

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	• \$47F yo \$47F • Vaccinations: \$47F \$47F \$47F • Date of death: \$47F • \$47F • \$47F
Assessment	The transfer of the state of the state of

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

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) Regulatory or programmatic action for consideration by TGA or OHP?

Nil

Communication with JIC?

RFI sent to JIC and email reply received \$47F

Any other follow-up actions required?

Nil required

Decision(s)

Unlikely Causality

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



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) • \$22 • \$22

Vaccine Brand Fatal AEFI report & \$47F COVID -19 vaccine

Case Summary • \$47F_{yo}\$47F

• \$47F

s47F

Assessment s47F

Outcome

Classification s47F

Unlikely

Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP?

(include action N

required, action officer, Communication with JIC?

agreed date/s) RFI sent to JIC and Death certificate

Any other follow-up actions required?

Nil

Decision(s) Causality assessment outcome:

Unlikely Causality

This decision open for review if further information is received in the future

Name/Signature

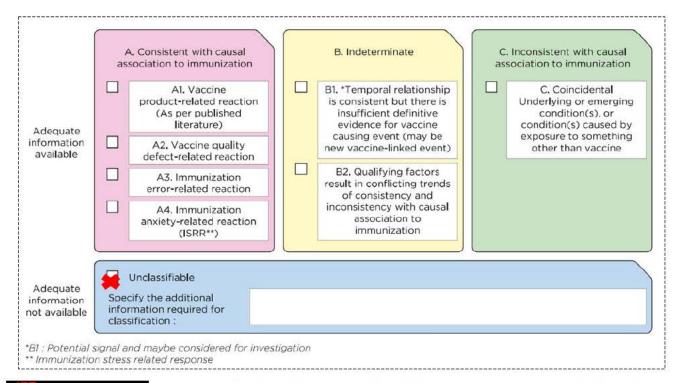




Note for file

TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary Participant(s) PB PB PB PB Fatal AEFI report & \$47F Topic COVID-19 vaccine Key point(s) Death. Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP? (include action Specify - state "Nil required" if none required, action officer, Communication with JIC and ACV? agreed date/s) RFI sent Any other follow-up actions required? Awaiting coroner Decision(s) Causality assessment outcome:

WHO=U





Note for file



		A. Consistent with causal ssociation to immunization	8	B. Indeterminate	327	. Inconsistent with causal sociation to immunization
Adequate nformation available		A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)		B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal essociation to immunization		C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
Adequate nformation ot available	info	Unclassifiable ecify the additional ermation required for sisification :				



Note for file

TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary Participant(s) PB PB PB Fatal AEFI report & COVID-19 vaccine Topic Key point(s) Death

Follow-up action(s) (include action

Regulatory or programmatic action for consideration by TGA or OHP?

Communication with JIC and ACV? required, action officer, agreed date/s)

RFI to JIC 547

TTD S47F COD

Any other follow-up actions required?

Decision(s) Causality assessment outcome:

WHO=

		A. Consistent with causal ssociation to immunization	B. Indeterminate	 . Inconsistent with causal sociation to immunization
Adequate formation available		A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)	B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal essociation to immunization	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
dequate formation t available	info	Unclassifiable ecify the additional ermation required for sification :		



Note for file

TGA REF \$47F

Date and time

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	PVB TGA
s22	S22 PVB TGA
s22	PVB TGA

Key points

- s47F
- TTD
- COD **547**
- WHO=

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

		A. Consistent with causal sociation to immunization		B. Indeterminate	100	Inconsistent with causal sociation to immunization	
Adequate information available		A1. Vaccine product-related reaction (As per published literature)		B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine	7	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by	
		A2. Vaccine quality defect-related reaction		causing event (may be new vaccine-linked event)		exposure to something other than vaccine	
	1	A3. Immunization error-related reaction		B2. Qualifying factors result in conflicting trends of consistency and			
		A4. Immunization anxiety-related reaction (ISRR**)		inconsistency with causal association to immunization			
Adequate information not available	Spec	Unclassifiable cify the additional rmation required for					

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



Note for file

TGA REF

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & S47F COVID-19 vaccine

Participants

Name	Details
s22	S22 PVB TGA

Key points

- \$47F
- Unknow \$47F
- 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



Note for file

TGA REF \$47F

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COVID-19 Vaccine \$47F

Participants

Name	Details
s22	PVB TGA
s22	s22 PVB TGA
s22	PVB TGA
s22	S22 PVB TGA
s22	s22 PVB TGA

Key points

- s47F
- s47F
- s47F
- COD 547F

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; \$47F
- Any other follow-up actions required.

Decisions



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	PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	s22 PVB TGA
s22	PVB TGA

Key points

- **s**47
- 547F
- s47F

Rereviewed \$47F

- 54/F
- WHO=C

Follow-up action

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

- Regulatory or programmatic action for consideration by TGA or OHP;
 Feedback received \$47F
- Communication with JIC and ACV; RFI sent
- Any other follow-up actions required. s47F

Decisions



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

Key points

\$47F
 Deceased \$47F
 \$47F
 \$47F
 \$47F

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



Note for file

TGA REF	S 4	7	F					
---------	------------	---	---	--	--	--	--	--

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & S47F COVID-19 vaccine

Participants [Add/delete as appropriate]

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

Key points

- s47F_{y/o}s47F
- Deceased \$47F
- 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. \$47F

Decisions

Awaiting Feedback \$47F



Note for file

TGA REF \$47F

Date and time

Type of event Fatal AEFI Investigation Team Meeting

Topic S47F COVID-19 vaccine and Fatal

Participants

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

Key points

- Deceased s47F

 s47F

 s47F

 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



Note for file

TGA REF s47F

Date and time \$47F

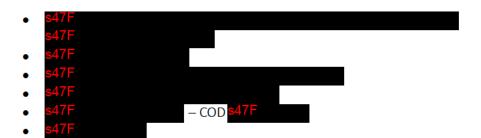
Type of event Fatal AEFI Investigation Team Meeting

Topic COVID-19 Vaccine s47F and Fatal

Participants

Name	Details
s22	PSAB TGA
s22	s22 PSAB TGA
s22	S22 PSAB TGA

Key points



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



Note for file

TGA REF \$47F

Date and time s47F

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COVID-19 Vaccine \$47F

Participants

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

Key points Reviewed 30/09/2021

- Deceased \$47F
 \$47F
 \$47F
- s47F
- s47F

Rereviewed \$47F

• COD <mark>s47F</mark>

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

required, action officer, agreed date/s)

Decisions



Note for file

TGA REF s47F

Date and time

Type of event Fatal AEFI Investigation Team Meeting

Topic COVID-19 Vaccine 47F and Fatal

Participants

Name	Details
s22	PVB TGA
s22	S22 PVB TGA

Key points

- S47Fy/o S47F • Deceased S47F
- s47F
- · COD \$47F
- 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



Note for file

TGA REF	s47F
Date and time	s47F

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & 47F COVID-19 vaccine

Participants

Name	Details
s22	PVB TGA
s22	s22 PVB TGA

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

Unlikely causality



Note for file

TGA REF \$47F

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COVID-19 Vaccine \$47F

Participants

Name	Details
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

- s4/F_{yo}s4/F
- s47
- s47F
- TTO **\$47**F

Rereviewed \$47F

- 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

required, action officer, agreed date/s) • Any other follow-up actions required.

Decisions

		A. Consistent with causal sociation to immunization	B. Indeterminate		. Inconsistent with causal Sociation to immunization
Adequate		A1. Vaccine product-related reaction (As per published literature)	B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine	M	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by
information available		A2. Vaccine quality defect-related reaction	causing event (may be new vaccine-linked event)	4	exposure to something other than vaccine
		A3. Immunization error-related reaction	B2. Qualifying factors result in conflicting trends of consistency and		
		A4. Immunization anxiety-related reaction (ISRR**)	inconsistency with causal association to immunization		
		Unclassifiable			
Adequate information not available	info	cify the additional rmation required for sification :			

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



Note for file

TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary

Participant(s) PB

PB

Topic Fatal AEFI report & COVID-19 Vaccine 547F

Key point(s) yo

Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP?

(include action

required, action officer,

Communication with JIC and ACV?

JIC RFI agreed date/s)

Any other follow-up actions required?

NIL

Decision(s) Causality assessment outcome:

WHO=C Unlikely Causality

		A. Consistent with causal sociation to immunization	B. Indeterminate	 . Inconsistent with causal sociation to immunization
Adequate nformation available		A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction	B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal essociation to	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
Adequate of the state of the st	info	Unclassifiable cify the additional rmation required for sification :	immunization	



Note for file

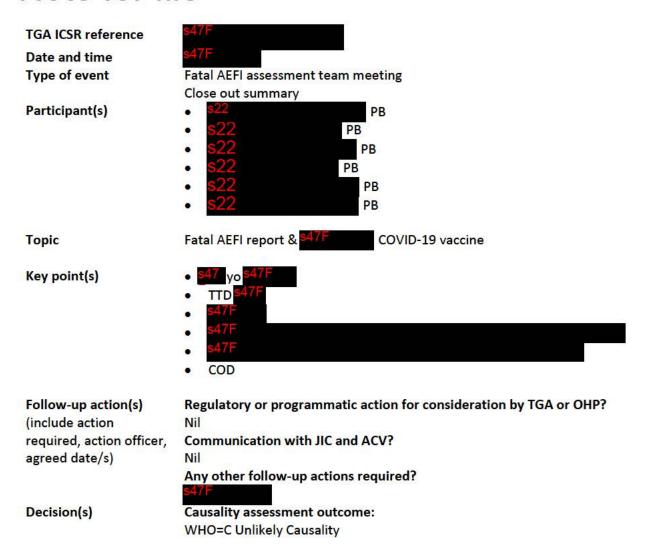
TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary Participant(s) PB PB PB PB Topic Fatal AEFI report & COVID-19 Vaccine 471 Key point(s) Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP? (include action Communication with JIC and ACV? required, action officer, agreed date/s) Any other follow-up actions required? Causality assessment outcome: Decision(s)

WHO=C Unlikely Causality

	A. Consistent with causal association to immunization		B. Indeterminate		C. Inconsistent with causal ssociation to immunization
Adequate information available	A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)		B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	**	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
	Unclassifiable Specify the additional information required for classification: ignal and maybe considered for investigns stress related response	gation			



Note for file



	A. Consistent with causal association to immunization	B. Indeterminate	C. Inconsistent with causal association to immunization
Adequate	Al. Vaccine product-related reaction (As per published literature)	B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by
information available	A2. Vaccine quality defect-related reaction	causing event (may be new vaccine-linked event)	exposure to something other than vaccine
	A3. Immunization error-related reaction	B2. Qualifying factors result in conflicting trends of consistency and	
	A4. Immunization anxiety-related reaction (ISRR**)	inconsistency with causal association to immunization	
Adequate information not available	Unclassifiable Specify the additional information required for classification :		
	signal and maybe considered for investi n stress related response	gation	



Note for file

TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary Participant(s) PB PB PB PB COVID-19 vaccine Fatal AEFI report & 47F Topic Key point(s) Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP? (include action Communication with JIC and ACV? required, action officer, agreed date/s) Any other follow-up actions required? Decision(s) Causality assessment outcome: Who=C Unlikely

	A. Consistent with causal association to immunization	B. Indeterminate	C. Inconsistent with causal association to immunization
Adequate nformation available	A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)	B1, *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2, Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
Adequate nformation ot available	Unclassifiable Specify the additional information required for classification :		



Note for file

TGA ICSR reference Date and time Type of event Fatal AEFI assessment team meeting Close out summary Participant(s) PB PB PB PB Topic Fatal AEFI report &COVID-19 Vaccine \$476 Key point(s) Follow-up action(s) Regulatory or programmatic action for consideration by TGA or OHP? (include action Communication with JIC and ACV? required, action officer,

Clinical documents from JIC

Who=C Unlikely

Causality assessment outcome:

Any other follow-up actions required?

agreed date/s)

Decision(s)

		A. Consistent with causal sociation to immunization		B. Indeterminate	307	. Inconsistent with causal sociation to immunization
Adequate information available		A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction		B1, *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)	*	C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
		A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)		B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization		
Adequate formation t available	info	Unclassifiable cify the additional rmation required for slification :				



Note for file

TGA REF s47F

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COVID-19 Vaccine \$47F

Participants

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

Key points

- s47F_y/o s47FDeceased s47F
- s47F
- e/17F
- s47F

Rereviewed \$47F

• 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; \$47F
- Any other follow-up actions required. NIL

Decisions



Note for file

GA REF \$4/F	I GA ILLI	ΓGA	REF	s47	F	
--------------	-----------	-----	-----	-----	---	--

Date and time

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COVID-19 Vaccine \$47F

Participants

Name	Details
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 \$47F

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; \$47F
- Any other follow-up actions required.

Decisions