RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING POST-MARKETING SURVEILLANCE OF REGULATED PRODUCTS

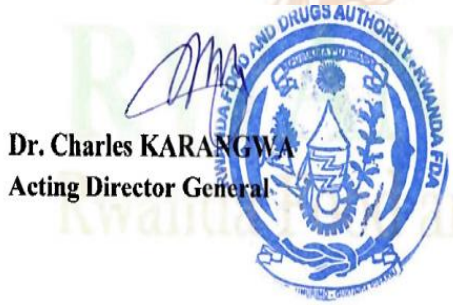
(Rwanda FDA law No 003/2018 of 09/02/2018, Article 8 paragraph 9)

REGULATIONS DEVELOPMENT HISTORY

DRAFT ZERO BY CONSULTANTS	17th April 2021
ADOPTION BY RWANDA FDA	17th May 2021
STAKEHOLDERS' CONSULTATION	18th June 2021
ADOPTION OF STAKEHOLDERS' COMMENTS	25th June 2021
DATE FOR COMING INTO EFFECT	21st July 2021

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N^{0} 8 paragraph 9 of the Law N^{o} 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning hereby ADOPTS and ISSUES these regulations No.: CBD/TRG/018 Rev_0 governing post-marketing surveillance of regulated products, made this 21st day of July, 2021.



Dr. Charles KARANGWA
Acting Director General

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ABBREVIATIONS

CAPA		Corrective Action Preventive Action
MAH	-	Marketing Authorization Holder
PMS	-	Post Marketing Surveillance
QA		Quality Assurance
QC		Quality Control
Rwanda FDA		Rwanda Food and Drugs Authority
SF products		Substandard Falsified products
WHO		World Health Organisation

CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient regulation of post marketing surveillance of regulated products and providing an open transparent and non-discriminatory process for the post marketing surveillance of regulated products.

Article 2: Citation

These regulations may be cited as the Regulations Governing the Post Marketing Surveillance of Products Regulated under Law No 003/2018 of 09/02/2018 and shall come into operation on the date of publication.

Article 3: Application and scope

These regulations shall apply to all regulated products that are manufactured, imported, distributed, stored, sold and used in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires-

"Appropriate fee" means the fee prescribed in the Regulations No.: CBD/TRG/004 Related to Regulatory Service Tariff/fees and Fines

"Authority" means the Rwanda Food and Drug Authority.

"Rwanda FDA" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA".

"Active surveillance" means active measures taken to monitor adverse events

"Law" means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning;

"Marketing Authorisation Holder (MAH)" means an individual or corporate entity responsible for placing a pharmaceutical product on the market;

"Pharmacovigilance (PV)" means the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems;

"Post-marketing surveillance" means surveillance activities that occur following market approval of a regulated product including maintenance of product authorisation and/or registration of variations or renewals; regular inspection of manufacturers, wholesalers, distributors and retailers; quality control testing; public reporting of poor quality products; handling of market complaints; and removal and disposal of non-compliant products

"Noncompliant products" nonregistered products or noncompliant with specifications including substandard and falsified products.

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

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

"Falsified products": that deliberately/fraudulently misrepresent their identity, composition or source.

CHAPTER II: POST-MARKETING SURVEILLANCE SYSTEM

Article 5: Requirement for a post-marketing surveillance system

a. The Authority establishes and maintains a national post-marketing surveillance system.
b. The post-marketing surveillance system shall monitor the overall quality and safety of regulated products and respond to public health risks.
c. All manufacturers and Marketing Authorisation Holders have joint responsibility for carrying out post-marketing surveillance activities and shall cooperate with all national post-marketing surveillance programmes.
d. The post-marketing surveillance system shall ensure support of the product life cycle, particularly through post-approval activities that include registration and approval of variations to the marketing authorisation; regular inspections of approved premises in the supply chain; quality control testing; pharmacovigilance, promotion control; public reporting of poor quality products; handling of market complaints; and removal and disposal of non-compliant products.

Article 6: Post-marketing surveillance system

The post marketing system shall:

a. Safeguard access of the public to quality products by detecting and removing non-compliant regulated products
b. Periodically diagnose the quality assurance (QA) system that is in place to identify any gaps
c. Evaluate the quality of regulated products available on the market, in selected areas, regions, at various levels of the distribution/supply chain with the aim of assessing the exposure of the population to poor-quality products and proposing appropriate actions;
d. Evaluate the quality of specific medical products used in public health programmes;
e. Carry out PMS studies to compare the quality of domestically produced and imported regulated products in order to recommend appropriate regulatory actions;
f. Identify possible causes of inferior quality of specific products to which the population are exposed and to propose possible strategies and implementation plans to address the problems identified;

Article 7: Coordination of stakeholders

The authority shall:

a. Establish a list of relevant PMS stakeholders, and MoU or agreement shall be signed where necessary.
b. Undertake regular meeting with relevant stakeholders to discuss and share PMS information.
c. Communicate the planned PMS activities and regulatory action taken to all relevant stakeholders

Article 8: Post-marketing surveillance roles and responsibilities

The authority shall:

a. coordinates all Post marketing surveillance activities of regulated products
b. Prepare and implement annual post marketing plan, Conduct customer complaint survey,
c. Take a relevant regulatory action based on post marketing surveillance data and ensure its implementation
d. Carry out investigations in collaboration with MAH, on SF products identified throughout the supply chain.
e.
f. Analyse and follow up on reports related on suspected poor quality regulated products.

1. The Marketing Authorisation Holder shall:

a. Cooperate with the authority in undertaking PMS activities,
b. Ensure that only the approved product is available on the market,
c. Implement regulatory actions taken by the authority,
d. Report of quality issues on regulated products and propose Corrective Actions and Preventive Actions,
e. Avail required samples for PMS purposes.

2. Other PMS stakeholders shall:

a. Report any suspected poor quality regulated products to the authority,
b. Implement regulatory action taken by the authority,
c. Avail required samples for PMS purposes,
d. Stop distribution and dispensing of suspected poor quality regulated products and SF products

Article 9: Prohibitions

The manufacture, import, export, supply, distribution or sale of SF medical products is prohibited

Article 10: Prevention of Substandard and/or Falsified medical products

The authority shall:

a. Put in place measures for prevention and detection of SF medical products,
b. Enforce regulatory action on detected SF medical products.
c. Conduct regular monitoring for online sales of medical products

Article 11: Sampling and Testing

The authority shall:

a. Apply risk based sampling approach,
b. Carry out sampling activities guided by a developed and approved sampling plan
c. Transport and store samples according to manufacturers' storage conditions
d. Carry out Sampling for PMS purposes at all level of the supply chain
e. Conduct 3-level testing methodology as detailed in relevant guidelines if applicable.
f. Conduct quality control tests on the samples obtained using validated and/or approved methods and provide evidence-based test results to inform regulatory action.

Article 12: Regulatory actions

Based on carefully analysed information the Authority shall:

a. Take immediate action to remove SF products from the market.
b. Decide the level of corrective and preventive actions for substandard products.
c. Quarantine or recall of SF regulated products
d. Suspend or withdraw of marketing authorization.
e. Enforce fines prescribed in regulations No. CBD/TRG/004

Article 13: Communication / Sharing of information

The authority shall:

a. inform the market authorization holder on the non-conformance detected prior to the public communication.

b. Communicate immediately to the public, the regulatory actions taken as results of PMS activities and an aggregate on quarterly basis;
c. make information on PMS activities available to stakeholders or to public through official channels;
d. Approve PMS findings before publication for the PMS activities conducted by stakeholders in Rwanda

Article 14: Reliance

The authority shall:

a. rely on PMS decisions from other regulatory authorities, regional and international regulatory bodies when deemed necessary
b. establish the procedures, circumstances, collaborative and agreement for reliance

Article 15: Establishment of PMS committee

a. The authority shall establish a PMS committee with clear terms of references;
b. The committee shall be composed of multidisciplinary experts and specialisation in relevant fields to assess all quality issues related on regulated products.

Article 16: Power to issue guidelines for PMS

The Authority shall issue guidelines, SOPs, forms, formats and tools necessary for the implementation of these regulations.

Article 17: Appeals to the Authority

a. Any person aggrieved by a decision of the Authority may apply to the authority for review of the decision showing grounds for dissatisfaction within thirty (30) working days from the date of notice;
b. The authority shall, within fifteen (15) working days from the date of receiving the application, review, reject or vary its own decision;
c. If the applicant is not satisfied by the decision of the Authority, he/she may appeal to the supervising authority.

Article 18: Commencement

These regulations come into force on the date of signature and publication on the Rwanda FDA website.

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