ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING FORM

Report Type: ❒ Initial ❒ Follow-up

Patient's Details **Date of Reporting:** D D M M Y Y Y Y

Patient's Name:

Age at the time of onset: ☐☐**Years** ☐☐**Months** ☐☐**Days**

OR

Date of Birth: D D M M Y Y Y Y

Height (in cm): _____ **Weight (in Kg):** _____

Gender: ❒ **Male** ❒ **Female** ❒**Others**

Pregnant: ❒ **Yes** ❒ **No** ❒ **Unknown** ❒ **Not Applicable**

Gestational Age (If Pregnant): ❒ **1st Trimester** ❒ **2nd Trimester** ❒**3rd Trimester /** ❒ **Lactating** ❒ **Not Applicable**

Telephone: _____

Patient's address:

_____

_____

Reporter Details

Reporter's Name: _____

Institution: _____

Designation & Department: _____

_____

Address: _____

_____

_____

Contact phone number: _____

Email: _____

Date Event first notified to Healthcare System: D D M M Y Y Y Y

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Health facility (place or vaccination centre) Name & Address:_____

_____

Sign & date: _____

Vaccine and diluent details

Indication:

Vaccine										*Diluent*		
Name of vaccine (Generic)	Brand Name incl. Name of Manufacturer	Indication	Date of vaccination	Time of vaccination	Route of administration	Dose/ strength	Dose (1st, 2nd, etc.)	Batch/ Lot number	Expiry date	*Batch/ Lot number	Expiry /Retest date	Time of reconstitution (if available)

Action taken with vaccine:

❒Withdrawn ❒Dose increased ❒Dose reduced ❒Dose not changed ❒Not Applicable ❒ Unknown

Date AEFI started: D D M M Y Y Y Y

Time of onset: _ _: _ _ (HH:MM)

AEFI stopped date: D D M M Y Y Y Y

AEFI stopped time: _ _: _ _ (HH:MM)

Description of AEFI (Signs & Symptoms): _____

_____

_____

_____

_____

_____

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Management of AEFI: _____

_____

_____

_____

Adverse event(s):

❒ Severe local reaction
○ > 3 Days
○Beyond Nearest Joint
○Febrile
○Afebrile
❒ Pruritus
❒ Redness at site of Injection
❒ Swelling at site of Injection
❒ Rash at site of Injection
❒ Anaphylaxis
❒ Myalgia
❒ Other (specify)_____
❒ Rash
❒ Headache
❒ Diarrhoea
❒ Nausea/vomiting
❒Fever≥38°C

Seriousness: ❒ **Serious** ❒ **Non-serious**

Severity: ❒ Mild ❒ Moderate ❒ Severe

If Serious, select criteria
□ Death
□ Life threatening
□ Persistent or significant disability
□ Hospitalization
□ Congenital anomaly
□ Other important medical event (specify) _____

Causality Assessment:

❒ Consistent ❒ Indeterminate ❒ Coincidental ❒ Unclassifiable

Outcome:

❒ Recovering ❒ Recovered ❒ Recovered with sequelae ❒ Not Recovered ❒ Unknown ❒ Death

If Death, Date of death: D D M M Y Y Y Y

Time of Death (HH:MM): _ _: _ _

Autopsy done: ❒ Yes ❒ No ❒ Unknown

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Past medical and medication history (including history of similar reaction or other allergies): _____

_____

_____

_____

_____

Concomitant medication/Vaccination and other relevant information (e.g. other cases):

Sr. No.	Name (Brand/ Generic)	Dose	Route	Frequency (OD, BD etc.)	Therapy Dates		Indication
					Start date	Stop date	
I							
II							
III							
IV							

Send this report to (PV Site)	**To be filled by Manufacturer/PV Personnel:**
Company Name & Address	**Date received by receiver:** DD/MMM/YYYY **Name and sign of receiver:** **Safety Report ID:**