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|  | Department/Division/Office/Unit |  FDISM/PVSM |
| Document Type: **Form** | Doc. No | : FDISM/PVSM/FOM/013 |
|  |  **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 |

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| **Type of Report** | **Seriousness of ADR/AEFI** | **Category of Suspected Product** |
| Initial Follow up | SeriousNot 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:** hospitalizationProlonged hospitalizationDisability Congenital abnormality Life threatening  | **(e)Causality of the ADR/AEFI (If performed):**CertainProbable/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| **(c) Action Taken:**Drug withdrawn Dose increased Dose reduced Dose not changed Substituted Antidote **Other*( Specify):***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)** |
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| **Other medicines used at the same time and/ or in the last one month (including herbal medicines)** |
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| **B. Details of Suspected Vaccine** | **Diluent (if applicable)** |
| **Name of vaccine** | **Date of vaccination** | **Time of vaccination** | **Dose (1st, 2nd, 3rd etc.)** | **Batch/Lot No****&Expiry date** | **Name of diluent** | **Batch/Lot No& Expiry date** | **Date & time of re- constitution** |
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| **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. Once this form is completed please send it to Rwanda FDA via the following email:* ***pv\_sm@rwandafda.gov.rw*** |