



Note for file

TGA REF AU-TGA-000 [REDACTED]

Date and time 6 April 2022

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & Astra Zeneca COVID-19 Vaccine

Participants

Name	Details
s22 [REDACTED]	MO5 VERA, PVB TGA
[REDACTED]	MO4 VERA, PVB TGA
[REDACTED]	MO2 VERA, PVB TGA
s22 [REDACTED]	Assistant Director VERA, PVB TGA
s22 [REDACTED]	CCU RN, VERA, PVB TGA
s22 [REDACTED]	APSS VERA, PVB TGA

Key points

- 48F
- D4 post AZ D1, [REDACTED]
- [REDACTED] thrombo-embolic event s22 [REDACTED]
- VSIG 16/04/2021

Rereviewed 07/04/2022

- Confirmed
- COD TTS

Follow-up action
(include action required, action officer, agreed date/s)

- Regulatory or programmatic action for consideration by TGA or OHP; nil further
- Communication with JIC and ACV; nil further
- Any other follow-up actions required; ongoing monitoring

Decisions

- VSIG concluded **WHO A1** – Causality confirmed

<p>Adequate information available</p>	<p>A. Consistent with causal association to immunization</p> <p><input checked="" type="checkbox"/> A1. Vaccine product-related reaction (As per published literature)</p> <p><input type="checkbox"/> A2. Vaccine quality defect-related reaction</p> <p><input type="checkbox"/> A3. Immunization error-related reaction</p> <p><input type="checkbox"/> A4. Immunization anxiety-related reaction (ISRR**)</p>	<p>B. Indeterminate</p> <p><input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)</p> <p><input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization</p>	<p>C. Inconsistent with causal association to immunization</p> <p><input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine</p>
<p>Adequate information not available</p>	<p><input type="checkbox"/> Unclassifiable</p> <p>Specify the additional information required for classification :</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		

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