Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement 2 - Thursday 6 and Friday 7 April 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 seven for Type A – new Chemical/Biological entities, four associated with Type C – extension and indications, a major variation (Type F) and a new generic medicine application (Type A).

Number of applications	Application Type	Main consideration by ACM (among other items)
7	Type A - New Chemical /Biological Entity	For general consideration
1	Type C - Extension of indication	For consideration of broader indication without substantiating supportive evidence.
2	Type C - Extension of indication	For general consideration
1	Type C - Extension of indication	For consideration of the modified indication, the limited evidence and associated PI
1	Type D - New generic medicine	For general consideration
1	Type F - Major variation (dosage) and (strength)	For general consideration

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 delay from when an application was considered at ACM, and the publication of the AusPar. Browse all AusPARs.

Section B: Post-Market items

No items were referred to ACM.

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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