



Australian Government

## COVID-19 VACCINATION

# COVID-19 vaccine



## 6 steps to approve a vaccine

### Easy Read fact sheet



The Australian Government wrote this fact sheet.  
When you see the word 'we', it means the  
Australian Government.



We wrote this fact sheet in an easy to read way.  
We use pictures to explain some ideas.



You can ask for help to read  
this fact sheet. A friend, family  
member or support person  
may be able to help you.



## What is this fact sheet about?



A **vaccine** is a type of medicine that:

- helps people fight a virus if they come in contact with it
- can stop people from getting very sick from the virus.



The COVID-19 vaccine teaches your body how to fight COVID-19.



The COVID-19 vaccine is a safe way to protect:

- you
- your family
- the community.



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



The TGA is a group of **independent** medical experts.



This means they make their own decisions using the scientific information they have.



The TGA makes sure the medicines we use in Australia work well.



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

We explain those 6 steps on the following pages.

## Step 1 – Before the application

There are many companies around the world that:



- make medicines and vaccines



- send out medicines and vaccines.



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

We call this an **application**.



Before a company can send the TGA an application, they must tell the TGA first.

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



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



- 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.

If the TGA decides that the company provided enough information, they will move on to Step 3.



## 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 questions if they need to.

## Step 4 – Making the decision



After Stage 3, 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 (ARTG).



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

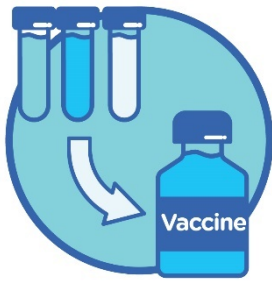
The record includes:



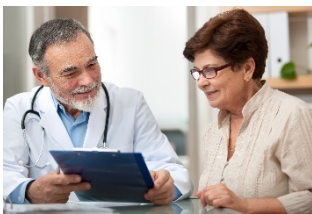
- the name of the company



- 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 ARTG, the company can start to send out the vaccine.

## Step 6 – Keeping track of the vaccine



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 their approval if they need to.

## More information



You can call the Disability Gateway on **1800 643 787**.

They are open from 8 am to 8 pm, Monday to Friday.



You can visit the Department of Health website at [www.health.gov.au](http://www.health.gov.au) for more information about the vaccine.



You can call the National Coronavirus and COVID-19 Vaccine Helpline on **1800 020 080**.



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



If you are deaf, or have a hearing or speech impairment, you can call the National Relay Service on **133 677**.



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