Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 31, Thursday 3 and Friday 4 February 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 10 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type A (new biological entity)		
anifrolumab (SAPHNELO)	AstraZeneca Pty Ltd	For the treatment of systemic lupus erythematosus
bimekizumab (BIMZELX)	UCB Australia Pty Ltd	For the treatment of plaque psoriasis
enfortumab vedotin (PADCEV)	Astellas Pharma Australia Pty Ltd	For the treatment of locally advanced (LA) or metastatic urothelial cancer (mUC)
tixagevimab and cilgavimab (EVUSHELD)	AstraZeneca Pty Ltd	For treatment / prophylaxis of COVID-19 (provisional registration)
Type A (new chemical entity)		
diroximel fumarate (VUMERITY)	Biogen Australia Pty Ltd	For the treatment of relapsing multiple sclerosis
sotorasib (LUMAKRAS)	Amgen Australia Pty Ltd	For the treatment of non-small cell lung cancer
Type C (extension of indications)		
abemaciclib (VERZENIO)	Eli Lilly Australia Pty Ltd	Adjuvant therapy for breast cancer

ozanimod (ZEPOSIA)	Celgene Pty Ltd	For the treatment of active ulcerative colitis
semaglutide (WEGOVY)	Novo Nordisk Pharmaceuticals Pty Ltd	For weight management
tafenoquine (KOZENIS)	GlaxoSmithKline Australia Pty Ltd	For prevention of relapse of Plasmodium vivax malaria

*These application types are published on the Prescription medicines: applications under evaluation page 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). Please note that there is a delay from when an application was considered at ACM and the publication of the AusPAR. To browse all AusPARs see: <https://www.tga.gov.au/browse-auspars-active-ingredient>

Section B: Post-market item referred for advice

Sedating antihistamines and use in children

Accidental or therapeutic error exposure of children to first-generation oral antihistamines has been commonly associated with over the counter (OTC) cough, cold, and allergy medications. Despite current risk mitigation measures, both Australian and international evidence sources have shown that misuse of these products in children has led to serious adverse outcomes.

ACM advice was sought on the safety concern of serious adverse outcomes and off-label use of first-generation sedating antihistamines in children.

The ACM highlighted the lack of efficacy data to support the use of first-generation sedating antihistamine-containing drugs in children for the treatment of coughs and colds, and noted that efficacy in the treatment of allergy had not been assessed. In addition, all clinical guidelines for the treatment of allergy specifically advise the selection of non-sedating antihistamines. The ACM expressed concern regarding the safety of first-generation sedating antihistamine use in children and the evidence of attributable harm that has been shown by Australian and international data.

The ACM advised that first-generation sedating antihistamines should be at least Schedule 3 (Pharmacist Only).

The ACM was supportive of any first-generation sedating antihistamine products targeted for use in children aged 2 to 5 years be discontinued and removed from the ARTG.

The ACM advised that communication to health professionals and consumers is warranted to address the safety concerns associated with inappropriate or accidental use of first-generation sedating antihistamines in children.

Further information

For further information on the Advisory Committee on Medicines, please visit: https://www.tga.gov.au/committee/advisory-committee-medicines-acm or contact the ACM Secretary by email: ACM@health.gov.au.