RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR POST-MARKETING SURVEILLANCE OF PHARMACEUTICAL PRODUCTS

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FORWARD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. According to the law, especially in its article 8 paragraph 9, the authority is mandated to conduct pharmacovigilance and post-marketing surveillance for quality of products regulated.

These guidelines were developed, reviewed and adopted in order to provide guidance to the Authority, stakeholders, and other interested parties in carrying out surveillance activities related to the monitoring of the quality and safety of pharmaceutical products placed on the Rwandan market. The implementation of these guidelines helps the Authority to respond to public health threats posed by substandard and falsified medical products.

It also provides guidance on how to disseminate information about pharmaceutical product quality to health professionals, stakeholders, and other interested parties.
The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Based on the provisions of the regulations No.: CBD/TRG/018 governing Post-marketing surveillance of regulated products as well as the requirement of the established Quality Management System, the Authority, issues the Guidelines No.: FDISM/PVSM/GDL/003 Revision-01 on Post marketing surveillance of Pharmaceutical products.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

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30/09/2022	01	1. Editorial and formatting changes were made as needed in accordance with the current document control SOP 2. Strategies for prevention, detection and response to SF medical products were included 3. Post Marketing Surveillance Screening Form was included

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ABBREVIATIONS

1. PMS : Post Marketing Surveillance.
2. RB-PMS : Risk Based Post Marketing Surveillance.
3. RBPMS-TC : Risk Based Post Marketing Surveillance Technical Committee
4. MedRS tool : Medicines Risk Based Surveillance Tool.
5. SF : Substandard and Falsified medical products.
6. GMP : Good Manufacturing Practices
7. ISO/IEC : International Standardization Organization and International Electro technical Commission
8. PQM : Promoting the Quality of Medicines
9. USAID : United States Agency for International Development
10. Rwanda FDA : Rwanda Food and Drugs Authority
11. WHO : World Health Organization
12. SOP : Standard Operating Procedures
13. QA : Quality Assurance
14. MAH : Marketing Authorization Holder

DEFINITIONS

Authority: Rwanda Food and Drugs Authority (Rwanda FDA)

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. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

Unregistered/unlicensed/unauthorised Pharmaceutical products: Pharmaceutical products that have not undergone evaluation and/or approval by the Authority for the market authorization, subject to permitted conditions under national regulation and legislation;

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;

Falsified Pharmaceutical products: Pharmaceutical products that deliberately/fraudulently misrepresent their identity, composition or source;

Non-compliant products: Non-registered products or non-conform with specifications including substandard and falsified products;

Post-marketing surveillance : Surveillance activities that occur following market approval of a medicine, including: maintenance of product authorization and/or registration of variations or renewals; control of import and export of medical products, regular inspections of manufacturers, wholesalers, distributors, and retailers; quality control testing; pharmacovigilance; promotion control; public reporting of poor- quality products; handling of market complaints; and removal and disposal of non-compliant products.

Risk based Post Marketing surveillance: Post Marketing Surveillance using Several criteria to define a risk-based programme of control by considering different types of risks in relation with the four risk dimensions: Medicines risk, Region risk, city risk and facility risk.

CHAPTER ONE: INTRODUCTION

The burden of substandard and falsified medicinal products is a global public health problem causing loss of confidence in health systems leading to treatment failure, increase of treatment cost and may lead to drug resistance, disability, injury and/or death. The estimated burden of substandard and falsified (SF) pharmaceutical products within the East African region is not known but around 10% of globally traded medicines are estimated to be falsified with an even higher number in low-income countries[1].

Ensuring that Pharmaceutical products available to the patients are of good quality and maintaining the quality throughout the supply chain requires a robust quality assurance (QA) system. The regulatory system is an important component of QA. The provisions of the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA as competent regulatory Authority, the mission of the Authority is to "regulate pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs, food supplements, food fortificants, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use by ensuring that Pharmaceutical products are safe and of good quality". An effective PMS system requires strong legislation, transparency, accountability, adequate human and financial resources, structured PMS planning, adequate quality control capacity, mechanisms for managing and communicating results and taking regulatory actions.

1.1.Scope of PMS guidelines

These guidelines cover all surveillance activities related to the planning, implementation, monitoring, and reporting of the quality and safety of pharmaceutical products placed on the Rwandan market while taking appropriate regulatory actions.
They also cover activities related to the implementation of a risk-based post-marketing surveillance approach to prevent, detect, and respond to threats caused by substandard and falsified (SF) medical products for public health protection.

1.2.Purpose of the PMS guidelines

The purpose of these Post-marketing guidelines is to establish a PMS system, develop a PMS plan, implement the plan and generate report for PMS activities for pharmaceutical products.

The Authority strives to build a strong PMS program that is comprehensive, inclusive, efficient, and sustainable. It will put in place the processes and use the tools and the resources that will help to implement the PMS program. The Authority will aspire to continuously monitor and evaluate the efficiency of the PMS activities implementation and make necessary changes and adjustments to meet obligations toward ensuring that the medicines available to the patients are safe and of good quality.

Effective implementation of PMS guidelines will enable the Authority to generate scientific evidence on the quality and safety of pharmaceutical products for improved health outcomes.

1.3. OBJECTIVES OF POST MARKETING SURVEILLANCE

1.3.1. General Objectives

Post-marketing surveillance of Pharmaceutical product quality is implemented to safeguard access of the public to quality products by early detecting, preventing and removing non-compliant pharmaceutical products and taking appropriate regulatory actions. PMS activities also allow periodic diagnosis of the Pharmaceutical quality assurance (QA) system that is in place to identify any gaps.

1.3.2. Specific objectives

PMS activities are carried out to:

a) Evaluate the quality of Pharmaceutical products available throughout the supply chain;
b) Remove non-compliant products from the market;
c) Initiate actions to address the source cause of noncompliant products;
d) Prevent non-compliant products from entering the supply chain;
e) Identify gaps in the quality assurance system

CHAPTER II: ORGANISATION OF POST MARKETING SURVEILLANCE SYSTEM

2.1.Strategies for Post-Marketing Program

The Authority's strategies for PMS system include but not limited to the following:

a) Control importation /exportation of products at the port of entry: this includes physical verification of documents and products, visual inspection, screening of products and sampling for compendia testing whenever necessary.
b) Receiving reports on suspected poor quality products and conducting deep investigation on received reports
c) Sampling and testing of products available in the supply chain of pharmaceutical products.
d) Take appropriate regulatory action as result of PMS activities

2.2.PMS program structure, roles and responsibilities

The structure of PMS program is composed with the Authority, Risk Based Post Marketing Surveillance technical committee and PMS stakeholders with the following role and responsibilities:

2.2.1. Regulatory Authority

The regulatory Authority coordinates all Post-marketing surveillance activities through respective divisions and units which include but not limited to the following:

a) To control importation and exportation of pharmaceutical products
b) To conduct quality control tests on the samples obtained using validated and/or approved methods;
c) To provide evidence-based test results to inform regulatory action against identified substandard products.
d) To develop sampling protocol and sampling plan;
e) To carry out sampling of selected products at different points of the supply chain including ports of entry and exit;
f) To report on PMS activities;
g) To conduct customer complaint survey, identify products to be included in the PMS sampling plan;
h) To inspect the implementation of a regulatory action taken like product recalls and products in quarantine;
i) To analyse and follow up on reports related to suspected poor quality pharmaceutical products.
j) To take and implement appropriate regulatory actions as results of PMS activities depending on the risk/benefit reported.

2.2.2. Risk-Based Post marketing surveillance technical committee

The Risk Based-PMS Technical committee (RB-PMS-TC) will be constituted of individuals with

technical as well as management expertise in health products and technologies quality control and market surveillance. Members will be drawn from those who actively participate in the medicine's quality and related issues. They should be competent enough to be involved in the planning of sampling, development of testing protocols, implementing, sampling, and testing activities, reporting and dissemination of information for medicines quality surveys conducted.

The RB-PMS-TC will be constituted of 20 to 30 members with representation from the Authority, public health programmes, private and public stakeholders.

The committee has the following roles and responsibilities:

a) Provide technical inputs, develop guidance documents and protocols for PMS activities in Rwanda.
b) Determine priorities and sampling plans for annual PMS rounds
c) Implement sampling activities
d) Develop, validate and send RB-PMS reports to the Authority in a timely and coordinated manner to disseminate to stakeholders
e) Monitor regulatory actions taken as a results of PMS findings
f) Monitor progress on implementation of PMS activities in Rwanda
g) Provide quality related recommendations to the Authority
h) Provide recommendations on actions to be taken on non-compliant Pharmaceutical products.

2.2.3. Post Marketing Surveillance stakeholders

The PMS stakeholders include Ministry of Health, Regional and International Organisations (WHO, EAC,...),pharmaceutical industries, MAH, pharmacy wholesalers, retail pharmacies, health facilities, universities, Research institution(s), Public Health Programs, Central Medical Store ,development partners , Health Professional bodies Organisations, media, enforcement organs such Ministry of Health, Rwanda National Police (RNP), Rwanda Investigation Bureau (RIB), Interpol,, Rwanda Revenue Authority (Customs Services) Rwanda Revenue Authority) Complementary and alternative medicine practitioners, etc.

All PMS stakeholders have the responsibilities which include but not limited to the following:

a) To report any suspected or confirmed poor quality pharmaceutical product to the Authority using the reporting form No**. FDISM/PVSM/FOM/016;**
b) To implement any regulatory action taken by the Authority as result of PMS activities;
c) To submit research protocol related to post-marketing survey or study for approval. The results from the survey or study shall be submitted to the Authority before publication.

2.3.Planned Post-Marketing surveillance activities

The Authority will design and implement at least once year a periodic post-marketing surveillance plan targeting selected pharmaceutical products using a risk-based approach. The periodicity of PMS

activities will be determined based on quality-related information previously collected and/or according to the needs that may arise. The Authority shall conduct PMS activities for Public Health Programs sponsored by development partners.

PMS activities for Health Programs could be planned and carried out in conjunction with other PMS activities for maximum effectiveness and resource management. These PMS activities should be encapsulated in a single protocol.

2.4. Management of Ad hoc PMS activities

In addition, the Authority may conduct impromptu PMS activities where sample and tests may be performed on pharmaceutical products in response to complaints from health professionals or consumers about efficacy or apparent adulteration.

It may also sample and test products that have been linked to serious adverse events.

If the facility inspected raises concerns, Rwanda FDA inspectors may collect samples at the inspection site.

2.5. Surveys/studies by external parties

The Rwanda FDA is the only entity mandated to regulate drugs' PMS activities in the country. The Authority will participate in the development, review of protocols and approval for studies/surveys on Pharmaceutical products quality sponsored by external parties (Universities and Non-Governmental Organizations). The Authority shall ensure proper implementation of the protocols and the approval of study reports before publication.

2.6. Implementing teams

Inspectors from the Authority are in charge of sampling pharmaceutical products according to a predefined sampling plan. However, the Authority may delegate some sampling activities to other delegated and trained staff from stakeholders or other collaborative institutions when deemed necessary. During the PMS activities, each sampling team will include at least one inspector from the Authority inspector.

CHAPTER III: IMPLEMENTATION OF PMS USING RISK-BASED APPROACH

A risk-based approach to post market surveillance is a method, which concentrates limited resources on the areas considered most likely to pose a risk of quality defects due to limited resources. PMS is one of the most challenging regulatory functions to implement, which calls for close collaboration within the regulatory authority and among the authority and stakeholders.

Considering that the number of Pharmaceutical products available on the market is very large, the high cost of sampling and testing, risk of products, risk of the region to SF products and the human resource needed, it is not conceivable to control the quality of all products on the market.

The use of a risk-based approach in the implementation of PMS has become mandatory. The Authority implements a risk-based PMS (RB-PMS) approach at all levels, from planning to sampling, testing, and regulatory action according to the below diagram.

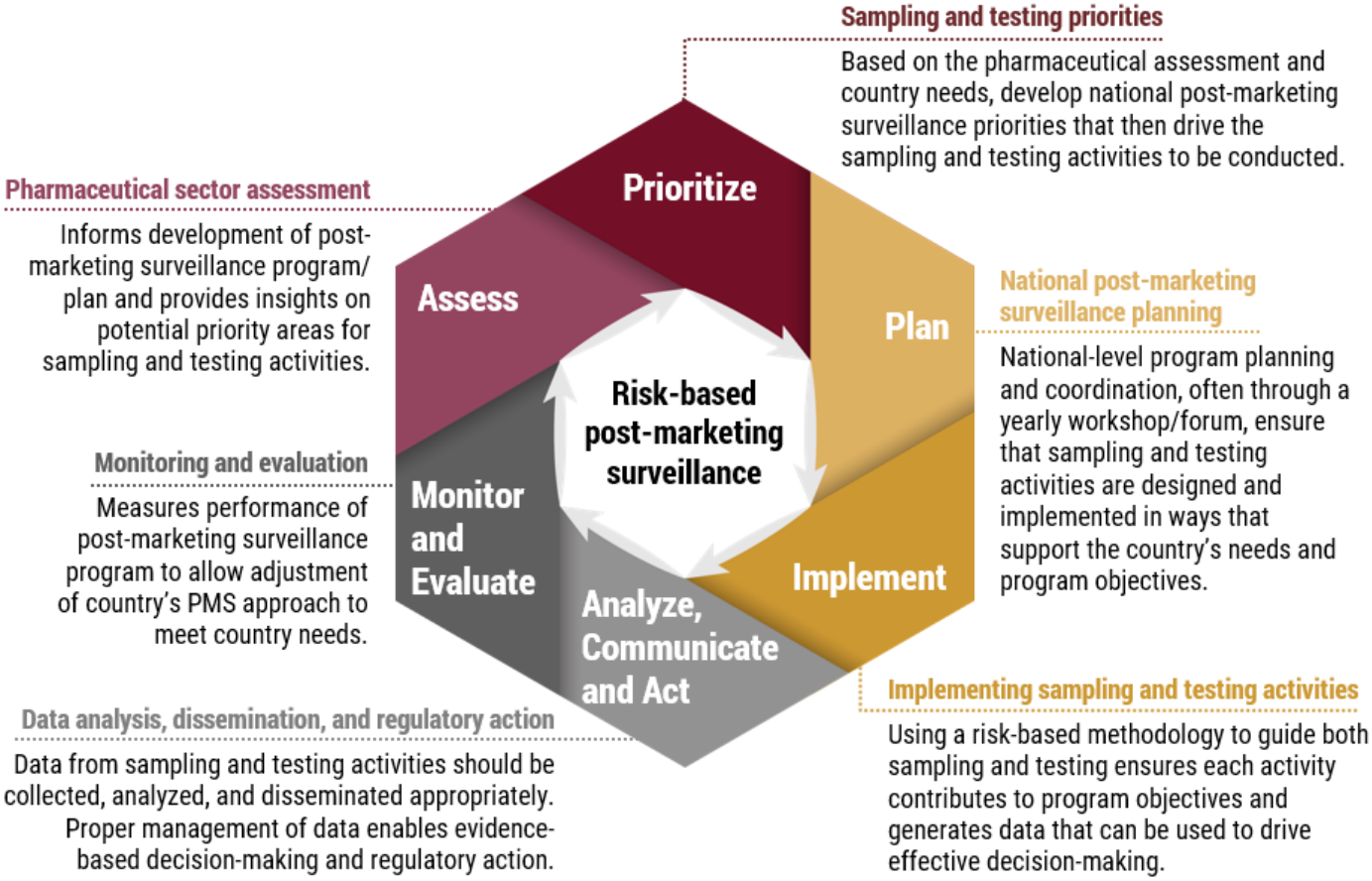

Figure 1: Risk based post marketing surveillance (Reference: PQM, 2018)

3.1.Planning

A plan for market surveillance plan shall be developed with available human and financial resources. The plan might include which products will be prioritized using a risk-based approach for closer surveillance. It should also describe roles and responsibilities, include elements of monitoring and

evaluation, timelines for the various activities and a budget.

3.1.1. Setting the objectives of PMS activities:

a) Gathering of information regarding the quality of medicines and possible/potential challenges in the supply chain
b) Identifying priority targets for post-marketing surveillance in consultation with stakeholders (Health programs, Central Medical Store, Pharmacists Association, etc…). Risk-based approach should be used to determine priority target products. The priority will be determined based on risk factors for the products to be surveyed and it should be given to products that are at high risk of presenting quality issues. High risk products may be for example those reported in routine Post marketing surveillance activities and pharmacovigilance, reported in our country and other countries etc.

3.1.2. Information needed for risk based sampling and testing

a) Selection of area to Sample

Administrative and health structure, updated demographic information, disease prevalence, medicines supply chain, pharmaceutical sector information (number of outlets for each sector).

b) Selection of pharmaceutical products

Most-used medicines according to the essential medicines list, complaint investigations, quality failures, most-sold medicines, higher risk medicines (stability, storage),supply system of targeted medicine, known points of distribution including online sale of pharmaceutical products. .

c) Selection of collection sites

Complete and up-to date information about the pharmaceutical sector in the area (number of outlets, levels of distribution, type of outlets, type of available sectors for supplies, geographical and administrative structure (e.g., number of provinces, number of districts), demographic information Government health institutions e.g. government hospitals, central and regional medical store, etc. and private sector institutions (e.g. wholesale pharmacies and drug stores, community/retail pharmacies, pharmacies and dispensaries at private hospitals).

d) Number of dosage units/sample, Number of samples/ medicine, Total number of samples/area

Based on the objectives and testing methodology of the activity, data on the specifications for the medicine and its dosage form are required and should be available at the Authority. The number of samples is determined based on the objectives and availability at the collection site.

e) Sample testing

Test to be applied or selected must be determined by quality assurance laboratory based on the objectives of the sampling and testing activity according to the Pharmacopeial specifications or manufacturers' specifications.

3.1.3. Development of PMS protocol using risk-based PMS approaches

Once the objectives of the round of PMS activities have been defined, development of PMS protocol can be initiated. MedRS or other tool/approach should be used based on the objectives of PMS activities.

A set of risk factors should be used for medical products selected for surveillance. Similarly, risk factors relating the sector (public, private,.), geographical area, and location should be considered. The mapping of all pharmaceutical establishments, updated on a regular basis, will be used to develop the sampling plan. As a PMS good practice, during each round of surveillance activities, the protocol should include the products/batches that have been reported to be falsified or substandard (e.g. WHO Rapid Alert reports). Inspectors should verify if these products are available at the sampling site.

a) Gather information on the availability of target products before finalising the sampling plan. This is important to avoid deviating too much from the sampling plan once in the field and realise that there are not enough units of a given medicine at a given facility to sample from. Consult with the stakeholders including supply chain managers.
b) Testing strategy for targeted products (3-Level approach, tiered-compendia testing) is adopted by the Authority. Once the sampling plan has been finalised, the testing plan can be developed. Targeted testing could be used based on the quality risk for a given product. For instance, if a given product can potentially have contaminants/impurities then priority will be given to impurities test;
c) Budgeting
d) Budget should be developed to cover the cost of PMS activities.

3.2.Steps in PMS planning.

The steps in PMS planning include the following:
Step1: Preparation of PMS protocol
Step 2: Preparation of sampling plan
Step 3: Training of sample collectors
Step 4: Procurement of samples/Sampling
Step 5: Dispatch of samples to the laboratory
Step 6: Analytical screening of samples
Step 7: Identification of samples for full analysis
Step 8: Collation and evaluation of result for analysis
Step 9: Evaluating results (in case you detect poor quality, it is required to report immediately to the surveillance study coordinator for urgent actions on quarantining and recalls)

Step 10: Preparation of Draft report of survey
Step 11: Presentation of the draft report to relevant stakeholders
Step 12: Preparation of final report
Step 13: Dissemination and Publication of report

3.3.Protocol for Post marketing surveillance

Protocol for post marketing surveillance is a written detailed document that clearly outlines/describes how the surveillance should be carried out. In principle, the protocol should, contain information such as

a) Background and significance of the study,
b) Study objectives,
c) Methodology
   i) Design of the study,
   ii) Selection of areas to be sampled
   iii) Selection of sample sites
   iv) sampling design
   v) Number of sample units to be collected
   vi) sample collection
   vii) Storage and transportation of samples
   viii) Data management
   ix) Brief description of the Quality Control Laboratory, and testing parameters.
d) Budget
e) National Health Research committee/ ethics committee and Rwanda FDA approvals whenever applicable

3.4. Sampling

3.4.1. Sampling designs:

3.4.1.1.Convenience sampling

Convenience sampling is a non-probability sampling technique based on the judgement of the survey organizer. The sites, however, should not be selected just because of their convenient accessibility and proximity. There should be defined rules guiding the selection in order to reflect the survey objectives. Whenever convenience sampling is used, it is necessary to report how the sites were identified and which types and what proportion of the outlets the selection represents.

If a wider picture is needed, subsequent surveys using probability sampling can be designed. If convenience surveys do not reveal a problem one should bear in mind that this may be a false-negative result. It is important to explain the limitations of this technique in reports and scientific papers. Despite

its limitations, convenience sampling is most suitable to identify high-risk areas for further regulatory actions.

3.4.1.2.Simple random sampling

Random sampling is a probability sampling technique that, if the sample size is sufficient, will give reliable estimates (with confidence intervals) of the prevalence of outlets selling poor-quality medicines. The disadvantages of random sampling are the large sample sizes needed, the necessity for complete lists of the locations of the target outlets and the additional costs in terms of labour and time. In addition, it is important to recognize that a random survey will only produce reliable and useful information if the list of outlets and actual within-outlet sampling is consistent with the primary aims of the survey. Comparisons with subsequent estimates using this same sampling design should, however, be valid and will allow the evaluation of interventions.

3.4.1.3.Stratified random sampling

Stratified sampling is a probability sampling technique wherein the entire group of outlets is divided into different subgroups (layers or strata), then randomly selects the final outlets proportionally from the different subgroups. Stratified sampling can be used to adjust for potential differences, e.g. sales volume, type of customers, or geographical, trade and socioeconomic variables. Stratification requires adjustment of the sample size calculation. Sampling that is proportional to the number of outlets will be more efficient than simple random sampling.

The Authority will use one of the above mentioned sampling designs depending on the objectives of the PMS activity.

There are instances where within a single outlet there will often be several different brands of the same medicine at different prices aimed at different market segments. In such cases a covert, mystery shopper approach may be appropriate. The mystery shopper mimics a “normal shopper” for the community in which the outlet is located and should dress, speak and behave appropriately for the community.

3.4.2. Types of sample collection sites

Sample collection sites in Rwanda are classified based on four risk dimensions (risk medicines, Region, Cities and facilities) as follow:

a) Public (government): including Central medical stores, District Pharmacies, Pharmacies for health facilities (Hospitals, Health canters etc)
b) Private: including Manufacturers/Industries, small scale manufacturers, Pharmacy Wholesale, Private hospitals and clinics, Retail Pharmacies
c) Non-governmental Organizations (NGOs)

The other type of classification for sample collection sites are based on the level of activity in the supply chain:

Level 1: Points of entry to the market, e.g. Ports of Entry and Exit, warehouses of importers or manufacturers, central medical stores, NGO central stores, other facilities supplied directly within various programs, central wholesalers/distributors;

Level 2: District Pharmacies, Retail Pharmacies, hospitals, health centers, Health posts/Clinics, community health workers;

Level 3: Informal outlets selling medicines outside the approved distribution system, e.g. street vendors, grocery shops, drug stores,

Sample collection should be performed in both the public and private sectors as well as in the "informal market". Types of sites for sample collection should be selected in a way to best serve the study objectives and the selection should be explained.

Quality of samples collected in the supply chain close to the point of sale to patients (Levels 2 and 3) may be influenced by distribution and storage conditions. If the medicine's quality is compromised due to degradation from distribution and storage problems, collection of additional samples of the same product at level 1 may highlight the bridge in the quality assurance system of supply chain management.

Samples collected at points of entry to the market (Level 1) may be less affected by storage and distribution conditions they may encounter during in-country distribution. Sampling at this point in the supply chain has the advantage of identifying the quality of products as supplied by manufacturers and detecting quality issues before the products reach patients. Corrective actions may be more easily put in place if the results are quickly available.

Once the types of sample collection sites are selected, the areas to be sampled need to be mapped. The sites where samples will be actually collected in the study should be identified according to address and type of facility.

Good knowledge of the distribution/supply chain structure for the target medicines is needed and cooperation with the Public Health program in this respect is very important. If the survey objectives require collection of samples offered by itinerant sellers, it may not be possible to map their “territory” and a pre-survey investigation, e.g. in households, may be needed. Another option would be to include a list of the outlets where itinerant vendors buy their medicines.

3.4.3. Selection of medicines to be surveyed

The category of medicines to be surveyed may be characterized in various ways, e.g. by the content of APIs, therapeutic group classification, formulation, specific programme under which they are supplied, manufacturer or distributor declared on the label. If collection of commonly used products is required, a

pre-survey investigation of treatment-seeking behaviour may be necessary. Collaborating with other sectors, such as public health programmes, may help to identify products used commonly. Selection of medicines is driven by the PMS objectives and public health considerations.
The potential public health impact of poor-quality medicines should be key guides for selection. To optimise use of available resources the survey should focus on medicines posing higher risk to patients, e.g. where the therapeutic index is narrow, substandard quality could lead to a significant change of the health outcome or categories particularly vulnerable to falsification.

3.4.4. Sampling tools

The Form No.: FDISM/PVSM/FOM/001 for Post Marketing Surveillance Programme Sample Collection, appropriate devices to record temperature and relative humidity, cool boxes, Ice packs for collecting samples of temperature sensitive products, Containers, MedRS tool, labels, makers, and other tools deemed necessary.

3.4.5. Storage and transportation of samples

a) Storage and transportation of the samples to the Quality control laboratory should be done according to regulatory requirements issued by the Authority. Handling of samples should be done as quickly and straight as possible so as not to jeopardize the quality of collected samples:
b) Storage and handling conditions of samples should comply with all national regulatory procedures.
c) Storage conditions for the pharmaceutical products sampled should be in compliance with the recommendations of the manufacturer.
d) Storage areas should be clean and free from accumulated waste and vermin. Sample collectors must ensure that premises and storage areas are cleaned regularly.
e) The samples should be kept in their original packaging and under storage conditions as specified on the label; freezing should be avoided and, where required, the cold chain should be retained.
f) For transport all samples should be packaged adequately and transported in such a way as to avoid breakage and contamination during transport. Any residual space in the container should be filled with a suitable material.
g) In case of temperature-sensitive medicines, temperature data loggers may be included within shipments to document adequate temperature in prolonged transit
h) Medicines and other health product samples should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors.

In the case that sample collectors are not transporting samples directly to the testing laboratory, samples with the accompanying documents should be sent by a courier service or as determined by the PMS management team. For each shipment it should be clearly "indicated that samples are sent for laboratory testing purposes only, will not be used on humans or animals, have no commercial value and will not be placed on the market". Copies of sample collection forms and, if available, copies of manufacturer's

batch certificates of analysis should also be sent to the survey coordinator or person preparing the survey report

3.4.6. Receipt and testing of samples by a testing laboratory

When samples are received, the testing laboratory should:

a) Inspect each sample to ensure that the labelling is in conformance with the information contained in the sample collection form or test request; an electronic databank (e.g. scanned pictures or photographs of the medicines, such as of the tablets, packaging, and package leaflet) is recommended; store the samples in line with the conditions on product labels, including compliance with any cold chain requirements;

b) Conduct quality testing in line with the testing protocol and in compliance with Good Practices for Pharmaceutical Quality Control Laboratories, including investigation and documentation of each Out of Specification result according to the laboratory SOP. If the Out of Specification result is confirmed, it should be reported as soon as possible to the surveillance study coordinator providing both results and investigation report to protect the population from using the poor quality products.

c) Complete analytical test reports/certificates of analysis containing information established by the Authority, the study coordinator should define the format of the outcome (e.g. separately for each sample or as a tabulated report);

d) Keep documents received with samples, records of testing of each sample including all raw data and retention samples according to the requirements defined by the study coordinator or internal procedure (e.g. for at least six months if the sample complied with the specifications, or until the expiry date, if it did not comply) and archive data according to the agreed conditions

3.5.Testing

Testing methodologies would be decided based on the products sampled. Whenever possible 3-leel methodology will be used.

Level-1: Visual inspection

All samples will undergo visual inspection using a formal checklist No.: FDISM/PVSM/FOM/030 for Post Marketing Surveillance Screening to detect any defect or indication of adulteration or non-compliance with good manufacturing practices. The visual inspection should refer to the information related to the specific product registration in Rwanda. Types of defect may include the following but not limited to: wrong labelling, particulates, crumbling tablets, under fill, glass particulates, mould contamination, discoloration, wrong fill, odour.

The visual inspection is an important test that may reveal noncompliance without further testing.
Sample selection for testing: visual inspection along with storage conditions recorded will help determine the samples that need further testing. If several samples of the same products are collected they will be visually compared to one another.

Level-2: Advanced screening whenever applicable

Advanced screening may involve the use of Minilab™ or other screening technology available to the Quality Control laboratory (See figure 2). Current spectroscopy-based technologies involving the use of handheld spectrometers could be used as screening tools to detect falsified medicines in the field. The Authority will determine the handheld spectrometers to be used to support its PMS activities. The quality control laboratory may be tasked to develop methods and methodologies for the implementation of handheld spectrometers in the field. Minilab™ should be used in the Quality control laboratory of the Authority.

Level-3: Compendia testing

In case a product was deemed noncompliant, the lab will confirm the results following compendia methods and internal standard operating procedure(s), (**See figure 3).**

Note: For the tests which cannot be done locally, samples can be sent to ISO/IEC 17025 Accredited or WHO prequalified laboratories for the analysis of medical products.

Figure 2. Guidance for visual and field-based screening (Levels 1 and 2)

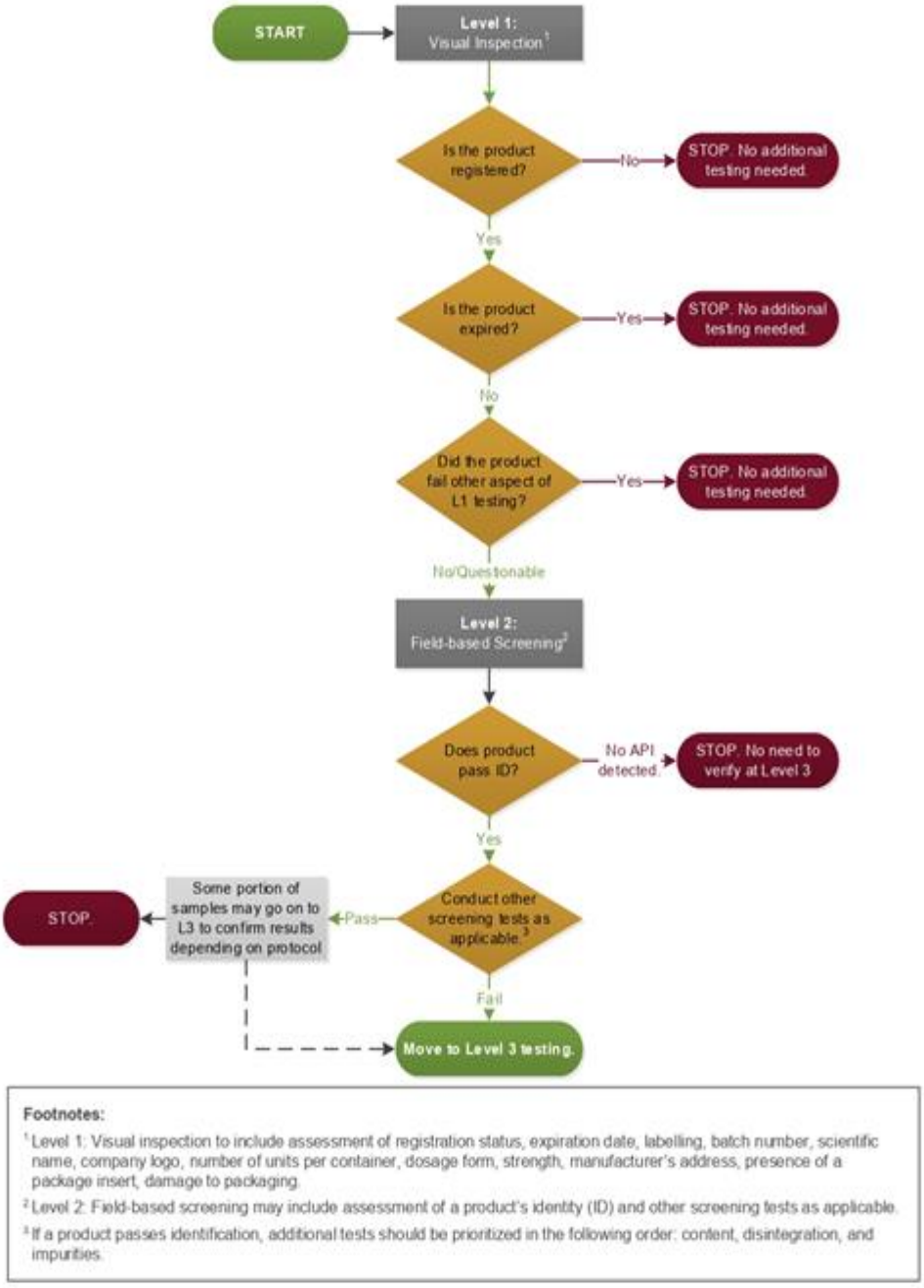

Figure 2. Guidance for Visual and Field-based screening (Level 1 and 2). (Reference: PQM, 2018)

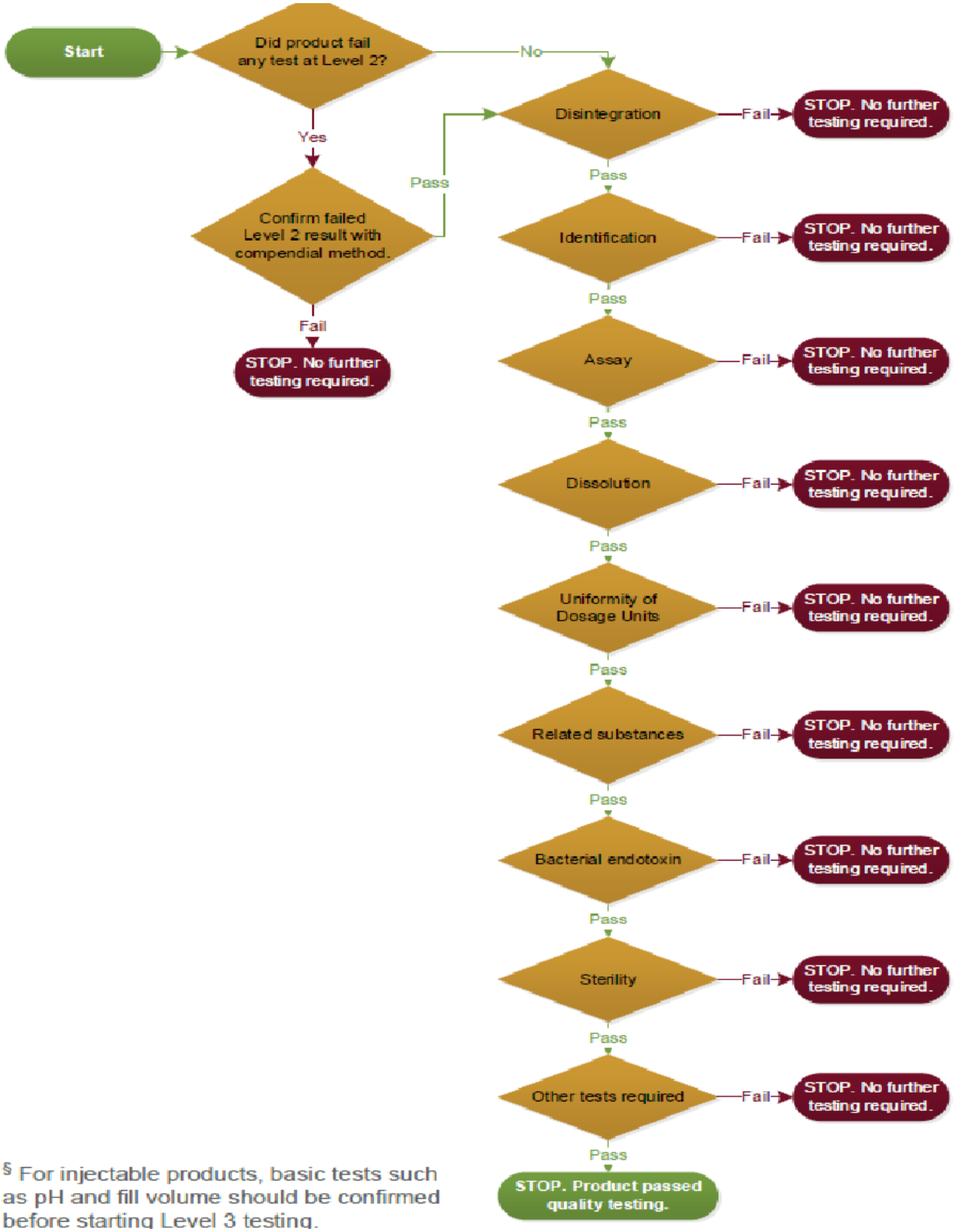

Figure3. Suggested prioritization for compendia testing (level 3). (RefereancePQM,2018)

Some cases should be chosen for further investigation using advanced analytical techniques to determine the nature or toxicity of detected poor quality products in the interests of greater safety and public health protection.

If the market authorization holder contests the test results, he or she will be responsible for the costs of re-testing by an independent ISO/IEC accredited or WHO pre-qualified laboratory, which will be mutually selected by Rwanda FDA and MAH.

In case the retesting results do not confirm the testing results, the Authority and MAH will decide on the second retest, and Rwanda FDA reserves the right to make the final decision.

3.6. Data management

Data generated through PMS activities will be recorded in a database and data will analysed to inform an appropriate regulatory decision report to be communicated to the stakeholders.

3.7. Reporting

3.7.1. Internal reporting:

The Authority will keep its department's personnel informed about PMS activities. The authority may have several departments involved in PMS planning and implementation. Internal reporting will follow the authority's internal communication procedures.

3.7.2. External reporting:

The Authority will inform stakeholders on PMS activities and results through official channels of communication

3.7.3. Third party PMS reporting

After completion of a PMS activity by a third party, results will not be published without approval of the Authority.

CHAPTER IV: PREVENTION, DETECTION AND RESPONSE TO SF MEDICAL PRODUCTS

The Authority has put in place mechanisms for preventing, detecting and response to SF medical products through different activities.

4.1.Prevention of SF medical products

Rwanda FDA is mandated to conduct Post marketing surveillance and has established mechanisms to tackle the issue of substandard and falsified medical products in a transparent and inclusive way. Among other strategies to prevent SF medical products there are control of import and export of medical products through regular physical inspection of imported and exported products at the Ports of Entry and Exit, training of health care professionals, awareness on radio and TV show on fighting against SF, regular meeting with stakeholders and dissemination of information to the general public on prevention of SF medical products.

The Authority shall promote and facilitate consultation, cooperation and collaboration on surveillance and monitoring of SF medical products with relevant stakeholders in a transparent and coordinated manner, including national, regional and other global efforts, to exchange experiences, lessons learnt, best practices and information.

4.2. Detection of SF medical product

The strategies of early detection of SF medical products that were established by the Authority include quality monitoring which include inspections for verification of current good manufacturing and distribution practices in the supply chain of medical products, verification of the medical products distribution chain; control (laboratory testing) in all level of the supply chain including supply and sale of medical products via the internet, licensing of levels of supply chain including online pharmacies, sampling of medical products for Post marketing surveillance purpose using principles of Risk Based - PMS, increasing of reporting channels of suspected poor quality medical products (reporting forms and Telephone).

The Authority shall receive alerts from different relevant stakeholders including the track and trace systems in those countries where such systems have been implemented; global and/or regional alerts issued from another regulatory authorities and/or WHO; reception, assessment and investigation of reports or notifications generated by any person, such as manufacturers, wholesalers, distributors, consumers and whistle-blowers, as appropriate.
During the PMS activities and depending on the nature of the available information, the Authority may also conduct a risk assessment to detect SF products which may include but is not limited to the following steps:

1) Verify and make sure, that the correct product was delivered and the presentation (configuration) of the product is what was ordered.
2) Verify and make sure that labelling matches the labelling for the product on
3) Ensure the manufacturer's address or contact details are present.
4) Check and confirm if the product is registered, or otherwise authorized for importation
5) Check for any evidence of tampering with labels and/or packaging such as cracks, abrasion, erosion, breaks, and seal integrity.
6) Check for problems with labelling and/or need for training, including inadequate instructions to the user; unclear, missing, worn out, incorrect or inaccurate labels; if intended users are required to be adequately trained according to the labelling requirements
7) Check for manufacturing, packaging or shipping problems, including defective components, defective products, damages prior to use, damage to the materials used to construct the cover or outer packaging (which can lead to compromised microbiological state, e.g. sterility of the product), missing listed components.
8) Check for storage conditions of the manufacturers and compare them with regulatory requirements
9) Check the certificate of analysis for the lot or serial number, if applicable, and use this as a reference for the physical inspection of the product name, product code, lot number, expiry date.

4.3.Response to SF medical products

In order to fight against SF medical products, the Authority shall take regulatory action to SF medical products such as recalling SF medical products and conducting recall audits in order to ensure the total removal of recalled SF medical products.
The Authority shall promote effective and prompt communication to avoid the use of SF products and prevent harm to consumers. Through the nominated /WHO Substandard and Falsified Medicines (SF) Focal Persons, the authority collaborates with the World Health Organization (WHO) to receive notifications on falsified medicines discovered in other nations (Rapid alert system).

The SF Focal Person shall send information to WHO via the Global Surveillance Monitoring System (GSMS) regarding falsified medications discovered on the market by the Authority, and WHO then shares this information with other regulatory authorities.

4.4.Regulatory action taking

The Authority will take immediate action to remove falsified products from the market nationwide. Investigations on how the product reached the supply chain will be carried out by the authority. In addition, through the RB -PMS Technical committee, the Authority may decide the level of corrective and preventive actions. The level of corrective actions should be proportional to the severity of noncompliance. The Authority will follow up with the manufacturer producing the noncompliant product until it addresses the cause of the noncompliance of its product.

The regulatory action that should be taken by the Authority include immediately removing SF medical products on the market, quarantine or recall SF medical products, suspend or withdraw of market Authorization and Enforcing fines prescribed in regulations No. CBD/TRG/004. Legislative sanctions for anyone who contravenes provision of legal framework for regulation of medical products are provided in Law Nº68/2018 of 30/08/2018 determining offences and penalties

4.5.Communication/Sharing of information

In its commitment to transparency, the Authority will make information on PMS activities publicly available on its website and through official channels. Prior to the publication, the Authority will inform the market authorization on the non-conformance detected. The authority may share the results of PMS activities including any regulatory actions taken.

CHAPTER V: MONITORING AND EVALUATION

In seeking continuous improvement of its processes, the Authority monitors and evaluates its PMS program. The monitoring and evaluation office will work closely with the PMS team to collect data on the implementation of the PMS program. The data collected shall be analysed and recommendations formulated to address any shortcoming in the implementation of PMS or explore opportunities for its improvement. PMS indicators shall be monitored and measured quarterly, and annually-to review the trend of PMS performance.

5.1.Indicator types and definition

Indicator types	Definition
Structural	Measure key aspects of regulation, infrastructure, National Regulatory Authority functions and structure, Quality Assurance/Quality Control systems, supply chains, storage, and distribution in the pharmaceutical sector.
Process/Inputs	Measure the resources needed for the implementation of an activity or intervention and may include policies, human resources, materials, and financial resources needed to measure whether planned activities took place or not.
Output	Measure the direct results of an intervention and are mainly quantitative. Output indicators add more detail on the product ("output") of the activity.
Outcome	Measure the achievement of common objectives of Rwanda FDA to address address poor-quality products. Outcome indicators are used to demonstrate the degree to which post-marketing surveillance objectives are being met.
Impact	Measure the extent to which post-marketing surveillance program objectives contribute to safeguarding the public from harmful products. Measuring these indicators can be difficult due to multiple factors, interventions, and externalities that also affect impact.

The following indicators may be used and expanded:

5.1.1. Structural (STL) Indicators:

STL1 : Existence of Regulatory framework on PMS program.
STL2 : Existence of defined roles, responsibilities, and structure for post-marketing surveillance program.
STL3 : Existence of mechanism for collaboration with key stakeholders (e.g., police, customs)
STL4 : Existence of post-marketing surveillance activities targeted to national priority health programs/products.
STL5: Existence of evidence-based decision-making practice using post-marketing surveillance data

(e.g., evidence of regulatory actions taken against poor quality medicines based on post-marketing surveillance data).

STL6 : Existence of written SOPs for post-marketing surveillance related to planning, execution, and reporting PMS activities

STL7 : Existence of key tools used in post-marketing surveillance

STL8 : Existence of sampling strategies

STL9 : Existence of annual PMS plan

STL10 : Existence of reporting and dissemination mechanisms of results from PMS activities.

STL11 : Existence of screening and testing equipped facilities

5.1.2. Process/Input (PRS) Indicators:

PRS1 : Number of procedures implemented to perform post market surveillance and control

PRS2 : Number of skilled and experienced staff for post-marketing surveillance program

PRS 3 : Percentage change in financial resources for post-marketing surveillance activities

5.1.3. Output (OUT) Indicators:

OUT1 : Number of reports received for suspected falsified and substandard Pharmaceutical products

OUT2 : Number of follow-up done and feedback provided on reports about pharmaceutical products suspected to be falsified or substandard

OUT3 : Number of feedback provided to reporters about the pharmaceutical products suspected to be falsified or substandard

OUT4 : Percentage of pharmaceutical product samples that failed Level 1 (visual inspection) and underwent confirmatory analysis

OUT5 : Number of individuals trained on topics related to post-marketing surveillance by year

OUT6 : Percentage of total post-marketing surveillance reports attributed to product quality defect are recorded in database compared to the previous calendar year

OUT7 : Percentage of licensed pharmaceutical establishments covered by post-marketing surveillance program in public and private sector

5.1.4. Outcome (OUE) Indicators:

OUE1 : Cost savings attributed to risk-based post-marketing surveillance activities

OUE2 : Percentage change in the number of licensed pharmaceutical establishments that sell falsified and substandard Pharmaceutical products (each year there should be a decrease in percentage compared to previous years)

OUE3 : Percentage of substandard or falsified Pharmaceutical products circulated in the market identified in the current year (each year there should be a decrease in percentage compared to previous years)

OUE4 : Percentage change in the number of post-marketing surveillance inspections in terms of

frequency from high-risk to low-risk areas as a result of effective risk-based post-marketing surveillance
OUE5 : Percentage of non-compliance samples followed by the Rwanda FDA with regulatory actions

5.1.5. Impact Indicators (IMT):

IMT1: Percentage change over time in medicine-related hospital admissions resulted from product quality defects
IMT2 : Percentage change in medicine-related deaths caused by medicines quality defects
IMT3 : Change in behaviour of supplier, distributor, and retailer handling pharmaceutical products to embrace the quality and safety as a key criterion in their practice

5.1.6. Continuous improvement Indicators (COI):

COI1 : Existence of a mechanism to promote transparency, accountability and communication in post-marketing surveillance program
COI2 : Existence and implementation of continuous improvement processes (Plan > Do > Check > Act)

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division manager of Pharmacovigilance and Food Safety Monitoring**	**Head of Department of Food and Drugs Inspection and Safety Monitoring**	**Quality Assurance Analyst**	**Director General**
Names	Lazare NTIRENGANYA	Dr. Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	30/09/2022	30/09/2022	30/09/2022	30/09/2022

RWANDA FOOD AND DRUGS AUTHORITY

Annex 1: FORM No.: FDISM/PVSM/FOM/001

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	FDISM/PVSM
Document Type: **Form**		Doc. No : FDISM/PVSM/FOM/001
RWANDA FDA Rwanda Food and Drugs Authority	Title: **POST MARKETING SURVEILLANCE PROGRAMME SAMPLE COLLECTION**	Revision Number : 02 Revision Date: : 30/09/2022 Effective Date : 15/10/2022 Review Due Date : 14/10/2025 Ref Doc. :FDISM/PVSM/GDL/003

1. Sample Unique code: _____

(Region name/Facility ID number/Product code/Number) (A/B/C e.g., KIG/2656/OX/000)

2. Type of collection premise: Private: ☐ Public: ☐
3. Name of facility from which sample was collected:

   _____

   a. Name of city_____ Region

      _____

   b. Physical Address (Town, Building and Street)

      _____

   c. Tel. Number

      _____

   d. EmailAddress_____

      ____

4. Product name of the sample:

   _____

   a. Name of active pharmaceutical ingredient(s) (INN) with strength:

      _____

   b. Dosage form (tablet, capsule, powder for injection, etc):

      _____

   c. Package size, type and packaging material of the container (where applicable):

      _____

   d. Batch/lot number:

      _____

   e. Date of manufacture: _____ Expiry date:

      _____

   f. Registration status in RWANDA (registration number, if applicable):

      _____

g. Name of the manufacturer:
_____

h. Address of manufacturer:
_____

5. Quantity collected (number of sample units or of multi-dose containers taken):
_____
6. Storage/climatic conditions at sampling site/point (temperature and humidity, indication of conditions during daytime only is acceptable):
_____
7. Comments on suitability of premises where products are stored at sample collection site
_____
_____
_____
_____
_____
_____
8. Abnormalities, remarks or observations that may be considered relevant, if any:
_____
_____
_____
_____
_____
_____
_____

Date of sample collection:
_____

Name & Signature of sample collectors:

1……..
2……..
3……..

Name & Signature of the premise representative

1……..
2……..
3……..

Note:
Samples collected must remain in their original containers, intact and unopened.
This Sample Information Collection form should always be kept with the sample collected.
Proper sampling procedures should be followed. The excel database should be properly filled

ANNEX 2: FORM No. FDISM/PVSM/FOM/016

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	FDISM/PVSM	
Document Type: **Form**		Doc. No	: FDISM/PVSM /FOM/016
RWANDA FDA Rwanda Food and Drugs Authority	**Title:** **SUSPECTED POOR QUALITYPRODUCT REPORTING FORM**	Revision Number	: 2
		Revision Date:	: 05/08/2022
		Effective Date	: 12/08/2022
		Review Due Date	: 05/08/2025
		Ref Doc.	:FDISM/PVSM/GDL/003

I. PRODUCT CATEGORY (Tick as appropriate)

Medicinal product ☐ Vaccine ☐ Other Biological Products ☐ Herbal product ☐ Other *(Please Specify):*

……

II. PRODUCT DETAILS

Brand name				Generic Name			
Batch/Lot N°		Manufacturing Date		Expiry date		Date of receipt	
Name of manufacturer				Physical Address and Country of Origin			
Name of Distributor/Supplier				Distributor/ Supplier's Address			

III. PRODUCT FORMULATION

- ☐ Tablets /capsules
- ☐ Suspension/Syrup
- ☐ Injectable/Infusions
- ☐ Creams/Ointment/Liniment/Paste
- ☐ Pessaries
- ☐ Suppository
- ☐ Powder for reconstitution of oral suspension
- ☐ Powder for reconstitution of injection
- ☐ Ear/Eye drops
- ☐ Diluents
- ☐ Nebulizing solutions
- ☐ Other *(Please Specify)* ……

IV. DESCRIPTION OF PRODUCT COMPLAINT

- ☐ 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
- ☐ Separating
- ☐ Incomplete packs
- ☐ Powdering/crumbling
- ☐ Suspected falsified/ Substandard
- ☐ Others*Specify)* ……

Describe the Complaint in details:

……

……

V. PRODUCT STORAGE CONDITIONS

Does product require refrigeration? **YES☐NO☐**

Does product require protection from light? **YES☐NO☐**

Does product require protection from Moisture? **YES☐NO ☐**

Was it stored following manufacturer/Rwanda FDA guidelines? **YES☐ NO☐**

Other Storage details *(if necessary):*

VI. CIRCUMSTANCE AND TIME OF THE POOR-QUALITY DETECTION

When did you notice the poor-quality problem?

- ☐ Before taking/administering the product
- ☐ While taking/administering the product
- ☐ After taking/administering the product
- ☐ When the patient returned the product

- ☐ After a complaint of the patient
- ☐ After Visual inspection
- ☐ After quality control
- ☐ Other(specify)……

VII. ACTION TAKEN

- ☐ Stop Taking/Administration of the product
- ☐ Quarantining the product
- ☐ Returning the product to the supplier
- ☐ Other (specify):……

Have you experienced any adverse event after taking this medicine? **YES** ☐ **NO** ☐ If **YES,** please complete the ADR/AEFI Reporting Form.

VIII. REPORTER INFORMATION

Name of reporter:		Qualification:		Phone number:	
Name of Health Facility		District:		Report Reference No:	
E-mail Address:		Contact/Tel No:		Date of report:	

All information is held in strict confidentiality and will not disclose reporter's identity in response to any public request. Information supplied will contribute to the improvement of safety and vigilance of Medical Products in Rwanda. Once this form is completed please send it to Rwanda FDA via the following email: ***pv_sm@rwandafda.gov.rw***

Annex 3: Form No.: QCL/FOM/001

Document type: **Form**		Doc. Number : QCL/FOM/001
RWANDA FDA	**Title:** Test Request Form	Revision Number : 1 Revision Date : 01 June 2021 Effective Date : 14 June 2021

1. Full Description
   (Generic name / Trade name if any, other names)
   ……
   ……
   Composition: ……
   ……
   Strength and Dosage form: ……
   ……
2. Manufacturer Names and Address:
   ……
   ……
   ……
   Batch No: ……
   MFG Date: ……
   EXP Date: ……
   Retest date (APIs and Pharmaceutical excipient) : .
   ……
3. Size of submitted sample: ……
4. Size of the consignment/package: ……
5. Required storage condition: ……
   ……
6. Physical condition of the sample upon arrival:
   State: Frozen, Chilled, Room temp
   Packaging: Sealed, Unsealed, Damaged, Un-damaged
   General appearance : Good, Poor
   Discrepancies: ……
7. Reason for analysis request: ……
   ……
8. Specification to be used for testing:
   ……
9. Parameters to be tested :
   ……
   ……
   ……
10. Would you like QCL to choose the Appropriate test method(s) to be used in above tests? Yes / No if no suggest :
    ……
11. Source of the sample:
    Institution / Company: ……
    Country: ……
    Address / Tel : ……
    ……
12. Marketing Authorization number: ……
13. Date sample collected: ……
14. Sample Submitted by :
    Institution: ……
    Position: ……
    Address / Tel:……
    ……
    Signature & Date:
    ……
15. Receiver's name & signature :
    ……
    Date and time of submission: ……
16. Laboratory Sample registration number:……
    ……
17. Turnaround time: ……
18. **Note, if any:** ……

19. For Laboratory use only…..

Received by		Date & signature	
Assigned Analyst		Date & signature	

20. Sample transfer

Quantity (mg, ml,..)	Transferred by	Received by	Time and date	Signature

Annex 4: Form No.: FDISM/PVSM/FOM/030

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	FDISM/PVSM	
Document Type: **Form**		Doc. No	: FDISM/PVSM/FOM/030
RWANDA FDA Rwanda Food and Drugs Authority	Title: **POST MARKETING SURVEILLANCE SCREENING FORM**	Revision Number	: 00
		Revision Date:	: 30/09/2022
		Effective Date	: 15/10/2022
		Review Due Dat	: 15/10/2022
		Ref Doc.	: FDISM/PVSM/GDL/003

Compliance with the basic requirements for information accompanying the product and report on Minilab testing

Product/sample code number:_____
Product name:_____
INNs:_____

1- External packaging	**Information present on the label**	
Product name	YES ☐	NO ☐
INN	YES ☐	NO ☐
Strength	YES ☐	NO ☐
Batch number	YES ☐	NO ☐
Manufacturing date	YES ☐	NO ☐
Expiry date	YES ☐	NO ☐
Manufacturer Name & Physical address	…… …… ……	
Recommended manufacturer storage conditions on the label	……	

2- Primary packaging	**Information present on the label**	
Product name	YES ☐	NO ☐
Strength	YES ☐	NO ☐
Unit dose per blister or container stated	YES ☐	NO ☐
Batch number	YES ☐	NO ☐
Manufacturing date	YES ☐	NO ☐
Expiry date	YES ☐	NO ☐
Manufacturer name (specify only if different from the	YES ☐ ……	NO ☐

external packaging under point 1)	

3- Package leaflet		
Presence of the leaflet	YES ☐	NO ☐
Language(s) of the leaflet	……..……	
Composition	YES ☐	NO ☐
Manufacturer name & physical address (specify only if different from the external packaging under point 1)	YES ☐ ……..……..…… ……..……..……	NO ☐
Storage conditions (specify only if different from the external packaging under point 1)	YES ☐ ……..……..…… ……..……..……	NO ☐

4- Observation on any discrepancy between the above points 1, 2 or 3 or non-compliance, if any (such as uniformity of words and font size used in labeling, color of packaging materials, integrity of primary and secondary packaging etc)

_____

_____

_____

5- Report on Minilab testing:

PHYSICAL/VISUAL INSPECTION TEST	
Description of dosage form	
Shape (circular, oval, flat sides, other)	
Uniformity of shape	
Uniformity of color	
No physical damage (cracks, breaks, erosion, abrasion, sticky)	
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)	

DISINTEGRATION TEST		
Time of complete Disintegration expected (30 minutes for uncoated tablet)	Time in minute of complete disintegration observed ----------	Did the drug pass disintegration test? ☐ Yes ☐ No
RESULT OF TLC TEST (see Appendix 2 for TLC result interpretation)		

Rf Standard (---): ---------- Rf Standard (---): ---------- Rf Standard (---): ---------- Rf Standard (---): ---------- Rf Sample (1): ---------- Rf Sample (2): ---------- Rf Sample (3): ---------- Rf Sample (4): ----------	Did the drug and the standard Spots have the same intensity? ---------- Was there any contaminant spot on TLC? ----------	Did The sample pass quality by using the TLC Test? ☐ Yes ☐ No
FINAL COMMENTS ☐ The sample conformed with basic testing specifications ☐ The sample not-conformed with basic quality testing (Reason:……..……) ☐ The sample is doubtful for its basic quality testing (Reason:……..……..……..……)		
REPORT PREPARED BY: Date: ……... Name: ……..…… Signature: ……	REPORT REVIEWED BY: Date: …….. Name: …… Signature:……..……	
ACTION TO BE TAKEN BY THE SAMPLE COLLECTOR		
Report the result to Division Manager Date of report …….. Signature…….……	Send the remaining sample units together with this Form to the Rwanda FDA QC lab for further testing Date……Signature……	
Reasons given for the chosen action: ----------		