Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 32, Friday 1 April 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 7 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type A (new biological entity)		
aducanumab (ADUHELM)	Biogen Australia Pty Ltd	For treatment of Alzheimer's disease
Type C (extension of indications)		
dupilumab (DUPIXENT)	Sanofi Aventis Australia Pty Ltd	For the treatment of asthma
nitric oxide (INOMAX)	Ikaria Australia Pty Ltd	For the treatment of a respiratory condition
rivaroxaban (XARELTO)	Bayer Australia Pty Ltd	For the treatment of VTE

*These application types are published on the Prescription medicines: applications under evaluation page https://www.tga.gov.au/prescription-medicines-applications-under-evaluation

In addition to:

- One for the registration of a new chemical entity (accepted for evaluation prior to the publication of applications under evaluation)
- One seeking a major variation (change in dosage)
- One for the registration of a new biosimilar medicine

Further details of the ACM discussion and advice associated with these items may be released within the Australian Public Assessment Reports (AusPARs). Please note that there is a delay from when an application was considered at ACM and the publication of the AusPAR. To browse all AusPARs see: <https://www.tga.gov.au/browse-auspars-active-ingredient>

Further information

For further information on the Advisory Committee on Medicines, please visit: https://www.tga.gov.au/committee/advisory-committee-medicines-acm or contact the ACM Secretary by email: ACM@health.gov.au.