Australia's COVID-19 Vaccine Roadmap

COVID-19 Vaccine Approval Process

25 JANUARY 2021



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TGA COVID-19 Vaccine Approval Process

This page provides a summary of the TGA's provisional approval pathway for vaccines. More information on the TGA's COVID-19 vaccine approval process is available at: www.tga.gov.au/covid-19-vaccine-approval-process



PRE APPLICATION

To be approved under the TGA's provisional pathway, a pharmaceutical company or 'sponsor' must first submit a provisional determination application.

The TGA will assess the application against specific eligibility criteria, including the preliminary clinical data, evidence of a plan to submit subsequent comprehensive clinical data, and the clinical need.



APPLICATION

If the TGA grants provisional determination, the sponsor may submit an application for provisional registration of the vaccine in the Australian Register of Therapeutic Goods (ARTG).

The application must include specific information on clinical studies, non-clinical/ toxicology studies, quality, manufacturing and risk management to demonstrate that the benefits of the vaccine outweigh any risks in the intended population.

For COVID-19 Vaccine applications, the TGA is accepting rolling data as the data becomes available.



Technical experts within the TGA will commence formal evaluation of the available data. Additional data is provided to the TGA in tranches, and the TGA works closely with sponsors to determine when the additional data will be submitted.

The TGA can request further information from the sponsor for any data gaps, and may seek independent expert advice.



Once the evaluation is complete, the TGA delegate will make a decision whether to provisionally register the vaccine in the ARTG. The approval decision for a new vaccine is always made on the basis that the benefits outweigh the risks, and considers the safety, quality and effectiveness of the vaccine.



Once registered on the ARTG, the provisionally registered vaccine can then be lawfully supplied in Australia by the sponsor.

Approved vaccines will appear in the searchable ARTG on the TGA website.

The provisional registration is for an initial period of two years, and the sponsor can apply for two extensions, up to a maximum of six years.

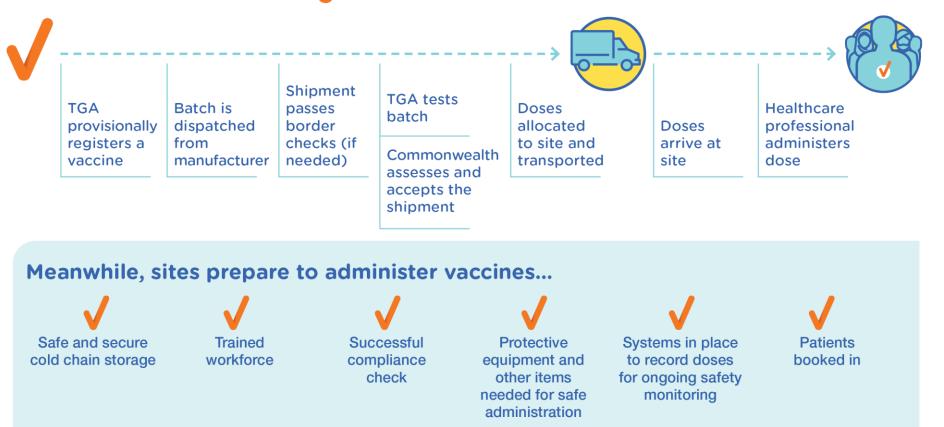


Once provisionally approved, the vaccine will be closed monitored by TGA's safety monitoring system which can rapidly detect, investigate and respond to any emerging safety issues identified for COVID-19 vaccines.

For the latest updates on COVID-19 vaccines visit: www.health.gov.au/covid19-vaccines



What happens to COVID-19 vaccines once the TGA has registered them?





COVID-19 vaccine national roll-out strategy

Phase 1a – up to 1.4m doses Ongoing Quarantine and 70,000 border workers Phase 1b – up to 14.8m doses Frontline health care Elderly adults aged worker sub-groups for 100,000 1,045,000 80 years and over prioritisation Phase 2a – up to 15.8m doses Elderly adults aged Aged care and 1,858,000 318,000 70-79 years disability care staff Adults aged 60-69 2,650,000 Other health care Aged care and 953,000 years Phase 2b – up to 16m doses workers disability care 190,000 Adults aged 50-59 Aboriginal and residents 3,080,000 years Torres Strait Islander 87,000 Total 678.000 Balance of adult Aboriginal and people > 556.643.000 Phase 3 – up to 13.6m doses population Torres Strait Islander 387,000 Younger adults with people 18-54 an underlying Catch up any medical condition, 2,000,000 unvaccinated < 16 if recommended 5,670,000 including those with Other critical and Australians from 453,000 a disability high risk workers previous phases Critical and high risk workers including Total 6.570.000 defence, police, 196,000 fire, emergency services and meat processing 6,139,000 Total

Population numbers are current estimates for each category.

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