Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 47, 3 and 4 October 2024

Section A: Premarket registration applications

At this meeting, the committee provided advice on 5 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)			
Sotatercept (WINREVAIR)	Merck Sharp & Dohme Australia	Pulmonary arterial hypertension	Priority Orphan
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
Atropine sulfate monohydrate (EIKANCE 0.05%)	Aspen Pharmacare Australia	Paediatric myopia	
Semaglutide (WEGOVY)	Novo Nordisk Pharmaceuticals	Cardiovascular disease	

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Fenfluramine hydrochloride (FINTEPLA)	UCB Australia	Dravet syndrome Lennox-Gastaut syndrome	
Risankizumab (SKYRIZI)	Abbvie	Ulcerative colitis	

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

PRIVIGEN AU

Intravenous immunoglobulin (IVIg) is a blood product used in immunomodulatory therapies, and to treat immunodeficiency in both adult and paediatric patients. PRIVIGEN AU is an IVIg product first marketed for use in Australia in April 2023 replacing another IVIg product, INTRAGAM 10. PRIVGEN AU is a human normal immunoglobulin product composed mainly of immunoglobulin G (IgG) from Australian plasma donors and is distinct from another registered IVIg product, PRIVIGEN which is made from internationally sourced plasma.

The Therapeutic Goods Administration (TGA) received a safety signal indicating a higher rate of adverse events were being experienced by patients treated with PRIVIGEN AU, compared to other IVIg products. There was particular concern with the adverse reaction of aseptic meningitis syndrome (AMS) which is a known side effect of this product.

The ACM was asked to provide advice on whether they considered there to be evidence of an increased rate of adverse events beyond what was expected for a new IVIg product and what the clinical significance of this was. They were also asked to provide advice on whether regulatory action was required by the TGA at this time.

The ACM noted that the allocation of IVIg products is managed by the National Blood Authority and PRIVIGEN AU is preferentially allocated to paediatric patients and patients with primary immunodeficiency. The ACM advised that consideration of the patient and condition being treated is of significance when interpreting data relating to use of IVIg products as the dosing varies depending on the use and patient. Adverse events are generally accepted to be dose and infusion rate related.

They noted that there is a known first dose effect with IVIg products, whereby the first dose of a new product is more likely to cause an adverse reaction. This can occur when switching between IVIg products or if there is a change in manufacturing process of an existing product.

The ACM discussed the data presented and noted a number of factors that may contribute to the apparent increased rates of adverse events seen with PRIVIGEN AU. These included the known first dose effect when a new product is introduced, the preferential allocation of PRIVIGEN AU to paediatric patients and patients with primary immunodeficiency which would affect the interpretation of the adverse event data, as well as potential for reporting bias.

The committee also noted inherent limitations in post market reporting of adverse events namely their voluntary nature and the potential for reporting bias in the data presented.

The ACM advised that at present, there is insufficient evidence to support the conclusion that there is an increased rate of adverse events associated with PRIVIGEN AU. The timing of the rise in adverse events reported coincides with the switch from INTRAGAM 10 and is consistent with a first dose effect that would be expected with a new IVIg product.

The ACM further noted that while at present it is unclear whether the increased number of reports reflects reporting bias, an expected rise in adverse events due to use of a new product or a true safety signal, they were of the view that the issue warrants ongoing monitoring and data collection to enable further evaluation.

Noting the deficiencies of the available evidence, and the presence of plausible alternative explanations for the reported increase in adverse events, the ACM was of the view that no change to the current warnings in the PI or additional communication with prescribers is warranted at present.

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