

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

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**

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	Sender Details:
Report Type: Spontaneous report	Name:
	Organisation: Department of Health
Report Date: 11/03/2022 Date sent to WHO: 25/02/2023 Modified on: 25/02/2023	Address:
Causality: Causality possible Serious ICSR: Yes	Type: Regional Pharmacovigilance Centre ICSR identifier:
Reporter Details: Name: Qualification: Physician Organisation: Children's Hospital Address:	Patient Details: Patient initials: Sex: Male Weight: Age: 7 Date of birth:
State: Phone:	State: Ethnicity:
Case narrative: Cardiac arrest	
FMTriage 1 FMOutcome Awaiting Feedback FMDate 17Mar2022 FM	
WHO=[U]	
Verbal update at JIC meeting 15/03/2022: 7M post D1 Comirnaty. Referred to co	proner.
Follow-up received 17/03/2022. COVID Comirnaty (Pfizer) dose 1:	
Progress Notes - ED Assessment: 7 yo boy,	generalised tonic clonic seizure
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 outcome "fatal".

"Cardiac arrest".

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			Hospital emergency department	Fatal
Generalised tonic-clonic seizure			Hospital emergency department	Fatal

Drug information:

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

Case ID: AU-TGA-0000724023

Dosage information: Treatment details:

Indication:
Action Taken:

Case Details		Se	Sender Details:		
Report Type: Spo	ntaneous report		Name: Organisation: Unknown		
Report Date: 25/03/2022 Date sent to WHO: 09/04/2022 Modified on: 09/04/2022			Address:		
Causality: Causality possible Serious ICSR: Yes			Type: Patient/Consumer ICSR identifier:		
Reporter Details Name: Qualification: Organisation: Address: State: Phone:	cation: sation:		Patient Details: Patient initials: Sex: Female Weight: Age: 9 Date of birth: State: Ethnicity:		
Case narrative: Cardiac arrest					
FMTriage 1 FMOutcome Await FMDate 31Mar202 FMWHO=[U] Reactions:	_				
Preferred term	Onset date	End date	Management of Event	Outcome	
Cardiac arrest			Hospital admission	Fatal	
Drug information	:				
(1) COMIRNATY O	COVID-19 VACCIN	IE (tozinamera	n) - Suspect		

From:

Thursday, 17 March 2022 6:37 PM Sent:

To: TGA AEFI Reports

Cc:

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:

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:



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)



4. Any past medical history



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
- 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, Registered Nurse | Immunisation Services "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:

Cc: 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 TGA reference number AU-TGA-0000719838). This report describes death of a 7 year old male who was administered Comirnaty COVID-19 vaccine on 2022 and died on 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 1st 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 <u>TGA.AEFI.Reports@health.gov.au</u> or call me on any questions or would like to discuss.

Thank you for your assistance with this matter.

Kind regards,

MBBS MPH
Medical Officer
Vaccine Epidemiological Rapid Assessment Section

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

PO Box 100, Woden ACT 2606

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DO NOT WRITE IN BINDING MARGIN

EMERGENCY ASSESSMENT Continuation

Me	
Su S	_i.e.
Fo	
Gender: D.O.D.	

		Gender:	D.O	,D,
			Doctor	
Patient Name:	Time of r	eview: 2308		
Doctor: Consultant				
Progress Notes: 7yo boy				
generalised tonic clonic seizure				
Had COVID 19 vaccination				
transported to ED				

Declared deceased

Signed:

DO NOT WRITE IN BINDING MARGIN

EMERGENCY ASSESSMENT Continuation

Med Rec. No:
Surname:
Forename:
Gender: D.O.B.

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	15/03/2022				
case line list					
Triage applied	15/03/2022				Level 1
RN review	15/03/2022				
Escalated (within	15/03/2022				
VERA)					
MO review	15/03/2022				MO2 and MO5
Request for	15/03/2022				RFI sent
information					
Additional information					
received					
Case summary	15/03/2022				
commenced					
VERA fatal case review	17/03/2022				
meeting					
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
	MO5 PVB TGA
	MO4 PVB TGA
	MO2 PVB TGA
	Assistant Director , PVB TGA
	RN, PVB TGA
	APS5 , PVB TGA

Key points

- 7 yo Male
- TTD
- Cardiac arrest
- RFI sent 15/3. Verbal update on Tuesday @ JIC meeting 7M D1or2
 Comirnaty

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

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



- 3. Approval of minutes from the last teleconference 15 March 2022 See Attachment 1
- 4. Action items from the previous meetings



5. Roundtable



6. TGA serious AEFI update



- 7. Policy and workflow processes
- 8. Other business



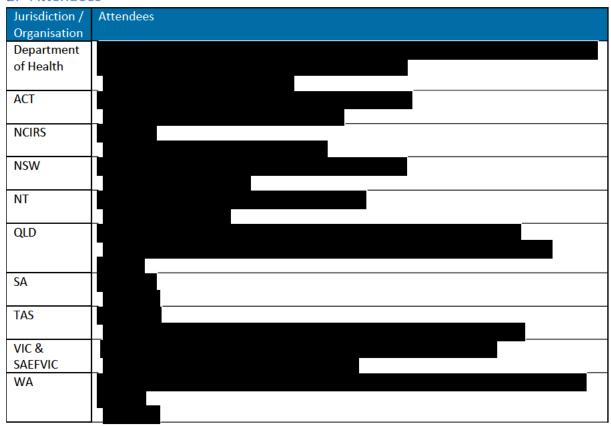
9. Meeting adjourned

Attachment 1

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

Date: Tuesday 15 March 2022 Chair: Associate Professor

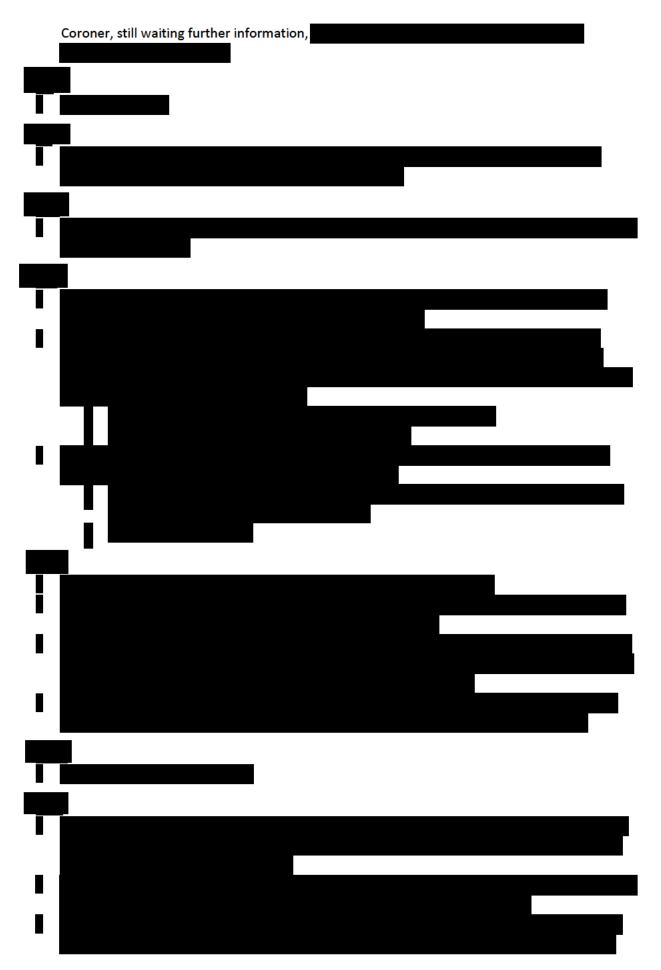
- 1. Acknowledgement of country
- 2. Attendees



- 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



IN CONFIDENCE



Page 3 of 6



Page 4 of 6





From: Sent: To: Subject:	Tuesday, 29 March 2022 2:16 PM ADR Reports FW: [EXTERNAL]Request for information AU-TGA-0000724023 [SEC=OFFICIAL]
To: Cc: ADR Reports	P.9 March 2022 2:06 PM TERNAL]Request for information AU-TGA-0000724023 [SEC=OFFICIAL]
	nk before you click! This email originated from outside our organisation. Only click links or open ou recognise the sender and know the content is safe.
Hi We only received	d this report yesterday from the TGA, at this stage we have no further information
Kind regards,	
Immunisation N	Nurse
From Sent: Monday, 2	28 March 2022 4:52 PM

To:

Cc: ADR Reports < 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

Re: TGA AE Reference: AU-TGA-0000724023

Initials:

DOB

Drug: COVID-19 Comirnaty (Pfizer)

I am emailing in regards to a fatal AEFI that was reported 25/03/2022 to the 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
- o Death certificate
- Autopsy report (if available)
- Australian Immunisation record (if available)
- o [Additional information]

Please do not hesitate to email me on 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

Nurse Coordinator

Vaccines Epidemiological Rapid Assessment Section

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

PO Box 100, Woden ACT 2606

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From: ADR Reports <adr.reports@health.gov.au>

Sent: <u>Monday</u>, 28 March 2022 3:37 PM

To: @gmail.com

Subject: Adverse Event Report - Ref AU-TGA-0000724023 [SEC=OFFICIAL]

Dear

Thank you for the adverse event report that you submitted to the TGA on 25th 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. 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.

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,

Senior Pharmacovigilance Officer
Adverse Event & Medicine Defect Section
Pharmacovigilance Branch

Phone: 1800 020 653 Email: info@health.gov.au

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

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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

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



- 3. Approval of minutes from the last teleconference 29 March 2022 See Attachment 1
- 4. Action items from the previous meetings Nil
- 5. Roundtable



6. TGA serious AEFI update



- 7. Policy and workflow processes
- 8. Other business



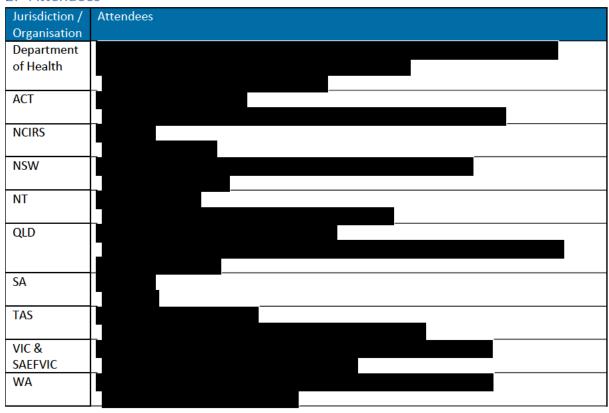
9. Meeting adjourned

Attachment 1

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

Date: Tuesday 29 March 2022 Chair: Associate Professor

- 1. Acknowledgement of country
- 2. Attendees



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







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.





Page 5 of 6

IN CONFIDENCE



8. Meeting Adjourned

Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: Tuesday 12 April 2022

Chair: Associate Professor

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



- 3. Approval of minutes from the last teleconference 5 April 2022 See Attachment 1
- 4. Action items from the previous meetings **Nil**
- 5. Roundtable



6. TGA serious AEFI update



- 7. Policy and workflow processes
- 8. Other business



9. Meeting adjourned

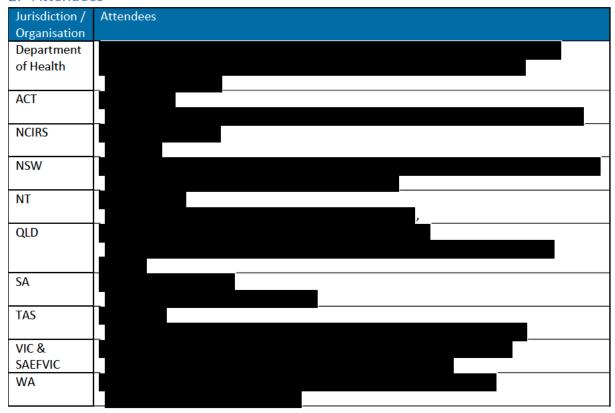
Attachment 1

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

Date: Tuesday 5 April 2022 Chair: Associate Professor

1. Acknowledgement of country

2. Attendees



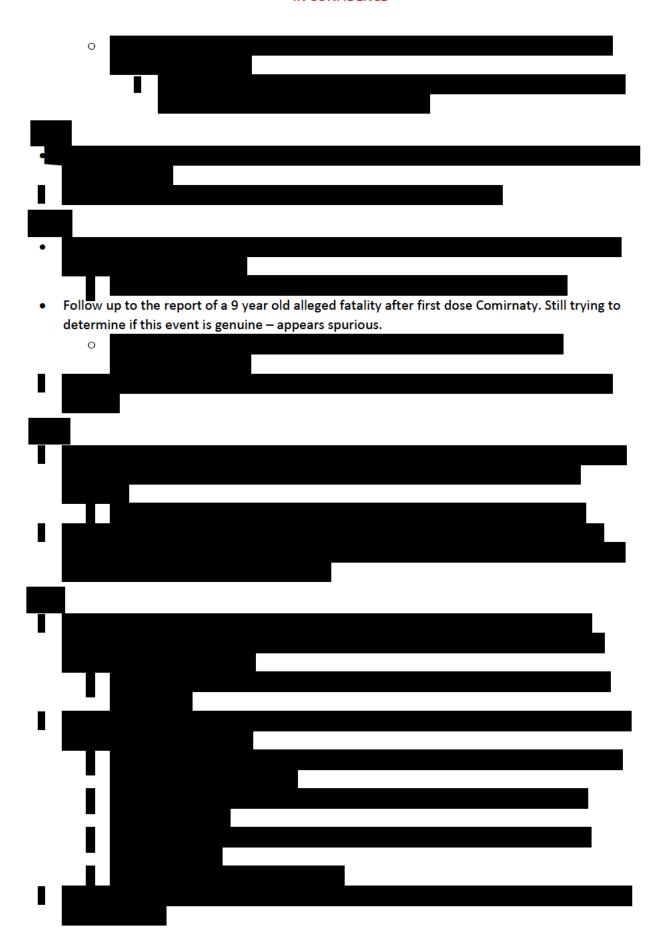
3. Minutes of the previous teleconference – 29 March 2022 Agreed and accepted.

4. Action items and outcomes

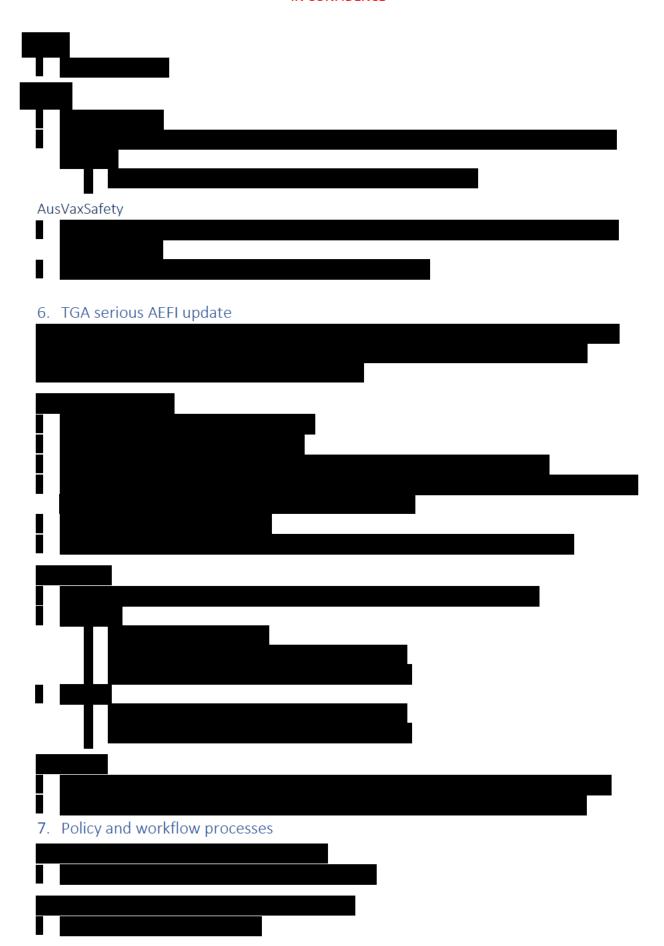
Nil action items to report back on.

5. Roundtable





IN CONFIDENCE



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)		Χ			
Reconciliation on daily	28/03/2022				Manual search
case line list					
Triage applied	28/03/2022				Level 1
RN review					
Escalated (within	28/03/2022				
VERA)					
MO review	28/03/2022				MO2 review
Request for	28/03/2022				
information					
Additional information					
received					
Case summary	28/03/2022				
commenced					
VERA fatal case review	31/03/2022				
meeting					
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
	MO5 PVB TGA
	MO4 PVB TGA
	MO2 PVB TGA
	Assistant Director PVB TGA
	RN, PVB TGA
	APS5 PVB TGA

Key points

- 9 yo
- 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]

	100	A. Consistent with causal sociation to immunization	B. Indeterminate	100	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		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		
		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

Agedcare ReportDate VAXDate

Death

Reaction Reporter

TGAICSRIdentifier

Vaccine

Age Sex

State

