



What is the PBS?

The Pharmaceutical Benefits Scheme (PBS) is a key component of the Australian healthcare system.

The PBS subsidises the cost of hundreds of medicines, ensuring Australians have affordable access to medicines when they need them. Under the PBS, Australians currently pay a maximum of \$42.50 per prescription, or \$6.80 for concession card holders, until they reach a set threshold, at which point medicines become cheaper or free¹.

How do medicines get listed on the PBS?

Before a medicine can be listed on the PBS, there is a multi-stage approvals process.



Firstly, the Therapeutic Goods Administration (TGA) must provide regulatory approval for registration of a medicine. One of the roles of the TGA is to assess the safety, quality, and efficacy of a medicine.

If the TGA approves a medicine, that medicine is legally able to be sold in Australia.

Unless a medicine is listed on the PBS, patients must pay the full cost of that medicine, which may be prohibitively expensive for many people.²

That is why sponsors (often pharmaceutical companies) will apply to the Pharmaceutical Benefits Advisory Committee (PBAC) for a drug to be recommended for listing.

The PBAC is an independent body of experts that assesses how well a medicine works, what potential risks it may have, and the cost-effectiveness of a drug compared with other treatments.³

After considering these factors, the PBAC makes recommendations to the Minister for Health about whether a medicine should be listed on the PBS. A medicine cannot be listed on the PBS unless it has received a positive recommendation from the PBAC.³

Once a positive recommendation from the PBAC is received, a sponsor then negotiates pricing arrangements with Government before the medicine is eventually listed on the PBS.

Difference between the TGA and Pharmaceutical Benefits Advisory Committee (PBAC)



TGA

Assesses whether a medicine is effective and what undesired effects might occur



PBAC

Assesses cost-effectiveness of medicines

Recommends whether medicine should be subsidised on PBS

Are all medicines listed on the PBS?

906

There are approximately 906 medicines (as at June 2021) listed on the PBS however not all medicines that have been registered by the Therapeutic Goods Administration (TGA) are available on the PBS.⁴

391 days

The process to receive advice from the PBAC for listing a medicine on the PBS can be lengthy. On Australia, it takes on average 391 days after TGA registration to list a medicine on the PBS.²

For some disease areas, such as cancer, it can take even longer. On average it takes 610 days for a cancer treatment to be listed on the PBS in Australia after the TGA has determined can be registered.⁵

610 days

The lack of availability of medicines on the PBS may create health inequities. Patients able to afford the full cost of a medicine are able to access it, while those who cannot, may miss out on a treatment.³



Strengthening the PBS

The PBS is a fundamental component of Australia's healthcare system and has served the country well for decades.

As more innovative medicines and treatments are rolled out, however, there is a need to ensure the PBS approvals process is modernised so that it can keep up with this rate of innovation and provide Australians with affordable access to the latest medicines.

The process for medicines becoming listed on the PBS will be reviewed this year.⁶ This is an important opportunity to continue building a stronger PBS in Australia and ensuring patients have access to affordable medicines for a range of serious diseases, such as diabetes and cancer.

1. Health Direct, 'Pharmaceutical Benefits Scheme' www.healthdirect.gov.au/pharmaceutical-benefits-scheme-pbs Accessed May 2022 2. MSD Australia, 'Making the case for investment in cancer in Australia: Extended briefing', Data on file 3. Australian Government Department of Health, 'Pharmaceutical Benefits Advisory Committee' www.pbs.gov.au/pbs/industry/listing/participants/pbac Accessed May 2022 4. Australian Government Department of Health, 'PBS Expenditure and Prescriptions Report 1 July 2020 to 30 June 2021' www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-30-june-2021 Accessed May 2022 5. Medicines Australia, 'Medicines Australia (Comparison of Access and Reimbursement Environments: A report benchmarking Australia's access to new medicines - Edition 4' www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/MA_Compare-final.pdf Accessed May 2022 6. Medicines Australia, 'Reforming Australia's Health Technology Assessment (HTA) system' <https://www.medicinesaustralia.com.au/policy/health-technology-assessment-hta/> Accessed May 2022