Ethiopian Food and Drug Authority (EFDA)
REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

*Patient Name or initials: _____	*Reporter's Name: _____
*Patient's full Address: _____	Institution: _____
Telephone: _____	Title & Department: _____
Sex: M ☐ F ☐ Pregnant ☐ Lactating ☐	Address: _____
*Date of birth: __ __/__ __/__ __ __ __	Telephone: _____
Or Age at onset: ☐ ☐ years ☐ ☐ months ☐ ☐ ☐ days	Email: _____
Or Age group at onset: < 1 year ☐ 1 to 5 yrs ☐ 6 to 15 yrs ☐	Date patient notified event to health system: __/__/__
16 to 60 yrs ☐ >60 yrs ☐	Today's date: __ __/__ __/____

Health facility (place or vaccination center) name & address:						
Vaccine						
*Name of vaccine	*Brand Name and, Name of Manufacturer	*Date of vaccination	*Time of vaccination	Dose (1st, 2nd, etc.)	*Batch /Lot number	Expiry date
Diluents *(if applicable)*						
Name of diluent	*Batch /Lot number	Expiry date	Date of reconstitution	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 ☐ Injection site reaction ☐ Generalized itch ☐ Rash ☐ Thrombosis	AEFI Onset Date: __/__/____ AEFI Onset Time: _____ Resolved Date (leave blank if ongoing): __/__/____ Resolved 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:	

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This ADE reporting form is prepared and printed by Ethiopian Food and Drug Authority (EFDA) in collaboration with the USAID Global Health Supply Chain Program- Procurement and Supply Management (GHSC-PSM) project .

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ETHIOPIAN FOOD AND DRUG AUTHORITY

Other means of Reporting
Electronic Reporting form on our website: www.efda.gov.et

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