

Advisory Committee on Medicines

Meeting Statement

Meeting 23, Thursday 1 and Friday 2 October 2020

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 8 applications under evaluation by the TGA. The applications included:

- one for the registration of a new chemical entity
- one for the registration of a new biological entity
- three seeking extension of indications
- three seeking major variations (change in dose form, route of administration and/or new strength)

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.

