

Fatal case review checklist

TGA Case reference number: AU-TGA-0000515141

TRIM container: E20-413470

Outcome: Unlikely

	Yes (date)	No	N/A	Initials	Additional information
Escalated (from AEMS)	10/02/2022			s22	
Reconciliation on daily case line list	10/02/2022				
Triage applied	10/02/2022				Triage Level 5
RN review	10/02/2022				
Escalated (within VERA)	10/02/2022				Review by MO2
Request for information			X		
Additional information received			X		
Case summary commenced	10/02/2022				
VERA fatal case review meeting	10/02/2022				
Further action required		X			
Action completed			X		
Presentation of cases and actions at PV Branch fatal case review			X		
Status recorded in AEMS	10/02/2022				
Case to VSIG		X			
Case summary closed	10/02/2022				
Case summary and check list attached in AEMS	10/02/2022				



Australian Government
Department of Health

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Note for file

TGA REF AU-TGA-0000515141

Date and time 10 February 2022

Type of event Fatal AEFI Assessment Team Meeting

Topic Fatal report & COMIRNATY COVID-19 vaccine

Participants

Name	Details
s22	Acting MO5 VERA, PVB TGA
	MO4 VERA, PVB TGA
	MO2 VERA, PVB TGA
	Assistant Director VERA, PVB TGA
	CCU RN, VERA, PVB TGA
	APS5 VERA, PVB TGA

Key points

- 47 Female
- TTD 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; Nil
- Any other follow-up actions required.

Decisions

- Unlikely Causality

From: [ADR Reports](#)
To: s22
Subject: Follow-up received - AEFI – SERIOUS – COVID Pfizer – Death – AU-TGA-0000515141 [SEC=OFFICIAL]
Date: Thursday, 10 February 2022 6:50:28 AM
Attachments: [image001.gif](#)

This report is from a sponsor.

The company assessed the events of death, sepsis, Intestinal ischaemia, Pneumonia, Hypotension, Renal failure, Tooth infection, Bacteraemia, Arthritis, Arthritis bacterial, Endocarditis, Nausea and Lower respiratory tract infection s47F

The event Intestinal ischaemia and Renal failure s47F

. The event Pneumonia and Lower respiratory tract infection s47F

The event sepsis, Endocarditis, Bacteraemia and Tooth infection s47F

Arthritis s47F

Arthritis bacterial and Nausea s47F

bacteraemia and endocarditis. Hypotension s47F

AU-TGA-0000515141 - 20220207130017

<http://crmprod.production.tga.gov.au/AEMS/main.aspx?etc=10103&extraqs=formid%3d1fa2157a-8b20-4789-867f-a6249e75522b&id=%7bC6EBC709-EC88-EC11-814A-005056A99CD9%7d&pagetype=entityrecord>

Regards

s22

Adverse Event & Medicine Defect Section
Pharmacovigilance Branch

Email: adr.reports@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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Case details:

Original received date: 13/10/2020

Creation date: 27/03/2022

Date sent to WHO: 28/03/2022

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

s22

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Patient details:

Patient initials: s22

Sex: Female

Another term:

Gender:

Different Term:

Weight:

Age:

Date of birth: s22

Pregnancy status:

State:

Ethnicity sub-group:

Ethnicity:

Reporter details:

s22

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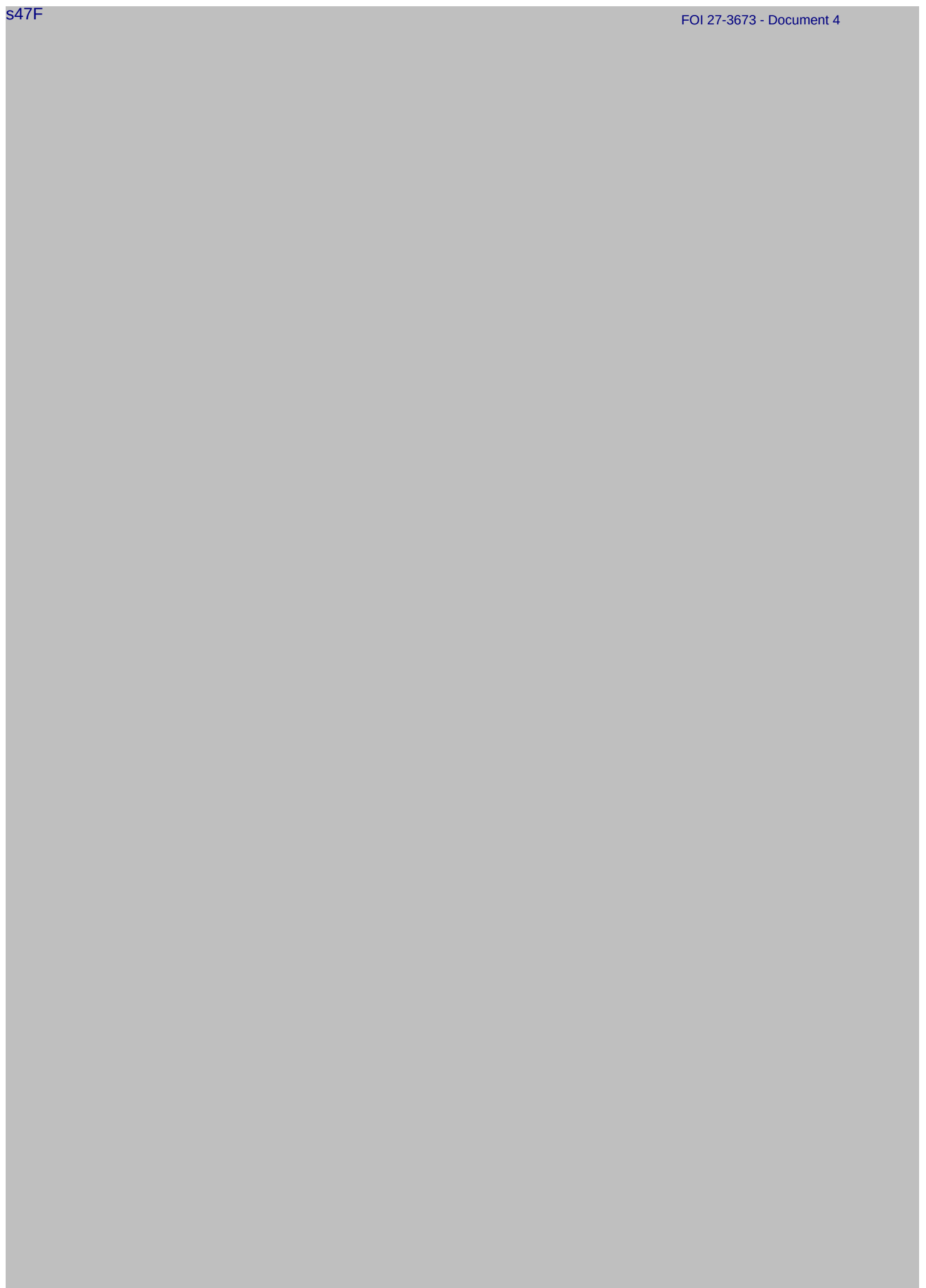
Phone:

Case narrative:

s47F

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Reactions:

Preferred term	Onset date	End date	Outcome
Abdominal discomfort	s47F		
Abdominal distension			
Abdominal pain			
Adverse event following immunisation			
Arthritis			
Arthritis bacterial			

Bacteraemia
COVID-19 immunisation
Drug ineffective
Dyspnoea exertional
Endocarditis
Fatigue
Fluid retention
Gastrointestinal stoma output abnormal
Gastrointestinal stoma output decreased
Headache
Hepatomegaly
Hunger
Hypervolaemia
Hypotension
Inappropriate schedule of product administration
Incorrect dose administered
Intestinal ischaemia
Joint swelling
Lethargy
Liver function test abnormal
Lower respiratory tract infection
Malaise
Myalgia
Nausea
Peripheral swelling
Pneumonia
Rash
Renal failure
Sepsis
Splenomegaly
Therapeutic product effect decreased
Thirst
Tooth infection
Urine output decreased
Vomiting
Weight increased

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FOI 27-3673 - Document 4

Drug information:

FOI 27-3673 - Document 4

Product name				Role characterisation	Action taken	
TN010191 COMIRNATY COVID-19 vaccine - COMIRNATY COVID-19 vaccine				Suspect	Unknown	
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
1.000000 Dose Unspecified		INJECTION	Information Not Provided By Sponsor	s47F		
Reported Indication/s						
s47F						

Product name				Role characterisation	Action taken	
TN008561 Revestive - Revestive				Suspect	Not applicable	
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.400000 Millilitre	1 Day	Solution for injection	Subcutaneous			
Reported Indication/s						
s47F						
Additional information						
ALCOHOL SWAB,NEEDLES,PRE-FILLED SYRINGE,SYRINGES						

Product name				Role characterisation	Action taken	
TN008561 Revestive - Revestive				Suspect	Not applicable	
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.300000 Millilitre	1 Day	Solution for injection	Subcutaneous			
Reported Indication/s						
s47F						
Additional information						
ALCOHOL SWAB,NEEDLES,PRE-FILLED SYRINGE,SYRINGES						

Product name		Role characterisation		Action taken		
TN008561 Revestive - Revestive		Suspect		Not applicable		
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.200000 Millilitre	1 Day	Solution for injection	Subcutaneous			
Additional information						
ALCOHOL SWAB,NEEDLES,PRE-FILLED SYRINGE,SYRINGES						

Product name		Role characterisation		Action taken		
TN008561 Revestive - Revestive		Suspect		Not applicable		
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.150000 Millilitre	1 Day	Solution for injection	Subcutaneous			
Additional information						
ALCOHOL SWAB,NEEDLES,PRE-FILLED SYRINGE,SYRINGES						

Product name		Role characterisation		Action taken		
TN008561 Revestive - Revestive		Suspect		Not applicable		
Dosage/s						
Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.150000 Millilitre	1 Day	Solution for injection	Subcutaneous	s47F		
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Product name		Role characterisation		Action taken		
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Additional information							
ALCOHOL SWAB,NEEDLES,PRE-FILLED SYRINGE,SYRINGES							

Tests and procedures:

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