Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 25, Thursday 4 and Friday 5 February 2021

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 fixed dose combination containing a new chemical entity
- one for the registration of a new biological entity
- four seeking extension of indications
- one seeking a major variation (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>

Section B: Post-market item referred for advice

The Delegate sought advice on the requirements and timelines for sponsors to report *Significant Safety Issues* ('SSI'), as outlined in the Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements. The changes aim to improve the efficiency of significant safety issue reporting, and reduce the administrative burden on the TGA and industry, while ensuring that the reporting requirements remain proportionate to the risk of patient harm or the potential for major change to the benefit-risk balance of a medicine (including vaccines) which may result in changes to the way the product is used.

The proposed revisions have undergone consultation with Medicines Australia (peak body representing innovative medicines industry). Further consultations will be undertaken.

The ACM supported the initiative to revise the reporting scheme to ensure that the TGA will be informed of Significant Safety Issues for medicines in a timely manner, proportionate to the potential for patient harm or change in risk-benefit balance.

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.