Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 44, 4 and 5 April 2024

Section A: Premarket registration applications

At this meeting, the committee provided advice on 10 applications under evaluation by the TGA.

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)			
Ebglyss	Eli Lilly Australia Pty Ltd	Atopic Dermatitis	
Elrexfio	Pfizer Australia Pty Ltd	Myeloma	Provisional
TBC	Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes Mellitus	
Velsipity	Pfizer Australia Pty Ltd	Ulcerative Colitis	
Tevimbra	Beigene Aus Pty Ltd	Oesophageal Cancer	

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TBC	AstraZeneca Pty Ltd	Breast cancer	
Applications for a 'new combination', where two or more already approved medicines are combined into a single product (Application Type B)			
Sidapvia 10/100	AstraZeneca Pty Ltd	Type 2 Diabetes Mellitus	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Talzenna	Pfizer Australia Pty Ltd	Breast cancer	

The committee also provided advice on:

- 2 applications for major variations (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration) (Application Type F).

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

Sodium valproate in pregnancy, and in reproductive males

Sodium valproate is currently indicated for the treatment of multiple presentations of epilepsy, as well as treatment of mania where other therapies have proved inadequate or inappropriate. It is available in a variety of forms from multiple sponsors. Sodium valproate is a Category D drug in Australia's categorisation system for prescribing medicines in pregnancy.

The ACM discussed use of sodium valproate in June 2018 recommending prescribers be educated on the risks of use in pregnancy. The ACM did not support any additional pregnancy prevention measures at that time.

In November 2023, the UK's Medical and Healthcare products Regulatory Agency (MHRA) introduced new safety measures to reduce risks of effects of sodium valproate in pregnancy, and in male patients contributing to reproduction.

The ACM considered the data used by the MHRA to support its decision, noting that the data regarding paternal exposure was under re-evaluation. Further data on maternal and paternal exposure was examined by the ACM.

The ACM advised that findings regarding risk of neurodevelopmental delay in children of male patients taking an antiepileptic therapy (including sodium valproate) should be interpreted with caution, due to methodological limitations.

Due to the limited supporting data, the ACM advised there was insufficient evidence to support amendment to the indication for sodium valproate products to exclude particular patient groups.

The ACM suggested product information documents for sodium valproate products should encourage prescribers to consider the potential impacts on fertility, teratogenic risks, pregnancy prevention, and contraceptive advice for all patients regardless of biological sex.

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