ACT Government | ACT Health

OFFICE USE ONLY
ACT NO:
TGA NO:

COVID-19 Vaccine Adverse Event Following Immunisation Reporting Form

DETAILS OF PERSON WHO EXPERIENCED THE ADVERSE EVENT

Name_____DOB ____/____ / _____

Gender M/F/ unknown (circle) Address:_____

State: _____ Postcode: _____ Phone: _____ Country of Birth:_____

Weight:_____ If a child, Parent/Guardian Name_____

Aboriginal ☐ Torres Strait Islander ☐ Aboriginal & Torres Strait Islander ☐ Neither ☐

PAST MEDICAL HISTORY

Any known allergies?_____

Important medical history? _____

Medications in the past 3 months?_____

Prior reactions following immunisation? Yes/No/Unknown: If Yes, provide details: _____

History of COVID 19 illness? Yes/No Date of 1st symptom: _____ Date tested: _____ Test result: _____

Pregnant at time of vaccination? Yes/No Gestation in weeks: _____

Aged care resident? Yes/No

Was the person ill before the vaccine was given? Yes/No If Yes, provide details: _____

_____

VACCINATION DETAILS

Clinical setting: _____

Vaccine Provider Name: _____Provider Type: GP RN Pharmacist Other: _____

Provider Address: _____

Suburb: _____ Post code: _____

Phone: _____ Fax: _____ Email:_____

Vaccine Brand/Type	Dose No	Date given	Time given	Batch No	Serial No	Route/Site/Side (left or right)

Were any other vaccines given within 4 weeks prior to the adverse event? **NO/YES:** If Yes, specify details:

_____

ADVERSE EVENT DETAILS

Onset of event

Date and time reaction occurred: _____

If unknown, time elapsed between vaccination and adverse event: _____

(Please complete page 2)

Detailed description the adverse event:

_____

_____

_____

_____

_____

_____

_____

_____

_____

MANAGEMENT OF EVENT

None/Nurse/GP/Hospital ED Was hospitalisation required? yes/no

Date of admission: ___ / ___ / ___ Date of discharge: ___ / ___ / ___

Detailed description of any treatment provided (e.g. antibiotics, adrenaline, advice, counselling, etc.):

_____

_____

_____

_____

OUTCOME

Have the symptoms resolved? yes/no/unknown If yes, time and date: _____

If no, symptoms ongoing as of (time and date): _____

Please describe ongoing symptoms: _____

_____

_____

DETAILS OF PERSON REPORTING THIS ADVERSE EVENT

Name: _____ Phone: _____ Date: ___ /___ / ___

Address: _____Suburb: _____ Post code: _____

Reporter type GP/ Medical Specialist/Pharmacist/Nurse RN/EN/Vaccinated person/parent/guardian/

Other: _____

Consent Statement

I, the reporter, agree to be contacted for further follow up regarding this adverse event if necessary.

☐ Yes ☐ No Signature/initials*

Date

Please advise the parent/patient that contact details will be used to follow up if information is needed.

** For verbal reports indicate how consent was obtained*

On completion, fax this form to 5124 9307, or email to: immunisation@act.gov.au.

To discuss further call the Immunisation Unit on 5124 9800

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Is this considered a serious AEFI? Yes/No

If yes, please specify: _____

_____

Is follow up on patient required? Yes/No Immediately/next day/next 30 days/next 60 days

Date report received: _____ Date scanned to TGA: _____

Privacy statement

Health Professionals reporting on behalf of a patient should provide the patient with a copy of this privacy statement.

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The Therapeutic Goods Administration (the TGA) is part of the Department of Health. The TGA can be contacted by phone on 1800 020 653, by email at info@tga.gov.au, or by post at PO Box 100, Woden ACT 2606, Australia.

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 of AEFIs are assessed and entered into the TGA's Australian Adverse Drugs Reactions System (the ADRS).

The TGA collects personal information relating to adverse events following immunisation (AEFIs). At times, this information is collected from someone other than the individual to whom the personal information relates. This can occur when AEFIs are reported to a person or an entity other than the TGA (such as a health professional), and that person or entity passes the information on to the TGA (either directly or through a State or Territory health agency).

Collection of personal information from sponsors of therapeutic goods is required or authorised under Chapter 3 of the Act.

Personal information about patients is collected and used to:

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

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). For reports related 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.