



Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 25 – Wednesday 29 September 2021

Section A: Submissions for registration

The committee provided advice on 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 Pharmacovigilance Plan

The ACV has previously [provided advice](#) (September 2020) and [endorsed](#) (February 2021) the TGA's [COVID-19 vaccine safety monitoring plan](#).

From commencement of supply of COVID-19 vaccines six months ago, the TGA now has a better understanding of what information is available and reliable regarding COVID-19 vaccine adverse events and administered doses.

The ACV provided advice on the changes to the implementation of the plan regarding:

- access to Australian Immunisation Register (AIR) and vaccine distribution data for calculating COVID-19 immunisation rates
- refined processes and statistical methods for analysing observed COVID-19 adverse events following immunisation for detecting safety signals
- enhanced processes to determine if the frequency of a particular event is higher than expected
- processes for conducting subpopulation analyses to identify and investigate potential safety signals in at-risk populations
- additional or revised terminology for the adverse events that have been reported to the TGA.

The ACV supported a focussed effort to access/obtain current Australian background rates for reported events, such as via hospital admission data, NPS MedicineWise and/or general practice data.

Further information

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