RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/PV-SM division	
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RWANDA FDA Rwanda Food and Drugs Authority	Title: **Communication with stakeholders in vigilance activities**	Revision Number	:0
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1.0 Purpose

To provide a procedure for communication with stakeholders in matters related to vigilance activities of medical products

2.0 Scope

This SOP describes procedures for communication of vigilance activities, this includes internal and external communication on different safety information on medical products and the respective regulatory actions

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 Regulation CBD/TRG/016 governing pharmacovigilance of pharmaceutical products and medical devices

3.3 Guidelines PSM/GDL/011 on safety and vigilance of medical products and health technologies

4.0 Definitions and Abbreviations

4.1 **Definitions**

4.1.1 **"Marketing Authorization Holder (MAH)":** The company or legal entity in whose name the marketing authorization for a product has been granted and is responsible for all aspects of the product and compliance with the conditions of marketing authorization.

4.1.2 **"Pharmacovigilance System Master File":** A document that describes the pharmacovigilance system for one or more products of the marketing authorization holder.

4.1.3 **"Periodic Safety Update Report (PSUR)":** An update of the world-wide safety experience of a product obtained at defined times post marketing authorization. A Periodic Safety Update Report (PSUR) is a pharmacovigilance document intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points post-authorization.

4.1.4 **"Risk Management Plan":** A systematic approach and set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to products, and the assessment of effectiveness of those interventions and how these risks will be communicated to the NRAs and the general population

4.1.5 **"Internal stakeholders"** includes Rwanda FDA divisions and departments contributing to vigilance activities, this include Medicine and health technology assessment division, Drug and food inspection and compliance division, quality control Laboratory division

4.1.6 **External stakeholders** include other NRA, regional and international bodies, public and Private institutions and organizations collaborating with Rwanda FDA in matters related to vigilance activities

4.2 **Abbreviations**

4.2.1 **NMRA** : means National Medicine Regulatory Authorities
4.2.2 **PSUR** : Periodic Safety Update Report
4.2.3 **MAH** : Marketing Authorization Holder
4.2.4 **RMP** : Risk Management Plan
4.2.5 **NRA** : National Regulatory Authority
4.2.6 **PBRER** : Periodic Benefit Risk Evaluation Report
4.2.7 **PASS** : Post Authorisation Safety Studies

5.0 Responsibility

5.1 Director General of Rwanda FDA is responsible for overall approval of all communication of the vigilance activities of medical products to be shared with stakeholders

5.2 Head of department of Food and Drugs Inspection and Safety Monitoring is responsible shall review all communication of vigilance activities to stakeholders.

5.3 Division Manager for pharmacovigilance and food safety monitoring shall

- Ensure that all communication to stakeholders of the vigilance activities and decision are shared according to this SOP.
- Coordinate communication meetings and platforms while sharing of the safety information to stakeholders

5.4 Division Manager of Medicine and health technology assessment shall share relevant information from registration process with pharmacovigilance and food safety monitoring division upon request

5.5 PV PMS analyst and specialist shall

- Prepare safety information and choose appropriate communication channels to be used while communicating to stakeholders
- Plan the communication of the vigilance activities and safety information to be addressed to internal and external stakeholders.

6.0 Distribution list

6.1 Director General

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

6.3 Division Manager of Pharmacovigilance & Food Safety Monitoring,

6.4 Pharmacovigilance and post market surveillance Analyst

6.5 Pharmacovigilance and Post Marketing Surveillance specialist

6.6 Quality assurance Analyst

7.0 Reference

N/A

8.0 Safety Precautions

N/A

9.0 Materials and equipment

N/A

10.0Procedures

- PV PMS specialist and analyst shall:
  - Receive and analyse different safety information and reports on medical products from both in-country and outside the country
  - Prepare the communication on vigilance activities that include:

- The new medical product safety information
- Signals under investigation or confirmed
- Regulatory actions proposed or taken due to safety issues
- List of medical products withdrawn from the market due safety issues
- Risk management plan for medical products in the country
- Updated information from PSUR/PBRER analysis
- Finding for Pharmacovigilance inspections
- Finding from PASS/Post authorization efficacy studies
- Communication proposed or issued to the public due to safety crisis of medical products

- Division Manager for pharmacovigilance and safety monitoring shall:
  - review and submit the serious or complex cases to the National Pharmacovigilance Advisory committee for review
  - Share communication on vigilance activities and regulatory action taken to internal stakeholders by:
    - Notifying through E-mails all new safety information and Dear Healthcare communication within 24 hours
    - Distributing Signal under investigation or confirmed, Medicine safety bulletin published, Medicine withdrawn from market due to safety issues through letters within 48 hours
    - Organising and chairing on monthly basis Inter-department meeting on New safety information, Signal under investigation or confirmed, Medicine safety bulletin published, Medicine withdrawn from market due to safety issues, RMP adjustment, Regulatory actions recommended by the National Pharmacovigilance advisory committee, Regulatory actions taken on medical products by other NRA
    - Planning Peer committee meeting and/or Licensing committee whenever deemed necessary
  - Propose the vigilance information to be published on website
  - Share with external stakeholders signals under investigation or confirmed by Rwanda FDA, regulatory actions taken due to safety issues, list of medical products withdrawn from the market due safety issues, risk management plan for medical products in the country, communication issued to the public due to safety crisis of medical products through:

- Notification letters transmitting new safety information published, signal under investigation or confirmed, medicine withdrawn from market due to safety issues within 48 hours from approval
- Distributing published medicine safety bulletin on a regular basis and not later than one month after publication

11.0Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
01/06/2021	0	PV & PMS Specialist	First issue