



# Advisory Committee on Vaccines

Meeting Statement 31 – Tuesday 8 February 2022

## Section A: Submissions for registration

The committee provided advice on one application:

- extension of indication for a vaccine with provisional registration for active immunisation to prevent COVID-19 (product name Spikevax; active ingredient Elasmomeran; sponsor Moderna Australia Pty Ltd) that had been [under evaluation](#) from November 2021.

Details of the ACV advice associated with this premarket item have been released within the Australian Public Assessment Report (AusPAR). To browse all AusPARs see [AusPAR search](#).

## Section B: Safety

The committee provided advice on the following safety matter.

### **Risk of Haemophagocytic lymphohistiocytosis (HLH) associated with Vaxzevria (formerly known as COVID-19 vaccine AstraZeneca)**

Haemophagocytic lymphohistiocytosis (HLH) is a rare condition caused by an overactive, abnormal response of the immune system. Adults with HLH may present with recurrent fever, cytopaenia, liver dysfunction, organomegaly, elevated ferritin and inflammatory markers, and can rapidly progress to multiorgan failure. Early symptoms are often non-specific including fatigue, breathlessness, diarrhoea, bleeding, rash, joint pain and enlarged lymph nodes.

The ACV acknowledged that a definitive diagnosis of HLH is inherently difficult as the condition can mimic the symptoms of disseminated viral infection (particularly in immunocompromised individuals) and is primarily a syndromal diagnosis that requires specialised blood tests.

The four cases of HLH identified and sourced from reports received by the TGA, published literature and international regulators were discussed by the ACV, with the committee concluding that a definitive diagnosis of HLH cannot be assumed for all reported cases.

The ACV recommended that continued monitoring is appropriate at this time, as there is currently insufficient evidence to support a causal association between Vaxzevria and HLH.

The ACV highlighted the importance of the current practice of monitoring for adverse events following vaccination and seeking medical attention if unwell or concerned.

### **Further information**

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