RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Pharmacovigilance and Food Safety Monitoring Division	
Document Type: **Standard Operating Procedure**		Doc. Number	: DIS/SOP/
RWANDA FDA Rwanda Food and Drugs Authority	Title: **PREVENTION AND DETECTION OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**	Revision Number	:0
		Revision Date:	:20/05/2021
		Effective Date	:01/06/2021
		Review Due Date	:01/06/2024

1.0 Purpose

1.1 The objective of this SOP is to define the procedure for detection and prevention of substandard and falsified medical products on the market of Rwanda.

2.0 Scope

The scope of this SOP shall apply to all regulated products that are manufactured, imported, distributed, stored, sold and used in Rwanda.

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/018 governing post market surveillance of regulated products

3.3 Guidelines for Post Marketing Surveillance of pharmaceutical products N° PSM/GDL/015

4.0 Definitions and Abbreviations

4.1 **Substandard medical products**: Also called "out of specification", these are authorized Pharmaceutical products that fail to meet either their quality standards or their specifications, or both.

4.2 **Falsified medical products:** that deliberately/fraudulently misrepresents their identity, composition or source.

4.3 **Suspected poor quality products**: Pharmaceutical products with suspicious on its quality due to the following factors such such as color/odor change, molding, turbidity, mislabelling,poor packaging/ lack of patient leaflet/ lack measuring devices,therapeutic ineffectiveness, particulate matter, seal integrity of packs and/ or leakage, caking, sedimentation, incomplete packs, powdering/crumbling, suspected falsified/ substandard and other physical properties defect that can be specified by reporters.

4.4 **Reporters:** Anyone who wishes to report to the Authority any suspected poor quality medical products due to suspicious on the quality of pharmaceutical products.

5.0 Responsibility

5.1 The Director General is responsible for the overall approval of decisions to be taken due confirmed substandard and falsified medical products

5.2 Head of department of Food and Drugs Inspection and Safety Monitoring are responsible for:

a) Advise Division Manager of Pharmacovigilance and Food Safety Monitoring on different proposed regulatory action based on the analysis and investigation for a given substandard and falsified medical products detected
b) Approval of all activities related to the investigation, analysis and inspection for detected substandard and falsified medical products.

5.3 Chief Finance officer is responsible for:

a) Allocation of funds related to the investigation and inspection for a reported substandard and falsified medical product

5.4 The Division managers of Pharmacovigilance and Food Safety Monitoring

a) Review of all activities of the Division of Pharmacovigilance and Food Safety Monitoring related to the investigation analysis and inspection for reported substandard and falsified medical products
b) Coordination of all investigation, analysis and inspection for all reported substandard and falsified medical products
c) Review of all reports of investigation and inspection for reported substandard and falsified medical products.

5.5 The Division manager of Quality Control Laboratory Division

a) To ensure the quality control tests on the samples obtained using validated and/or approved methods;
b) To provide evidence based test results to inform regulatory action against identified substandard products.

5.6 Analysts and Specialists are responsible for:

a) To receive and analyse all reports of suspected poor quality product reported as substandard and falsified medical products

b) Conducting a physical verification for all medical products that are going to be imported and exported at the port of entry by the port of entry specialists
c) To conduct investigation and inspection based on the reported substandard and falsified medical products
d) To Develop sampling protocol and sampling plan;
e) To carry out sampling of selected products;
f) To prepare report of activities conducted on each received report of substandard and falsified medical products
g) To conduct customer complaint survey in order to identify products to be included in sampling plan
h) To inspect the implementation of a regulatory action taken.

6.0 Distribution

6.1 Director General
6.2 Heads of Department
6.3 Chief of Finance Officer
6.4 Division Managers
6.5 Analysts and Specialists

7.0 Reference

N/A

8.0 Safety Precautions

N/A

9.0 Materials and equipment

9.1 Suspected poor quality product reporting form
9.2 Post Marketing Surveillance Sample collection form
9.3 Check list for physical inspection of medicines to early detect and prevent SF medical products
9.3 Minutes form/PV de Constat
9.4Email box of Pharmacovigilance and Food safety Monitoring Division **pv_sm@rwandafda.gov.rw**

10.0 PROCEDURES

10.1 Pharmacovigilance and Post Marketing Surveillance Specialist shall receive all reports related to substandard and falsified medical products via email, telephone, electronic reporting system, and international alerts.

10.2 At the port of entry, Port of entry specialist shall conduct a physical verification for each imported and exported medical products to early detect and prevent substandard and falsified medical products

10.3 Pharmacovigilance and Post Marketing Surveillance Specialist shall Conduct deep investigation for all received reports of substandard and falsified medical products so that final action should be taken based on the findings of investigation

10.4 Pharmacovigilance and Post marketing surveillance specialist shall prepare the report of substandard and falsified medical products investigated.

10.5 Pharmacovigilance and Post marketing surveillance analyst shall prepare annual sampling plan

10.6 Pharmacovigilance and Post marketing surveillance Specialist shall carry out sampling activities based on sampling plan

10.7 Pharmacovigilance and Post marketing surveillance Specialist shall send the sampled medical products to the Quality control laboratory tests.

10.8 Quality control laboratory shall ensure the quality control tests on the samples obtained using validated and/or approved methods;

10.9 The Authority shall take regulatory action based on quality control laboratory test results

10.10 Pharmacovigilance and Post marketing surveillance Specialist shall conduct quarterly customer complaint survey activity

10.11 Pharmacovigilance and Post marketing surveillance Specialist shall regularly Conduct inspection to enforce the implementation of regulatory action within pharmaceutical establishment

11.0 Document Revision History

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Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
20/05/2021	0	QMS Specialist	First issue