Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 41 – 5 and 6 October 2023

Section A: Premarket registration applications

At this meeting, the committee provided advice on 10 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)			
heparin sodium (HEPARIN INTERPHARMA)	Interpharma Pty Ltd	For the treatment of thrombotic and thromboembolic disorders.	
nefopam hydrochloride (NEFOPAM SXP/ NEFOPAM HMH)	Southern XP IP Pty Ltd	For the treatment of pain associated with surgical procedures.	
nirsevimab (BEYFORTUS)	Sanofi-Aventis Australia Pty Ltd	For the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease.	

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palovarotene (SOHONOS)	Ipsen Pty Ltd	For the treatment of heterotopic ossification.	Orphan
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
incobotulinum toxin A (XEOMIN)	Merz Australia Pty Ltd	For the treatment of chronic sialorrhea and spasticity of the lower limb or upper limb.	
pembrolizumab (KEYTRUDA)	Merck Sharp & Dohme Australia Pty Ltd	For the treatment of non-small cell lung cancer.	
tacrolimus monohydrate (TACROLIMUS OINTMENT)	Accord Healthcare Pty Ltd	For the treatment of atopic dermatitis.	
tucatinib (TUKYSA)	Merck Sharp & Dohme Australia Pty Ltd	For the treatment of colorectal cancer.	Provisional

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 major variations (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration) (Application Type F)
- 1 application for changes to Product Information requiring evaluation of clinical, nonclinical or bioequivalence data (Application Type J)

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