From: TGA AEFI Reports

To: \$22 Cc: \$22 ADR Reports

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

Date: Tuesday, 15 March 2022 9:14:00 AM

Attachments: image001.png

## 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 and died on 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 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

P: **52** 

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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.