Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement 11 - Thursday 4 October 2018

Section A: Submissions for registration

The committee's advice was sought on six new pre-market applications for prescription medicines, as tabulated below.

Pre-market Application Types

Number of applications	Application Type	Main consideration by ACM
1	Type A - New Chemical /Biological Entity/Biosimilar	For general consideration
3	Type C - Extension of indication	For consideration of broader indication with or without substantiating supportive evidence.
2	Type F – Major variation (New Dose Form/New Route of Administration)	For general consideration

The committee's advice was also sought on one Category 3 application for a registered medicine.

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: Post-Market items referred for advice

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.