-saving-drugs-program-lsdp.pdf (section 3 – "Guidance for preparing applications – LSDP Application: Funding criteria" at p. 9).

13 https://www.health.gov.au/sites/default/files/documents/2022/04/life-saving-drugs-program-lsdp-medicines-reviews-recommendations-lsdpep-medicines-reviews-recommendations.pdf

14 Currently, Belgium, Finland, Ireland, Italy, Malta, the Netherlands, New Zealand, Norway, Slovenia, Sweden and the United Kingdom.

15 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).

16 https://www.pbs.gov.au/info/about-the-pbs#What_are_the_current_patient_fees_and_ charges

17 Section 85 of the National Health Act.

18 Section 101 of the National Health Act sets out the functions of the PBAC.

19 Section 101(3A) of the National Health Act.

20 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 Programme and IVF Programme (https://www.pbs.gov.au/browse/section100).

21 https://pbac.pbs.gov.au/content/information/files/pbac-guidelines-version-5.pdf

22 Page 4, PBAC Guidelines.

23 https://www.pbs.gov.au/industry/listing/procedure-guidance/files/Procedure-guidance-for-listing-medicines-on-the-Pharmaceutical-Benefits-Scheme-v2.5.pdf

24 Section 85AB of the National Health Act.

25 https://www.pbs.gov.au/info/general/independent-review/independent-review-pbs-info-for-applicants

26 https://www.health.gov.au/sites/default/files/2024-06/eighth-community-pharmacy-agreement.pdf

27 Section 85AD of the National Health Act.

28 Page 60, PBAC Guidelines.

29 Section 85E of the National Health Act empowers the Minister to enter into such deeds on behalf of the Commonwealth.

30 Sections 99ACF, 99ACHB, 99ACJA, 99ACKA, 99ACKB and 99ACP of the National Health Act, as introduced by amendments under the Strategic Agreement 2022–2027. "Catch-up" price reductions are found in sections 99ACM, 99ACN and 99ACNA.

31 Section 99ACB of the National Health Act.

32 Part 7, Division 2 – Subdivision B (sections 71–81) of the *National Health (Pharmaceutical Benefits) Regulations* 2017 (Cth).

33 Section 103(2)(a) of the National Health Act.

34 Section 103(2A) of the National Health Act.

35 https://www.pbs.gov.au/info/general/biosimilars

36 https://www.pbs.gov.au/info/industry/useful-resources/memorandum

37 https://www.gbma.com.au/wp-content/uploads/2015/09/GMiA_StrategicAgreement_SignedCommonwealthandGMiA_-150524_FINAL.pdf

38 https://www.gbma.com.au/wp-content/uploads/2016/01/GBMA-agreement.pdf

39 https://www.medicinesaustralia.com.au/policy/strategic-agreement-2022-2027

40 https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/09/Medicines-Australia-Strategic-Agreement-2022-2027.pdf

41 https://www.gbma.com.au/wp-content/uploads/2021/09/GBMA-Strategic-Agreement-Signed.pdf

42 https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review

43 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

44 https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/attachment-a-pdf-printable-version-of-guidelines-for-deeds-of-agreement-for-the-pbs.pdf

45 https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/06/Medicines-Australia-Facts-Book-2021.pdf

46 https://www.pbs.gov.au/general/process-improvements/Stage-1-and-2-PBS-Process-Improvements-Metrics-Report-2022-23.pdf

47 https://www.pbs.gov.au/medicinestatus/home.html

48 https://www.pbs.gov.au/info/news/2020/04/procedure-guidance-standardised-redactions-to-psds

49 https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review; https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf

50 https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf

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