



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 35, Thursday 6 and Friday 7 October 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 11 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type A (new biological entity)		
letibotulinum toxin A (LETYBO)	CROMA Australia Pty Ltd	For treatment of glabellar frown lines.
Type A (new chemical entity)		
deucravacitinib (SOTYKTU)	Bristol-Myers Squibb Australia Pty Ltd	For the treatment of adult patients with moderate to severe plaque psoriasis.
icosapent ethyl (VAZKEPA)	AA-Med Pty Ltd	For reducing the risk of cardiovascular events.
difelikefalin (KORSUVA)	Vifor Australia Pty Ltd	For treatment of pruritus associated with chronic kidney disease
Type B (new combination)		
foslevodopa and foscabidopa (VYALEV)	AbbVie Pty Ltd	For treatment of Parkinson's disease.
Type C (extension of indications)		
empagliflozin (JARDIANCE)	Boehringer Ingelheim	For treatment of symptomatic heart failure.

migalastat (GALAFOLD)	Amicus Therapeutics Pty Ltd	For treatment of Fabry disease.
cabozantinib (CABOMETYX)	Ipsen Pty Ltd	For treatment of thyroid carcinoma.
pembrolizumab (KEYTRUDA)	Merck Sharp and Dohme (Australia) Pty Ltd	For treatment of melanoma.

*These application types are published on the Prescription medicines: applications under evaluation page <https://www.tga.gov.au/prescription-medicines-applications-under-evaluation>

In addition to:

- One for the transition from provisional to full registration.
- One for the registration of a new biosimilar medicine

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>>

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.