



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement – Meeting 12, Thursday 6 December 2018

Section A: Submissions for registration

The advice of the Advisory Committee on Medicines (ACM) was sought on eleven new pre-market applications for prescription medicines, as tabulated below.

Number of applications considered	Application Type	Main consideration by ACM
5	Type A - New chemical /biological entity	For general consideration
1	Type B – New combination of active ingredients	For general consideration
1	Type B – New combination of active ingredients and Type A – New chemical entity	For general consideration
3	Type C - Extension of indication	For consideration of broader indication with or without substantiating supportive evidence.
1	Type C - Extension of indication and Type F - Major variation (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 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 post-market items were referred for advice.

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.