Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement 4 - Friday 4 August 2017

Section A: Submissions for registration

The committee's advice was sought on 10 new pre-market applications for prescription medicines. The applications (table below) included four associated with Type A – new Chemical/Biological entities or Biosimilar, 4 associated with Type C – extension and indications, one application relating to an extension of indication with new directions for use, and one application relating to a generic medicine (Type D).

Number of applications	Application Type	Main consideration by ACM (among other items)
4	Type A - New Chemical /Biological Entity/Biosimilar	For general consideration
4	Type C - Extension of indication	For consideration of broader indication with or without substantiating supportive evidence.
1	Type F – New directions for Use and Type C Extension of indications	For general consideration
1	Type D -Generic medicine	For consideration relating to the product formulation

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: Safety

No pharmacovigilance items were discussed.

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.

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