Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 46, 1 and 2 August 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 (TRADE NAME)	Sponsor	Therapeutic area	Application designations
Applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently or previously approved in Australia (Application Type A)			
Ustekinumab (STEQEYMA)	Celltrion Healthcare Australia Pty Ltd	Plaque Psoriasis Psoriatic Arthritis Crohn's Disease Ulcerative Colitis	
Vorasidenib (VORANIGO)	Servier Laboratories Australia Pty Ltd	Non-Enhancing Astrocytoma Oligodendroma	Orphan Priority
Natalizumab (TYRUKO)	Sandoz Pty Ltd	Multiple Sclerosis	

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Fruquintinib (FRUZAQLA)	Takeda Pharmaceuticals Australia Pty Ltd	Colorectal Cancer	
Lecanemab (LEQEMBI)	Eisai Australia Pty Ltd	Alzheimer's Dementia	
Applications for a 'new combination', where two or more already approved medicines are combined into a single product (Application Type B)			
Macitentan, Tadalafil (OPSYNVI)	Janssen-Cilag Pty Ltd	Pulmonary Arterial Hypertension	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Osimertinib Mesilate (TAGRISSO)	AstraZeneca Pty Ltd	Lung Cancer	
Brexpiprazole (REXULTI)	Lundbeck Australia Pty Ltd	Alzheimer's Dementia	
Tirzepatide (MOUNJARO)	Eli Lilly Australia Pty Ltd	Chronic Weight Management	
Faricimab (VABYSMO)	Roche Products Pty Ltd	Macular Oedema	

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:

- 1 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

Mountelukast and Neuropsychiatric Events

Montelukast is a medicine prescribed for asthma or allergic rhinitis.

The origin of this signal investigation was notification by the TGA's international regulatory counterparts that their existing warnings about neuropsychiatric effects in montelukast product information documents will be strengthened. In addition, the TGA has been approached by consumer advocacy groups who have informed the TGA that in their view patients and prescribers are not adequately aware of the risks.

Montelukast and associated neuropsychiatric events were considered by the ACM in their 8th meeting, in April 2018. A safety alert on this issue was published by the TGA in July 2018.

At the 46th meeting, the ACM advised that the term 'neuropsychiatric events' encompasses too wide a range of symptoms and presentations to be meaningful and confuses symptoms with diagnosis. However, the ACM acknowledged that this term is used by international regulators. The ACM was asked to provide advice on the TGA's current risk mitigation strategies for Montelukast and how these related to that of international regulatory counterparts. Specifically, the ACM was asked to advise whether a boxed warning should be added to the Australian PI regarding the association with neuropsychiatric adverse events.

The ACM advised that a 2024 review of the evidence did not identify any new neuropsychiatric risks associated with montelukast. The existing evidence for the potential association between montelukast and neuropsychiatric risks is uncertain, and has not changed.

However, on balance, the ACM advised that while the scientific and clinical evidence to 2024 does not demonstrate a causal association between montelukast and neuropsychiatric symptoms, alignment with international regulators in this case and in acknowledgment of consumer concerns, it would now be appropriate to implement a boxed warning.

In formulating the boxed warning, the ACM supported careful wording that neuropsychiatric events (with examples) are generally mild and may be coincidental.

The ACM also recommended additional changes to the Australian PI to add wording around discontinuation of montelukast if neuropsychiatric symptoms emerge, in line with wording found in the Canadian monograph.

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