



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Medicines

## Meeting Statement

Meeting 15, Friday 7 June 2019

### Overview of therapeutic goods referred for advice

At this meeting, the committee's advice was sought on 9 applications under evaluation by the TGA. The applications included:

- one for the registration of a new chemical entity
- five seeking extensions of indications
- one seeking registration of a new dose
- one seeking safety-related changes to the Product Information.

The ACM also provided additional advice on the registration of a new chemical entity which had first been considered at an earlier ACM meeting.

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>>

### Overview of the safety reviews referred for advice

The TGA continually monitors therapeutic goods supplied in Australia to ensure their ongoing safety, efficacy and quality. As part of this process, the TGA routinely undertakes safety reviews of therapeutic goods. No review was referred to the ACM at this meeting.

### 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).