



Australian Government

Department of Health  
Therapeutic Goods Administration

# Advisory Committee on Vaccines

## Meeting Statement 20 – Wednesday 14 April 2021

### Section A: Submissions for registration

The committee was not asked to provide advice on a submission for registration.

### Section B: Safety

The committee provided advice on two matters relating to pharmacovigilance.

For both matters, the documents provided to the committee were based on a data lock point of 4 April 2021. At the data lock point, COVID-19 Vaccine AstraZeneca had been supplied for 35 days in Australia, and Comirnaty (Pfizer's BNT162b2 [mRNA] vaccine) had been supplied for 43 days.

#### COVID-19 Vaccine AstraZeneca and potential risk of thrombosis

The ACV provided advice on the TGA's methods for identifying reports of thrombosis with thrombocytopenia, and investigating the potential safety signal of COVID-19 vaccine AstraZeneca and thrombosis.

The ACV advised that a multistep process is needed, including review by jurisdictional public health units, TGA review, and a VSIG, when appropriate. [VSIG (Vaccine Safety Investigation Group) is the name for each time-limited working group convened by the TGA to provide specialist immunisation advice, as discussed at [ACV meeting 10.](#)]

The ACV advised that professional societies, general practice groups and ATAGI are best placed to develop additional measures to mitigate the potential risk of rare thrombosis with thrombocytopenia syndrome following COVID-19 vaccine AstraZeneca.

#### Anaphylaxis and COVID-19 Vaccines

The ACV noted that the majority of initial reports of allergic-type reactions did not meet the Brighton Collaboration case definition for anaphylaxis.

The presented data did not show a significant safety signal for anaphylaxis for the AstraZeneca COVID-19 Vaccine.

The presented data on the Pfizer Comirnaty vaccine showed a higher rate of anaphylaxis (39 per million doses) than is observed for the AstraZeneca COVID-19 vaccine or following vaccination for other diseases.

## **Section C: Immunisation Programs**

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

### **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).