How a medicine gets on to the Pharmaceutical Benefits Scheme (PBS)

The Pharmaceutical Benefits Scheme, or PBS, is an Australian Government Scheme that funds access to medicines for Australians. The PBS has provided Australians with access to life-saving and life-improving medicines for over 75 years.

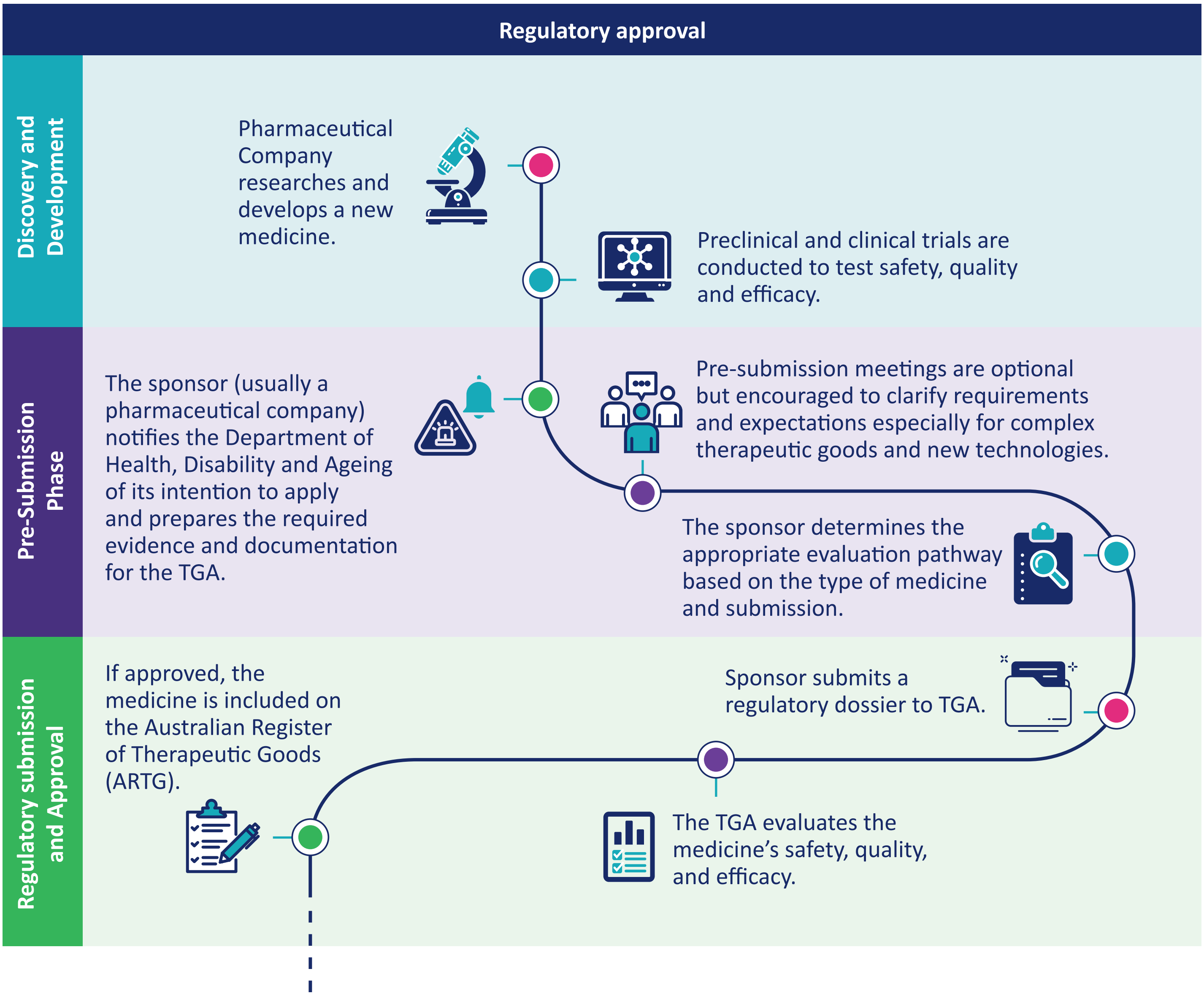
For medicines to be listed on the PBS, a pharmaceutical company must go through a structured and multi-step process. There are two main phases: regulatory approval and reimbursed access.

The PBS helps ensure Australians have affordable and equitable access to vital medicines.

Regulatory approval

Medicines are approved for sale in Australia by the Therapeutic Goods Administration (TGA). The TGA is responsible for assessing the package of evidence collected after years of research, to verify the claimed quality, safety and efficacy of the medicine. This process takes about twelve months and includes specialist evaluation and analysis of all data collected during the years of investigation of the new treatment.

Once the TGA approves a medicine, it is listed on the Australian Register for Therapeutic Goods (ARTG). At this point, the medicine is considered to have "TGA registration" or "marketing authorisation" and can legally be sold in Australia.



Government reimbursed access
Once a medicine has regulatory approval the sponsor can seek reimbursed access.

PBS Listing Process (Post-TGA Approval)

Sponsor applies for PBS listing.

The Pharmaceutical Benefits Advisory Committee (PBAC) evaluates the submission.

The PBAC uses a health technology assessment (HTA) system to evaluate new medicines against existing treatments for safety, effectiveness, cost-effectiveness, and total cost to the Government, based on information submitted by the sponsor.

The PBAC decides whether or not to recommend a medicine for listing on the PBS.

If the PBAC does not recommend a medicine for listing on the PBS, the sponsor will have to re-apply with additional information in order for the medicine to be reconsidered for listing on the PBS.

It often takes two or three applications by the pharmaceutical company and several meetings of the PBAC before a medicine is recommended for inclusion on the PBS.

Post-PBAC Process

Final arrangements are made regarding:
- Pricing
- Supply arrangements

Approval by the Minister for Health is required.

Listing on the PBS

PBS

Once all agreements are finalised, the medicine is officially listed on the PBS.

On the PBS and available to patients

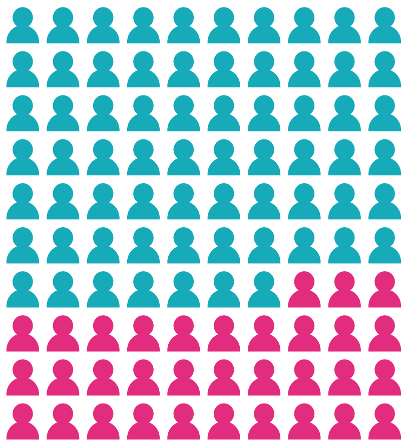
Once listed on the PBS, the medicine is subsidised by the Government.

Doctors can prescribe and Australians can access the medicine with a co-payment.

Reimbursed access

To list on the PBS, the manufacturer of the medicine needs to submit a package of clinical and economic evidence to the PBAC, to demonstrate the medicine's relative safety and efficacy and cost effectiveness compared to alternative treatments.

The PBAC consists of doctors, health professionals, health economists and consumer representatives, and is responsible for recommending to the Minister for Health which medicines are value for money and should be subsidised through the PBS.



In 2022–23, 17.8 million individual Australians, or

67%

of the population, had a PBS medicine dispensed.

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