REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

***Patient Name or initials*:** ***Patient's full Address*:** Telephone: Sex: ☐ M ☐ F Pregnant ☐ Lactating ☐ ***Date of birth* :** _ _ / _ _ / _ _ *OR Age at onset:* ☐☐ *Years* ☐☐ *Months* ☐☐☐ *Days* *OR Age Group at onset:* ☐ *<1 Year* ☐ *1 to 5 Years* ☐ *>5 Years-15 Years* ☐ *>15 years-60 Years* ☐ *>60 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 center) name & address:

Vaccine							*Diluent (if applicable)*			
Name of vaccine	***Brand Name and, Name of Manufacturer***	***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 sequela ☐ 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 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 : _ _ / _ _ / _ _

National level to complete:

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

Email Address: pharmacovigilance@efda.gov.et