Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

Date report received:

Notification ID:

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

National Adverse Events Following Immunisation (AEFI) reporting form

Vaccinated person's details	
Personal details	
Surname:	
First name:	
Gender:	☐ Male ☐ Female ☐ Unknown
Date of Birth:	**or**
Age:	Months or Years
Street address:	
Suburb:	
State:	
Postcode:	
Name of parent/guardian: (if relevant)	
Phone: Landline (inc. area code) or mobile	

Vaccinated person's details	
Additional details	
Indigenous status: Is the person of Aboriginal or Torres Strait Islander origin?	☐ No ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander ☐ Yes, both Aboriginal and Torres Strait Islander
Important medical history	
Allergies	
Has the vaccinated person had previous reactions to vaccinations?	☐ No ☐ Yes - please specify: ☐ Unknown

Vaccination provider details	
Surname:	
First name:	
Street address:	
Suburb:	
State:	
Postcode:	
Phone: landline (incl. area code)	
Phone: mobile	

Vaccination provider details		
Email:		
Fax:		
Profession:	☐ Medical practitioner ☐ Registered Nurse ☐ Other, please specify:	
Clinical setting	☐ GP practice ☐ Council clinic ☐ Aged care facility ☐ School vaccination program ☐ Hospital ☐ Other, please specify: ☐ Unknown	
Address of service where vaccine was administered	☐ As per vaccination provider (above) **or**	
	Name of practice/clinic/provider	
	Street address:	
	Suburb:	
	State:	
	Postcode:	
	Phone: landline: (incl. area code)	
	Phone: mobile	
	Email:	

Reporter details	
☐ As per vaccinated person's details (above) **or** ☐ As per vaccination provider details (above) **or**	
Surname:	
First name:	
Practice name: (if relevant)	
Street address:	
Suburb:	
State:	
Postcode:	
Phone: landline: (incl. area code)	
Phone: mobile:	
Email:	
Additional details	
Date of report:	
Reporter type:	☐ Medical practitioner ☐ Registered Nurse ☐ Vaccinated person ☐ Parent/guardian ☐ Other, please specify:

Reporter details

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*

Vaccine details

Vaccine (brand name)	Dose no.	Batch no.	Date given	Time given	Route of administration	Injection site
					☐ O ☐ IM ☐ SC ☐ ID ☐ IN ☐ U	☐ RL ☐ LL ☐ RA ☐ LA ☐ U ☐ NA
					☐ O ☐ IM ☐ SC ☐ ID ☐ IN ☐ U	☐ RL ☐ LL ☐ RA ☐ LA ☐ U ☐ NA
					☐ O ☐ IM ☐ SC ☐ ID ☐ IN ☐ U	☐ RL ☐ LL ☐ RA ☐ LA ☐ U ☐ NA
					☐ O ☐ IM ☐ SC ☐ ID ☐ IN ☐ U	☐ RL ☐ LL ☐ RA ☐ LA ☐ U ☐ NA
					☐ O ☐ IM ☐ SC ☐ ID ☐ IN ☐ U	☐ RL ☐ LL ☐ RA ☐ LA ☐ U ☐ NA

Abbreviations

Route of administration: O = oral IM = intramuscular SC = subcutaneous ID = intradermal IN = intranasal U = unknown
Injection site: RL = right leg LL = left leg RA = right arm LA = left arm U = unknown NA = Not Applicable

Adverse event details	
Onset of event	Date: Time:
Description of events, including timeline of occurrences:	
Management of event (tick as many as apply)	☐ None ☐ Nurse assessment ☐ GP assessment ☐ Hospital emergency department ☐ Hospital admission: Number of days(if applicable): Date of discharge: ☐ Unknown ☐ Other, please specify:
Please specify the treatment/care provided (e.g. antibiotics, adrenaline, advice, counselling, etc.):	

Adverse event details	
Outcome	
Have the symptoms resolved?	☐ **Yes** - By what time had they resolved? **Date:** **Time:** ☐ **No** - Symptoms are ongoing as of: **Date:** **Time:** Please describe ongoing symptoms: ☐ **Unknown**

Once completed, send to the TGA

- By mail to: Post-market Surveillance Branch, Reply Paid 100, Woden ACT 2606
- By fax to: 02 6232 8392
- By email to: adr.reports@tga.gov.au

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.