



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Vaccines

**Meeting Statement 22 – Wednesday 16 June 2021**

## **Section A: Submissions for registration**

The committee provided advice on one application to extend the indication of a vaccine.

Further details of the ACV discussion and advice associated with these pre-market items 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**

The committee provided advice on one matter relating to pharmacovigilance.

### **Comirnaty and myocarditis / pericarditis**

The ACV provided advice on the strength of evidence for the safety signal for Comirnaty (Pfizer's BNT1622b2 [mRNA]) COVID-19 vaccine) of risk of myocarditis/pericarditis.

Data from the US suggested that the majority of cases of myocarditis and/or pericarditis after mRNA COVID-19 vaccines (both Pfizer and Moderna) analysed to date occurred in older adolescents and young adults (aged 16 to 30 years), with highest risk in younger males within days after dose 2. Most cases were mild and recovered within days with a median duration of hospitalisation of 1 day.

Myocarditis / pericarditis is a rare but important complication in otherwise healthy persons.

The ACV advised that relevant statements should be included in the Product Information, including:

- Rare cases of myocarditis and pericarditis have been reported following vaccination with Comirnaty, although a causal association is not established.
- Reported cases have occurred predominantly but not exclusively in male adolescents and young adults.
- Onset was typically within several days after vaccination, and cases have occurred more often after the second dose than the first dose.
- Current available data from short term follow-up suggest most individuals have had resolution of symptoms, however information regarding potential long term sequelae is not known.

- Clinicians should consider myocarditis and pericarditis in adolescents or young adults presenting with acute chest pain, shortness of breath, or palpitations several days after vaccination, and should consider consultation with cardiologists, or referral to an emergency department, for assistance with cardiac evaluation and management.

### **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).