RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: **Standard Operating Procedure**		Doc. Number : DIS/SOP/051
RWANDA FDA Rwanda Food and Drugs Authority	Title: **REVIEW AND PROCESSING ADVERSE DRUG REACTION/ADVERSE EVENT FOLLOWING IMMUNISATION REPORTS**.	Revision Number : 0 Revision Date: : 19 May, 2021 Effective Date : 1 June, 2021 Review Due Date : 01 June, 2024

1.0 Purpose

To provide guidance for Pharmacovigilance and Food Safety Monitoring Division staff for receiving and processing of adverse drug reaction (ADR/AEFI) reports.

2.0 Scope

This Standard Operating Procedure Shall be applied to all Adverse Drugs Reactions and Adverse event following Immunizations reports received by Rwanda FDA in the Division of Pharmacovigilance and Food Safety Monitoring.

3.0 Policy

3.1 Law N° 003/2018 of 9/2/2018 establishing Rwanda FDA and determining its mission, organization and functioning.

3.2 Regulations N° CBD/TRG/016 governing pharmacovigilance of pharmaceutical products and medical devices

3.3 Rwanda FDA guidelines N° PSM/GDL/011 on Safety and vigilance of medical products and health technologies.

4.0 Definitions and Abbreviations

4.1 Definitions

4.1.1 **Pharmaceutical products**: any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions.

4.1.2 **Adverse Drug Reactions (ADRs)** means a response to a medical product that is noxious and unintended and which occurs at a dose normally used for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.

4.1.3 **Adverse event following Immunization (AEFI):** Any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the usage of the vaccine.

4.1.4 **Adverse Event** means any untoward occurrence that may present during treatment with a pharmaceutical product which does not necessarily have a causal relationship with the treatment

4.1.5 Reporters: Anyone who wishes to report any ADRs/AEFIs appeared due to the use of medicines or vaccines.

4.2 Abbreviations

4.1.2 SOPs: Standards Operating Procedures
4.1.3 Rwanda FDA: Rwanda Food and Drugs Authority
4.1.4 AEFI: Adverse event following immunization
4.1.5 ADRs: Adverse event reactions
4.1.6 SAE: Serious Adverse Events
4.1.7 **ADEs:** Adverse Drug Events

5.0 Responsibility

5.1 The Director General is responsible for the overall approval of:
i. All investigation activities due to serious ADRs/AEFIs on the field
ii. All regulatory action taken due to ADRs/AEFIs

5.2 Head of department of Food and Drugs Inspection and Safety Monitoring are responsible for:
a) Providing guidance to the Division Manager of Pharmacovigilance and Food Safety Monitoring on coordination of all activities related to the handling, review and processing of ADRs/AEFIs.
b) Approve the feedback related to received AEFI/ADR reports to the reporters

5.3 Chief Finance officer is responsible for:
a) Allocation of funds for conducting all activities related to the review and processing of ADRs/AEFI reports.

5.4 The Division managers of Pharmacovigilance and Food Safety Monitoring
a) Plan investigation activity due to received serious AEFI/ADR reports.
b) Review all causality assessment for serious ADRs/AEFIs conducted by the staff of Pharmacovigilance and Food safety Monitoring Division
c) Review the feedback related to received AEFI/ADR reports to the reporters

5.5 Analyst and Specialists are responsible for:

a) To receive and analyse all ADRs/AEFIs reports
b) To register in the database all received ADRs/AEFIs reports
c) To report all received ADRs/AEFIs reports in Vigiflow
d) To conduct a causality assessment for reported ADRs/AEFIs
e) To conduct a causality assessment for ADRs/AEFIs received from Pharmacovigilance online system (PViSM)
f) To carry out investigation for reported serious ADRs/AEFIs
g) To prepare investigation reports
h) To report to Uppsala Monitoring Center the received ADRs/AEFIs
i) To prepare feedback letter to the reporters based on conducted Causality assessment

5.6 Quality assurance Analyst

a) Ensuring that this SOP is regularly updated

6.0 Distribution

6.1 Director General

6.2 Head of Department of Food and Drugs Inspection and Safety Monitoring Department

6.3 Division Manager of Pharmacovigilance &Food Safety Monitoring Division Manager

6.4 Pharmacovigilance and post market surveillance Analyst

6.5 Pharmacovigilance and post market surveillance specialist

6.6 Quality assurance Analyst

7.0 Reference

7.1 Regulation governing Pharmacovigilance
7.2 Safety and Vigilance guidelines

8.0 Safety Precautions

NA

9.0 Materials and equipment

9.1 Adverse drug reaction/Adverse event following immunization reporting form

10.0 Procedure

10.1 PV&PMS specialist shall receive all ADRs/AEFIs reports from reporters via email, telephone, electronic reporting system and international alerts

10.2 PV&PMS specialist shall acknowledge the receipt of ADR/AEFI reported within 2days.

10.3 PV&PMS specialist shall sort medicine and vaccine related reports as “serious” or “non serious”. Serious reports are those which:

- Resulted into death
- Are life threatening (i.e. where the patient was at risk of death at the time of the reaction, not a reaction which hypothetically might have been fatal if it were more severe)
- Required inpatient hospitalization or prolongation of existing one
- Resulted into persistent or significant disability/incapacity
- Resulted into congenital anomaly/birth defect
- Others – medicines interaction reports (except well known) and medically important reactions e.g., hepatic, renal or haematological.

10.4PV&PMS specialist shall ensure that the following minimum data set has been included on the report:

- An identifiable reporter
- An identifiable patient
- An adverse reaction
- At least one suspected drug, vaccine, medical device or cosmetic product

10.5 PV&PMS specialist shall Annotate reports as those related to medicines, vaccines, cosmetics and clinical trials.

10.6 PV&PMS specialist shall ask for clarifications to the reporter in case of important missing information in the report in order to ensure the completeness of the report

10.7 PV&PMS specialist shall not consider the report if it is incomplete.

10.8 PV&PMS specialist shall log the completed ADR/AEFI report in the database.

10.9 PV&PMS specialist shall conduct a causality assessment for reported ADR/AEFI.

10.10 For serious ADRs the PV&PMS specialist shall conduct a thorough investigation

10.11 For each conducted Investigation the staff shall prepare investigation reports and submit it to the Division Manager of Pharmacovigilance and Food Safety Monitoring for review.

10.12 In case of serious AEFI investigated, the reports are compiled and submitted to the AEFI committee for conducting a causality assessment.

10.13 PV&PMS specialist shall report received ADRs/AEFIs to Uppsala Monitoring Center through Vigiflow.

10.14 PV&PMS specialist shall prepare a feedback to the reporter.

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
1/06/2021	0	QMS Specialist	First issue