



Australian Government

COVID-19 VACCINATION

6 steps to approve a vaccine



In Australia, the **Therapeutic Goods Administration (TGA)** approves all vaccines before they can be used.



The TGA is part of the Australian Government Department of Health.



The TGA makes sure the medicines we use in Australia:

- are safe
- work well.



The TGA always follow the same 6 steps to approve a vaccine in Australia.

Step 1 – Before making an application to have a vaccine approved



There are many companies around the world that make vaccines.

Companies must apply to the TGA for their vaccine to be approved.



Before a company can send the TGA an application, the company must tell the TGA:

- about the vaccine they want to be approved



- why people need the vaccine
- what clinical trials they have run.



A clinical trial is research to test if a vaccine:

- is safe
- works well.



The company must also tell the TGA how they will make sure in the future their vaccine:

- is safe
- works well.

If the TGA decides the company made the vaccine in the right way, they will tell them to apply.

Step 2 – The application to have a vaccine approved



The company must send an application to the TGA for their vaccine to be approved.



When they apply, the company must tell the TGA:

- how the clinical trials show the vaccine is safe and works well
- how the ingredients in the vaccine are safe



The company must also tell the TGA:

- how they will make the vaccine
- if there are any risks for people who have the vaccine.

Step 3 – Looking at the application



The TGA will carefully look at the:

- vaccine to make sure it is safe
- information the company provided.



The TGA will:

- work with other experts to make sure the vaccine is safe



- look at every ingredient in the vaccine to make sure it is safe.



The TGA will also:

- look at the clinical trials to make sure the vaccine is safe for everyone in Australia.



- make sure the vaccine meets Australian standards.



- look at how other countries around the world have used the vaccine.



The TGA might also ask the company more questions if they need to.

Step 4 – Making the decision



The TGA decides if they will approve the vaccine.



If the TGA approves the vaccine, they will approve it for 2 years.

After 2 years, the company can ask the TGA to approve the vaccine for up to 6 more years.

Step 5 – Registering the vaccine



After the TGA approves the vaccine, they will add it to the Australian Register of Therapeutic Goods (the Register).



The Register is a record of all the vaccines the TGA has approved in Australia.

The record includes:

- the name of the company
- the name of the vaccine
- what ingredients are in the vaccine
- information for people who get the vaccine.



After the vaccine is added to the Register, the company can start to send out the vaccine.

Step 6 – Keeping track of the vaccine

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The TGA will keep checking the vaccine as more people get it.



This is to make sure it:

- is still safe
- still works well.



If there are any problems, the TGA can:

- look into the problem with the vaccine
- give people new information about how safe the vaccine is
- take away the approval, if needed.

More information



You can visit the Department of Health website at www.health.gov.au/covid19-vaccines-languages for more information about the vaccine in your language.



You can call the National Coronavirus Helpline on **1800 020 080**.

If you need information in a language other than English, call the Translating and Interpreting Service on **131 450**.