



Australian Government  
Department of Health  
Therapeutic Goods Administration

Final

## Note for file

TGA ICSR reference	s47F
Date and time	s47F at 13:30 pm
Type of event	Fatal AEFI assessment team meeting
Participant(s)	s22 s22
Vaccine Brand	Fatal AEFI report & s47F COVID -19 vaccine
Case Summary	<ul style="list-style-type: none"> <li>s47F yo s47F</li> <li>Vaccinations: s47F and s47F s47F s47F and s47F</li> <li>Date of death: s47F</li> <li>s47F</li> </ul> <p>s47F</p>
Assessment	The medical conditions causing this person's death are unlikely to be related to the Covid-19 booster vaccination received immediately prior to death
Rationale	s47F vaccination has not been linked to the medical conditions causing this person's illnesses and subsequent death
Follow-up action(s) (include action required, action officer, agreed date/s)	<p><i>Regulatory or programmatic action for consideration by TGA or OHP?</i> Nil</p> <p><i>Communication with JIC?</i> RFI sent to JIC and email reply received s47F</p> <p><i>Any other follow-up actions required?</i> Nil required</p>
Decision(s)	Unlikely Causality

*This decision is open to review if further information is received.*



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**Department of Health**  
 Therapeutic Goods Administration

**Final**

# Note for file

<b>TGA ICSR reference</b>	s47F
<b>Date and time</b>	s47F at 13:30 pm
<b>Type of event</b>	Fatal AEFI assessment team meeting
<b>Participant(s)</b>	<ul style="list-style-type: none"> <li>• s22</li> <li>• s22</li> </ul>
<b>Vaccine Brand</b>	Fatal AEFI report & s47F COVID -19 vaccine
<b>Case Summary</b>	<ul style="list-style-type: none"> <li>• s47F yo s47F</li> <li>• s47F</li> <li>• s47F</li> <li>• s47F</li> </ul>
<b>Assessment</b>	s47F
<b>Outcome</b>	
<b>Classification</b>	s47F
	Unlikely
<b>Follow-up action(s)</b> (include action required, action officer, agreed date/s)	<b>Regulatory or programmatic action for consideration by TGA or OHP?</b> Nil <b>Communication with JIC?</b> RFI sent to JIC and Death certificate <b>Any other follow-up actions required?</b> Nil
<b>Decision(s)</b>	<b>Causality assessment outcome:</b> Unlikely Causality  This decision open for review if further information is received in the future <b>Name/Signature</b>

s22

s47F





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# Note for file

TGA ICSR reference

s47F

Date and time

s47F

Type of event

Fatal AEFI assessment team meeting  
 Close out summary

Participant(s)

- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB

Topic

Fatal AEFI report & s47F COVID-19 vaccine

Key point(s)

- s47F yo s47F
- Death, s47F

Follow-up action(s)

(include action required, action officer, agreed date/s)

Regulatory or programmatic action for consideration by TGA or OHP?

Specify - state "Nil required" if none

Communication with JIC and ACV?

RFI sent

Any other follow-up actions required?

Awaiting coroner

Decision(s)

Causality assessment outcome:

WHO=U

	A. Consistent with causal association to immunization	B. Indeterminate	C. Inconsistent with causal association to immunization
Adequate information available	<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:		

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

s47F





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# Note for file

TGA ICSR reference

s47F

Date and time

s47F

Type of event

Fatal AEFI assessment team meeting  
 Close out summary

Participant(s)

- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB

Topic

Fatal AEFI report & s47F COVID-19 vaccine

Key point(s)

- s47F yo s47F
- s47F
- 
- 
- 

Follow-up action(s)

(include action  
 required, action officer,  
 agreed date/s)

Regulatory or programmatic action for consideration by TGA or OHP?

Specify - state "Nil" if none

Communication with JIC and ACV?

RFI to JIC s47F


Any other follow-up actions required?

s47F

Decision(s)

Causality assessment outcome:

WHO=U

<p>Adequate information available</p> <p></p>	<p><b>A. Consistent with causal association to immunization</b></p> <p><input 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>B. Indeterminate</b></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><b>C. Inconsistent with causal association to immunization</b></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><input type="checkbox"/> <b>Unclassifiable</b></p> <p>Specify the additional information required for classification :</p> <div style="border: 1px solid black; height: 20px; width: 500px;"></div>		

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# Note for file

TGA ICSR reference	s47F
Date and time	s47F
Type of event	Fatal AEFI assessment team meeting Close out summary
Participant(s)	<ul style="list-style-type: none"> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> </ul>
Topic	Fatal AEFI report & s47F COVID-19 vaccine
Key point(s)	<ul style="list-style-type: none"> <li>• s47F yo s47F</li> <li>• Death</li> <li>• TTD s47F</li> <li>• COD</li> </ul>
Follow-up action(s) (include action required, action officer, agreed date/s)	Regulatory or programmatic action for consideration by TGA or OHP? Nil Communication with JIC and ACV? RFI to JIC s47F Any other follow-up actions required? s47F
Decision(s)	Causality assessment outcome: WHO=



 <p>Adequate information available</p>	<p><b>A. Consistent with causal association to immunization</b></p> <p><input 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>B. Indeterminate</b></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><b>C. Inconsistent with causal association to immunization</b></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><input type="checkbox"/> <b>Unclassifiable</b></p> <p>Specify the additional information required for classification :</p> <div style="border: 1px solid black; height: 20px; width: 500px;"></div>		

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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 vaccine

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F
- TTD s
- COD s47F
- WHO= s  
4

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

- Regulatory or programmatic action for consideration by TGA or OHP;
- Communication with JIC and ACV; s4
- Any other follow-up actions required.

### Decisions

- Unlikely Causality

s47F

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

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# Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & s47F COVID-19 vaccine

## Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

## Key points

- s47F
- Unknown s47F
- COD

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

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

## Decisions

- Causality





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# Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 Vaccine s47F

## Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

## Key points

- s47F
- s47F
- s47F
- COD s47F

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

- Regulatory or programmatic action for consideration by TGA or OHP;
- Communication with JIC and ACV; s47F
- Any other follow-up actions required.

## Decisions

- Unlikely Causality

s47F







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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & s47F COVID-19 vaccine

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47
- s47F
- s47F

Rereviewed s47F

- s47F
- WHO=C

s47F

**Follow-up action**

(include action  
required, action  
officer, agreed date/s)

- Regulatory or programmatic action for consideration by TGA or OHP;  
Feedback received s47F
- Communication with JIC and ACV; RFI sent
- Any other follow-up actions required. s47F

**Decisions**

- Unlikely Causality



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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & s47F COVID-19 vaccine

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F – s47F
- Deceased s47F
- s47F
- s47F
- s47F
- COD s47F

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

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

**Decisions**

- Unlikely Causality

s47F





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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & s47F COVID-19 vaccine

### Participants [Add/delete as appropriate]

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F y/o s47F
- Deceased s47F
- s47F
- s47F
- s47F

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

- Regulatory or programmatic action for consideration by TGA or OHP; Potential VSIG
- Communication with JIC and ACV; s47F
- Any other follow-up actions required. s47F

### Decisions

- Awaiting Feedback s47F

s47F





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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Investigation Team Meeting

**Topic** s47F COVID-19 vaccine and Fatal

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F y/o s47F s47F
- Deceased s47F
- s47F
- s47F
- s47F
- s47F – COD s47F
- Unlikely Causality

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

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

**Decisions**

- Unlikely Causality

s47F







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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Investigation Team Meeting

**Topic** COVID-19 Vaccine s47F and Fatal

### Participants

Name	Details
s22	s22 PSAB TGA
s22	s22 PSAB TGA
s22	s22 PSAB TGA

### Key points

- s47F
- s47F
- s47F
- s47F
- s47F
- s47F – COD s47F
- s47F

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

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

**Decisions**

- Unlikely Causality

s47F





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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 Vaccine s47F

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

Reviewed 30/09/2021

- s47F y/o s47F s47F
- Deceased s47F
- s47F
- s47F
- s47F
- s47F

Rereviewed s47F

- COD s47F

### Follow-up action (include action)

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

s47F

required, action  
officer, agreed date/s)

**Decisions**

- Unlikely Causality



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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Investigation Team Meeting

**Topic** COVID-19 Vaccine s47F and Fatal

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F y/o s47F
- Deceased s47F
- s47F
- COD – s47F
- Unlikely Causality

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

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

### Decisions

- Unlikely Causality



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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & s47F COVID-19 vaccine

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F
- COD s47F

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

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

### Decisions

- Unlikely causality





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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 Vaccine s47F

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F yo s47F
- s47F
- s47F
- TIO s47F

Rereviewed s47F

- COD s47F
- WHO=C

### Follow-up action (include action

- Regulatory or programmatic action for consideration by TGA or OHP;
- Communication with JIC and ACV; RFI sent

s47F

required, action  
officer, agreed date/s)

- Any other follow-up actions required.

## Decisions

- Unlikely Causality

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

\*B1 : Potential signal and maybe considered for investigation

\*\* Immunization stress related response



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<b>TGA ICSR reference</b>	s47F
<b>Date and time</b>	s47F
<b>Type of event</b>	Fatal AEFI assessment team meeting Close out summary
<b>Participant(s)</b>	<ul style="list-style-type: none"> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> </ul>
<b>Topic</b>	Fatal AEFI report & COVID-19 Vaccine s47F
<b>Key point(s)</b>	<ul style="list-style-type: none"> <li>• s47F yo s47F</li> <li>• s47F</li> <li>• TTD s47F</li> <li>• s47F</li> </ul>
<b>Follow-up action(s)</b> (include action required, action officer, agreed date/s)	<b>Regulatory or programmatic action for consideration by TGA or OHP?</b> Nil <b>Communication with JIC and ACV?</b> JIC RFI <b>Any other follow-up actions required?</b> NIL
<b>Decision(s)</b>	<b>Causality assessment outcome:</b> WHO=C Unlikely Causality

Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input checked="" 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 checked="" 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 type="checkbox"/> Unclassifiable Specify the additional information required for classification : <div style="border: 1px solid black; height: 20px; width: 500px; margin-top: 5px;"></div>		

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<b>TGA ICSR reference</b>	s47F
<b>Date and time</b>	s47F
<b>Type of event</b>	Fatal AEFI assessment team meeting Close out summary
<b>Participant(s)</b>	<ul style="list-style-type: none"> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> </ul>
<b>Topic</b>	Fatal AEFI report & COVID-19 Vaccine s47F
<b>Key point(s)</b>	<ul style="list-style-type: none"> <li>• s47F/yo s47F</li> <li>• s47F</li> <li>• TTD s47F</li> <li>• COD s47F</li> </ul>
<b>Follow-up action(s)</b> (include action required, action officer, agreed date/s)	<b>Regulatory or programmatic action for consideration by TGA or OHP?</b> Nil <b>Communication with JIC and ACV?</b> NIL <b>Any other follow-up actions required?</b> s47F
<b>Decision(s)</b>	<b>Causality assessment outcome:</b> WHO=C Unlikely Causality

Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input checked="" 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 checked="" 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 type="checkbox"/> Unclassifiable Specify the additional information required for classification : <div style="border: 1px solid black; height: 20px; width: 500px;"></div>		

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<b>TGA ICSR reference</b>	s47F
<b>Date and time</b>	s47F
<b>Type of event</b>	Fatal AEFI assessment team meeting Close out summary
<b>Participant(s)</b>	<ul style="list-style-type: none"> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> </ul>
<b>Topic</b>	Fatal AEFI report & s47F COVID-19 vaccine
<b>Key point(s)</b>	<ul style="list-style-type: none"> <li>• s47F yo s47F</li> <li>• TTD s47F</li> <li>• s47F</li> <li>• s47F</li> <li>• s47F</li> <li>• COD</li> </ul>
<b>Follow-up action(s)</b> (include action required, action officer, agreed date/s)	Regulatory or programmatic action for consideration by TGA or OHP? Nil Communication with JIC and ACV? Nil Any other follow-up actions required? s47F
<b>Decision(s)</b>	Causality assessment outcome: WHO=C Unlikely Causality



Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input checked="" 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 checked="" 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 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



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# Note for file

TGA ICSR reference

s47F

Date and time

s47F

Type of event

Fatal AEFI assessment team meeting  
 Close out summary

Participant(s)

- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB
- s22 PB

Topic

Fatal AEFI report & s47F COVID-19 vaccine

Key point(s)

- s47F yo s47F
- TTD s47F
- s47F
- COD s47F

Follow-up action(s)

(include action  
 required, action officer,  
 agreed date/s)

Regulatory or programmatic action for consideration by TGA or OHP?

s47F

Communication with JIC and ACV?

Nil

Any other follow-up actions required?

s47F

Decision(s)

Causality assessment outcome:  
 Who=C Unlikely

Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input checked="" 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 checked="" 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 type="checkbox"/> Unclassifiable Specify the additional information required for classification : <div style="border: 1px solid black; height: 20px; width: 500px; margin-top: 5px;"></div>		

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# Note for file

<b>TGA ICSR reference</b>	s47F
<b>Date and time</b>	s47F
<b>Type of event</b>	Fatal AEFI assessment team meeting Close out summary
<b>Participant(s)</b>	<ul style="list-style-type: none"> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> <li>• s22 PB</li> </ul>
<b>Topic</b>	Fatal AEFI report & COVID-19 Vaccine s47F
<b>Key point(s)</b>	<ul style="list-style-type: none"> <li>• s47Fyo s47F</li> <li>• TTD s47F</li> <li>• s47F</li> <li>• s47F</li> <li>• COD s47F</li> </ul>
<b>Follow-up action(s)</b> (include action required, action officer, agreed date/s)	<b>Regulatory or programmatic action for consideration by TGA or OHP?</b> Nil <b>Communication with JIC and ACV?</b> Clinical documents from JIC <b>Any other follow-up actions required?</b> s47F
<b>Decision(s)</b>	<b>Causality assessment outcome:</b> Who=C Unlikely

Adequate information available	<input type="checkbox"/> A. Consistent with causal association to immunization	<input type="checkbox"/> B. Indeterminate	<input checked="" 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 checked="" 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 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



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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 Vaccine s47F

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F y/o s47F
- Deceased s47F
- s47F
- s47F
- s47F

Rereviewed s47F

- s47F
- COD s47F

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

- Regulatory or programmatic action for consideration by TGA or OHP; NIL
- Communication with JIC and ACV; s47F
- Any other follow-up actions required. NIL

s47F

## Decisions

- Unlikely Causality



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## Note for file

**TGA REF** s47F

**Date and time** s47F

**Type of event** Fatal AEFI Assessment Team Meeting

**Topic** Fatal report & COVID-19 Vaccine s47F

### Participants

Name	Details
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA

### Key points

- s47F
- s47F

Rereviewed on s47F

- COD s47F

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

- Regulatory or programmatic action for consideration by TGA or OHP;
- Communication with JIC and ACV; s47F
- Any other follow-up actions required.

s47F



## Decisions

- Unlikely Causality