RWANDA FOOD AND DRUGS AUTHORITY	Food and Drugs Inspection and Safety Monitoring Department	Pharmacovigilance and Food Safety Monitoring Division	
Document Type:**Standard Operating Procedure**		Doc. Number	: DFC/SOP/00
RWANDA FDA Rwanda Food and Drugs Authority	Title: **RISK-BASED SAMPLING OF MEDICAL PRODUCTS FROM DIFFERENT POINTS OF THE SUPPLY CHAIN.**	Revision Number	:0
		Revision Date:	:24 May 2021
		Effective Date	:1 June 2021
		Review Due Date	: 1 June 2024

1.0 Purpose

This standard operating procedure (SOP) provides guidance for conducting effective, affordable and sustainable medicines sampling process for post-marketing surveillance purposes.

2.0 Scope

This Standard Operating Procedure applies to all routine post marketing surveillance sampling aiming to constantly balance the risks and benefits of medicines on Rwanda market.

3.0 Policy

3.1 Law Nº 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

PV & FSM: Pharmacovigilance and Food Safety Monitoring

5.0 Responsibility

5.1 Director General is responsible for approval of all sampling plan and sampling activities

5.2 Head of Food and Drugs Inspection and Safety Monitoring Department is responsible to ensure that this procedure is adhered to

5.3 Division managers for Pharmacovigilance and Food Safety Monitoring and Quality Control laboratory are responsible for preparation of annual sampling plan

5.4 PV PMS analyst and specialist are responsible for conducting all sampling activities

6.0 Distribution

6.1 Director General
6.2 Head of Food and Drugs Inspection and Safety Monitoring Department
6.3 Division Managers,
6.4 PV PMS Analyst
6.5 PV PMS specialists
6.6 Quality Assurance Analyst

7.0 Reference

1.1 Standard Procedure for Inspection of Retail and Wholesale Pharmacy (Post-Marketing Surveillance), Directorate General of Drug Administration (DGDA, Bangladesh)
1.2 Nkansah P.et al. Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries. 2017. U.S. Pharmacopeial Convention. The Promoting the Quality of Medicines Program.

8.0 Safety Precautions

NA

9.0 Materials and equipment

9.2 Post Marketing Surveillance Sample collection form
9.3 Minutes form/PV de Constant
9.4 Test request form

10.0 PROCEDURES

10.1.1 Division managers and analysts shall establish a list of medicines to be sampled for further testing based on pharmaceutical sector assessment
10.1.2 Division managers and analysts shall determine geographical area and sample collection sites in which sampling activities will be conducted. Sample collection site shall include points of entry to the market such as warehouses of importers or

manufacturers, central medical stores and decentralised level of distribution in both private and public sector.

10.1.3 PV PMS analyst shall develop sampling protocol and sampling plan

10.1.4 PV PMS specialists shall carry out sampling activities

10.1.5 PV PMS specialists shall examine each sampling unit and its packaging to ensure that it is intact

10.1.6 PV PMS specialists shall not collect products with damaged containers or those found to be non-uniform.

10.1.7 PV PMS specialists shall reject unlabelled sampling units.

10.1.8 PV PMS specialists shall collect only sample that have at least six months until expiry to allows testing before the product expires

10.1.9 PV PMS specialists shall consider the following important criteria during the sampling process:

- Each sample will be properly labelled with appropriate details, which at minimum includes the type of product, batch number, and date of sample collection
- The sampling process should be properly documented using the sample collection form
- The container used to store the sample should be labelled with sample type, name of material, sample code (if applicable), batch/lot number, quantity, date of sampling, storage conditions, and handling precaution

10.2.1. PV PMS specialists shall ensure compliance with manufacturer's storage conditions of each medicine sampled from collection sites to the location where quality testing will occur.

10.2.2. PV PMS specialists shall take a sample at central medical store to determine the effect of transportation on the medicines if a quality failure is observed at decentralised distribution level.

10.2.3. PV PMS specialists shall submit collected sample to quality control laboratory using well filled in test request form and

10.2.4. PV PMS specialists shall ensure that the labelling is in conformity with the information provided in test request form with the Quality control laboratory or laboratories.

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
24/05/2021	0	PV & PMS Specialist	First issue