



Note for file (draft)

TGA REF AU-TGA-0000647663

Date and time s22

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & SPIKEVAX COVID-19 Vaccine

Participants

Name	Details
s22	MO s22 PVB TGA
s22	MO s22 PVB TGA
s22	Assistant Director s22, PVB TGA
s22	s22 RN s22, PVB TGA

Key points

- 14F, s22
- s22
- s22 investigation/results incomplete
- Rediscussed s22 nil further information on AEMS
- s22 notes uploaded

Rereviewed on s22

- s22 unlikely myocarditis, possible s22 syndrome

Follow-up action

{include action required, action officer, agreed date/s}

- Regulatory or programmatic action for consideration by TGA or OHP; pending
- Communication with JIC and ACV; RFI completed
- Any other follow-up actions required. pending

- *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.*