

# Making a medicine: from testing to treatment

Medicines take years to make. They go through many steps to make sure they work and are safe.

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## Discovery

Researchers do many tests to find a new medicine. If researchers get good results, they may ask to test it on animals. A group of experts called an ethics committee approves and sets rules for this testing on animals. If this has good results, researchers move to testing the medicine on people. We call these tests clinical trials. Researchers need approval from another ethics committee for these trials.



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## Clinical Trials

Clinical trials have four phases:

Phase	Who	Tests	How many	How long
1	Healthy people	Safety, what the right doses are and any side effects.	Up to 100 people	Months
2	People with the illness	How well the medicine works.	Up to 300 people	Months to years
3	People with the illness	Re-tests how well the medicine works. Compares the medicines to current treatments and tracks side effects.	Up to 1000 people	Months to years
<b>After market approval (see below)</b>				
4	People in the real world	Safety and side effects of the medicine	1000s of people	Ongoing

In each phase 1-4, researchers gather more and more details about the medicine's safety and how it works. If the medicine passes Phase 3, the company that made it may ask to register and sell it in Australia.

Checking the safety and effects of the medicine continues during its use in Australia.

# 3

## Approval by Australia's Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) must approve all medicines before companies can sell them in Australia. The TGA checks:

- how well a company makes a medicine
- the amount of active ingredient in the medicine
- how safe the medicine is
- how well the medicine works to treat an illness.



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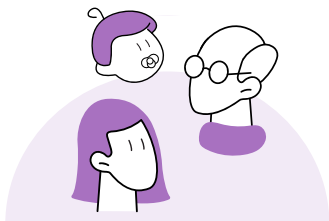
If approved, the TGA lists how and when to use the medicine. TGA approval lists:



The illnesses it can treat



Forms of the medicines available



The groups of people that can use it



The amount of medicine needed to treat illnesses

In special cases, doctors can access an 'unapproved' medicine. They might do this through Australia's Special Access Scheme.



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## Getting medicines in the community and at private hospitals

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When a healthcare professional thinks a medicine can help a person's illness, they need to write a prescription (script). Pharmacies use the script to supply the medicine.

### Pharmaceutical Benefits Scheme (PBS) Prescriptions

The PBS is a government funding program for medicines. The PBS covers most of the cost of the medicine, so it costs Australians less. An expert advisory committee for the PBS reviews medicines for listing on the PBS. It checks:

- how well the medicine works to treat an illness (benefits)
- how safe it is
- how it compares to current treatments
- its costs compared to the benefit it gives (value for money) and the costs of other treatments
- the costs to the government.

Over time, the PBS lists other brands of the same medicine, known as generic brands. This helps lower the cost of medicines. This means the PBS can fund more medicines for more people.

A local pharmacy can supply a PBS script.

### Private prescriptions

Health professionals can give private scripts. Private scripts are for medicines that are not covered by the PBS, so they can cost more.

A private health fund can sometimes help cover the cost.

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About the PBS



Generic Medicines



Understanding changing brands of biologics



## Getting medicines in public hospitals

State and Territory governments fund public hospital medicines. Each public hospital has a list of medicines for use. Hospitals call this a formulary. Medicines and Therapeutics Committees (MTCs) are a group of experts who decide which medicines to list on the formulary.

They use an agreed process to look at:

- a medicine's safety
- how well it treats an illness (benefit)
- if other choices exist
- how much it costs compared to:
  - the benefit it gives
  - other medicines.



The healthcare team will talk to you or a carer about where to get public hospital scripts.

To learn more about access to medicines in public hospitals, click or scan the QR codes



Off-label use of medicines



Medicines used through special access programs



High-cost medicines



Use of emerging and novel medicines

Researchers and healthcare professionals are finding new medicines and new ways of using medicines. This means that medicines and the way we use them often change.

**Australia's system to make and approve medicines aims to deliver the safest and best medicines.**

