Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 34, Thursday 4 and Friday 5 August 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 14 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type A (new chemical entity)		
difelikefalin (KORSUVA)	Vifor Australia Pty Ltd	For treatment of pruritus associated with chronic kidney disease.
maribavir (LIVTENCITY)	Takeda Pharmaceuticals Australia Pty Ltd	For treatment of post-transplant cytomegalovirus (CMV) infection.
mavacamten (CAMZYOS)	Bristol Myers Squibb Australia Pty Ltd	For treatment of symptomatic obstructive hypertrophic cardiomyopathy.
pemigatinib (PEMAZYRE) *(for provisional registration)*	Specialised Therapeutics Alim Pty Ltd	For treatment of cholangiocarcinoma.
treosulfan (TRECONDI)	Link Medical Products Pty Ltd	For conditioning treatment prior to allogeneic hematopoietic stem cell transplantation.
Type C (extension of indications)		
belimumab (BENLYSTA)	GlaxoSmithKline Australia Pty Ltd	For treatment of lupus nephritis.
brolucizumab (BEOVU/VISQQ)	Novartis Pharmaceuticals Australia Pty Ltd	For treatment of diabetic macular oedema.

durvalumab (IMFINZI) *(for provisional registration)*	AstraZeneca Pty Ltd	For treatment of unresectable Malignant Pleural Mesothelioma.
elexacaftor/tezacaftor/ivacaftor (TRIKAFTA)	Vertex Pharmaceuticals Australia Pty Ltd	For treatment of patients who have mutation in the cystic fibrosis transmembrane conductance regulator gene.
risankizumab (SKYRIZI)	AbbVie Pty Ltd	For treatment of Crohn's disease.
secukinumab (COSENTYX)	Novartis Pharmaceuticals Australia Pty Ltd	*Juvenile Idiopathic Arthritis (JIA)* *Enthesitis-Related Arthritis (ERA)* *Cosentyx is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate 1≥ NSAID and 1≥ DMARD.* *Juvenile Psoriatic Arthritis (JPsA)* *Cosentyx is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate 1≥ NSAID and 1≥ DMARD.*
upadacitinib (RINVOQ)	AbbVie Pty Ltd	For treatment of ulcerative colitis.

*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:

- Two seeking major variations including a change in dosage

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>

Section B: Post-market item referred for advice

Oral anticoagulants and the risk of anticoagulant-related nephropathy (ARN)

Anticoagulant-related nephropathy (ARN) is a serious adverse event with the potential to cause irreversible kidney damage and death. ARN associated with vitamin K antagonists (also known as 'warfarin-related nephropathy') is well documented in both peer-reviewed literature and international spontaneous reporting. Evidence regarding the occurrence of ARN in association with direct thrombin inhibitors and factor Xa inhibitors is also mounting.

The TGA investigation of oral anticoagulants and the risk of ARN concluded there to be sufficient evidence to warrant updating the product information (PI) for vitamin K antagonists and direct thrombin inhibitors to warn clinicians of the risk of ARN. While the ACM was not

asked to provide specific advice regarding vitamin K antagonists and direct thrombin inhibitors, the committee supported the TGA in this position.

The ACM was asked to consider the current evidence pertaining to the risk of ARN with factor Xa inhibitors (rivaroxaban and apixaban) for which the ACM advised is also sufficient to warrant updating the PI in line with the proposed updates for vitamin K antagonists and direct thrombin inhibitors.

The ACM highlighted that ARN is a rare, but serious event that is likely underdiagnosed and requires prescriber education around its presentation (as acute kidney injury) and management. Additionally, the ACM advised that the term 'anticoagulant-related nephropathy' should be included in the PI as an adverse event, distinct from 'haematuria or genitourinary haemorrhage' and 'acute kidney injury'.

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.