COVID-19 Vaccine Approval Process

25 JANUARY 2021

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

STAGE 1 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.

STAGE 2 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.

STAGE 3 EVALUATION

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.

STAGE 4 DECISION

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.

STAGE 5 REGISTRATION

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.

STAGE 6 MONITORING

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?

- ✓ TGA provisionally registers a vaccine
- Batch is dispatched from manufacturer
- Shipment passes border checks (if needed)
- TGA tests batch
- Commonwealth assesses and accepts the shipment
- Doses allocated to site and transported
- Doses arrive at site
- Healthcare professional administers dose

Meanwhile, sites prepare to administer vaccines...

- ✓ Safe and secure cold chain storage
- ✓ Trained workforce
- ✓ Successful compliance check
- ✓ Protective equipment and other items needed for safe administration
- ✓ Systems in place to record doses for ongoing safety monitoring
- ✓ Patients booked in

COVID-19 vaccine national roll-out strategy

Phase 1a – up to 1.4m doses

Ongoing

Quarantine and border workers	70,000
Frontline health care worker sub-groups for prioritisation	100,000
Aged care and disability care staff	318,000
Aged care and disability care residents	190,000
Total	**678,000**

Phase 1b – up to 14.8m doses

Elderly adults aged 80 years and over	1,045,000
Elderly adults aged 70-79 years	1,858,000
Other health care workers	953,000
Aboriginal and Torres Strait Islander people > 55	87,000
Younger adults with an underlying medical condition, including those with a disability	2,000,000
Critical and high risk workers including defence, police, fire, emergency services and meat processing	196,000
Total	**6,139,000**

Phase 2a – up to 15.8m doses

Adults aged 60-69 years	2,650,000
Adults aged 50-59 years	3,080,000
Aboriginal and Torres Strait Islander people 18- 54	387,000
Other critical and high risk workers	453,000
Total	**6,570,000**

Phase 2b – up to 16m doses

Balance of adult population	**6,643,000**
Catch up any unvaccinated Australians from previous phases	

Phase 3 – up to 13.6m doses

< 16 if recommended	**5,670,000**

Population numbers are current estimates for each category.

COVID-19 Vaccine Approval Process

25 JANUARY 2021