Australian Government

Department of Health

National Adverse Events Following Immunisation (AEFI) Reporting Form

Office Use Only
Date Report Received:
Notification ID:

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 (incl. area code) or mobile

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

Provider details:

Surname First name

Street Address

Suburb State Postcode

Phone: landline (incl. area code)

Phone: mobile

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 for 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

and

Date of report

Reporter type:

☐ Medical practitioner ☐ Registered nurse ☐ Vaccinated person ☐ Parent/guardian

☐ Other, please specify

Consent statement

Please advise the parent / patient that they may be contacted if additional information is needed. The contact details will be used for this purpose.

I, the parent / patient do not agree to be contacted. Please sign below (signature parent / patient) or if collecting information over the phone: The person has advised that they do not wish to be contacted (reporter to sign).

Signature/Initials* Date

**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 IN=intranasal 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 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 (eg antibiotics, adrenaline, advice, counselling, etc):

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: Office of Product Review, Reply Paid 100, Woden ACT 2606
- By fax to: 02 6232 8392
- By email to: adr.reports@tga.gov.au

Office use only

Is this considered a serious AEFI? □ No

□ Yes – Please specify:_____

_____

_____

_____

Is follow-up of the patient required? □ No □ Yes - Timeframe for follow up □ Immediately □ Next day □ Next 60 days

Feedback:_____ _____

Privacy statement

Personal information:
Personal information in this report about a patient is collected and used for the purpose of assessing the safety of medicines under the Therapeutic Goods Act 1989 (the Act). All reports are assessed and entered into the TGA's Australian Adverse Drugs Reactions System (the ADRS). Personal information in this report is only disclosed: (i) under subsection 61(3) of the Act to State and Territory Health Departments (if the information relates to vaccine events); or (ii) where the disclosure is otherwise required by, or authorised under, a law. For example, the Secretary of the Department of Health and Ageing can release information from this report under subsection 61(7) of the Act if it is necessary to do so to ensure the safe use of the medicine, including to the company responsible for its supply in Australia. The reporter's details are recorded in the ADRS so that they can be contacted if further information is required about the reported adverse event. Personal information about a reporter is only disclosed: (i) under subsection 61(3) of the Act to State and Territory Health Departments (if the information relates to vaccine events); or (ii) where the disclosure is otherwise required by, or authorised under, a law.

Adverse event information:
Specified kinds of information about reported adverse events can be released to the public by the Secretary under subsection 61(5C) of the Act. The information includes such details as the medicine reported to have been involved in an adverse event, and statistics such as the number of cases of reported adverse events relating to a medicine for any particular period of time. This information does not include any "personal information" within the meaning of the Privacy Act 1988 - that is, information from which an individual's identity might be apparent or reasonably ascertainable. Further information about how the TGA uses adverse event information that is reported to it is available at www.tga.gov.au/safety/problem.htm.