COVID-19 VACCINATION

Safe. Effective. Free.

Information sheet

About the Pfizer/BioNTech vaccine

The Pfizer/BioNTech vaccine has been provisionally approved by the Therapeutic Goods Administration (TGA) for individuals 16 years and older. Detailed information on the decision can be found on the TGA website www.tga.gov.au/covid-19-vaccines.

This vaccine requires two doses, at least 21 days apart.

The TGA has rigorously evaluated all clinical trial data and information provided by Pfizer/BioNTech. Further data on safety, quality and effectiveness will continue to be provided to the TGA by Pfizer/BioNTech.

As part of Australia's Vaccine and Treatment Strategy, the Australian Government has purchased an initial 10 million doses of the Pfizer/BioNTech vaccine, and has the option to purchase more doses. The vaccine will be manufactured overseas.

What happens now?

Now that Australia has a COVID-19 vaccine that has been provisionally registered by the TGA, there are a number of next steps it must go through before it can be rolled out.

Vaccine batches must be dispatched from the manufacturer, received at our borders and checked by the TGA, allocated and distributed to vaccination sites and then received by health care professionals to administer.

In anticipation of this governments are already preparing to administer vaccines by:

- preparing safe and secure cold chain storage
- training the workforce who will administer the vaccines
- organising and checking equipment
- activating systems for ongoing monitoring.

How will vaccines be rolled out?

The first group of Australians will start receiving the COVID-19 vaccine in February.

The Government's priority is to protect our most vulnerable Australians first, and the frontline heroes who are protecting all of us.

This includes aged care and disability care residents and workers, frontline health care workers, and quarantine and border workers.

The first priority groups will be vaccinated at up to 50 hospital sites across the country, and in residential aged care and disability facilities.

The vaccine will be rolled out in five phases over coming months. For details on the phased approach for the vaccine rollout visit www.health.gov.au/covid19-vaccines.

Where will vaccines be available?

Vaccination locations will be established across metropolitan, regional, rural and remote Australia.

About 30-50 locations will be established as ongoing Hospital Hubs in urban and rural Australia. The sites of these are being finalised in conjunction with States and Territories. They will manage cold chain storage and Pfizer vaccine only and will provide a distribution hub for hospital, quarantine and border staff and residential aged care and disability residents and staff.

Do I have to get a vaccine?

Australians have a great record in being immunised. The COVID-19 vaccine will be voluntary, universal and free. The Government aims to have as many Australians as possible choose to be vaccinated for COVID-19. If people choose not to have a COVID-19 vaccine, this will not affect their family's eligibility for Family Tax Benefit Part A or childcare fee assistance which only includes National Immunisation Program vaccines for those aged younger than 20.

It is possible that in future, vaccination against COVID-19 might become a requirement for travel to certain destinations or for people working in certain high-risk workplaces. If this becomes the case, there will be exemptions in place for people who are unable to be vaccinated.

What are likely side effects from COVID-19 vaccines?

As part of regulatory assessment the TGA considers information about possible side effects. For a vaccine to be registered for use in Australia, the benefits must outweigh the risks.

The TGA will continue to monitor vaccines after they are registered so that we can detect and respond to any safety concerns. Australia has a strong and well-established safety monitoring system for vaccines. Reports of suspected side effects from health professionals and consumers contribute to safety monitoring.

More information about how we're monitoring COVID-19 vaccine safety, what to do if you think you're experiencing a side effect, and how to report adverse events, is available from the TGA website.

Can pregnant and breastfeeding women get vaccinated?

Clinical trials for new medicines do not typically include pregnant or breastfeeding participants. Each country that is or has hosted clinical trials for COVID-19 vaccine candidates has different guidance regarding use of COVID-19 vaccines in pregnancy based on the benefits, risks and uncertainties in the context of the prevailing pandemic situation.

In preparation for vaccine rollout, the Australian Technical Advisory Group on Immunisation (ATAGI) is currently finalising clinical advice for health care providers on the use of COVID-19 vaccines in Australia in 2021. This is likely to include advice in relation to pregnant women. This advice will be provided as soon as it is received.

Can I get the COVID-19 vaccine and the annual influenza vaccine?

Routine scheduling and giving an influenza vaccine with a COVID-19 vaccine on the same day is not recommended. The preferred minimum interval between a dose of seasonal influenza vaccine and a dose of the Pfizer COVID-19 vaccine is 14 days.

People should talk to their health care professional for more information.

Will the vaccine be effective against new variants?

Clinical trials, so far, are showing that the Pfizer vaccine induces antibodies that are able to respond to a variety of mutations. We will continue to closely monitor developments and do our own genetic examination of local cases.

Where people can go for trusted information?

For the latest up-to-date information about COVID-19 vaccines visit the Department of Health website at www.health.gov.au/covid19-vaccines

People can also subscribe to regular updates from the website.

Information can also be accessed on the Department of Health's social media channels on Facebook, Twitter, Linkedin, Instagram and Youtube.

Vaccines & Immunisation

Immunisation

Immunisation is the process of both receiving a vaccine and becoming immune to the disease as a result. Immunisation protects you from harmful diseases before you come into contact with them, and protects others in the community by reducing the spread of the disease. It uses your body's natural defences to build resistance to specific diseases. If you come into contact with that disease in the future, your immune system remembers it, and responds quickly to prevent the disease from developing.

After immunisation, you are far less likely to catch the disease you have been immunised against.

If you do catch the disease, it is more likely your illness will be less severe. It is also more likely that your recovery will be quicker than an unimmunised person's recovery.

Vaccines

Vaccines train a person's immune system to quickly recognise and clear out germs (bacteria and viruses) that can cause serious illnesses. Vaccines strengthen your immune system by training it to recognise and fight against specific germs - a bit like exercise strengthens muscles.

Vaccines are a safe way of producing an immune response in the body without causing illness.

Vaccines contain either killed or weakened versions of the germ that causes disease or only a small part of the germ (such as a protein). When you get a vaccine, your immune system recognises these germs or parts of germs as foreign and responds by creating memory cells and antibodies to protect you against future infection.

Vaccination involves receiving a vaccine from a needle or drops in the mouth by a trained health professional.

About COVID-19 vaccines

What are some of the kinds of vaccines have been developed for COVID-19?

Messenger RNA (mRNA) vaccines like the Pfizer vaccine use genetic code (RNA) to instruct production of the specific spike protein of the COVID-19 virus. Once the mRNA enters the body's cells, the cells use the genetic code to produce the spike protein. Immune cells recognise the spike protein as foreign. This triggers an immune response through production of T cells and B cells (which make antibodies), preparing the immune system to fight the coronavirus if it later infects the body. The genetic material from the vaccine does not change or become part of the recipient's genetic material.

Protein subunit vaccines use a non-infectious component of the coronavirus, the spike protein on the surface of the virus, manufactured in a laboratory. When the vaccine enters the body, immune cells recognise the spike protein as foreign. This triggers an immune response through production of T cells and B cells (which make antibodies), preparing the immune system to fight the coronavirus if it later infects the body.

Vector vaccines use a harmless, weakened animal virus that contain the genetic code for a protein unique to COVID-19, also known as a viral vector. Once the viral vector enters the body, the genetic material instructs the cells to make a protein that is unique to the virus that causes COVID-19. Using these instructions, our cells make copies of the protein. This triggers an immune response through production of T cells and B cells (which make antibodies), preparing the immune system to fight the coronavirus if it later infects the body.

How COVID-19 vaccines are being tested?

Before a vaccine is registered for use, it is tested extensively during development and then in thousands of people. Testing first begins with laboratory research, then animal studies and finally human clinical trials.

Clinical trials involve testing the vaccine in volunteers, and are conducted in phases:

- Phase 1 clinical trials usually include a few dozen healthy adult volunteers and focus primarily on establishing that the vaccine is safe, and also on demonstrating that the vaccine induces an immune response.
- Phase 2 clinical trials have hundreds of volunteers, and can include groups for whom the new vaccine is intended, for example, older adults, children or people with pre-existing medical conditions. These trials aim to show the vaccine induces an immune response and confirm that it is safe with acceptable side effects.
- Phase 3 clinical trials include many thousands of participants and aim to show that it is effective in preventing people from getting the disease – in this case COVID-19. Phase 3 trials also thoroughly assess the vaccine for safety and side effects. In a Phase 3 trial, researchers usually compare vaccinated people with people who received a placebo (like a salt water injection). They compare the rate of disease, disease severity and reported side effects between the two groups.

We will still need other COVID-19 prevention measures like physical distancing while vaccines are being rolled out?

Even with a safe and effective vaccine available in Australia, this will only be one part of keeping the community safe and healthy. It will be important for Australians to continue to practise good hygiene and physical distancing during the rollout.

Everyone still needs to:
1. wash your hands as often as possible
2. keep your distance where you can
3. stay at home if you feel sick and get tested
4. download the COVIDSafe app.