Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement 5 – Thursday 5 – Friday 6 October, 2017

Section A: Submissions for registration

The committee's advice was sought on 13 new pre-market applications for prescription medicines. The applications (table below) included nine associated with Type A – new Chemical/Biological entities or Biosimilars, 3 associated with Type C – extension and indications and 1 application relating to an extension of indication with associated PI changes.

Number of applications	Application Type	Main consideration by ACM (among other items)
9	Type A - New Chemical /Biological Entity/Biosimilar	For general consideration
3	Type C - Extension of indication	For consideration of the broader indication
1	Type C – Extension of Indication and Type J Changes to the PI	For consideration of the extension of the indication and associated PI changes

Further details of the ACM discussions and advice associated with pre-market items are released within the Australian Public Assessment Reports (AusPars) for each new active. Please note that there is a delay from when an application was considered at ACM, and the publication of the AusPar. Browse all AusPARs.

Section B: Pharmacovigilance

One pharmacovigilance item was referred to the committee for its advice.

The TGA had undertaken a risk-benefit assessment of a medicine previously voluntarily withdrawn from the market.

The ACM provided advice on limitations of published studies, and whether there is now a positive benefit-to-risk balance for an amended indication.

Further information

For further information on the ACM, please visit Advisory Committee on Medicines

or contact the ACM Secretary by email ACM@health.gov.au.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8696 Fax: 02 6203 1605 Email: acm@health.gov.au
https://www.tga.gov.au

TGA Health Safety Regulation