Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 17 – Wednesday 2 December 2020

Section A: Submissions for registration

No submission for registration was discussed.

The committee provided high-level comment on pending submissions for vaccines for SARS-CoV-2 disease that will use the provisional approval pathway. Areas covered included:

- factors that should be considered when determining the benefit-risk balance for potential provisional registration of COVID-19 vaccines
- the theoretical/ potential safety concerns with new vaccine technologies (e.g. mRNA and genetically modified vaccines), potential areas of focus for evaluation, and risk minimisation strategies
- use of digital expiry dates for vaccines with limited shelf life stability data at the point of registration (if approved).

Section B: Safety

The committee provided advice on the duration of a pharmacovigilance study that is included in a Risk Management Plan.

Section C: Immunisation Programs

No matter related to 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.

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