We've released a trial (beta) version of a new ARTG search tool Please try it and provide feedback. (https://compliance.health.gov.au/artg/)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 treatments: Provisional determinations

6 December 2021

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

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 treatment 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 treatment will be provisionally approved for inclusion in the ARTG. Provisional determinations are effective for 6 months.

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

The provisional pathway provides a formal and transparent mechanism for speeding up the registration of promising new treatments with preliminary clinical data. 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 (//www.tga.gov.au/publication/provisional-determination).

In making its decision to grant these provisional determinations, the TGA considered 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.

Effective date	Sponsor	Name	Regulatory status
4 November 2021	AstraZeneca Pty Ltd	tixagevimab and cilgavimab (EVUSHELD)	Under evaluation

Effective date	Sponsor	Name	Regulatory status
5 October 2021	Pfizer Australia	PF-07321332 + ritonavir	Under evaluation
27 September 2021	Roche Products Pty Ltd	tocilizumab (ACTEMRA)	Provisionally approved on 1 December 2021
20 August 2021	Celltrion Healthcare Australia Pty Ltd	regdanvimab (REGKIRONA)	Provisionally approved on 6 December 2021
20 August 2021	Roche Products Pty Ltd	casirivimab + imdevimab (RONAPREVE)	Provisionally approved on 15 October 2021
9 August 2021	Merck Sharp and Dohme (Australia) Pty Ltd	molnupiravir (TBA)	Under evaluation
13 April 2021	GlaxoSmithKline Australia Pty Ltd	sotrovimab (XEVUDY)	Provisionally approved on 20 August 2021
6 July 2020	Gilead Sciences Pty Ltd	remdesivir (VEKLURY)	Provisionally approved on 10 July 2020

Category: Medicines
Tags: COVID-19 treatments
URL: https://www.tga.gov.au/node/938969 (https://www.tga.gov.au/node/938969)