Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 42, 30 November and 1 December 2023

Section A: Premarket registration applications

At this meeting, the committee provided advice on 13 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)			
Crisantaspase (ERWINASE)	PPD Australia Pty Ltd	For the treatment of acute lymphoblastic leukaemia.	Orphan
Fezolinetant (VEOZA)	Astellas Pharma Australia Pty Ltd	For the treatment of vasomotor symptoms associated with menopause.	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Brentuximab vedotin (ADCETRIS)	Takeda Pharmaceuticals Australia Pty Ltd	For the treatment of advanced Hodgkin lymphoma.	

Elexacaftor / Tezacaftor / Ivacaftor (TRIKAFTA)	Vertex Pharmaceuticals Australia Pty Ltd	For patients who have at least one F508del mutation in the CFTR gene.	Orphan
Empagliflozin (JARDIANCE)	Boehringer Ingelheim Pty Ltd	To reduce the risk of kidney disease progression.	
Glu-urea-lys(ahx)-hbed-CC (ILLUCCIX)	Telix Pharmaceuticals (ANZ) Pty Ltd	For use in patients with prostate cancer.	
Nivolumab (OPDIVO)	Bristol-Myers Squibb Australia Pty Ltd	For the treatment of melanoma.	
Ravulizumab (ULTOMIRIS)	Alexion Pharmaceuticals Australasia Pty Ltd	For the treatment of adult patients with Neuromyelitis Optica Spectrum Disorder (NMOSD).	
Relugolix, estradiol (as hemihydrate), norethisterone acetate (RYEQO)	Gedeon Richter Australia Pty Ltd	For the treatment of moderate to severe pain associated with endometriosis.	
Semaglutide (WEGOVY)	Novo Nordisk Pharmaceuticals Pty Ltd	For chronic weight management.	
Vosoritide (VOXZOGO)	BioMarin Pharmaceuticals Australia Pty Ltd	For the treatment of achondroplasia in paediatric patients.	Priority Orphan

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:

- One application for a new biosimilar medicine (Application Type A)
- One application for transition from provisional approval to full registration (Application Type S)

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

Azithromycin and cardiovascular death

The ACM was asked to consider the evidence associated with the signal of azithromycin and cardiovascular death and whether the term ‘cardiovascular death’ should be added to the Australian Product Information (PI).

The Australian PI for azithromycin does not currently list the term ‘cardiovascular death’ but does include ventricular arrhythmias associated with prolonged QT interval, including fatal arrhythmias.

The ACM discussed the available evidence including Australian and international case reports, a literature review, an analysis undertaken by the US Food and Drug Administration and a clinical usage review. Overall, the ACM noted that the case reports provided limited evidence to support this signal and the literature review was inconclusive for this signal due to inconsistent evidence. On balance, the ACM was of the view that the signal is very difficult to interpret, however, at this time, based on the available data, the ACM was unable to definitively state that there is not a signal of harm.

The ACM advised that while the evidence is currently inconsistent, an additional statement regarding the risk of cardiovascular death and requisite precautionary monitoring should be considered for inclusion within the Australian PI. The ACM noted that this proposed addition to the PI should alert but not alarm clinicians and patients.

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