



The Hon. Scott Morrison MP
Prime Minister

The Hon. Greg Hunt MP
Minister for Health and Aged Care

JOINT MEDIA RELEASE

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PFIZER VACCINE APPROVED

The Therapeutic Goods Administration (TGA) has today provisionally approved the Pfizer/BioNTech COVID-19 vaccine for use in Australia.

The Pfizer vaccine has met strict standards for safety, quality and efficacy.

The TGA provisional approval is for individuals 16 years of age and older. Two doses will be required – at least 21 days apart.

A priority group of Australians are expected to now receive their first dose of the vaccine as soon as it can be received from Pfizer and the necessary checks are undertaken by the TGA, prior to its distribution.

The latest advice given to the Government from Pfizer is that shipping and the first vaccinations are expected to be in late February.

If there are delays in shipping or production, the possibility remains that commencement could be in early March, however guidance remains for late February.

Prime Minister Scott Morrison said the TGA approval was an important step in the fight against COVID-19.

“I welcome the TGA’s approval of the Pfizer vaccine, with our own Australian experts finding it is safe, effective and of a high standard,” the Prime Minister said.

“Australians should take confidence in the thorough and careful approach taken by our world-class safety regulator.

“Our priority has always been to keep Australians safe and protect lives and livelihoods. Today’s approval is another big step forward for our community, particularly in the protection of our most vulnerable people.”

Minister for Health Greg Hunt said the-world class regulators at the TGA have been working tirelessly to introduce a safe and effective COVID-19 vaccine in Australia.

“The TGA’s processes are I believe the best in the world and we have ensured that they are thorough.” Minister Hunt said.

“The TGA has placed safety above all else.”

“Australia’s high bar has been met; the vaccine has been approved as effective in stopping severe disease. I thank all those involved in the development and assessment of this COVID-19 vaccine, including the researchers, Pfizer, BioNTech and the medical experts at the TGA who have worked around the clock and over Christmas.”

“This approval and the upcoming roll out of the vaccine will play an important part in our ability to manage the pandemic in 2021.”

“Australia’s vaccination program has been based on the medical advice from the medical expert panel led by Professor Brendan Murphy. As a result we are in the fortunate position of having secured 140 million doses of vaccine, one of the highest per capita rates in the world. We will continue to review the medical advice and monitor and adapt to developments around the world,” Minister Hunt said.

The Government continues to work with Pfizer on the final date of delivery of vaccines, noting that Pfizer has experienced some temporary production delays from its European manufacturing plant as it ramps up production to meet extraordinary global demand.

The Government’s latest advice remains that the first doses of Pfizer are expected to arrive and be rolled out in late February. Final dates will be confirmed by Pfizer shortly and are subject to shipping and distribution.

In Australia the vaccine will be rolled out in five phases over the coming months and, over time, will involve more than 1,000 vaccination administration sites.

Head of the TGA, Adjunct Professor John Skerritt said the TGA has been working non-stop to get the Pfizer vaccine assessed, while maintaining the most rigorous standards of safety, quality and efficacy.

“I would like to thank our clinical and medical officers, scientists, pharmacists and experts in statistics, laboratory analysis and manufacturing assessment who have worked tirelessly on assessing this vaccine,” Adjunct Professor Skerritt said.

“We’re thrilled to have this product pass the rigorous regulatory process and receive provisional approval.”

“Our job is by no means done. In fact the monitoring of vaccine safety post-approval is an important part of the regulatory review of vaccines.

“We now check the individual batches of vaccines that are destined for Australians while closely monitoring the safety and efficacy of the vaccine as it is rolled out.

“We will also continue our work on the regulatory review for potential approval of other vaccines, notably the AstraZeneca and Novavax vaccines, as well as vaccines delivered through the COVAX facility.”

As the rollout begins across 30 - 50 hospital sites, people who need protection the most will get the vaccine first. This includes aged care and disability care residents and workers, frontline health care workers, and quarantine and border workers.

The priority groups have been determined based on the advice of the Australian Technical Advisory Group on Immunisation (ATAGI) which oversees Australia’s highly successful immunisation program.

“There is intense ongoing work which will continue over the coming month, including batch testing of newly arrived doses, establishing cold storage facilities for the vaccine, training health providers to administer it, finalising distribution sites with states and territories, checking sites and protective equipment for safety, and scaling up systems for ongoing safety monitoring,” Minister Hunt said.

The Australia Government, states and territories, regulators and the health and medical sectors are working together to finalise arrangements under the Australian Vaccination Strategy and detailed roll out plans. Further information about the Australian Government’s COVID-19 Vaccine [National Roll-out Strategy](#) can be found [here](#).

Phase 1a	
Quarantine and border workers	
Frontline health care worker sub-groups for prioritisation	
Aged care and disability care staff	
Aged care and disability care residents	
Number of doses	up to 1.4m
Phase 1b	
Elderly adults aged 80 years and over	
Elderly adults aged 70-79 years	
Other health care workers	
Aboriginal and Torres Strait Islander people > 55	
Younger adults with an underlying medical condition, including those with a disability	
Critical and high risk workers including defence, police, fire, emergency services and meat processing	
Number of doses	up to 14.8m
Phase 2a	
Adults aged 60-69 years	

Adults aged 50-59 years	
Aboriginal and Torres Strait Islander people 18-54	
Other critical and high risk workers	
Number of doses	up to 15.8m
Phase 2b	
Balance of adult population	
Catch up any unvaccinated Australians from previous phases	
Number of doses	up to 16m
Phase 3	
< 16 if recommended	
Number of doses	up to 13.6m

About the TGA Provisional Approval Pathway

The provisional approval pathway allows sponsors to apply for time-limited provisional registration on the Australian Register of Therapeutic Goods (ARTG). Approval through the provisional pathway is on the basis of preliminary clinical data where there is the potential for a substantial benefit to Australian patients. For more information visit the [TGA website](#).

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Media Contacts:

Prime Minister's Press Office, (02) 6277 7744

Minister Hunt's office: James Perrin, 0447 534 427

The Hon. Scott Morrison MP, Sydney

Press Office of the Hon. Scott Morrison MP, Prime Minister, Canberra