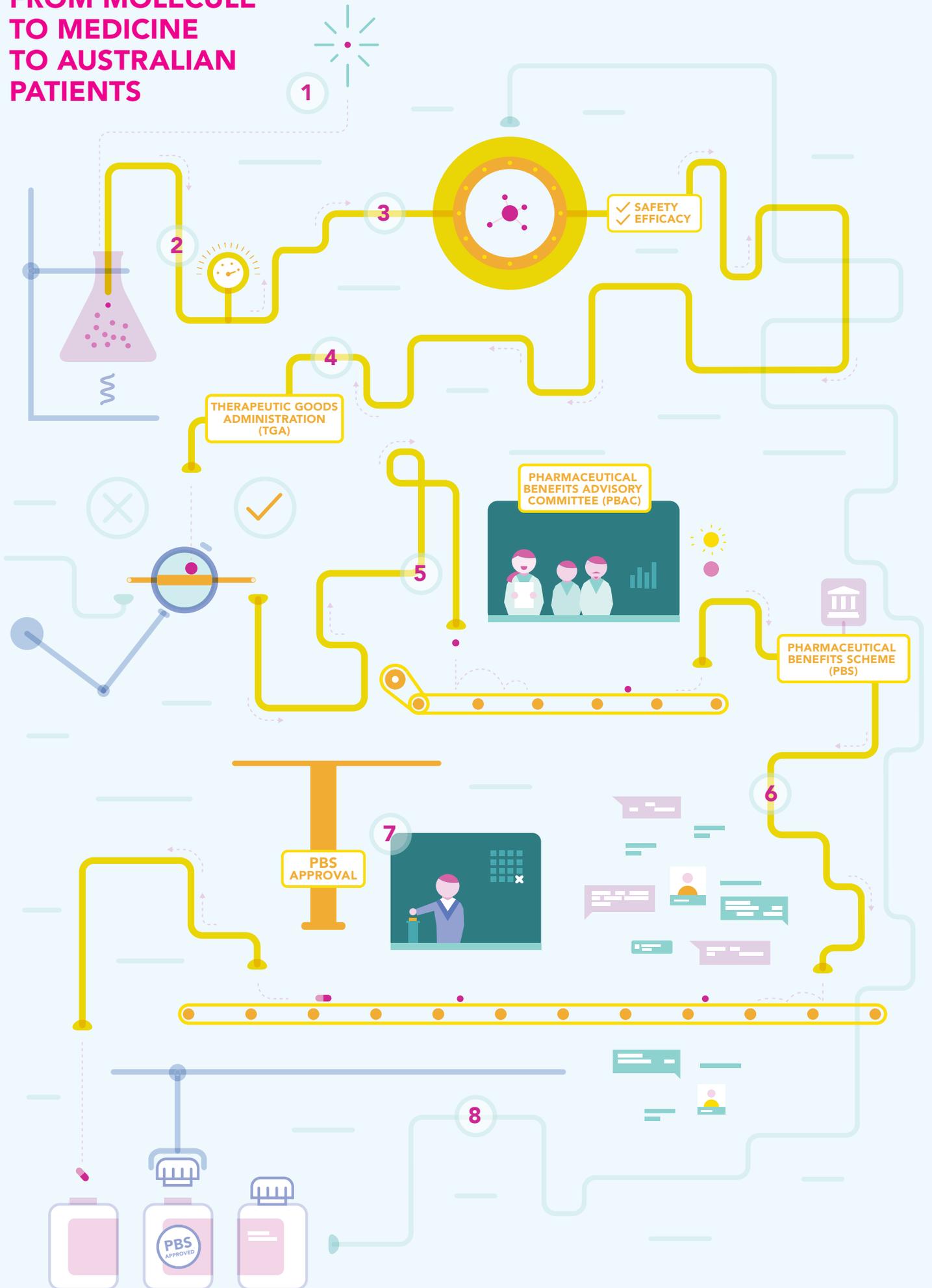


FROM MOLECULE TO MEDICINE TO AUSTRALIAN PATIENTS



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Access to safe and effective medicine has never been more important for Australian patients. The process by which a medicine is developed, trialled, reviewed and subsidised can be lengthy and complex. Developing a medicine has several key steps and must follow an established protocol. This guide provides an overview of the steps involved – from molecule to medicine to Australian patients – and how you can have an impact on the reimbursement approval process.

1 THE START OF SOMETHING BIG

Before a medicine becomes accessible to Australian patients, it starts off as a molecule, which is the foundation of every medicine.

2 EARLY PHASE AND PRE-CLINICAL RESEARCH

It all starts in the lab, where the aim is to discover the right molecule that can deliver the desired effect in a safe and effective manner. The molecule(s) are then developed into compounds, which can take 5–7 years on average.¹ Only the most promising compounds progress to testing in clinical trials.

3 CLINICAL TRIALS

Compounds are tested for efficacy and safety through a series of rigorous trials, which may take many years to conduct. If a compound is successful in clinical trials, it can then be considered for registration as a medicine.

4 REGISTRATION AND TGA REVIEW

The registration of a medicine is overseen by the Australian Government's Therapeutic Goods Administration (TGA) who determine whether a medicine is safe and effective for Australian patients. Medicines approved for registration are listed on the Australian Register of Therapeutic Goods (ARTG). The review and registration of a medicine with the TGA can take 1–2 years.¹

A medicine is usually registered by the TGA before it can be considered for subsidy by the Australian Government, although sometimes both reviews can take place in parallel.

5 REIMBURSEMENT AND PBAC REVIEW

The next step is for the Australian Government's Pharmaceutical Benefits Advisory Committee (PBAC) to determine if a medicine is clinically effective, safe and cost-effective. The PBAC is made up of healthcare professionals, health economists and consumer and pharmaceutical industry representatives.

The PBAC meets three times a year (March, July and November) to review medicines to be considered for subsidy by the Australian Government. On occasion, additional special meetings may be convened.

Submissions for medicines to be considered for subsidy by the Australian Government, usually from pharmaceutical companies, are evaluated for clinical benefit and cost-effectiveness.

6 HAVE YOUR SAY!

The PBAC welcomes input from caregivers, doctors, advocates and patients to help them make their decision.

If you're impacted by a disease for which a medicine is under review by the PBAC, you're encouraged to have your say during the PBAC review process.

10 weeks prior to each PBAC meeting, an agenda will be published, along with a call for comments from individuals and health professionals.

- To find out more about the PBAC review process, including details on how to submit consumer comments, you can visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-consumer-comments>
- For an opportunity to declare your interest in a particular medicine, you can access the PBAC online submission form at http://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form

7 PBS LISTING DATE

If the PBAC determines that a medicine is clinically effective, safe and cost-effective, it recommends the medicine for listing on the Pharmaceutical Benefits Schedule (PBS).*

A public summary document (PSD) is published approximately 4 months after the relevant PBAC meeting, which outlines the PBAC review and recommendation. The PBAC's recommendation is then reviewed by the Government and the Health Minister, who decide when the new medicine will be added to the PBS.

Once listed on the PBS, a medicine is subsidised by the Government and is affordable for Australian patients who need it.

8 NEW USE FOR OTHER CONDITIONS

If there's evidence to suggest that a medicine is effective in treating another condition, this can be explored through further clinical trials.**

So that is how a molecule becomes a medicine and is made available to Australian patients on the PBS. From the time of discovery of a molecule until it makes it to the patient, it takes an average of 12–16 years.¹

IT'S A LONG JOURNEY, BUT AN IMPORTANT ONE!

*If the PBAC rejects a medicine, it can still be reconsidered by the PBAC at a later date.

**In order for the medicine to treat another condition and be listed on the PBS, steps 2 through to 7 need to occur again.

Reference: 1. Medicines Australia. Medicines Australia Facts Book. Available at: www.medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/11/MAFactsBook4_update2015.pdf. Accessed November 2018.