AEFI reporting ID number:

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

***Patient Name*:** ***Patient's full Address*:** Telephone: Sex: ☐ M ☐ F ***Date of birth* : _ _ /_ _ /_ _** *OR Age at onset:* ☐☐ *Years* ☐☐ *Months* ☐☐☐ *Days* *OR Age Group at onset:* ☐ *<1 Year* ☐ *1 to 5 Years* ☐ *>5 Years*	***Reporter's Name*:** Institution: Designation & Department: Address: Telephone & E-mail: Date patient notified event to health system: _ _ /_ _ /_ _ Today's date : _ _ /_ _ /_ _

Health facility (place or vaccination centre) name & address:

Vaccine						***Diluent (if applicable)***			
Name of vaccine	***Date of vaccination***	***Time of vaccination***	Dose (1st, 2nd, etc.)	***Batch /Lot number***	Expiry date	Name of diluent	***Batch /Lot number***	Expiry date	Date and time of reconstitution

Adverse event(s): ☐ Severe local reaction ☐ *>3 days* ☐ *beyond nearest joint* ☐ Seizures ☐ *febrile* ☐ *afebrile* ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever ≥38°C ☐ Other (specify).....	Date AEFI started **:** _ _ /_ _/_ _ Time __ __:__ __ Describe AEFI (Signs & Symptoms):

Serious: Yes / No; ➔ If Yes ☐ Death ☐ Life threatening ☐ Persistent or significant disability ☐ Hospitalization ☐ Congenital anomaly
☐ Other important medical event (specify).....

Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown

☐ Died If Died, date of death : _ _ /_ _ /_ _ Autopsy done: ☐Yes ☐No ☐Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases)**.** *Use additional sheets if needed:*

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No	If Yes, date investigation planned : _ _ /_ _ /_ _

National level to complete:

Date report received at National level _ _ /_ _ /_ _	AEFI worldwide unique ID **:**
Comments:	

Compulsory field

Description of elements in the AEFI reporting form (revised Jan 2016)

	Reporting element	Description
	AEFI reporting ID number	Unique number assigned to the AEFI case as per the national guidelines
Patient identifier	***Patient's Name**	The name of the patient or initials as decided by the country
	***Patient's full Address**	Geographic location of the case (address), please try to provide landmarks
	Telephone	Number to contact to provide or receive additional information
	Sex	Male or Female
	***Date of birth**	Date** patient was born
	Age at onset	If date of birth is not known, this may be considered as first alternative
	Age Group at onset	If date of birth and age at onset is not known, this may be considered as second alternative
Reporter details	***Reporter´s Name**	Name of person who has reported this AEFI to the healthcare system and also completed this form
	Institution	The place where the reporter is working or is affiliated to
	Designation & Department	Reporter's designation and his/her section of work
	Address	Reporters full address - Please add the name of the country here as well
	Telephone	Reporter's phone number
	E-mail	Reporter's e-mail address
	Date patient notified event to health system	The date** when the event was first brought to the notice of the healthcare system
	Today's date	Date** when the report was compiled by the reporter (this can be different from the date of notification (above))
Details of vaccination, vaccine(s) and diluent(s)	Vaccination centre or place of vaccination - name & address	Name and address of the place where the child received the vaccine - provide details (e.g. mobile clinic, home etc.)
	***Name of vaccine**	The vaccine that is suspected to have caused the AEFI (provide brand name, if possible)
	Name (of other vaccines)	Other vaccines that were administered at the same time (provide brand name, if possible)
	***Date of vaccination**	Date** when the vaccine was administered
	***Time of vaccination**	Time** when vaccine was administered - try to be as accurate as possible
	***Batch/Lot number (of vaccine)**	Batch number/lot number of each of the vaccines mentioned above
	Dose (1st, 2nd, etc.)	Dose number of the vaccine for the vaccinee e.g. 2nd dose of DTP or 5th Dose of OPV etc.
	Expiry date	The date** of expiry for each vaccine
	***Batch/Lot number (of diluent)**	The batch/lot number of diluent (if applicable)
	Expiry date (of diluent)	The date** of expiry of the diluent
	Time of reconstitution	Time when the vaccine was reconstituted with the diluent
Adverse event(s)	***Adverse event(s)**	The details of the events suspected to be caused by immunization. Multiple events can occur in a single patient. They need to be documented here
	Date & Time AEFI started	Date** and time** the event was first noticed
	Describe AEFI (Signs & Symptoms)	Description of the events in chronological order
	***Serious: Yes / No**	If the case is serious, mark "Yes" and indicate one or several options: Death, Life threatening, Persistent or significant disability, Hospitalization, Congenital anomaly or Other important medical event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here
	***Outcome**	Outcome of the reaction(s). Indicate status of the patient at the time of reporting: Recovering, Recovered, Recovered with sequelae, Not Recovered, Unknown or Died
	Died	Provide date of death and details of autopsy, if available
	Past medical history	Please include history of similar reaction or other allergies, concomitant medication and other relevant information (e.g. other cases in the locality or among those vaccinated)
Response	First Decision making level to complete	This section has to be completed by the decision maker for a detailed field AEFI investigation.
	Investigation needed	Decision on detailed field AEFI investigation.
	Date investigation planned	Date** when detailed investigation (including field investigation) is planned to start.
	National level to complete	This section has to be completed by the National level to decide on the next steps.
	Date report received at National level	Date** this report was received at the National level
	AEFI worldwide unique ID	Unique ID number (e.g. regulatory authority's case report number) for the AEFI case automatically generated for electronic transmission from National level to International level
	Comments	Please add additional details that will help with processing this report. Please include other documents as attachments, if necessary

Compulsory field** — ***Items marked with an asterix (*) have to be completed

** Please use the local convention for the format e.g. DD/MM/YY or MM/DD/ YY or YY/MM/DD, for time use a 12 or 24 hours format