



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 23 – Friday 30 July 2021

Section A: Submissions for registration

The committee provided advice on one application to register a new vaccine, and one application to extend the indications of the vaccine.

Further details of the ACV discussion and advice associated with these pre-market items may be released within the Australian Public Assessment Report (AusPAR). Please note that there is a delay between when an application is considered by the ACV and the publication of the AusPAR. To browse all AusPARs see [AusPAR search](#).

Section B: Safety

The committee provided advice on one matter relating to pharmacovigilance.

COVID-19 vaccine AstraZeneca [now, Vaxzevria] and Guillain Barre Syndrome

The ACV provided advice on the strength of evidence for the risk of Guillain Barre Syndrome (GBS) following COVID-19 vaccine AstraZeneca.

The ACV advised that GBS should be added to the Product Information (PI) of this vaccine as a warning.

The ACV advised that information for consumers could include wording such as 'greater than expected', with an explanation that there is a background rate of GBS in the absence of vaccination. A simple tabulation of expected and observed cases could be useful.

Further information

For further information on the ACV, please visit [Advisory Committee on Vaccines](#) or contact the ACV by email ACV@health.gov.au.