# **COVID-19 Vaccine Information** Phase 1: Safety and approvals



Information collated by the Australian Chamber of Commerce and Industry, 5 Feb 2021



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- 5. How vaccines are tested and approved
- 6. Common questions

### COVID-19 ACCINATION

Video 1 : How COVID-19 vaccines work- explainer video



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### COVID-19 ACCINATION

Video 2: <u>TGA approval process – explainer video</u>





Video 3 : COVID-19 vaccines - Setting the scene (15 second)





Safe. Effective. Free.

health.gov.au/covid19-vaccines

To find out when it's your turn, visit health.gov.au

### COVID-19 ACCINATION

Video 4: COVID-19 vaccines - Setting the scene (30 second)





Video 5 : COVID-19 vaccines - Live action montage (30 second)



This montage is about how COVID-19 has impacted us, it explains the process on approving vaccines and how the roll-out of vaccines will be available in batches going to those who need it first.

### COVID-19 ACCINATION

Video 6 : COVID-19 vaccines - How to stay informed (30 second)



## **Campaign Materials: Poster**

A poster is available about how Australians can access accurate and reliable information on the COVID-19 vaccines and the rollout strategy.



### COVID-19 ACCINATION

## Campaign Materials: Social Media Tiles





https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/about-covid-19-vaccines/how-covid-19-vaccines-work 10

### **How COVID-19 Vaccines work**



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. It responds by creating memory cells and antibodies to protect you against future infection.

How COVID-19 vaccines work – explainer video

### **Development of COVID-19** vaccines

The urgency of this crisis means that all available resources and efforts are being directed towards finding an effective vaccine. Some COVID-19 vaccines may be registered and used within 12 to 18 months of the virus being discovered.

Some of the reasons behind this rapid progress include:

 Unprecedented levels of funding and collaboration between vaccine developers and governments around the world. Planning has been undertaken early, such as investing in manufacturing facilities before a vaccine is even available.



### **Development of COVID-19** vaccines

- Technology has evolved to make vaccine development faster than in the past. To develop a vaccine, scientists need to understand the virus's genetic code. New technology has allowed researchers to quickly identify the genetic code of the COVID-19 virus, soon after the virus emerged. This allowed scientists around the world to start work in designing and building vaccines.
- Clinical trials progress more quickly if a disease is widespread, which is the case for COVID-19 in many countries. This means researchers can evaluate the effect of a vaccine between the unvaccinated and vaccinated groups much sooner than for a rare disease.



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## **Types of vaccines being developed for COVID-19**

It is important to know that these vaccines do not use the live or whole virus that causes COVID-19. Here are some of the common types, and how they work:

#### Messenger RNA (mRNA)

mRNA vaccines use a genetic code called RNA - to spark the production of the coronavirus' specific spike protein. Once the mRNA enters the body's cells, the cells use the instructions contained in the RNA to make the spike protein. Immune cells then recognise the spike protein as foreign and begins building an immune response against it. The RNA from the vaccine does not change or interact with our DNA in any way.

#### **Protein**

Protein based vaccines use a non-infectious component of the coronavirus, usually the spike protein. This protein is found on the surface of the virus and is manufactured in a laboratory. When the vaccine enters the body, immune cells recognise the spike protein as foreign. Immune cells then recognise the spike protein as foreign and begins building an immune response against it.

#### **Vector**

Vector vaccines use a harmless. weakened animal virus that contains the genetic code for a protein unique to the coronavirus, usually the spike protein. This is known as a viral vector. Once the viral vector enters the body, it instructs our cells to make the coronavirus spike protein. Using these instructions, our cells make copies of the protein. Our immune cells then recognise the spike protein as foreign and begins building an immune response against.

### 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. Clinical trials must provide scientific evidence which demonstrates that the benefits of a vaccine greatly outweigh any risks.

#### Phase 1

Clinical trials usually include a few dozen healthy adult volunteers. They 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 specific groups for whom the new vaccine is intended. For example older adults, children or people with pre-existing medical conditions. These trials aim to test whether the vaccine causes an immune response and confirm that it is safe with minor side effects, such as a mild headache.

#### Phase 3

Phase 3 clinical trials include many thousands of participants. They aim to test whether a vaccine 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 data between vaccinated people and those who received a placebo (like a salt water injection). They compare the frequency of infection, disease severity and any reported side effects between the two groups.





#### 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 <u>Family Tax</u> <u>Benefit Part A</u> or <u>childcare fee assistance</u> which only includes <u>National Immunisation Program</u> vaccines for those aged younger than 20.

It is possible that in the 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 on the <u>TGA website</u>.





#### 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 <u>Australian Technical Advisory Group on Immunisation (ATAGI)</u> is currently finalising clinical advice for health care providers on the use of COVID-19 vaccines in Australia in 2021. This is will 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 (flu) vaccine?

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





#### **COVID-19 vaccine information for international travellers**

At this time, Australian Government advice for <u>international travellers</u> remains unchanged, regardless of your COVID-19 vaccination status.

Passengers travelling to Australia must be tested for COVID-19 72 hours or less prior to the scheduled flight departure, and display evidence of a negative test result at the time of check-in.

People arriving in Australia may be <u>quarantined for 14 days</u> and might have to comply with other <u>state and</u> <u>territory travel restrictions</u>.



### **3-Phase Communications Timeline**

#### Workplace Phase 2. Phase 3. Phase 1. Specific TBC TBC TBC Information Provide information on Inform people about how Reaffirm that COVID-19 To be developed and how the vaccine will be and where to get vaccines have been put distributed separately. rolled out, particularly to vaccinated, dosage through our world-leading priority groups, and requirements, and support independent approvals vaccine uptake. dosage requirements. process, ensuring both the safety and efficacy of our vaccine candidates.



### **3-Phase Vaccine Roll-out Plan**





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