Explanatory information accompanying this document is presented on page 2

Australian Government
Department of Health
Therapeutic Goods Administration

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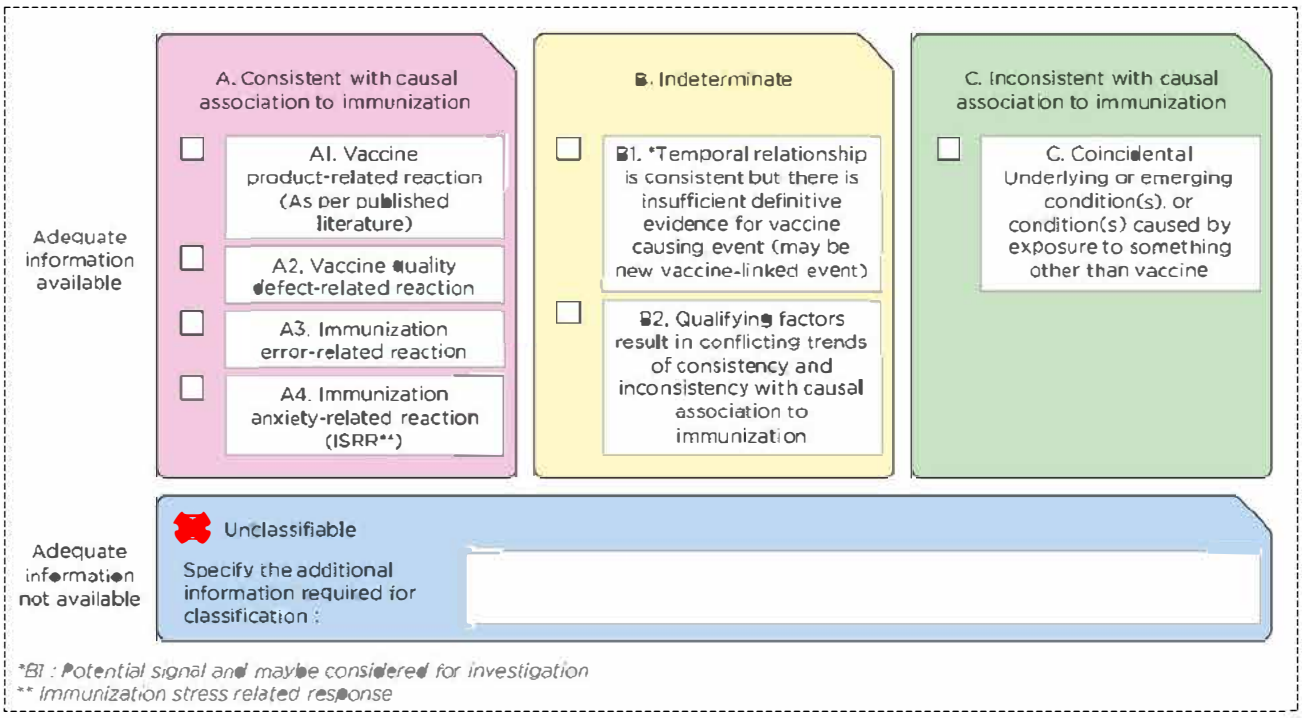
Note for file

TGA ICSR reference	AU-TGA-0000729139
Date and time	s22 [redacted]
Type of event	Fatal AEFI assessment team meeting Close out summary
Participant(s)	• s22 [redacted] MO [redacted] PB • s22 [redacted] MO [redacted] PB • s22 [redacted] MO s22 [redacted] PB • s22 [redacted] EL1 s22 [redacted] PB • s22 [redacted] EL1 s22 [redacted] PB • s22 [redacted] APS6 s22 [redacted] PB • s22 [redacted] APS6 s22 [redacted] PB
Topic	Fatal AEFI report & Spikevax COVID-19 vaccine
Key point(s)	• 21 Female [redacted] • [redacted] • 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 [redacted] mentioned at the [redacted] on [redacted] and have held an s22 [redacted]. It will be extremely complex and will depend on the information that comes through in the coming days/weeks/months. At this time s22 [redacted] This case will certainly require s22 [redacted] s22 [redacted] VSIG Rereviewed on s22 [redacted] • 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?** [redacted] notes received **Communication with JIC and ACV?** VSIG **Any other follow-up actions required?** s22 [redacted]
Decision(s)	**Causality assessment outcome:** WHO=U Awaiting [redacted]



- *These documents represent a 'point in time' assessment of information available to the TGA on the date of assessment. They are subject to ongoing review as new information comes to light and do not represent a final conclusion or final decision. Even when the TGA does not have sufficient information to undertake a causality assessment at a particular point in time (WHO criteria = U or unassessable/ unclassifiable), the TGA continues to code all reports with fatal outcome as "possibly" linked to COVID-19 vaccination. These cases are included in analyses of adverse event data to identify and investigate signals that may not be apparent through review of individual cases. This is consistent with the approach recommended by the WHO and used by other major global regulators and vaccine safety monitoring programs.*
- *The point-in-time causality decision included in these documents may be expressed in a variety of ways. In some documents, no decision has been made and the template text "causality" or text in square brackets remains. For other documents, WHO criteria is listed in the document and may be expressed as unassessable/unclassifiable (coded as "U") and "unlikely". This explanation has been included due to some misunderstandings about these words.*
- *The TGA released these documents to the FOI applicant but did not publish them in the disclosure log at the time given the sensitive nature of the documents. While personal information was redacted, it remains possible that a family member or of an individual may identify that the document relates to their family member. As such, a conservative approach to publishing the information in the disclosure log was taken, given the potential for causing distress to the family of the deceased. This approach was consistent with the TGA's obligations under the FOI Act as there are exemptions from publishing documents released under the FOI Act in appropriate circumstances. However, given that these documents have now been widely circulated in the community, we have re-considered our initial decision to include these documents on the disclosure log.*