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From: s22
s22
Sent: Thursday, 17 March 2022 6:37 PM
To: TGA AEFI Reports
Cc: s22
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: s22

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: s22
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)**
s2
4. **Any past medical history**
s22
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**
s22
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.**
s22

Thank you.

Kind regards,

s22

"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: s22

Cc: s22; 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 s22 (TGA reference number AU-TGA-0000719838). This report describes death of a 7 year old male who was administered Comirnaty COVID-19 vaccine on s22 and died on s22. 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 TGA.AEFI.Reports@health.gov.au or call me on s22 if you have any questions or would like to discuss.

Thank you for your assistance with this matter.

Kind regards,

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Vaccine Epidemiological Rapid Assessment Section

Medicines Regulation Division | Therapeutic Goods Administration

Pharmacovigilance Branch

Australian Government Department of Health

s22

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.

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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.

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