From: ADR Reports
To: s22 [redacted]
Subject: AEFI – SERIOUS – COVID [Pfizer] – [Cardiac arrest - Fatal] – [9 Female] – s22 – AU-TGA-0000724023 [SEC=OFFICIAL]
Date: Monday, 28 March 2022 10:10:38 AM
Attachments: AU-TGA-0000724023.docx

Dear s22 [redacted],

I, s22 [redacted], as delegate of the Secretary for the purposes of section 61 of the Therapeutic Goods Act 1989 (the Act), approve the release of the attached therapeutic goods information relating to adverse events following immunisation with vaccines (including seasonal influenza vaccines received by the TGA) to s22 [redacted]:

- s22 [redacted]
- [redacted]
- [redacted]

Should you have any queries please contact the Pharmacovigilanc Branch, TGA by email at adr.reports@health.gov.au

Yours faithfully

s22 [redacted]
Delegate of the Secretary to the Department of Health
Pharmacovigilance Branch, TGA
Fax No: (02) 6232 8392
e-mail: adr.reports@health.gov.au
TGA website: www.tga.gov.au

AU-TGA-0000724023

Case details:

Original received date: s22

Creation date: 25/03/2022

Date sent to WHO:

Involves an unapproved product?: No

Unapproved product access:

Modified on: 28/03/2022

Decision Reason:

Serious ICSR: Yes

Sender details:

s22

Sender type: s22

Sender's ICSR indentifier: s2

Patient details:

Patient initials: s2

Sex: Female

Weight:

Age: 9 (Year)

Date of birth: s22

State: s22

Ethnicity:

Reporter details:

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Phone:

Case narrative:

Cardiac arrest

Reactions:

Preferred term	Onset date	End date	Outcome
Cardiac arrest			Fatal

Drug information:

Product name	Role characterisation	Action taken
comirnaty	Suspect	

Product name	Role characterisation	Action taken
TN010191 COMIRNATY COVID-19 vaccine - COMIRNATY COVID-19 vaccine	Suspect	

Active Ingredient/s
tozinameran ( )

Tests and procedures: