Australian Government
Department of Health

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Note for file

TGA REF	AU-TGA-0000682908
Date and time	23 December 2021
Type of event	Fatal AEFI Assessment Team Meeting
Topic	Fatal report & COVID-19 Vaccine AstraZeneca

Participants

Name	Details
s22 [redacted]	Acting MO5 VERA, PVB TGA
s22 [redacted]	MO4 VERA, PVB TGA
s22 [redacted]	MO2 VERA, PVB TGA
s22 [redacted]	Assistant Director VERA, PVB TGA
s22 [redacted]	APS5 VERA, PVB TGA

Key points

- 89 Female
- s22 [redacted]
- s22 [redacted]
- s22 [redacted]
- CVA, s22 [redacted]

Rereviewed 03/02/2022

- COD Unrrelated to vaccination - s22 [redacted]

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 17/12/2021 – confirm if a death. • Any other follow-up actions required.
Decisions	• Unlikely Causality

Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health s22 [redacted]

Email Address: s22 [redacted]

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: s22 [redacted]

Thank you for your report documenting a fatal outcome in a patient who had been taking COVID Vaxzevria (AstraZeneca). Your report was entered into the Therapeutic Goods Administration's (TGA)'s Australian Adverse Event Management System (AEMS) in 17/12/2021. To assist with the assessment of this case, I would be grateful if you could provide the following additional information, quoting the AER Reference Number AU-TGA-0000682908 in your reply:

• Could you please clarify if this report refers to a fatal outcome? The case narrative refers to the patient being discharged home and we would appreciate clarification of this before we proceed with our investigation.

If the report does refer to a fatal outcome, could you please provide the following:
• The date, circumstances and mode of death
• The daily dose, dates of and reasons for administration of COVID Vaxzevria (AstraZeneca) and any other medications which were being taken by the patient in the lead up to death
• 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 a copy of the post-mortem report should be forwarded promptly as soon as it becomes available to your company
• Whether the case was referred to the Coroner. If so a copy of the coroner's report should be forwarded promptly as soon as it becomes available.

Please note that these details are requested by the TGA in respect of reports of fatal outcomes associated with adverse event reports.

Please refer to the Privacy Statement at the end of this letter for information about how the TGA handles information of this kind. The TGA does not include any personal information in

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our database that may have been inadvertently provided in the report, such as patient names but does keep information on the Sender of the report in case any clarification is needed.

The TGA undertakes regular analysis of the AEMS to identify new and emerging safety issues (signals) that may be related to medicines in use in Australia. When a signal is detected, further review is undertaken by the TGA to determine whether any action is required - such as changes to Product Information (PI), labelling or packaging, recall of a product or provision of information on the issue to prescribers and consumers of a medicine, including the issuing of Alerts.

Further information about medicines, such as Product Information, Consumer Medicine Information and Alerts can be found on the TGA website at http://www.tga.gov.au

If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at http://www.tga.gov.au/newsroom/subscribe-rss.htmThank you in anticipation of your ongoing assistance.

Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
17/12/2021

PRIVACY STATEMENT
For general privacy information, go to www.tga.gov.au/about/website-privacy.htm

Information in this report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports are assessed and entered into the TGA database for adverse events. Further information about how the TGA uses adverse event information that is reported to it is available at https://www.tga.gov.au/reporting-adverse-events

The TGA collects personal information in this report to:

- Assess the safety of medicines and vaccines under the Act.
- Contact the reporter of the adverse event if further information is required.
- Contact representatives of entities that supply therapeutic goods, to discuss reported adverse events.
- Check that the same information has not been received multiple times for the same adverse event.

At times, this information is collected from someone other than the individual to whom the personal information relates. This can occur when an adverse event is reported to a person or an entity other than the TGA (such as a health professional or a hospital), and that person or entity passes the information on to the TGA.

Personal information collected in this report may be disclosed by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates to vaccine events, personal information about the reporter or the patient may be disclosed to State and Territory health agencies under subsection 61(3) of the Act.

Acknowledgement email

Email	s22 [redacted]
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	17/12/2021 01:44:43 PM
Attachments	AU-TGA-0000682908 - 20211217024036-Request-for-information-regarding-an-adverse-reaction-resulting-in-death.pdf

Dear This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.

Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health s22 [redacted]

Email Address s22 [redacted]

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: s22 [redacted]

Thank you for submitting your adverse event report, which was entered into the Therapeutic Goods Administration's (TGA)'s Adverse Event Management System (AEMS) on 24/12/2021. To assist in the TGA's assessment of this report, could you please provide the following additional information:

- Could I please clarify if this was a fatal case as in the narrative the patient was discharged, however the reactions stated Fatal.

Please refer to the Privacy Statement at the end of this letter for information about how the TGA handles information of this kind. The TGA does not include any personal information in our database that may have been inadvertently provided in the report, such as patient names but does keep information on the Sender of the report in case any clarification is needed.

The TGA undertakes regular analysis of the AEMS to identify new and emerging safety issues (signals) that may be related to medicines in use in Australia. When a signal is detected, further review is undertaken by the TGA to determine whether any action is required - such as changes to Product Information (PI), labelling or packaging, recall of a product or provision of information on the issue to prescribers and consumers of a medicine, including the issuing of Alerts.

Further information about medicines, such as Product Information, Consumer Medicine Information and Alerts can be found on the TGA website at http://www.tga.gov.au

If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at http://www.tga.gov.au/newsroom/subscribe-rss.htmThank you in anticipation of your ongoing assistance.

TGA Health Safety Regulation

Please quote the TGA AER Reference AU-TGA-0000682908in your reply. If you have any queries about this report then please don't hesitate to contact me via adr.reports@tga.gov.au

Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
24/12/2021

PRIVACY STATEMENT

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Information in this report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports are assessed and entered into the Therapeutic Goods Administration's (TGA's) Australian Adverse Event Management System. Further information about how the TGA uses adverse event information that is reported to it is available at https://www.tga.gov.au/reporting-adverse-events

The TGA collects personal information in this report to:

- Assess the safety of medicines and vaccines under the Act.
- Contact the reporter of the adverse event if further information is required.
- Contact representatives of entities that supply therapeutic goods, to discuss reported adverse events.
- Check that the same information has not been received multiple times for the same adverse event.

At times, adverse event information is collected from someone other than the individual to whom the personal information relates. This can occur when an adverse event is reported to a person or an entity other than the TGA (such as a health professional or a hospital or a sponsor), and that person or entity passes the information on to the TGA. In those cases, the TGA will not collect the name and contact details of patients. However, the TGA may collect other information relating to patients including the date of birth or age, gender, weight, initials and information about the relevant adverse event.

Personal information collected in your report may be used or disclosed as permitted under the Privacy Act 1988, including by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates to vaccine events, any personal information in the adverse event report may be disclosed to State and Territory health agencies under section 61(3) of the Act.

Acknowledgement email

Email	s22 [redacted]
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	07/01/2022 01:04:16 PM
Attachments	AU-TGA-0000682908 - 20220107020232-Request-for-information-regarding-an-adverse-reaction-resulting-in-death.pdf

Dear This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.

Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health s22 [redacted]

Email Address s22 [redacted]

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: s22 [redacted]

Thank you for your report documenting a fatal outcome in a patient who had been taking COVID Vaxzevria (AstraZeneca). Your report was entered into the Therapeutic Goods Administration's (TGA)'s Australian Adverse Event Management System (AEMS) in 15/12/2022. To assist with the assessment of this case, I would be grateful if you could provide the following additional information, quoting the AER Reference Number AU-TGA-0000682908 in your reply:

- The mode of death/death certificate if available
- Details of treatment of the reported event
- A copy of the inpatient summary and consultant's report from the reported hospital admission
- Whether a post-mortem examination was performed. If so a copy of the post-mortem report should be forwarded promptly as soon as it becomes available to your company
- Whether the case was referred to the Coroner. If so a copy of the coroner's report should be forwarded promptly as soon as it becomes available.

Please note that these details are requested by the TGA in respect of reports of fatal outcomes associated with adverse event reports.

Please refer to the Privacy Statement at the end of this letter for information about how the TGA handles information of this kind. The TGA does not include any personal information in our database that may have been inadvertently provided in the report, such as patient names but does keep information on the Sender of the report in case any clarification is needed.

The TGA undertakes regular analysis of the AEMS to identify new and emerging safety issues (signals) that may be related to medicines in use in Australia. When a signal is detected, further review is undertaken by the TGA to determine whether any action is required - such as changes to Product Information (PI), labelling or packaging, recall of a product or provision

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of information on the issue to prescribers and consumers of a medicine, including the issuing of Alerts.

Further information about medicines, such as Product Information, Consumer Medicine Information and Alerts can be found on the TGA website at http://www.tga.gov.au

If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at http://www.tga.gov.au/newsroom/subscribe-rss.htmThank you in anticipation of your ongoing assistance.

Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
7/1/2022

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The TGA collects personal information in this report to:

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Personal information collected in this report may be disclosed by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates to vaccine events, personal information about the reporter or the patient may be disclosed to State and Territory health agencies under subsection 61(3) of the Act.

TGAICSRIdentifier	Vaccine	Age	Sex	State	Agedcare	ReportDate	VAXDate
s22							
AU-TGA-0000682908	COVID-19 Vaccine AstraZeneca	89	Female	s22	-	15/12/2021	s22
s22							

Death	TTD	Reaction	Reportertype
s22 [redacted]			
-	-	Cerebrovascular accident ; Concomitant disease aggravated ; Fall	Regional Pharmacovigilance Centre
s22 [redacted]			

CaseNarrative	DOB	Patient_Atsi_Category	Medicalhistory
s22 [redacted]			
s22 [redacted]	[redacted]		s22 [redacted]
s22 [redacted]			

reportersviewoncausality	Triage	Referredtocoroner	Commentsotherinformation	Panel Review Date
s22 [redacted]				
not stated	5			23/12/2021
s22 [redacted]				

Attendees

s22 [redacted]

Outcome	Other Notes
s22 [redacted]	

Not fatal report	s22 to contact AEMS
s22 [redacted]	

Outcome	Other notes	Rereview	Outcome	Notes
s22 [redacted]				

s22 [redacted]

TGAICSRIdentifier	Vaccine	Age	Sex	State	Agedcare	ReportDate	VAXDate	Death	TTD	Reaction

s22

s22

Case Updates

s22

AU-TGA-0000682908	COVID-19 Vaccine AstraZeneca	89	Female	s22	-	15/12/2021	s22 s22	-	-	Adverse event following immunisation ; Cerebrovascular accident ; Fall

s22

Reportertype	CaseNarrative	DOB	Patient_Atsi_Category	SenderOrganisation	Dose
s22	[redacted]				

522

s22

s22

Regional Pharmacovigilance Centre

Regional Pharmacovigilance Centre

Medicalhistory	reportersviewoncausality	Triage	Referredtocoroner	Commentsotherinformation	Panel review date	Outcome	Other notes
s22	[redacted]						

s22

[redacted]

				Panel review							
s22 [redacted]											
s22 [redacted]	not stated	5		23/12/2021	Reject	Not A Fatal Report	3/02/2022	Unlikely	Unrrelated to vaccination	s22 [redacted]	
s22 [redacted]											

Attendance

s22 [redacted]

s22

Acknowledgement email

Email	s22 [redacted]
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	24/12/2021 02:26:41 PM
Attachments	AU-TGA-0000682908 - 20211224032437-Acknowledgement-request-for -additional-information.pdf

Dear This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.