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COVID-19 vaccine provisional determinations

24 June 2021

The Therapeutic Goods Administration (TGA), part of the Department of Health, has granted a number of provisional determinations in relation to COVID-19 vaccines.

The granting of a provisional determination means that the TGA has made a decision that relevant sponsors are now eligible to apply for provisional registration for the vaccine in the Australian Register of Therapeutic Goods (ARTG).

Provisional determination is the first step in the process and does not mean that an application has or will be made, or that the vaccine will be provisionally approved for inclusion in the ARTG. Provisional determinations are effective for 6 months.

Normally for a vaccine to be registered in Australia, a sponsor (usually a pharmaceutical company) is required to sub[illegible] complete and comprehensive package of data to the TGA. A formal evaluation is then carried out in multiple stages experts, prior to a decision being made.

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The provisional pathway provides a formal and transparent mechanism for speeding up the registration of promising new medicines with preliminary clinical data. In order to apply for provisional registration, the sponsor must first apply for a provisional determination. Further information on eligibility criteria can be found at: Provisional determination: A step-by-step guide for prescription medicines.

In making its decision to grant these provisional determinations, the TGA considered all eligibility criteria, including factors such as the evidence of a plan to submit comprehensive clinical data and the seriousness of the current COVID-19 pandemic.

In addition to these determination, the TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world, and is part of a network of international regulators that meet regularly to discuss the development of COVID-19 vaccines and the establishment of systems for monitoring the efficacy and safety of COVID-19 vaccines once they have reached the market. The ability to access early data and planned collaboration with international regulators will assist the TGA to expedite the evaluation of any new vaccines without compromising on our strict requirements for safety, quality and effectiveness of products.

Effective date	Sponsor	Name	Type
24 June 2021	Moderna Australia Pty Ltd	Elasomeran	mRNA
19 January 2021	Biocelect Pty Ltd (on behalf of Novavax Inc.)	NVX-CoV2373	Protein sub-unit
16 November 2020	Janssen-Cilag Pty Ltd	Ad26.COV2.S	Viral vector
14 October 2020	Pfizer Australia Pty Ltd	BNT162b2 [mRNA]	mRNA
9 October 2020	AstraZeneca Pty Ltd	ChAdOx1-S [recombinant]	Viral vector

Category: Prescription medicines
Tags: COVID-19 vaccines, vaccines
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