Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 43, 1 and 2 February 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)			
Clascoterone (WINLEVI)	Sun Pharma ANZ Pty Ltd	For the treatment of acne vulgaris.	
Etranacogene dezaparvovec (HEMGENIX)	CSL Behring Australia Pty Ltd	For the treatment of adults with haemophilia B.	Provisional Orphan
Indocyanine Green (VERDYE)	Regulatory Approval Services Pty Ltd	For diagnostic use only.	
Nelarabine (NELARABINE REACH)	Reach Pharmaceuticals Pty Ltd	For the treatment of T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma.	Orphan

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Sodium Zirconium Cyclosilicate Hydrate (LOKELMA)	AstraZeneca Pty Ltd	For the treatment of hyperkalaemia in adult patients.	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Bimekizumab (BIMZELX)	UCB Australia Pty Ltd	For the treatment of adult patients with active psoriatic arthritis, ankylosing spondylitis or non-radiographic axial spondyloarthritis.	
Eptacog alfa (activated) (NOVOSEVEN RT)	Novo Nordisk Pharmaceuticals Pty Ltd	For the treatment of severe postpartum haemorrhage.	

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

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