Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 16, Thursday 1 and Friday 2 August 2019

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 10 applications under evaluation by the TGA. The applications included:

- five for the registration of a new chemical entity
- one for the registration of a new biological entity
- two for the registration of a new combination of active ingredients
- one seeking extension of indications
- one seeking changes to the Product Information document that required evaluation of data.

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

Signs of potential liver injury have been observed in some patients treated with tolvaptan (tradename Jinarc) for autosomal dominant polycystic kidney disease (ADPKD). This is described in the boxed warning and the Product Information for this medicine.

A Risk Management Plan (RMP) is a set of pharmacovigilance and risk minimisation activities designed to identify, characterise and mitigate the important safety concerns relating to a medicine. To mitigate the risk of liver injury, the RMP for Jinarc includes educational materials for prescribers, pharmacists and nurses, and a patient education brochure and alert card. At the time of this meeting, the RMP also included a restricted access program that limits prescribing to nephrologists who are included in a registry held by the sponsor, and distribution of the medicine through a single distribution channel. At this meeting, the committee's advice was sought on the restricted access program.

Patients require blood tests for hepatic transaminases prior to initiation, then monthly for 18 months, then every 3 months during treatment with JINARC. At the time of this meeting, the restricted access program mandated review by the prescriber of the monthly blood test results and confirmation or not, via an online system, whether to continue or discontinue treatment ('blood for drug').

The ACM advised that current data from Europe tended to support the efficacy of the European risk minimisation program (which does not include 'blood for drug'). As the signal for liver injury is low the committee noted that it may not be possible to determine if the more intensive Australian and Canadian approaches actually result in fewer liver injury events than in Europe.

The ACM advised that the requirement of 'blood for drug' did appear to be overly burdensome to nephrologists with no evidence that this requirement improved the outcome for patients. A restricted access program that potentially involves the medicine's sponsor contacting the patient appeared to be unnecessary.

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.