



**The Hon Mark Butler MP**  
**Minister for Health and Aged Care**

Ref No: MS23-900131

Senator Marielle Smith  
Chair  
Community Affairs Legislation Committee  
PO Box 6100  
CANBERRA ACT 2600  
[Community.Affairs.Sen@aph.gov.au](mailto:Community.Affairs.Sen@aph.gov.au)

Dear Senator *Marielle*

Pursuant to the Order of the Senate dated 13 May 2009 concerning public interest immunity claims, I am writing about a request made by Senator Malcolm Roberts during the Senate Estimates hearing of the Community Affairs Legislation Committee on 16 February 2023.

Senator Roberts asked Adjunct Professor John Skerritt, Deputy Secretary, Health Products Regulation Group for data on a seven-year-old and a nine-year-old child who were reported to the Therapeutic Goods Administration (TGA) as having died after receiving a COVID-19 vaccination (see pages 61 and 101 of the Hansard report dated 16 February 2023, with the request on page 102 being for the data and the request on page 62 being for an unredacted document, forming part of the data, the Deputy Secretary had before him). In response to Senator Roberts' request, Adj Prof Skerritt raised issues of privacy concerning the data.

The TGA has identified 14 documents containing data falling within the terms of Senator Roberts' requests. Adj Prof Skerritt has referred the documents to me and I have concluded that it would not be in the public interest to disclose the documents to the Committee, without appropriate redactions to protect the privacy of the deceased and their families.

The documents contain:

- information that is capable of identifying the deceased children and/or their families
- personal information of the deceased and their families (including medical choices, treatment and circumstances of death) noting the deceased may be identifiable to some in their communities
- names and other identifying information of Commonwealth and State officials who dealt with the cases.

As you would appreciate, the sudden death of a child is a matter of distress for the child's family and friends in any circumstances. The public interest calls for the privacy of the deceased child and his or her family to be protected from the release of information that could identify the deceased or their families or provide intimate and additional details about their deaths to the community that may already know the identities of the deceased individuals.

There is still a heightened emotional response in parts of the community to issues surrounding COVID-19 vaccinations in children, which makes the public interest in protecting privacy even more significant. This is not just to minimise the family's distress about release of intimate personal information but to protect them from unwelcome contact. The TGA is aware of one case where the mother of a young adult who died after receiving a COVID-19 vaccination received unsolicited contact from a Senator, and where documents about her daughter's death that had been released by the TGA pursuant to a freedom of information request were projected on a screen at a 'vaccination conference'. The TGA is aware that information pertaining to the 7 and 9-year-olds has been used in a similar way.

Senator Roberts' request for documents was qualified by stating that he was happy for names to be redacted. However, other information in the TGA's documents is also potentially capable of identifying the deceased children. Because the sudden death of a child is a relatively rare event, details such as the date of birth, date of vaccination, patient state, date and place of death, patient's initials, and the like may be sufficient to enable identification.

As noted above, providing details about the circumstances of death (including medical treatment and choices by families of the deceased) would disclose additional personal information to those who may already know the identities of the deceased and their families.

Details of the events surrounding the children's deaths (apart from the publicly reported adverse event) and other information about their health are deeply personal and I am satisfied that their disclosure would amount to an unreasonable invasion of the privacy of the deceased children and their families. Whilst there is a public interest in investigating any possible links between vaccination and death, that interest does not extend to making intimate details known to the world at large, particularly in cases where it has not been determined that there was a causal link between vaccination and death.

I also believe disclosing personal information would undermine the TGA's adverse event reporting system and make others less likely to report in future.

The TGA's documents also contain the names and other identifying information of Commonwealth and State officials who dealt with the reports of the two deaths. If this information is disclosed, it may also mean States and Territories, who are the major reporter of vaccine adverse events, are reluctant to share adverse event reports with the TGA in the future. Further, there have also been numerous instances of TGA staff receiving threats (including over two dozen death threats), abuse and harassment based on their work with COVID-19 vaccines. This has included harassment by demonstrators at the TGA office site in Canberra.

I am satisfied that it is not in the public interest for the names, contact details and other information capable of identifying TGA staff to be made public. It is both an unreasonable invasion of their privacy and could reasonably be expected to endanger their life or physical safety.

I am therefore making a claim of public interest immunity over part of the 14 TGA documents on the grounds that disclosure of the relevant content amounts to an unreasonable infringement of privacy and/or could reasonably be expected to endanger the life or physical safety of TGA staff. A redacted set of documents is attached.

Yours sincerely

Mark Butler

30/03 / 2023

Encl (14)

- A. Full Case Details of the two relevant cases extracted from the TGA's Adverse Event Management System, which is the TGA's internal adverse event database (document 1)
- B. Email correspondence requesting further details of death of 7-year-old and response (document 2a)
- C. Hospital notes relating to 7-year-old attached to email (note that this document was partially redacted to remove the patient's and doctor's names before it was provided to the TGA) (document 2b)
- D. TGA fatal case review checklist relating to 7-year-old (document 3)
- E. TGA file note relating to 7-year-old (document 4)
- F. Agenda for meeting of TGA Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference on 22 March 2022 and minutes of previous meeting (document 5)
- G. Email chain seeking further information about death of 9-year-old (document 6)
- H. Email acknowledging receipt of the report and seeking further information about death of 9-year-old from the reporter (document 7)
- I. Agenda for meeting of TGA Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference on 29 March 2022 and minutes of previous meeting (document 8)
- J. Agenda for meeting of TGA Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference on 12 April 2022 and minutes of previous meeting (document 9)
- K. TGA fatal case review checklist relating to 9-year-old (document 10)
- L. TGA file note relating to 9-year-old (document 11)
- M. TGA meeting notes – summary of fatal cases 11-17 March 2022 (document 12)
- N. TGA meeting notes – summary of fatal cases 25-31 March 2022 (document 13)



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Full Case Details

Filter(s):

TGA ICSR Identifier: 719838,724023.

**Number of cases in this report: 2.**

1 March 2023

Page 1 of 5

© Commonwealth of Australia 2017.

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the Copyright Act 1968 or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and enquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

## **Limitations of the data**

This document contains information from reports of adverse events that the TGA has received in relation to therapeutic goods. It does not contain all known information, and an assessment of the safety of a medicine cannot be made based on this information.

## **Causality**

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. The reporter may be a health professional, a sponsor, or a member of the public.
- Adverse events are suspected of being related to a therapeutic good, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.

## Case ID: AU-TGA-0000719838

### Case Details

Report Type: Spontaneous report

Report Date: 11/03/2022

Date sent to WHO: 25/02/2023

Modified on: 25/02/2023

Causality: Causality possible

Serious ICSR: Yes

### Reporter Details:

Name: [REDACTED]

Qualification: Physician

Organisation: [REDACTED] Children's Hospital

Address: [REDACTED]

State: [REDACTED]

Phone: [REDACTED]

### Sender Details:

Name:

Organisation: Department of Health [REDACTED]

Address:

Type: Regional Pharmacovigilance Centre

ICSR identifier: [REDACTED]

### Patient Details:

Patient initials: [REDACTED]

Sex: Male

Weight:

Age: 7

Date of birth: [REDACTED]

State: [REDACTED]

Ethnicity:

### Case narrative:

Cardiac arrest

[REDACTED]

[REDACTED]

FM Triage 1

FM Outcome Awaiting Feedback

FM Date 17 Mar 2022 FM

WHO=[U]

Verbal update at JIC meeting 15/03/2022:

7M [REDACTED] post D1 Comirnaty. Referred to coroner. [REDACTED]

[REDACTED]

[REDACTED]

Follow-up received 17/03/2022.

COVID Comirnaty (Pfizer) dose 1: [REDACTED]

Progress Notes - ED Assessment: 7 yo boy, [REDACTED]

[REDACTED] generalised tonic clonic seizure [REDACTED]

[REDACTED]

From duplicate:

This is a spontaneous report received from contactable reporter(s) (Other HCP and Consumer or other non HCP) from Regulatory Authority. Regulatory number: 719838 (TGA ADR#).

A 7-year-old male patient received BNT162b2 (COMIRNATY), as dose 1, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: CARDIAC ARREST (death, medically significant) with onset [REDACTED] outcome "fatal". [REDACTED]  
[REDACTED] "Cardiac arrest". [REDACTED]

Clinical information: It was reported as In the course of my duties, I observed a comment which can be constituted as a reportable event relating to a side effect. A 7 year old died of a cardiac arrest after an mRNA COVID vaccine.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow up (29Dec2022): This is a spontaneous follow up report from the a non-contactable Consumer or other non HCP. Updated information included: new reporter (consumer) and clinical information was added.

Follow-up attempts are completed. No further information is expected.

#### Reactions:

Preferred term	Onset date	End date	Management of Event	Outcome
Cardiac arrest	[REDACTED]	[REDACTED]	Hospital emergency department	Fatal
Generalised tonic-clonic seizure	[REDACTED]	[REDACTED]	Hospital emergency department	Fatal

#### Drug information:

(1) COMIRNATY COVID-19 VACCINE (tozinameran) - Suspect	
Dosage information:	Dose: 1 Dose Unspecified , Dose form: INJECTION
Treatment details:	Started: [REDACTED]
Indication:	
Action Taken:	

## Case ID: AU-TGA-0000724023

### Case Details

Report Type: Spontaneous report

Report Date: 25/03/2022

Date sent to WHO: 09/04/2022

Modified on: 09/04/2022

Causality: Causality possible

Serious ICSR: Yes

### Reporter Details:

Name:

Qualification:

Organisation:

Address:

State:

Phone:

### Sender Details:

Name: [REDACTED]

Organisation: Unknown

Address:

Type: Patient/Consumer

ICSR identifier: [REDACTED]

### Patient Details:

Patient initials: [REDACTED]

Sex: Female

Weight:

Age: 9

Date of birth: [REDACTED]

State: [REDACTED]

Ethnicity:

### Case narrative:

Cardiac arrest

FM Triage 1

FM Outcome Awaiting feedback

FM Date 31Mar2022

FM WHO=[U]

### Reactions:

Preferred term	Onset date	End date	Management of Event	Outcome
Cardiac arrest			Hospital admission	Fatal

### Drug information:

(1) COMIRNATY COVID-19 VACCINE (tozinameran) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



[REDACTED]

**From:** [REDACTED]  
**Sent:** Thursday, 17 March 2022 6:37 PM  
**To:** TGA AEFI Reports  
**Cc:** [REDACTED]  
**Subject:** RE: Fatal Adverse Event Report AU-TGA-0000719838 [SEC=OFFICIAL]  
**Attachments:** TGA-0000719838.pdf  
**Categories:** Follow-up, Fatal

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear TGA Team,

Re: TGA AE Reference: AU-TGA-0000719838

Drug: COVID Comirnaty (Pfizer)

Reference: [REDACTED]

Thank you for your email.

1. **The date, circumstances and mode of death**  
Please find the attached document for information.
2. **Detail of vaccination**  
COVID Comirnaty (Pfizer) dose 1: [REDACTED]
3. **Details of any other medications which were being taken by the patient in the lead up to death (e.g. daily dose, reasons for administration)**  
[REDACTED]
4. **Any past medical history**  
[REDACTED]
5. **Details of treatment of the reported event**  
Please find the attached document for information
6. **If the patient died in hospital, a copy of the inpatient summary and consultant's report**  
Please find the attached document for information.
7. **Whether a post-mortem examination was performed. If so, please forward a copy of the post-mortem report as soon as it becomes available**  
[REDACTED].
8. **Whether the case was referred to the Coroner. If so, please forward a copy of the coroner's report as soon as it becomes available.**  
Yes, case sent to coroner.

Thank you.

Kind regards,

[REDACTED]  
Registered Nurse | Immunisation Services  
[REDACTED]

"I acknowledge Aboriginal and Torres Strait Islander people as the Traditional Owners of this country throughout Australia and recognise their continuing connection to land, waters and community. I pay my respect to them, their cultures and to the Elders both past and present.

---

**From:** TGA AEFI Reports

**Sent:** Tuesday, 15 March 2022 6:14 AM

**To:** [REDACTED]

**Cc:** [REDACTED] ADR Reports

**Subject:** Fatal Adverse Event Report AU-TGA-0000719838 [SEC=OFFICIAL]

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Good morning,

I am emailing in regards to a fatal AEFI that was reported 11 March 2022 to the TGA [REDACTED] TGA reference number AU-TGA-0000719838). This report describes death of a 7 year old male who was administered Comirnaty COVID-19 vaccine on [REDACTED] 2022 and died on [REDACTED] 2022. Thank you for submitting this AEFI report.

We would appreciate your expedient provision of any information pertaining to this death. It would greatly assist our review of this case if you were able to provide any information listed below:

- Circumstances and mode of death (please provide more information about cardiac arrest)
- Details of vaccination (timing of 1<sup>st</sup> dose)
- Details of any other medications which were being taken by the patient in the lead up to death (e.g. daily dose, reasons for administration)
- Any past medical history
- Details of treatment of the reported event
- If the patient died in hospital, a copy of the inpatient summary and consultant's report
- Whether a post-mortem examination was performed. If so, please forward a copy of the post-mortem report as soon as it becomes available
- Whether the case was referred to the Coroner. If so, please forward a copy of the coroner's report as soon as it becomes available.

Please do not hesitate to contact me at [TGA.AEFI.Reports@health.gov.au](mailto:TGA.AEFI.Reports@health.gov.au) or call me on [REDACTED] if you have any questions or would like to discuss.

Thank you for your assistance with this matter.

Kind regards,

[REDACTED] MBBS MPH  
Medical Officer  
Vaccine Epidemiological Rapid Assessment Section

---

Medicines Regulation Division | Therapeutic Goods Administration  
Pharmacovigilance Branch  
Australian Government Department of Health

[REDACTED]  
[REDACTED]  
PO Box 100, Woden ACT 2606

*The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past, present and emerging.*

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly

*prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

***This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.***

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

**EMERGENCY ASSESSMENT  
Continuation**

Me [redacted] Male: \_\_\_\_\_  
Su [redacted] Time: \_\_\_\_\_  
Fo [redacted] Male PUB ED \_\_\_\_\_  
Gender: \_\_\_\_\_ D.O.B. \_\_\_\_\_

Doctor [redacted]

Patient Name: [redacted]

Time of review: 2308

Doctor: [redacted] Consultant

**Progress Notes:**

7yo boy

[redacted]

generalised tonic clonic seizure

[redacted]  
Had COVID 19 vaccination [redacted]

[redacted]

transported to ED

[redacted]

Declared deceased [redacted]

Signed: [redacted]



PQ120020

DO NOT WRITE IN BINDING MARGIN

MR 301.02A / 806.20A EMERGENCY ASSESSMENT CONTINUATION



**EMERGENCY ASSESSMENT  
Continuation**

Med Rec. No: .....

Surname: .....

Forename: .....

Gender: ..... D.O.B. ....

DO NOT WRITE IN BINDING MARGIN

# Fatal case review checklist

TGA Case reference number: AU-TGA-0000719838

TRIM container: E22-538282

Outcome:

	Yes (date)	No	N/A	Initials	Additional information
Escalated (from AEMS)	15/03/2022			█	
Reconciliation on daily case line list	15/03/2022			█	
Triage applied	15/03/2022			█	Level 1
RN review	15/03/2022			█	
Escalated (within VERA)	15/03/2022			█	
MO review	15/03/2022			█	MO2 and MO5
Request for information	15/03/2022			█	RFI sent
Additional information received					
Case summary commenced	15/03/2022			█	
VERA fatal case review meeting	17/03/2022			█	
Further action required					
Action completed					
Presentation of cases and actions at PV Branch fatal case review					
Status recorded in AEMS					
Case to VSIG					
Case summary closed					
Case summary and check list attached in AEMS					



## Note for file

**TGA REF** AU-TGA-0000719838

**Date and time** 17 March 2022

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

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

### Participants

Name	Details
[REDACTED]	MO5 [REDACTED], PVB TGA
[REDACTED]	MO4 [REDACTED], PVB TGA
[REDACTED]	MO2 [REDACTED], PVB TGA
[REDACTED]	Assistant Director [REDACTED], PVB TGA
[REDACTED]	[REDACTED] RN, [REDACTED] PVB TGA
[REDACTED]	APSS [REDACTED], PVB TGA

### Key points

- 7 yo Male [REDACTED]
- TTD
- Cardiac arrest
- RFI sent 15/3. Verbal update on Tuesday @ JIC meeting - 7M D1or2 Comirnaty [REDACTED]
- Referred to coroner.
- [Add relevant clinical information here](#)

### Follow-up action (include action)

- [Regulatory or programmatic action for consideration by TGA or OHP;](#)

required, action  
officer, agreed date/s)

- Communication with JIC and ACV; RFI sent 15/03/2022
- Any other follow-up actions required.

**Decisions**

- Causality
- WHO=U



# Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 22 March 2022

Chair: Associate Professor [REDACTED]

## Agenda

### 1. Acknowledgement of Country

I would like to acknowledge the traditional custodians on the lands on which we are all meeting today and pay my respects to their Elders past, present and emerging. I would like to extend that acknowledgement to any Aboriginal and Torres Strait Islander peoples joining us today.

### 2. Welcome and apologies

[REDACTED]

### 3. Approval of minutes from the last teleconference – 15 March 2022

See Attachment 1

### 4. Action items from the previous meetings

[REDACTED]

### 5. Roundtable

- [REDACTED]

### 6. TGA serious AEFI update

- [REDACTED]
- [REDACTED]
- [REDACTED]

### 7. Policy and workflow processes

### 8. Other business

[REDACTED]

### 9. Meeting adjourned

[REDACTED]

## Attachment 1

### Minutes for the Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 15 March 2022

Chair: Associate Professor [REDACTED]

1. Acknowledgement of country
2. Attendees

Jurisdiction / Organisation	Attendees
Department of Health	[REDACTED]
ACT	[REDACTED]
NCIRS	[REDACTED]
NSW	[REDACTED]
NT	[REDACTED]
QLD	[REDACTED]
SA	[REDACTED]
TAS	[REDACTED]
VIC & SAEFVIC	[REDACTED]
WA	[REDACTED]

3. Minutes of the previous teleconference – 8 March 2022

Agreed and accepted.

4. Action items and outcomes

Nil action items to report back on.

5. Roundtable

- A fatal case in a 7 year old male, [REDACTED], not much information at present. [REDACTED]

Coroner, still waiting further information, [REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

TGA

- [REDACTED]

AusVaxSafety

- [REDACTED]

6. TGA serious AEFI update

[REDACTED]





[REDACTED]

---

**From:** [REDACTED]  
**Sent:** Tuesday, 29 March 2022 2:16 PM  
**To:** ADR Reports  
**Subject:** FW: [EXTERNAL]Request for information AU-TGA-0000724023 [SEC=OFFICIAL]

---

**From:** [REDACTED]  
**Sent:** Tuesday, 29 March 2022 2:06 PM  
**To:** [REDACTED]  
**Cc:** ADR Reports  
**Subject:** Re: [EXTERNAL]Request for information AU-TGA-0000724023 [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi [REDACTED]

We only received this report yesterday from the TGA, at this stage we have no further information

Kind regards,

[REDACTED]

Immunisation Nurse

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

---

**From:** [REDACTED]  
**Sent:** Monday, 28 March 2022 4:52 PM  
**To:** [REDACTED]

Cc: ADR Reports <[ADR.Reports@health.gov.au](mailto:ADR.Reports@health.gov.au)>  
Subject: [EXTERNAL]Request for information AU-TGA-0000724023 [SEC=OFFICIAL]

**CAUTION: External Email. Please be cautious with attachments and clicking links**

Dear [REDACTED]

Re: TGA AE Reference: AU-TGA-0000724023  
Initials: [REDACTED]  
DOB [REDACTED]  
Drug: COVID-19 Comirnaty (Pfizer)

I am emailing in regards to a fatal AEFI that was reported 25/03/2022 to the TGA [REDACTED] (TGA reference number AU-TGA-0000724023). This report describes the very sad case of a 9 year old female who was administered Covid-19 Comirnaty (Pfizer) Vaccine and sadly died from cardiac arrest with unknown date of death.

It would greatly assist our review of this case if you were able to provide any of the documents listed below:

- Hospital discharge summary
- Death certificate
- Autopsy report (if available)
- Australian Immunisation record (if available)
- [Additional information]

Please do not hesitate to email me on [adr.reports@health.gov.au](mailto:adr.reports@health.gov.au) if you have any questions or wish to discuss this further.

Thank you for your assistance with this matter.

Kind Regards

[REDACTED]

[REDACTED]

Nurse Coordinator

[REDACTED]

Vaccines Epidemiological Rapid Assessment Section

---

Medicines Regulation Division | Therapeutic Goods Administration  
Pharmacovigilance Branch  
Australian Government Department of Health

[REDACTED]

PO Box 100, Woden ACT 2606

*The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.*

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

**This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.**

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this



communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

This e-mail and any attachments to it (the "Communication") are, unless otherwise stated, confidential, may contain copyright material and is for the use only of the intended recipient. If you receive the Communication in error, please notify the sender immediately by return e-mail, delete the Communication and the return e-mail, and do not read, copy, retransmit or otherwise deal with it. Any views expressed in the Communication are those of the individual sender only, unless expressly stated to be those of [REDACTED]. [REDACTED] does not accept liability in connection with the integrity of or errors in the Communication, computer virus, data corruption, interference or delay arising from or in respect of the Communication.

[REDACTED]

---

**From:** ADR Reports <adr.reports@health.gov.au>  
**Sent:** Monday, 28 March 2022 3:37 PM  
**To:** [REDACTED]@gmail.com  
**Subject:** Adverse Event Report - Ref AU-TGA-0000724023 [SEC=OFFICIAL]

Dear [REDACTED]

Thank you for the adverse event report that you submitted to the TGA on 25<sup>th</sup> March 2022 via our online reporting form. Your report has now been included in the TGA's Adverse Event Management System (AEMS). The report number is AU-TGA-0000724023 – please quote this TGA reference number if you submit any further information.

I was very sorry to hear of the challenging health journey and subsequent death of the 9 year old girl with initials [REDACTED]. Thank you for taking the time to report to the TGA during what must be a very difficult time. I acknowledge that receiving and responding to emails relating to events surrounding her death must be extremely distressing and would like to emphasise that I do not wish to add to your suffering.

I understand if you choose not to respond at this time, however additional medical documentation relating to her symptoms and diagnoses would greatly assist the TGA's investigation. I am writing to you at this time to enquire about the possibility of providing copies of any of the following documentation:

- The name & number of her general practitioner
- Date and dose in series (eg. Dose 1 or 2) of Pfizer vaccine administered
- Her full name
- Her date of death

If you wish to further clarify or contact me regarding the information requested, please contact me via email at [TGA.AEFI.Reports@health.gov.au](mailto:TGA.AEFI.Reports@health.gov.au).

The TGA has a role in ongoing medicine safety through monitoring and investigating adverse event reports. Reporting of adverse events helps the TGA to build a detailed profile of the safety of medicines available in Australia. I wanted to again extend my gratitude to you for bringing her experience to our attention.

Kind regards,

[REDACTED]  
**Senior Pharmacovigilance Officer**  
Adverse Event & Medicine Defect Section  
Pharmacovigilance Branch

Phone: 1800 020 653  
Email: [info@health.gov.au](mailto:info@health.gov.au)

Therapeutic Goods Administration  
Department of Health  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

 Please consider the environment before printing this email.

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*

# Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 5 April 2022

Chair: Associate Professor [REDACTED]

## Agenda

### 1. Acknowledgement of Country

I would like to acknowledge the traditional custodians on the lands on which we are all meeting today and pay my respects to their Elders past, present and emerging. I would like to extend that acknowledgement to any Aboriginal and Torres Strait Islander peoples joining us today.

### 2. Welcome and apologies

2.1 [REDACTED]

### 3. Approval of minutes from the last teleconference – 29 March 2022

See Attachment 1

### 4. Action items from the previous meetings

Nil

### 5. Roundtable

• [REDACTED]

### 6. TGA serious AEFI update

• [REDACTED]

### 7. Policy and workflow processes

### 8. Other business

• [REDACTED]

### 9. Meeting adjourned

## Attachment 1

### Minutes for the Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 29 March 2022

Chair: Associate Professor [REDACTED]

1. Acknowledgement of country
2. Attendees

Jurisdiction / Organisation	Attendees
Department of Health	[REDACTED]
ACT	[REDACTED]
NCIRS	[REDACTED]
NSW	[REDACTED]
NT	[REDACTED]
QLD	[REDACTED]
SA	[REDACTED]
TAS	[REDACTED]
VIC & SAEFVIC	[REDACTED]
WA	[REDACTED]

3. Minutes of the previous teleconference – 22 March 2022

Agreed and accepted.

4. Action items and outcomes

Nil action items to report back on.

5. Roundtable

- [REDACTED]



[REDACTED]

- Follow up to the report of a 9 year old fatality. The Coroner's office was unaware of any matching report. Both tertiary referral hospitals were also unaware of this case. Still trying to determine if this event existed.

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

AusVaxSafety

[REDACTED]

#### 6. TGA serious AEFI update

[REDACTED]

[REDACTED]



[REDACTED]

7. Policy and workflow processes

[REDACTED]

8. Meeting Adjourned

# Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 12 April 2022

Chair: Associate Professor [REDACTED]

## Agenda

### 1. Acknowledgement of Country

I would like to acknowledge the traditional custodians on the lands on which we are all meeting today and pay my respects to their Elders past, present and emerging. I would like to extend that acknowledgement to any Aboriginal and Torres Strait Islander peoples joining us today.

### 2. Welcome and apologies

[REDACTED]

### 3. Approval of minutes from the last teleconference – 5 April 2022

See Attachment 1

### 4. Action items from the previous meetings

Nil

### 5. Roundtable

[REDACTED]

### 6. TGA serious AEFI update

[REDACTED]

### 7. Policy and workflow processes

### 8. Other business

[REDACTED]

### 9. Meeting adjourned

## Attachment 1

### Minutes for the Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 5 April 2022

Chair: Associate Professor [REDACTED]

1. Acknowledgement of country
2. Attendees

Jurisdiction / Organisation	Attendees
Department of Health	[REDACTED]
ACT	[REDACTED]
NCIRS	[REDACTED]
NSW	[REDACTED]
NT	[REDACTED]
QLD	[REDACTED]
SA	[REDACTED]
TAS	[REDACTED]
VIC & SAEFVIC	[REDACTED]
WA	[REDACTED]

3. Minutes of the previous teleconference – 29 March 2022

Agreed and accepted.

4. Action items and outcomes

Nil action items to report back on.

5. Roundtable

- [REDACTED]
- [REDACTED]
- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

- Follow up to the report of a 9 year old alleged fatality after first dose Comirnaty. Still trying to determine if this event is genuine – appears spurious.

- [REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

AusVaxSafety

[Redacted]

### 6. TGA serious AEFI update

[Redacted]

[Redacted]

[Redacted]

[Redacted]

### 7. Policy and workflow processes

[Redacted]

8. Meeting Adjourned

# Fatal case review checklist

TGA Case reference number: AU-TGA-0000724023

TRIM container: E22-544319

Outcome:

	Yes (date)	No	N/A	Initials	Additional information
Escalated (from AEMS)		X			
Reconciliation on daily case line list	28/03/2022			█	Manual search
Triage applied	28/03/2022			█	Level 1
RN review					
Escalated (within VERA)	28/03/2022			█	
MO review	28/03/2022			█	MO2 review
Request for information	28/03/2022			█	
Additional information received					
Case summary commenced	28/03/2022			█	
VERA fatal case review meeting	31/03/2022			█	
Further action required					
Action completed					
Presentation of cases and actions at PV Branch fatal case review					
Status recorded in AEMS					
Case to VSIG					
Case summary closed					
Case summary and check list attached in AEMS					



# Note for file

**TGA REF** AU-TGA-0000724023

**Date and time** 31 March 2022

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

**Topic** Fatal report & [

## Participants

Name	Details
[REDACTED]	MO5 [REDACTED] PVB TGA
[REDACTED]	MO4 [REDACTED] PVB TGA
[REDACTED]	MO2 [REDACTED] PVB TGA
[REDACTED]	Assistant Director [REDACTED] PVB TGA
[REDACTED]	[REDACTED] RN, [REDACTED] PVB TGA
[REDACTED]	APSS [REDACTED] PVB TGA

## Key points

- 9 yo [REDACTED]
- Cardiac arrest
- [Add relevant clinical information here](#)

## 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; S61 and RFI on 28/03/2022](#)
- [Any other follow-up actions required.](#)

## Decisions

- [\[Causality assessment outcome\]](#)



<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>Adequate information not available</p>	<p><input type="checkbox"/> Unclassifiable</p> <p>Specify the additional information required for classification :</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		

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

TGAICSRIdentifier

Vaccine

Age Sex

State

Agedcare

ReportDate

VAXDate

Death

TTD

Reaction Reporter

AU-TGA-0000719838

COMIRNA  
TY COVID-  
19 vaccine 7

Male

[Redacted]

-

11/03/2022

[Redacted]

[Redacted]

Regional  
Pharmac  
Cardiac ovigilanc  
arrest e Centre

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



CaseNarrative	DOB	Patient_Atsi_Categor	SenderOrg;Dose	Medicalhis reportersviewoncause	Triage	Comments	Panel review date
<p>cardiac arrest</p>	[REDACTED]	[REDACTED]	<p>Departme nt of Health</p>	[REDACTED]	1	<p>Referred to Coroner</p>	<p>17/03/2022</p>

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------	------------	------------	------------



Outcome	WHO	Other notes
Awaiting feedback	U	RFI sent 15/3. Verbal update on Tuesday @ JIC meeting - 7M D1or2 Comirnaty [Redacted] Referred to coroner. [Redacted]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
------------	------------	------------	------------	------------	------------







TGAICSRIdentifier

Vaccine

Age

Sex

State

Agedcare

ReportDate

VAXDate

Death

TTD

Reactor Reporter

AU-TGA-0000724023

COMIRNA  
TY COVID-

19 vaccine 9

Female

-

25/03/2022

Patient/  
Cardiac Consum  
arrest er

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



CaseNarrative	DOB	Patient_Atspi_Categor	SenderOrg; Dose	Medicalhisreportersviewoncausa	Triage	Commentsotherinfor
---------------	-----	-----------------------	-----------------	--------------------------------	--------	--------------------

Cardiac arrest			Unknown	unknown	1	
----------------	--	--	---------	---------	---	--

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------	------------	------------	------------	------------

[REDACTED]



Panel review date	Outcome	Other notes	WHO
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
31/03/2022	Awaiting feedback	No record of case in [REDACTED] hospitals, or coroner.	U

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

