



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

COVID-19 vaccines regulatory status

Last updated:

27 July 2023

Before any COVID-19 vaccine is approved for use in Australia, it is subject to the well-established and rigorous evaluation processes of the Therapeutic Goods Administration (TGA), part of the Department of Health and Aged Care. The regulatory status of COVID-19 vaccines in Australia are listed below.

Provisionally approved vaccines and those granted full registration have undergone a thorough and independent review by the TGA and have met the high safety, efficacy and quality standards required for use in Australia. Further information about the provisional registration pathway and transitioning to full registration can be found below.

Sponsor	Vaccine Name	Vaccine Type	Application	Provisional status	Full registration
AstraZeneca Pty Ltd	VAXZEVRIA (ChAdOx1-S [recombinant]) (previously COVID-19 Vaccine AstraZeneca) (https://www.tga.gov.au/covid-19-vaccine-astrazeneca-vaxzevria).	Viral vector	a. Vaccination for individuals aged 18 years and over	Provisionally approved 15 February 2021	

Sponsor	Vaccine Name	Vaccine Type	Application	Provisional status	Full registration
			b. Booster dose for individuals aged 18 years and over	Provisionally approved 8 February 2022	
Bioclect Pty Ltd on behalf of Novavax Inc	<u>NUVAXOVID (SARS-CoV-2 rS vaccine with Matrix-M1 adjuvant)</u> (https://www.tga.gov.au/bioclect-pty-ltd-novavax-covid-19-vaccine-nuvaxovid-use-in-dividuals-aged-12-17-years).	Protein vaccine	a. Vaccination for individuals aged 18 years and over	Provisionally approved 19 January 2022	Under evaluation for full registration
			b. Booster dose for individuals aged 18 years and over	Provisionally approved 9 June 2022	Under evaluation for full registration
			c. Vaccination for individuals aged 12-17 years	Provisionally approved 22 July 2022	Under evaluation for full registration
Grand Pacific CRO Australia (on behalf of Medigen Vaccine Biologics Corp)	<u>MVC COVID-19 vaccine (MVC-COV1901)</u> (http://www.tga.gov.au/resources/prescription-medicines-under-evaluation/mvc-covid-19-vaccine-grand-pacific-cro-australia).	Protein subunit	Vaccination for adults aged 18 years and older	Application for provisional registration withdrawn 25 July 2023	
Graythan Regulatory Services Pty Ltd (on behalf of Vaxxinity Inc.)	<u>COSMOVAXX (S1-RBD-sFc Th/CTL Peptides)</u> (https://www.tga.gov.au/resources/prescription-medicines-under-evaluation/cosmovaxx-graythan-regulatory-services-pty-ltd).	Multitope protein-peptide	Booster dose for individuals aged 16 years and older	Under evaluation for provisional registration	

Sponsor	Vaccine Name	Vaccine Type	Application	Provisional status	Full registration
Janssen-Cilag Pty Ltd	<u>COVID-19 Vaccine Janssen (Ad26.COV2.S)</u> (https://www.tga.gov.au/news/news/covid-19-vaccine-janssen).	Viral vector	Vaccination for individuals aged 18 years and over	Provisionally approved 25 June 2021	
Moderna Australia Pty Ltd	<u>SPIKEVAX (elasomeran)</u> (https://www.tga.gov.au/news/news/covid-19-vaccine-spikevax-elasomeran).	mRNA	a. Vaccination for adults aged 18 years and over	Provisionally approved 9 August 2021	Full registration granted 21 April 2023
			b. Vaccination for individuals aged 12-17 years	Provisionally approved 3 September 2021	Full registration granted 21 April 2023
			c. Booster dose for individuals aged 18 years and over	Provisionally approved 7 December 2021	Full registration granted 21 April 2023
			d. Vaccination for individuals aged 6-11 years	Provisionally approved 17 February 2022	Full registration granted 21 April 2023
			e. Booster dose for individuals aged 12 years and over	Provisionally approved 19 October 2022	Full registration granted 21 April 2023
			f. Vaccination for individuals aged 6 months to less than 19	Provisionally approved 19 July 2022	

Sponsor	Vaccine Name	Vaccine Type	6 years Application	Provisional status	Full registration
Moderna Australia Pty Ltd	SPIKEVAX Bivalent (https://www.tga.gov.au/covid-19-vaccine-spikevax-bivalent-originalomicron-elasomeranimelasomeran) Original/Omicron (elasomeran/imelasomeran) (https://www.tga.gov.au/covid-19-vaccine-spikevax-bivalent-originalomicron-elasomeranimelasomeran) (Previously SPIKEVAX Bivalent Zero/Omicron (elasomeran/elasomeran 0- omicron))	mRNA	Booster dose for adults aged 18 years and over	Provisionally approved 29 August 2022	
Moderna Australia Pty Ltd	SPIKEVAX Bivalent Original/Omicron BA.4-5 (elasomeran/davesomeran) (https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-provisional-registrations/moderna-covid-19-bivalent-spikevax-bivalent-originalomicron-ba4-5-booster-dose-vaccine)	mRNA	Booster dose for individuals 12 years of age and over	Provisionally approved 17 February 2023	Under evaluation for full registration
Pfizer Australia Pty Ltd	COMIRNATY - (tozinameran) (https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-tozinameran-mrna)	mRNA	a. Vaccination for individuals aged 16 years and over	Provisionally approved 25 January 2021	Full registration granted 13 July 2023
			b. Booster dose for individuals aged 12-15 years	Provisionally approved 22 July 2021	Full registration granted 13 July 2023

Sponsor	Vaccine Name	Vaccine Type	Application	Provisional status	Full registration
			c. Booster dose for individuals aged 18 years and over	Provisionally approved 26 October 2021	Full registration granted 13 July 2023
			d. Vaccination for individuals aged 5-11 years	Provisionally approved 3 December 2021	Full registration granted 13 July 2023
			e. Booster dose for individuals aged 16-17 years	Provisionally approved 27 January 2022	Full registration granted 13 July 2023
			f. Booster dose for individuals aged 12-15 years	Provisionally approved 7 April 2022	Full registration granted 13 July 2023
			g. Booster dose for individuals aged 5-11 years	Provisionally approved 20 September 2022	Full registration granted 13 July 2023
			h. Vaccination for individuals aged 6 months to less than 5 years	Provisionally approved 29 September 2022	Full registration granted 13 July 2023

Sponsor	Vaccine Name	Vaccine Type	Application	Provisional status	Full registration
Pfizer Australia Pty Ltd	<u>COMIRNATY Original/Omicron BA.1 (tozinameran and riltozinameran)</u> (https://www.tga.gov.au/pfizer-bivalent-covid-19-vaccine-use-booster-dose-adults).	mRNA	Booster dose for individuals aged 18 years and over	Provisionally approved 27 October 2022	
Pfizer Australia Pty Ltd	<u>COMIRNATY BIVALENT Original/ Omicron BA.4-BA.5 COVID-19 VACCINE (tozinameran and famtozinameran)</u> (https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-provisional-registrations/pfizer-covid-19-bivalent-comirnaty-originalomicron-ba4-5-covid-19-vaccine-booster-dose-vaccine).	mRNA	a. Booster dose for individuals 12 years of age and older b. Booster dose for individuals aged 5-11 years	Provisionally approved 20 January 2023 Under evaluation for provisional registration	

Provisional registration pathway and transition to full registration

All COVID-19 vaccine applications are treated with the greatest priority as part of the Department of Health and Aged Care's response to the pandemic. Under normal circumstances, the TGA's assessment (for both provisional and full registration) begins once all information to support registration is available. For COVID-19 vaccines, the TGA has agreed to accept rolling data to enable early evaluation of data as it comes to hand using the [provisional pathway](#) ([link](#)).

The TGA will only make a provisional registration decision for a vaccine once all required data relating to safety, quality and efficacy has been provided and assessed.

With rolling submissions, collaboration with international regulators, and proactively working with sponsors, it is expected the evaluation of COVID-19 vaccines will be significantly expedited without compromising on our strict standards of safety, quality and efficacy. However, the timeframe for the evaluation of each vaccine will ultimately depend on when the complete data package is

provided by sponsors.

Sponsors may apply to transition a provisional registration to full registration (<https://www.tga.gov.au/resources/resource/guidance/provisional-registration-extension-and-transition-full-registration>), when there is more clinical data to confirm the safety of the vaccine.

Further information on the TGA's evaluation process for vaccines is available at COVID-19 vaccine approval process (<https://www.tga.gov.au/node/288046>).

Labels for COVID-19 vaccines

To enable timely distribution of COVID-19 vaccines, international labels will be used during the initial global rollout, including in Australia.

Some information typically present on the Australian label may be absent and/or modified on the international label, as well as additional information present that is not relevant to the Australian context.

Labels for COVID-19 vaccines (<https://www.tga.gov.au/resources/resource/guidance/labels-covid-19-vaccines>).

Batch release assessment of COVID-19 vaccines

The TGA ensures there is an independent quality assessment of every batch of vaccine supplied in Australia. COVID-19 vaccines have a priority release schedule.

Learn more about the Batch release assessment of COVID-19 vaccines (<https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines>).

Post-approval changes

After the initial registration of a vaccine, the sponsor may request changes to the registration details, which require additional assessment and approval (<https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-prescription-medicine/post-approval-changes-covid-19-vaccines>), by the TGA.

Emergency use of vaccines in other countries

The TGA is aware that other countries may consider exercising emergency use provisions that allow access to unapproved vaccines prior to formal regulatory approval based on assessment of early safety and efficacy data. Exercising these provisions is a matter for those countries, taking into account the risks versus benefits in the context of the prevailing domestic pandemic situation.

Topics:

[COVID-19 \(https://www.tga.gov.au/products/covid-19\)](https://www.tga.gov.au/products/covid-19)

[Medicines \(https://www.tga.gov.au/products/medicines\)](https://www.tga.gov.au/products/medicines)

[COVID-19 vaccines \(https://www.tga.gov.au/products/covid-19/covid-19-vaccines\)](https://www.tga.gov.au/products/covid-19/covid-19-vaccines)