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/050
RWANDA FDA Rwanda Food and Drugs Authority	Title: **SHARING DATA AND SAFETY INFORMATION OF REGULATED PRODUCTS**	Revision Number : 0 Revision Date: : 18 May 2021 Effective Date : 1 June 2021 Review Due Date : 01 June ,2024

1.0 Purpose

The purpose of this SOP is to ensure that Rwanda FDA staff and stakeholders share data and safety information of regulated products within the country and other NMRAs in a consistent manner..

2.0 Scope

This SOP applies to all signals generated by Rwanda FDA. It also applies to Individual Case Safety Reports (ICSR), Serious Adverse Events (SAE) from Phase IV Clinical Trials, Suspected Unexpected Serious Adverse Events (SUSARs), periodic report of safety data analysis when requested by another national regulatory authority (NRA) or deemed necessary to be shared to other stakeholders.

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^{O} 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 **Stakeholders:** The stakeholders include pharmaceutical industries, MAH, wholesale pharmacies, retail pharmacies, health facilities, research institution(s), contract research organisations (CROs), Public Health Programs, Central Medical Stores health professional bodies and the general public.

4.2 Abbreviations

4.2.1 NRAs: National Regulatory Authorities

4.2.2 SOPs: Standards Operating Procedures

4.2.3 Rwanda FDA: Rwanda Food and Drugs Authority

4.2.4 ICSR: Individual Case Safety Reports

4.2.5 **SAE:** Serious Adverse Events

4.2.6 CROs: contract research organisations

4.2.7 **SUSARs:** Suspected Unexpected Serious Adverse Events

4.2.8 **MAHs:** Marketing authorisation holders

5.0 Responsibility

5.1 The Director General is responsible for the overall approval of sharing data and safety information of regulated products

5.2 Head of department of Food & Drugs Inspection and Safety Monitoring and division manager of Pharmacovigilance and food safety monitoring are responsible for:

a) Ensuring that this SOP is correctly and consistently implemented during the process of sharing data and safety information of regulated products to others NRAs or Stakeholders.

b) Reviewing and providing regulatory guidance before data and safety information is received and/or shared.

5.3 Pharmacovigilance and post market surveillance Analyst and Pharmacovigilance and post market surveillance Specialists are responsible for:

a) Complying with this SOP whenever reviewing or sharing safety information of regulated products

b) check and compile safety data and information related to the specific medical product (s) and other regulated products received.

c) Preparing feedback for the received safety data and information.

4.4 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

6.3 Division Manager of Pharmacovigilance & Food Safety Monitoring,

6.4 Pharmacovigilance and post market surveillance Analyst

6.5 Pharmacovigilance and post market surveillance specialists

6.6 Quality assurance analyst

7.0 Reference

Cooperation Framework Agreement for EAC Partner States National Medicines Regulatory Authorities, Final Draft April 2018

6.2 European Commission, Mutual Recognition Revision 5

8.0 Safety Precautions

NA

9.0 Materials and equipment

ADR/AEFI reporting form No PSM/FOM/008

AEFI Investigation form No DIS/FOM/059

10.0 PROCEDURES

10.1 Sharing information from detected signals

10.1.1 PV/PMS specialist /analyst will check and compile safety data and information related to the specific medical product (s) and other regulated products received locally.

10.1.2 PV/PMS specialist and Analyst will analyse safety data and information

received and share any signal detected with other NRAs or stakeholders

10.1.3 The received safety data and information, after analysis, shall be used to take and communicate regulatory actions for public health protection.

10.1.4 In case the concerned NRA requires clarifications, such information shall be requested by mail to Rwanda FDA.

10.1.5 The information shared is confidential unless it is agreed that information is public and non-confidential.

10.2 Request of information from signals detected by stakeholders and NRA

10.2.1 PV/PMS specialist shall write a letter to the concerned NRA or other stakeholders requesting safety data and information of specific regulated products.

10.2.2 after reception of safety data and information, PV/PMS specialist shall send an acknowledgement letter via email to the concerned NRA or other stakeholders.

10.2.3 PV/PMS specialist/Analyst will analyse the safety data and information of specific regulated products received from other NRA or stakeholders and publish any signal detected.

10.2.4 The received safety data and information, after analysis, shall be used to take and communicate regulatory actions for public health protection.

10.0 Document Revision History

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Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
…/…/2021	0	QAA	First issue