RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
Document Type:**Standard Operating Procedure**		Doc. Number	:DIS/SOP/
RWANDA FDA Rwanda Food and Drugs Authority	Title: **PREPARATION AND COMMUNICATION OF MEDICINE SAFETY INFORMATION**	Revision Number	:0
		Revision Date:	:24/05/2021
		Effective Date	:01/06/2021
		Review Due Date	:01/06/2024

1.0 Purpose

This SOP is to provide procedures for preparation and communication of drug safety information to the public and stakeholders.

2.0 Scope

This SOP applies to drug safety information published by Rwanda FDA

3.0 Policy

3.1 Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning

3.2 Rwanda FDA Guidelines for safety and vigilance of medical products and health technologies

4.0 Definitions and Abbreviations

"Stakeholders" including Academic researches, Local technical representatives, Hospitals, Retail and district pharmacies, Central medical store, Rwanda Biomedical Center, Ministry of Health, Veterinary association, National Pharmacy council, Ethics committees, Medical representative Association, Consumer Association, Food and Drugs local manufacturers, and Contracted Research Organizations

"General public" means a person other than healthcare professionals

5.0 Responsibility

5.1 Director General is responsible for the overall approval of drug safety information before any publication.

5.2 Heads of departments of food & Drug inspection and Safety monitoring is responsible for providing guidance on the drug safety information to be shared.

5.3 The Division manager is responsible for reviewing and analyzing information used in drug safety information

5.4 Drug products information and advertisement specialist is responsible for drafting drug safety information to be reviewed by supervisors.

5.5 Quality Assurance Analyst ensure that this sop is regularly updated

6.0 Distribution

6.1 Director General

6.2 Head of Department of food &Drug inspection and Safety monitoring Department

6.3 Division Manager of Pharmacovigilance& Food Safety monitoring

6.4 Drug products information, promotion and advertisement officer

6.5 Quality assurance analyst

7.0 Reference

7.1 WHO pharmaceuticals newsletters

8.0 Safety Precautions

NA

9.0 Materials and equipment

NA

10.0 PROCEDURES

10.1 Drug product information, promotion and advertisement specialist shall

10.1.1 Gather information and data around the identified topic at global, regional and national level depending on the relevance of information to be communicated and the target audience.

10.1.2 identify and develop an important information to be communicated to the healthcare professionals and to the general public from medicinal products related issues raised by community or safety information published by WHO, European Medicine Agency or any tangible source of information

10.1.3 Develop the safety information by highlighting: literature review, information to the healthcare professionals; patients and marketing authorisation holders aiming at protecting general public as component to the rational use of medical products

10.1.4 Write safety information in Kinyarwanda and any other official language used in Rwanda.

10.1.5 Disseminate the approved safety information to the public through all possible communication channels.

10.2 Division manager of Pharmacovigilance and Food safety monitoring shall:

10.2.1 Review the safety information and submit it to Head of Food and Drugs Inspection and safety monitoring department for further review.

10.2.2 Supervise dissemination of medicine safety information to the target audience.

10.3 Head of Food and Drugs Inspection and safety monitoring department shall:

Review and provide regulatory guidance on the safety information received from the Division manager of Pharmacovigilance and Food safety monitoring and submit it to Director General for approval.

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16/11/2020	0	QMS Specialist	First issue