



Note for file

TGA ICSR reference	AU-TGA-0000729139
Date and time	s22
Type of event	Fatal AEFI assessment team meeting Close out summary
Participant(s)	<ul style="list-style-type: none">• s22 MO s22 PB• s22 MO s22 PB• s22 MO s22 PB• s22 EL1 s22 PB• s22 EL1 s22 PB• s22 APS6 s22 PB• s22 APS6 s22 PB
Topic	Fatal AEFI report & Spikevax COVID-19 vaccine
Key point(s)	<ul style="list-style-type: none">• 21 Female s22• s22• Abdominal pain ; Cardiac arrest ; Cardiogenic shock ; Echocardiogram abnormal ; Fatigue ; Femoral artery embolism ; Malaise ; Myocarditis ; Nausea ; Paraesthesia ; Peripheral ischaemia ; Pyrexia ; Renal impairment ; Spinal cord infarction ; Troponin increased ; Ventricular dysfunction• This is the case that s22 mentioned at the s22 on s22 and have held an s22 . It will be extremely complex and will depend on the information that comes through in the coming days/weeks/months. At this time s22 <p>s22</p> <p>This case will certainly require s22</p> <p>s22 VSIG</p>
	Rereviewed on s22
	<ul style="list-style-type: none">• exploring options re genetic testing with
Follow-up action(s) (include action required, action officer, agreed date/s)	Regulatory or programmatic action for consideration by TGA or OHP? s22 notes received Communication with JIC and ACV? VSIG Any other follow-up actions required? s22
Decision(s)	Causality assessment outcome: WHO=U Awaiting s22

Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input type="checkbox"/> C. Inconsistent with causal association to immunization
	<input type="checkbox"/> A1. Vaccine product-related reaction (As per published literature) <input type="checkbox"/> A2. Vaccine quality defect-related reaction <input type="checkbox"/> A3. Immunization error-related reaction <input type="checkbox"/> A4. Immunization anxiety-related reaction (ISRR**)	<input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) <input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	<input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
Adequate information not available	<input checked="" type="checkbox"/> Unclassifiable Specify the additional information required for classification : <div style="border: 1px solid black; height: 20px; width: 500px;"></div>		

*B1 : Potential signal and maybe considered for investigation
 ** Immunization stress related response