Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Vaccine Safety Investigation Group (VSIG) meeting

Meeting outcomes

TGA Health Safety Regulation

VSIG meeting held on 7 September 2022 on WebEx (10-11 am)

Attendees

Members:

Name (affiliation)	Expertise
s22	Paediatric infectious diseases and vaccines s22
s22	Public Health Physician - communicable diseases and vaccines s22
s22	Consumer representative s22 s22
s22	Staff specialist general paediatrician Vaccine safety
s22	Physician, Cardiologist
s22	Social scientist – immunisation, infectious diseases, and community engagement
s22	General Practitioner s22
s22	Infectious diseases s22
s22	Immunisation Nurse Practitioner s22

ACV Advisory Committee on Vaccines
ATAGI Australian Technical Advisory Group on Immunisation

Observers:

Name (affiliation)	Expertise
s22	
	Public Health Registrar
s22	Public Health Physician
s22	Epidemiologist
s22	Infectious diseases, epidemiology

MCRI Murdoch Children's Research Institute

Departmental staff in attendance for all or part of the meeting:

Health Products Regulation Group staff:
Adjunct Professor John Skerritt, Deputy Secretary, Health Products Regulation Group
Mr Nick Henderson, First Assistant Secretary, Medicines Regulation Division
s22

National COVID-19 Vaccine Taskforce staff:

s22 [redacted]

Secretariat:

s22 [redacted]

Purpose of the meeting

The TGA convened the Vaccine Safety Investigation Group (VSIG) to discuss the regulatory and program implications of a fatal case of myocarditis in a 21-year-old female following COVID-19 vaccination booster with s22 vaccine).

Details of the case

The woman complained of feeling generally unwell 48 hours after receiving a s22 booster and had symptoms of fever, nausea, fatigue, and abdominal pain. She presented to an emergency department twice in the following fortnight with atypical symptoms before being admitted to an intensive care unit with myocarditis after a third presentation to hospital. The woman sadly died 3 weeks after being admitted to hospital.

Prior to this meeting, a TGA assessment found that this case of myocarditis demonstrated a consistent causal association with the vaccine based on the information available. It was explained that the purpose of causality assessment from a regulatory perspective is to identify and characterise the strength of the evidence supporting the likelihood of a causal association between an adverse event and a vaccine and to consider potential public health action. It was noted that a definitive causal association (or absence of association) often cannot be established for an individual event.

It was emphasised that regulatory assessment does not pre-empt or replace other reviews of this case. In particular, it was acknowledged that there is an open Coroner's investigation and there have been multiple expert panel assessments of the case at the state level.

Questions to VSIG

The expert panel was asked to consider the issue of public confidence and provide advice on public communication about this case through the TGA's COVID-19 vaccine safety report. They were also asked to determine if any regulatory actions were needed, including whether the current wording on myocarditis in the Product Information document is sufficient, and if any updates are needed to clinical guidance and general vaccination recommendations through referral to the Australian Technical Advisory Group on Immunisation (ATAGI).

Meeting outcomes

- The panel agreed with the TGA's assessment that myocarditis was likely to have been related to vaccination given the available information, including the absence of other apparent causes of the myocarditis, and the timeframe for the onset of symptoms.
- The panel acknowledged there were several other complicating factors that may have contributed to this person dying and noted the cause and circumstances of death remain subject to investigation by the Victorian Coroner.
- The panel confirmed that myocarditis was a rare but known risk of the mRNA vaccines and the overall benefit-risk balance for s22 remained positive.
- The panel recommended, as a priority, adding more detail to the existing warnings about myocarditis in the product information for s22 and s22 . This is to clarify that fatal cases of myocarditis have been reported, cases can occur in females as well as males and after a booster vaccine dose, and presenting symptoms may be atypical.

- As myocarditis is more commonly seen in boys aged 12-17 and men under 30 after a second vaccine dose, members noted there may be less awareness generally that myocarditis can also occur in females and after a booster dose. The panel recommended raising awareness of this in the community. This includes ensuring patients, male and female, are informed about the risk of myocarditis before receiving a vaccine dose
- The panel referred this case to the ATAGI to consider:
    - Updating existing clinical guidance around vaccine-induced myocarditis to raise awareness amongst healthcare professionals in line with the proposed PI changes. In addition, the panel emphasised the importance of routinely obtaining vaccination status as part of history taking and having a high index of suspicion for myocarditis for typical and atypical presentations temporally related to vaccination.
    - Reviewing any implications for general vaccine recommendations arising from this case.
- The panel acknowledged the tragic circumstances of this case and extends its sincerest condolences to the family and loved ones of this young woman. They noted the de-identified outcomes of the VSIG meeting would be published in the COVID-19 vaccine safety report after the family has been consulted, and were aware contact would occur in accordance with the family's wishes, likely through state forensic services.