



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 34 – Wednesday 6 July 2022

Section A: Submissions for registration

The committee provided advice on two applications for vaccines:

- Extension of indication (primary series for infants and children 6 months to 5 years of age), and a new strength formulation, for provisional registration for active immunisation to prevent COVID-19 (product name Spikevax; active ingredient elasomeran [mRNA]; sponsor Moderna Australia Pty Ltd).
- Extension of indication (primary series for individuals 12 to 18 years of age) for provisional registration for active immunisation to prevent COVID-19 (product name Nuvaxovid; active ingredient SARS-CoV-2 rS with Matrix-M adjuvant; sponsor Bioelect Pty Ltd).

Details of the ACV advice associated with these premarket items has been or will be released within the Australian Public Assessment Report (AusPAR). To browse all AusPARs see [AusPAR search](#).

Section B: Safety

The committee was not asked to provide advice on any safety matter.

Section C: Immunisation program

The committee was not asked to provide advice on any program matter.

Section D: Other areas of advice

As an internationally-respected regulator, the TGA is involved in many activities with overseas organisations, including the Coalition for Epidemic Preparedness Innovations (CEPI).

CEPI is funding the development of Nipah virus vaccines. Nipah virus can spread between animals (e.g. flying foxes, pigs) and people. Infection with the virus can be asymptomatic but can also cause respiratory illness, encephalitis (swelling of the brain) and death. Outbreaks have occurred in south Asia. No human case of Nipah infection has been detected in Australia.

The ACV provided advice on regulatory requirements and issues to be considered, if a submission for a Nipah virus vaccine is submitted to the TGA in the future. The ACV considered the use of animal efficacy data and endpoints that could be examined in the development program for a vaccine.

Further information

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