Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 48, 5 and 6 December 2024

Section A: Premarket registration applications

At this meeting, the committee provided advice on 11 applications under evaluation by the TGA, as below.

Active ingredient (TRADENAME)	Sponsor	Therapeutic area	Application designations
Applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia (Application Type A)			
rozanolixizumab (RYSTIGGO)	UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia	Generalised Myasthenia Gravis	
teprotumumab (TEPEZZA)	Amgen Australia Pty Ltd	Thyroid Eye Disease	Priority
tezepelumab (TEZSPIRE)	AstraZeneca Pty Ltd	Asthma	
palopegteriparatide (YORVIPATH)	Specialised Therapeutics Pharma Pty Ltd	Hypoparathyroidism	Orphan Priority
garadacimab (ANDEMBRY)	CSL Behring Australia Pty Ltd	Hereditary Angioedema	Orphan

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605
Email: info@tga.gov.au https://www.tga.gov.au

Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
dapagliflozin propanediol monohydrate (FORXIGA)	AstraZeneca Pty Ltd	Chronic Kidney Disease	
blinatumomab (BLINCYTO)	Amgen Australia Pty Ltd	B-Cell precursor acute lymphoblastic leukemia	
pegcetacoplan (SYFOVRE)	Apellis Australia Pty Ltd	Geographic atrophy secondary to age-related macular degeneration	
dupilumab (DUPIXENT	Sanofi-Aventis Australia Pty Ltd	Chronic Obstructive Pulmonary Disease	Priority

The dates of commencement of the evaluation of these applications are available at Prescription medicines: applications under evaluation, see: https://www.tga.gov.au/prescription-medicines-applications-under-evaluation

The committee also provided advice on:

- 2 applications for major variations (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration) (Application Type F)

Further details of the ACM discussion and advice associated with these items may be released within the Australian Public Assessment Reports (AusPARs). To browse all AusPARs see: https://www.tga.gov.au/resources/auspar

Section B: Post-market items

The ACM was not asked to provide advice on a post-market or safety issue.

Further information

For further information on the Advisory Committee on Medicines, please visit:

https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-medicines-acm

or contact the ACM Secretary by email: ACM@health.gov.au