



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 10 – Wednesday 3 October 2018

Section A: Submissions for registration

The committee's advice was sought on one application seeking to extend the indication for the vaccine and also to register a new strength of this vaccine.

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 and Section C: Immunisation Programs

The committee's advice was sought on a proposal for time-limited working groups to be convened when specific criteria for a vaccine safety signal are met, to provide independent specialist immunisation and other relevant advice to assist the TGA and Office of Health Protection to investigate and manage safety signals of concern relating to vaccines. Activities of a working group could include: causality assessment; root cause analysis; multi-case investigation; development of communication material and risk communication messages including advice for clinicians; advice on programmatic action; and advice on risk minimisation through regulatory action.

The ACV provided advice on the draft work instructions for such a group, in respect of membership, the criteria to convene a meeting and working processes.

Further information

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