Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	FDISM/PVSM
Document Type: **Form**		Doc. No : FDISM/PVSM/FOM/013
RWANDA FDA Rwanda Food and Drugs Authority	**ADVERSE DRUG REACTION / ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING FORM**	Revision Number : 02 Revision Date: : 25/07/2022 Effective Date : 13/08/2022 Review Due Date : 25/07/2025 Ref Doc. :FDISM/PVSM/GDL/002

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 N° _____

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: hospitalization☐ Prolonged hospitalization☐ Disability ☐ Congenital abnormality☐ 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Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐Dose not changed ☐Substituted ☐Antidote ☐**Other☐*(Specify):*** ……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 N°. & 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 N° &Expiry date**	**Diluent (if applicable)** Name of diluent	Batch/Lot N°& Expiry date	Date & time of re-constitution

IV. REPORTER INFORMATION

Name of reporter:		Qualification:		Phone number	
Health Facility Name:		District:		Report Reference N°	
E mail Address of Reporter:		Contact/Tel N°:		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. Once this form is completed please send it to Rwanda FDA via the following email: ***pv_sm@rwandafda.gov.rw***