

STANDARD REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION

*Patient name or initials: 6 *Patient's full Address: 4 21 Telephone: 8 Sex: ☐ M ☐ F (8 Trimester I ☐ II ☐ III ☐ /Lactating ☐) *Date of birth (DD/MM/YYYY): ____/____/____ 7 OR Age at onset: ☐ ☐ Years ☐ ☐ Months ☐ ☐ ☐ Days OR Age Group: ☐ 0 < 1 year ☐ 1-5 years ☐ > 5 years - 18 years ☐ > 18 years – 60 years ☐ > 60 years	*Reporter's Name: 20 Institution: Designation & Department: 22 Address: 3 23 Telephone & e-mail: Date patient notified event to health system (DD/MM/YYYY): ____/____/____ 24 Today's date (DD/MM/YYYY): ____/____/____
---	---

Health facility (or vaccination centre) name: 15 2									
Vaccine							Diluent		
Name of vaccine (Generic)	*Brand Name incl. Name of Manufacturer	*Date of vaccination	*Time of vaccination	Dose (1 st , 2 nd , etc.)	*Batch/Lot number	Expiry date	*Batch/ Lot number	Expiry date	Time of reconstitution
10	11				13	12	14		

*Adverse event (s): 17 ☐ Severe local reaction ☐ >3 days ☐ beyond nearest joint ☐ Seizures ☐ febrile ☐ afebrile ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever ≥38°C ☐ Other (specify) 16 Date & Time A 19 (DD/MM/YYYY): ____/____/____ ☐ ☐ Hr ☐ ☐ Min	Describe AEFI (Signs and symptoms): 9
*Serious: Yes / No ; ➔ If Yes ☐ Death ☐ Life threatening ☐ Disability ☐ Hospitalization ☐ Congenital anomaly ☐ Other important medical event (Specify _____)	
*Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died 18 of death (DD/MM/YYYY): ____/____/____ Autopsy done: ☐ Yes ☐ No ☐ Unknown	
Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) other relevant information (e.g. other cases). Use additional sheet if needed :	

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No	If yes, date investigation planned (DD/MM/YYYY): ____/____/____ 1 5
--	--

National level to complete:

Date report received at national level (DD/MM/YYYY): ____/____/____	AEFI worldwide unique ID :
Comments: 25	

*Compulsory field

Description	# Core variable	Suggested Heading	Terminology used in the WHO standard AEFI reporting form	Description
Record Identifier	1	Date AEFI report first received at national centre	Date report received at national level	Date this report was received at the National level
	2	Place of vaccination	Health facility (or vaccination centre) name	Geographic location of the place where recipient got vaccinated
	3	Country where this AEFI reported	Reporter address	The name of the country where the data is first entered
	4	Location (address)	Patient's full Address	Geographic location of the case (province)
	5	Worldwide unique number	AEFI worldwide unique ID	Unique number used for communicating the details of the case at the international level
Patient	6	Patient identifier	Patient name or initials	The name of the patient or initials as decided by the country
	7	Date of birth (or)	Date of birth	Date patient was born
	7	Age at time of onset (or)	Age at onset	If date of birth is not known, this may be considered as first alternative
	7	Age group at onset	Age Group	If date of birth and age at onset is not known, this may be considered as second alternative
	8	Sex	Sex	Male or Female
Vaccine	9	History of Event	Describe AEFI (Signs and symptoms):	Free text
	10	Primary suspect vaccine name (generic)	Name of vaccine (Generic)	The vaccine that is suspected to have caused the AEFI (Generic)
	10	Primary suspect vaccine name (brand)	Brand Name incl. Name of Manufacturer	The vaccine that is suspected to have caused the AEFI (Brand name)
	11	Other vaccines given just prior to AEFI	Other vaccines	Other vaccines given prior to the AEFI
	12	Vaccine Batch number	Batch/ Lot number	Batch number/lot number of each of the vaccines mentioned above
Event	13	Vaccine dose number for this particular vaccine	Dose (1st, 2nd, etc.)	The dose number for the vaccinee
	14	Diluent batch/ lot number	Diluent Batch/ Lot number	Batch number/lot number of the diluent that was actually used (if applicable)
	15	Date and time of vaccination	Date & Time of vaccination	Date and time when the vaccine was administered
	16	Date and time of AEFI onset	Date & Time AEFI started	Date and time the event was first identified by/ in the recipient
	17	Adverse event	Adverse Event(s)	The case diagnosis + signs and symptoms
	18	Outcome of AEFI	Outcome	Indicate status of the patient at the time of reporting: Recovering, Recovered, Recovered with sequelae, Not Recovered, Unknown or Died
	19	Serious	Serious	If the event resulted in death, threatened the patient's life, caused disability, hospitalization or congenital anomaly
	20	Name of first reporter of AEFI	Reporter's Name	Name of person who has reported this AEFI to the healthcare system and also completed this form
Reporter	21	Institution/location	Institution	The place where the reporter is working or is affiliated to
	22	Position/department	Designation & Department	Reporter's designation
	23	e-mail Id & Telephone number	Telephone & e-mail	email id of the reporter
	24	Date of report	Today's date	Date when the report was compiled by the reporter
Other	25	Comments (if any)	Comments	Free text