Australian Government
Department of Health
Therapeutic Goods Administration

# Advisory Committee on Vaccines

**Meeting Statement 15 – Wednesday 3 June 2020**

## Section A: Submissions for registration

The committee's advice was sought on two applications to register new vaccines.

Further details of the ACV discussion and advice associated with this pre-market item 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

A Risk Management Plan (RMP) is a set of pharmacovigilance and risk minimisation activities designed to identify, characterise and manage the important safety concerns relating to a vaccine. The committee was asked to provide general advice about safety concerns that would be considered important for inclusion in the RMP. The committee advised that a safety specification should have a focus on the adverse events that in clinical practice would be unexpected/novel.

## Section C: Immunisation Programs

No matter related to the immunisation programs was discussed.

## Further information

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