MINISTRY OF HEALTH AND MEDICAL SERVICES

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) REPORTING and INVESTIGATION FORM

BASIC DETAILS

Name: _____ **NHN:** _____ **DOB:** _____ **Age:** ____
Address: **Phone:** **Sex:** □ M □ F **Ethnicity:**

Place of Vaccination: **Address of Vaccination Site:**

Name of Reporting Officer: **Designation/ Position:**
Phone: **Email:** **Date of Report:**

Vaccine:

Generic Name	Brand Name (incl. name of manufacturer)	Batch/ Lot #	Dose (1st, 2nd, etc)	Site		Route	Exp. Date
				L	R		

Diluent:

Batch/ Lot #	Exp. Date	Time of Reconstit-ution	Time of Discard

Date of vaccination: _____ **Time of vaccination:** _____
Date of 1st key AEFI: _____ **Time of 1st key AEFI:** _____
Signs and symptoms in chronological order from time of vaccination:

Date reported to health facility: **Date of Hospitalization:**
Status on date of report: □ Died □ Disabled □ Recovering □ Recovered Completely □ Unknown
If deceased, date, and time of death (D/M/Y): _____/_____/_____ **(hh-mm):** _____-_____
Autopsy Done? □ Yes (date): _____ □ No □ Planned on (date): _____ (time): _____
****Attach Report (if available)**

******Only fill these next sections if it is a SERIOUS AEFI or an IMPORTANT MEDICAL EVENT or if you are UNSURE ******

RELEVANT PATIENT INFORMATION PRIOR TO IMMUNIZATION

Criteria	*Finding*	*Remarks (if yes, provide details)*
Past history of similar event	Yes / No / Unkn	
Adverse Event after previous vaccination(s)	Yes / No / Unkn	
History of allergy to vaccine, drug, or food	Yes / No / Unkn	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unkn	
History of hospitalization in last 30days, with cause	Yes / No / Unkn	
Patient currently on concomitant medication? (If yes: name the drug, indication, doses, & treatment dates)	Yes / No / Unkn	
Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unkn	

For adult women: ❀ Currently pregnant? Yes (weeks) _____ / No / Unknown ❀ Currently breastfeeding: □ Yes □ No

For infants: ❀ The birth was: □ Full-term □ Pre-term □ Post-term ❀ Birth weight: _____kg
❀ Delivery procedure was: □ Normal □ Caesarean □ Assisted (forceps, vacuum, etc) □ with complication (specify)_____

DETAILS OF FIRST EXAMINATION

Source(s) of information: □ Examination by investigator □ Documents □ Verbal autopsy (mention source) _____
□ Other (specify) _____

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Name of person who 1st examined / treated patient: _____
Name of other persons treating patient: _____
Other sources who provided information (specify): _____

****If patient has received medical care**- attach copies of all available documents (including diagnosis sheet, discharge summary, lab reports, and autopsy reports, if available) and include information not available on the attached documents)
****If patient has not received medical care**- obtain history, examine the patient and write your findings below (add additional sheets if necessary)

Provisional/ Final Diagnosis: _____

DETAILS OF VACCINES PROVIDED AT THE SITE LINKED TO AEFI ON THE CORRESPONDING DAY

Number immunized for each antigen at session site (Attach record if available)	Vaccine Name					
	Number of doses					

When was the patient immunized? □ Within the 1st vaccinations of the session □ Within the last vaccinations of the session □ Unknown

In the case of multidose vials, vaccine was given: □ Within the 1st few doses □ Within the last doses □ Unknown

Was there an error in prescribing or non-adherence to recommendations for use of this vaccine? □ Yes □ No

After investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes / No / Unable to assess
After investigation, do you feel that the vaccine's physical condition was abnormal at the time of administration (e.g., colour, turbidity, foreign substances, etc)?	Yes / No / Unable to assess
After investigation, do you feel that there was an error in vaccine reconstitution/ preparation by the vaccinator (e.g., wrong product, wrong diluent, improper mixing, improper syringe filling, etc)?	Yes / No / Unable to assess
After investigation, do you feel that there was an error in vaccine handling (e.g., break in cold chain during)?	Yes / No / Unable to assess
After investigation, do you feel that the vaccine was administered incorrectly (e.g., wrong dose, site, route needle size, not following good injection practice, etc)	Yes / No / Unable to assess
Could the vaccine given to this patient have a quality defect, or is substandard, or falsified?	Yes / No / Unable to assess
Could this event be a stress response related to immunization? (e.g., acute stress response, etc)	Yes / No / Unable to assess
Is this case part of a cluster? *** *It is compulsory for you to provide explanations for these answers separately**** • If yes, how many other cases have been detected in the cluster? _____ • Did all the cases in the cluster receive vaccine from the same vial? Yes / No / Unknown • If no, number of vials used in the cluster (enter details separately) _____	Yes / No / Unable to assess

IMMUNIZATION PRACTICES AT THE PLACE(S) WHERE CONCERNED VACCINE WAS USED (Complete this Section by Asking/ Observing Practice)

SYRINGES and NEEDLES:

- Are AD syringes used for immunization? □ Yes □ No □ Unknown
- If no, specify the type of syringes used: □ Glass □ Disposable □ Recycled disposable □ Other _____
- Specific key findings /additional observations and comments:

RECONSTITUTION: (complete only if applicable)

- Procedure:
  - Same reconstitution syringe used for multiple vials of the same vaccine? □ Yes □ No □ N/A
  - Same reconstitution syringe used for reconstituting different vaccines? □ Yes □ No □ N/A
- Are the vaccines and diluents the same as those recommended by the manufacturer? □ Yes □ No □ N/A
- Specific key findings/ additional observations and comments:

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INJECTION TECHNIQUE in Vaccinators: (observe another session in the same locality- same or different place)

- Correct dose and route Yes / No
- Time of reconstitution mentioned on vial? Yes / No
- Contraindications screened prior to vaccination? Yes / No
- Non-touch technique followed? Yes / No
- How many AEFI were reported from the centre that distributed the vaccine in the last 30 days? _____
- Training received by the vaccinator: □ No □ Yes (specify the date of last training) _____
- Specific key findings/ additional observations and comments:

COLD CHAIN AND TRANSPORT (Complete this section by asking/ observing practice)

LAST VACCINE STORAGE POINT:

- Is the temperature of the vaccine storage refrigerator monitored? □ Yes (provide details of monitoring separately) □ No
  - If "yes", was there any deviation outside of 2 – 8 °C after the vaccine was placed inside? □ Yes □ No
- Was the correct procedure for storing vaccines, diluents and syringes followed? □ Yes □ No □ Unknown
- Was any other item (other than EPI vaccines and diluents) in the refrigerator/ freezer? □ Yes □ No □ Unknown
- Were any partially reconstituted vaccines in the refrigerator? □ Yes □ No □ Unknown
- Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator? □ Yes □ No □ Unknown
- Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store? □ Yes □ No □ Unknown
- Specific key findings/ additional observations and comments:

VACCINE TRANSPORTATION:

- Type of vaccine carrier used: _____
- Was the vaccine carrier sent to the site on the same day as the vaccination? □ Yes □ No □ Unknown
- Was the vaccine carrier returned from the site on the same day as the vaccination? □ Yes □ No □ Unknown
- Was a conditioned icepack used? □ Yes □ No □ Unknown
- Specific key findings/ additional observations and comments:

COMMUNITY INVESTIGATION (Please visit locality and interview parents and/ or others)

- Were there any similar events reported within a good time period similar to when the adverse event occurred and in the same locality?
  □ No □ Unknown □ Yes, describe:_____
  _____
- If yes, how many events/ episodes? _____
- Of those effected, how many are: Vaccinated: _____ Not vaccinated: _____ Unknown: _____
- Other comments:

OTHER FINDINGS/ OBSERVATIONS/ COMMENTS

INVESTIGATOR(S) DETAILS

Name(s) with Designation(s)/ Position(s): _____
_____

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_____

Date of investigation: _____

Mobile(s): _____

Email(s):

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