



Advisory Committee on Medicines

Meeting Statement

Meeting 45, 6 and 7 June 2024

Section A: Premarket registration applications

At this meeting, the committee provided advice on 7 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)			
Bulevirtide acetate (HEPCLUDEX)	Gilead Sciences Pty Ltd	For the treatment of chronic hepatitis delta virus.	Orphan Priority
Lutetium (177Lu) vipivotide tetraxetan (PLUVICTO)	Novartis Pharmaceuticals Australia Pty Ltd	For the treatment of prostate cancer.	
Lecanemab (LEQEMBI)	Eisai Australia Pty Ltd	For the treatment of patients with Alzheimer's disease.	
Linzagolix choline (YSELTY)	Theramex Australia Pty Ltd	For the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	

Zilucoplan tetrasodium (TBC)	UCB Australia Pty Ltf T/A UCB Pharma Division of UCB Australia	For the treatment of adult patients with generalised myasthenia gravis (gMG).	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Triamcinolone acetonide (ARCATUS)	Arctic Vision Australia Pty Ltd	For the treatment of macular oedema.	
Empagliflozin (JARDIANCE)	Boehringer Ingelheim Pty Ltd	For the treatment of type 2 diabetes.	
Empagliflozin, metformin hydrochloride (JARDIAMET)	Boehringer Ingelheim Pty Ltd	For the treatment of type 2 diabetes.	

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>

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