



Australian Government

Department of Health  
Therapeutic Goods Administration

# Advisory Committee on Medicines

## Meeting Statement

Meeting 28, Thursday 5 and Friday 6 August 2021

### Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 16 applications under evaluation by the TGA. The applications included:

- four for the registration of a new chemical entity
- nine seeking extension of indications (some including major variations)
- one seeking major variations (new strength and change to the patient group)
- one seeking conversion from provisional to full registration
- one seeking a minor variation

Following the standing meeting, one application for registration of a new biological entity for the treatment of COVID-19 was considered at an out-of-session ACM meeting on Thursday 12 August.

Further details of the ACM discussion and advice associated with these items are released within the Australian Public Assessment Reports (AusPARs). Please note that there is a delay from when an application was considered at ACM and the publication of the AusPAR. To browse all AusPARs see: <<https://www.tga.gov.au/browse-auspars-active-ingredient>>

### Further information

For further information on the Advisory Committee on Medicines, please visit: <https://www.tga.gov.au/committee/advisory-committee-medicines-acm> or contact the ACM Secretary by email: [ACM@health.gov.au](mailto:ACM@health.gov.au).