| RWANDA FOOD AND DRUGS AUTHORITY | Department/Division/ Directorate | Pharmacovigilance and Food Safety Monitoring Division | |
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| Document Type:**Standard Operating Procedure** | | Doc. Number | : DIS/SOP/052 |
| RWANDA FDA<br>Rwanda Food and Drugs Authority | Title:<br>**HANDLING SUSPECTED POOR QUALITY PHARMACEUTICAL PRODUCTS REPORT** | Revision Number | :0 |
| | | Revision Date: | :19 March 2021 |
| | | Effective Date | :01 June 2021 |
| | | Review Due Date | :01 June 2024 |

## 1.0 Purpose

1.1 The objective of this SOP is to define the procedure for detection and management of suspected poor quality products. All the complaints must be carefully reviewed and actions must be taken to avoid its recurrence. The objective is to provide a method to be followed in case of any suspected poor quality products occurred.

## 2.0 Scope

The scope of this SOP applies to handling of all suspected poor quality products report of medical products.

## 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 **Pharmaceutical products**: any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions.

4.2 **Noncompliant product:** on registered products or noncompliant with specifications including substandard and falsified products.

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

4.4 **Unregistered/unauthorised Pharmaceutical products:** Pharmaceutical products that have not undergone evaluation and/or approval by the Rwanda FDA for the market in which they are marketed/distributed or used, subject to permitted conditions under national regulation and legislation.

4.5 **Falsified Pharmaceutical product**: that is deliberately/fraudulently misrepresented their identity, composition or source.

4.6 **Suspected poor quality products**: Pharmaceutical products with suspicious on its quality due to the following factors such as colour/odour 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.

4.7 **Reporters:** Anyone who wishes to report to Rwanda FDA any suspected poor quality products due to suspicious on the quality of medical products

4.8 **Market complaint:** Any written, electronic or oral communication that alleges defect/ deficiency related to quality, safety, efficacy or effectiveness of a medical product.

4.9 Market complaints shall be categorized as critical, major or minor.

i. **Critical-** Complaints related to defective products that are potential life threatening or the use of products could result in serious health risk/adverse events or even death. (e.g., wrong product label and contents are different, correct product but wrong strength)

ii. **Major-** Complaints that can result in illness or mistreatment but are not life-threatening e.g., chemical/physical contamination

iii. **Minor**- Complaint which may not pose significant health hazard e.g., damage to containers

## 5.0 Responsibility

5.1 The Director General is responsible for the overall approval of decisions taken due to suspected poor quality products

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

a) Advise Division Manager of Pharmacovigilance and Food Safety Monitoring on different proposed regulatory action based on the analysis and investigation of a given suspected poor quality products

b) Approval of all activities related to the investigation, analysis and inspection for a given Suspected poor quality products.

5.3 Chief Finance officer is responsible for:

a) Allocation of funds related to the investigation and inspection for a given suspected poor quality products

5.4 The Division manager of Pharmacovigilance and Food Safety Monitoring

a) Review of all activities related to the investigation analysis and inspection for a suspected poor quality products
b) Coordination of all investigation, analysis and inspection for a received suspected poor quality products
c) Review of all reports of investigation and inspection for a given suspected poor quality 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 PV&PMS Analysts and Specialists are responsible for:

a) To receive and analyse all suspected poor quality product reports
b) To ensure the completeness of the report and request additional information if deemed necessary
c) To record any complaints received in a database
d) To conduct investigation and inspection based on the received suspected poor quality products
e) To carry out sampling of the suspected medical products reported
f) To report on all activities conducted of received suspected poor quality products to the Division Manager of Pharmacovigilance and Food Safety Monitoring

g) 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 Office
6.4 Division Managers
6.5 Analysts and Specialists

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## 7.0 Reference

N/A

## 8.0 Safety Precautions

NA

## 9.0 Materials and equipment

9.1 Suspected poor quality product reporting form

9.2 Post Marketing Surveillance Sample collection form

9.3 Minutes form/PV de Constant

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 and review all product suspected poor quality products/ reports via email, telephone, electronic reporting system, international alerts.

10.2 Pharmacovigilance and Post Marketing Surveillance Analyst shall categorize the complaint in respect to the type of product (medical product, medical devices or intro-diagnostics).

10.3 Pharmacovigilance and Post Marketing Surveillance Specialist shall log the complaint reports in the database.

10.4 Pharmacovigilance and Post Marketing Surveillance Specialist shall acknowledge the receipt of suspected poor quality products/report, within 2 working days.

10.5 Pharmacovigilance and Post Marketing specialist shall review and conduct deep investigation of the reported suspected poor quality products

10.6 PV&PMS specialist shall conduct investigation activities by collecting evidence of the reported complaints such as additional information from the reporter, supplier, MAH/LTR or manufacturer, samples of the reported products, sent the collected samples to the quality control laboratory for analysis.

10.7 Pharmacovigilance and Post marketing Surveillance specialist shall prepare the report of investigation for suspected poor quality products and submit it to the Division Manager of Pharmacovigilance and Food Safety monitoring.

10.8 Based on the findings of investigation of reported suspected poor quality products, regulatory actions shall be taken and be communicated to the public and other stakeholders.

10.9 Pharmacovigilance and Post Marketing Surveillance Specialist shall document progress of regulatory actions and closure of the suspected poor quality products file.

10.10 A summarized list of all suspected poor quality products received will be prepared annually by Pharmacovigilance and Post Marketing Surveillance Analyst and include respective regulatory actions which were taken for each suspected poor quality products.

10.11 The report of annually summarized list of all suspected poor quality products will be sent to the 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 |