Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 40 – 3 and 4 August 2023

Section A: Premarket registration applications

At this meeting, the committee provided advice on 14 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)			
mirikizumab (OMVOH)	Eli Lilly Australia Pty Ltd	For treatment of moderately to severely active ulcerative colitis	
spesolimab (SPEVIGO)	Boehringer Ingelheim Pty Ltd	For treatment of generalised pustular psoriasis.	Orphan
tirbanibulin (ONAKTA)	Seqirus Pty Ltd	For the topical field treatment of actinic keratosis.	
vadadustat (VAFSEO)	Adjutor Healthcare Pty Ltd	For treatment of anaemia associated	

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		with chronic kidney disease.	
Applications for a 'new combination', where two or more already approved medicines are combined into a single product (Application Type B)			
foslevodopa and foscarbidopa (TBA at time of commencement of evaluation)	AbbVie Pty Ltd	For treatment of Parkinson's disease.	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
apremilast (OTEZLA)	Amgen Australia Pty Ltd	For the treatment of adult patients with oral ulcers and plaque psoriasis.	
dabrafenib (TAFINLAR)	Novartis Pharmaceuticals Australia Pty Ltd	For treatment of glioma.	
trametinib (MEKINIST)	Novartis Pharmaceuticals Australia Pty Ltd	For treatment of glioma.	
melatonin (IMELLA, MELATONIN-LINK, RYLAKSO, VOQUILLY)	Link Medical Products Pty Ltd	For treatment of jet lag and sleep disorders	
olaparib (LYNPARZA)	AstraZeneca Pty Ltd	For treatment of prostate cancer	
secukinumab (COSENTYX)	Novartis Pharmaceuticals Australia	For treatment of hidradenitis suppurativa	
somapacitan (SOGROYA)	Novo Nordisk Pharmaceuticals Pty Ltd	For the extension of indications to include paediatric patients	

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