RWANDA FDA
Rwanda Food and Drugs Authority
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ADVERSE DRUG REACTION/ADVERSE EVENT FOLLOWING IMMUNIZATIONREPORTING FORM

Type of Report	**Seriousness of ADR/AEFI**	**Category of Suspected Product**
Initial☐ Follow up☐	Serious☐Not Serious☐	Medical product☐ Vaccine☐

I.PATIENT INFORMATION

Patient ID/initials: _____**Gender**: Male ☐Female ☐**Weight**(kg)_____

Height (m): _____Pregnancy Status: **YES** ☐ **NO** ☐**Date of birth**: _____/____/_____

Patient Address: Village _____Cell: _____

Sector: _____District: _____ Phone Nº _____

Patient's Medical History(Provide any relevant medical history and laboratory results including dates (if done):
……
……
……
……
……

II. INFORMATION ON ADVERSE EVENT(S)

Brief description of the ADR/AEFI:

(a) Information on Onset:
Date of ADR/AEFI onset: ____ /_____/_____(dd/mm/yyyy)
Time of onset: _____/____ _/_____ (hours, Min, Sec)
Date ADR/AEFI stopped: _____ / ____/_____(dd/mm/yyyy)

(d) Adverse Event Evolution/ Outcome:
Recovered ☐ Recovering ☐ Recovered with sequelae ☐
Not recovered ☐ Congenital abnormality ☐ Death ☐ Unknown ☐

(b)Severity of the ADR/AEFI: Mild ☐ Moderate ☐ Severe ☐ Unknown ☐

Reason for seriousness: Prolonged hospitalization☐Disability ☐Congenital abnormality☐Death☐Life threatening☐

(e)Causality of the ADR/AEFI (If performed):
Certain☐Probable/Likely ☐Possible ☐Unlikely ☐Unclassifiable ☐

(c) Action Taken:
Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐Dose not changed ☐Substituted ☐Antidote ☐**Other**☐***(Specify):*** ……
……
……

(f) Optional information:
☐Therapeutic Failure *(Provide information on medicine (s) or vaccine (s) that showed lack of efficacy*……
☐Medication errors *(Provide details of medication errors)*
……

III. INFORMATION ON SUSPECTED PRODUCT

A. Details of suspected medicinal product Source/Supplier:……

Product brand name&manufacturer	**Generic name/ /Strength/ Dosage form**	**Route of Administration**	**Dose and frequency**	**Starting Date and Time**	**Stopping Date and Time**	**Batch Nº. & Expiry date**	**Indications (Reason for use)**
Other medicines used at the same time and/ or in the last one month (including herbal medicines)							

B. Details of Suspected Vaccine

Name of vaccine	**Date of vaccination**	**Time of vaccination**	**Dose (1st, 2nd, 3rd etc.)**	**Batch/Lot Nº &Expiry date**	**Diluent (if applicable)** Name of diluent	Batch/Lot Nº& Expiry date	Date & time of re-constitution

IV. REPORTER INFORMATION

Name of reporter:		Qualification:		Phone number	
Health Facility Name:		District:		Report Reference Nº	
E mail Address of Reporter:		Contact/Tel Nº:		Date of report:	

Note: Reporters and patients' identity are held in strict confidentiality by Rwanda FDA and protected to the fullest extent of the Law