



## Advisory Committee on Medicines

### Meeting Statement

**Meeting 50, Friday 4 April 2025**

#### Section A: Premarket registration applications

At this meeting, the committee provided advice on 7 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 approved in Australia (Application Type A)			
donanemab (KISUNLA)	Eli Lilly Australia Pty Ltd	Alzheimer's Disease	
Nemolizumab (NEMLUVIO)	Galderma Australia Pty Ltd	Atopic Dermatitis, Prurigo Nodularis	
Omaveloxolone (SKYCLARYS)	Biogen Australia Pty Ltd	Friedrich's Ataxia	Orphan
Gadopiclenol (ELUCIREM/VUEWAY)	Guerbet Australia Pty Ltd	Contrast Magnetic Resonance Imaging	
Pegunigalsidase alfa (ELFABRIO)	Chiesi Australia Pty Ltd	Fabry Disease	

Lonapegsomatropin (SKYTROFA)	Specialised Therapeutics Pharma Pty Ltd	Growth Hormone Deficiency	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
IncobotulinumtoxinA (XEOMIN)	Merz Australia Pty Ltd	Limb Spasticity	

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>

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](mailto:ACM@health.gov.au).