RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING PHARMACOVIGILANCE OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

(Rwanda FDA Law Nº 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

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0	First issue
1	1. The regulation was revised to comply with the newly updated document control by: removing the watermark and using the new format for regulations

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization, and functioning, hereby ADOPTS and ISSUES these regulations No.: Doc No.: *DD/PVCT/TRG/002* Rev_1 *Governing Pharmacovigilance of Pharmaceutical Products and Medical Devices on* 11/02/2024.

Digitally signed by Rwanda FDA (Director General)
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Prof. Emile BIENVENU
Director General

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CHAPTER I: GENERAL PROVISIONS

Article one: Purpose

The purpose of these Regulations is to provide a legal framework for the effective and efficient pharmacovigilance of pharmaceutical products and medical devices

They provide an open transparent and non-discriminatory process for the Pharmacovigilance system to protect the public health from substandard, falsified, unsafe pharmaceutical products and medical devices.

Article 2: Citation

These regulations may be cited as "*Regulations Governing Pharmacovigilance of pharmaceutical products and medical devices"*

Article 3: Application

These regulations shall apply to the pharmacovigilance activities of pharmaceutical products and medical devices manufactured, imported, exported, advertised, sold, distributed or used in healthcare practice in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

1. **"Authority"** means the Rwanda Food and Drug Authority, or acronyms 'Rwanda FDA' established by Law N°: 003/2018 of 09/02/2018 establishing Rwanda FDA, determining its mission, organization, and functioning.

2. **"Active surveillance"** means active measures taken to monitor adverse events.

3. **"Adverse Drug Reactions (ADRs)"** means a response to a medical product that is noxious and unintended and which occurs at a dose normally used for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function;

4. **"Adverse Event"** means any untoward occurrence that may present during treatment with a pharmaceutical product, which does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, symptom or disease, temporarily associated with the use of the product whether or not related to the product;

5. **"Development Safety Update Report (DSUR)"** means a periodic report on a medical product under development (including marketed products that are under further studies) deemed to be recognised by the Authority;

6. **"Health care providers"** means medically qualified persons, including physicians, dentists, pharmacists, nurses, assistant medical officers and clinical officers, pharmacy technicians, laboratory technicians, laboratory technologists;

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

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

9. **"Medication error"** means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or the consumer. Such events may be related to professional practice, health care products and procedures and systems, including prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use;

10. **"Medical device" means** any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection

11. **"Over dosage"** means accidental or intentional use of a medical product in an amount that is more than recommended dose;

12. **"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;

13. **"Pharmaceutical product"** means 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, and equipment and farm houses.

14. **"Post-marketing surveillance"** means surveillance activities that occur following market approval of a medical product including maintenance of product authorisation and/or registration of variations or renewals; regular inspection 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;

15. **"Periodic Benefit-Risk Evaluation Report (PBER)"** means a comprehensive safety evaluation report produced by the Marketing Authorisation Holders at defined time points after a medicine has been given;

16. **"Periodic Safety Update Report (PSUR)"** means an update of the world-wide safety experience of a product at defined times post marketing authorisation;

17. **"Serious Adverse Event (SAE)"** means an adverse event which results in death, is life threatening requires inpatient hospitalisation, results in prolonged hospitalisation, or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or in a congenital anomaly/birth defect;

18. **"Serious Adverse Drugs Reactions"** means an adverse reaction which results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or in a congenital anomaly/birth defect;

19. **"Serious undesirable effects"** means undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death

20. **"life threatening"** means a reaction in which the patient was at risk of death at the time of the reaction, but not including a reaction that hypothetically might have caused death if more severe

CHAPTER II: PHARMACOVIGILANCE

Article 5: Pharmacovigilance system

1. Pharmacovigilance and Safety Monitoring Division within the Authority plays the role of National pharmacovigilance Centre;

2. The functions of the Authority shall be to collect, manage, assess, analyse, identify signals and communicate safety information related to pharmaceutical products and medical devices.

3. Pharmacovigilance system shall cover structures, responsibilities, procedures, processes, resources, compliance management, record management and outcomes from pharmacovigilance activities.

4. All manufacturers and Marketing Authorisation Holders shall:
   a) Establish a pharmacovigilance system for receiving, handling, assessment and reporting of adverse drug reactions (ADR) to sustain ADR reporting system**.**
   b) Have the responsibility to ensure that the pharmacovigilance system in place is adequately resourced, continually improved and that roles, responsibilities and authorities are defined, communicated and implemented.
   c) Permanently have a Qualified Person for Pharmacovigilance (QPPV) responsible for pharmacovigilance system and have a sufficient number of competent qualified personnel involved in implementation of the pharmacovigilance system;
   d) Put in place procedures and processes in place to ensure continuous monitoring of pharmacovigilance data and scientific evaluation of all information on the risks of products;
   e) Foster good cooperation between the Authority, public health programs, patients, healthcare professionals and other relevant bodies for public health protection

5. Public Health Programs, Health facilities, suppliers, Research institutions, Contract Research Organizations (CROs), professional bodies, academia, distributors, and several other stakeholders of pharmaceutical products and medical devices shall establish pharmacovigilance system to enable them to fulfil their obligations towards the patient and public safety.

6. All stakeholders dealing with Pharmaceutical products and medical devices shall establish a system for collecting, managing, and reporting adverse events to the Authority and shall appoint a focal person for coordination of pharmacovigilance activities

Article 6: Quality Management System

1. For the purpose of Good Pharmacovigilance Practices, every system shall have a Quality Management System as part of the pharmacovigilance system;

2. The objective of the quality management system is to ensure that it complies with legal and regulatory requirements, prevention from adverse reactions, promotion of safe and effective use of pharmaceutical products and medical devices;

3. The quality management system shall involve planning, adherence, control, assurance, record management, and improvements of Pharmacovigilance activities.

Article 7: Good Pharmacovigilance Practices

Any manufacturer, marketing authorization holder, and other stakeholders in Pharmacovigilance shall comply with the Good Pharmacovigilance Practice requirements as described in the relevant guidelines.

Article 8: Stakeholders in pharmacovigilance

1. The pharmacovigilance system shall have different stakeholders to fulfill its regulatory requirements and responsibilities in relation to pharmacovigilance of Pharmaceutical products and medical devices;

2. The stakeholders in pharmacovigilance shall include the policymakers, regulatory authority, public and private health facilities, Public health programs, marketing authorization holders, health care providers, patients, consumers, research institutions, outlets, and any other person dealing with pharmaceutical products and medical devices;

Article 9: Processes, Roles and responsibilities

1. The Authority shall describe in the relevant guidelines the critical processes for pharmacovigilance system;

2. Without prejudice to other laws and regulations, the roles and responsibilities of each stakeholder in pharmacovigilance shall be described in the relevant guidelines issued by the Authority for the implementation of these regulations;

3. The Authority shall coordinate all pharmacovigilance activities in Rwanda;

4. The Authority shall maintain the ADRs database and coordinate safety communication to the public;

5. The Authority shall maintain a multilateral relationship with other National Pharmacovigilance Centres and a bilateral relationship with the Uppsala Monitoring Centre (UMC) as a participating member of the WHO Collaborating Centre for International Drug Monitoring.

Article 10: Establishment of Pharmacovigilance Advisory Committee

1. The Authority shall establish a Pharmacovigilance Advisory Committee with clear terms of reference;

2. The committee shall be composed of multidisciplinary experts and specialisation in relevant fields to assess all safety issues on pharmaceutical products and medical devices;

Article 11: Capacity building in pharmacovigilance

1. Market Authorization Holder and other stakeholders in Pharmacovigilance shall provide initial and continued training to personnel involved of pharmacovigilance activities;

2. Training plans shall be based on the roles and responsibilities of the personnel;

3. Training effectiveness shall be verified and records of training shall be kept;

4. The training shall also apply to external partners and shall be clearly stipulated in the contractual agreements and audited regularly.

5. Market Authorization Holder and other stakeholders in Pharmacovigilance shall ensure personnel involved in pharmacovigilance are efficiently capacitated as per their respective roles

Article 12: Pharmacovigilance Inspections

1. The Authority shall, at any time it deems necessary, conduct pharmacovigilance inspections for the purpose of ensuring compliance with Good Pharmacovigilance Practices and the provisions of these Regulations;

2. The inspection shall include the premises, records, documents, and pharmacovigilance system master file (PSMF) or any companies employed by the marketing authorisation holder to perform pharmacovigilance activities;

3. The inspection shall also involve review of procedures, systems, personnel, product-related issues and facilities to determine their compliance with regulatory requirements;

4. The scope and type of inspection shall be in the relevant guidelines issued by the Authority for the implementation of these regulations;

5. The Public Health Programs (PHPs), Marketing Authorization Holders (MAHs) and Health facilities shall permit the Authority to access, copy, and verify any records or reports made with regard to pharmacovigilance activities;

6. The PHPs, MAHs and Health facilities shall carry out a self-audit/assessment using assessment tools issued by the Authority to monitor performance and effectiveness of a pharmacovigilance system and records shall be kept within facilities;

7. The results of the pharmacovigilance inspection shall be provided to the inspected entity for comments on any non-compliance identified within timelines prescribed by the Authority. Any non-compliance shall be rectified in a timely manner through the implementation of corrective and preventive action plan;

8. The Authority shall grade the inspection findings as 'Critical', 'Major' and 'Minor' in order to indicate their relative criticality to risks impacting the pharmacovigilance system and processes.

Article 13: Establishment of Risk Management System

1. Marketing Authorisation Holder shall be required to establish a risk management system for collection of data relevant to the safety profile of pharmaceutical products and medical devices as well as identifying the risks from continuous evaluation of safety signals of their products within and outside Rwanda;

2. The Marketing Authorisation Holder shall plan for the risk management system very early in product's life cycle, including characterisation and minimisation of the risks associated with the product in the post-authorisation;

3. The Marketing Authorisation Holders may be requested by the Authority to submit a Risk Management Plan (RMP) focused on safety concerns as prescribed in the relevant guidelines;

4. The Marketing Authorisation Holders shall monitor the outcome of risk minimization measures which are contained in the risk management plan and take appropriate measures as necessary;

5. The Marketing Authorisation Holders shall update the risk management system and the RMP accordingly.

Article 14: Reporting of adverse drug reactions/Events

1. Marketing Authorisation Holders, Health facilities, Public Health Programmes (PHPs), manufacturers, Health Care providers, Patients or any other designated person shall have obligations to report to the Authority any of the following adverse events:
    a. All suspected Adverse Drug Reactions as a result of prescription and non-prescription medicines;
    b. Unexpected reactions, regardless of their nature and severity, whether or not consistent with product information or labelling;

c. All Adverse Drug Reactions regardless of whether or not the product was used in accordance with the product information provided by the company marketing the product;
d. All adverse events following immunisation or use of biological products;
e. All adverse events, incidences, associated with use of medical devices or vitro diagnostic medical devices;
f. An observed increase in frequency of a given adverse reaction;
g. A serious reaction, whether expected or not;
h. All suspected Adverse Drug Reactions associated with drug-drug, drug-food, or drug-food supplement interactions;
i. Adverse Drug Reactions in special fields of interest including drug abuse and drug use in pregnancy and during lactation
j. Adverse Drug Reactions occurring from overdose or medication errors;
k. Unusual lack of efficacy or when suspected quality defects are observed; and Product quality problems.

2. The Marketing Authorisation Holders, Health facilities, Public Health Programmes (PHPs), manufacturers, Health Care providers, Patients or any other designated person shall report adverse drug reactions/events to the Authority in the prescribed format and timelines.

Article 15: Reporting of unusual failure in efficacy or performance

All reports of unusual failure in efficacy or performance shall be reported to the Authority by Marketing Authorisation Holders, health care providers, public health programs and other stakeholders in Pharmacovigilance

Article 16: Reporting of medication errors

Medication errors that arise during routine clinical practice shall be reported to the Authority using a prescribed format of reporting.

Article 17: Periodic Safety Update Reports, Periodic Benefit-Risk Evaluation Reports and the Development safety update reports

1. The MAH shall submit to the Authority the Periodic Safety Update Reports (PSUR) for the pharmaceutical product placed on market within and outside Rwanda based on all available safety data, including clinical trials data in unauthorized indications and populations.

2. The Periodic Safety Update Report and Periodic Benefit-Risk Evaluation Reports (PSURs /PBRER) shall be submitted to the Authority according to the timelines specified in the relevant guidelines.

3. The Periodic Safety Update Report and Periodic Benefit-Risk Evaluation Reports (PSURs /PBRER) shall be submitted to the Authority in prescribed format specified in the relevant guidelines

4. The Development safety update reports (DSUR) shall be submitted to the Authority in the format and timelines prescribed in the relevant guidelines

Article 18: Reporting of Post Authorization Safety and Post Authorization Efficacy Studies

1. The MAHs shall conduct Post Authorization Safety Studies (PASS)/Post Authorization Efficacy Study (PAES) for the purpose of identifying, characterising or quantifying a safety hazard, and confirming the safety profile of a pharmaceutical product or measuring the effectiveness of risk management measures;

2. The MAH shall submit PASS/PAES reports to the Authority in prescribed format and timelines specified in relevant guidelines;

3. The MAH shall be required to submit to the Authority the PASS study protocol in the prescribed format for review and approval;

4. The Authority shall require MAHs to conduct post-authorization studies on safety and efficacy as a condition at time of the granting of the marketing authorization or later as and when required.

Article 19: Pharmacovigilance system master file

1. Every manufacturer and Marketing authorization holder shall maintain and make available upon request by the Authority a copy of Pharmacovigilance System Master file;

2. The Pharmacovigilance master file shall be located and available at the manufacturer's site and the marketing authorization holder's designated qualified person in pharmacovigilance (QPPV);

3. During application for marketing authorization, the manufacturers and marketing authorization holders shall submit summary information about their pharmacovigilance system including the location of the Pharmacovigilance System Master file;

4. The marketing authorization holder may subcontract certain activities of the pharmacovigilance system to third parties. It shall nevertheless retain full responsibility for the completeness and accuracy of the Pharmacovigilance System master file;

Article 20: Reporting of unregistered, substandard and/or Falsified Products

1. The Authority, MAHs, Local technical representatives (LTR) and distributors shall establish mechanisms for reporting pharmaceutical product and medical devices that are suspected to be substandard, falsified or unregistered for public health protection.

2. The Manufacturer, marketing authorisation holder, distributor, healthcare professional or any other person shall be required to report to the Authority any substandard, falsified or

unregistered pharmaceutical product and medical devices using prescribed format in the relevant guidelines.

3. Without prejudice to other laws and regulations, the Authority may require the manufacturer or Marketing Authorisation Holder to conduct extra monitoring for the suspected substandard or falsified pharmaceutical products and medical devices

Article 21: Reporting Channels

1. The reports of adverse reactions/event or event associated with use of the product from MAHs, Health facilities, Public Health Programmes (PHPs), manufacturers, Health Care providers, Patients and consumers shall be appropriately channelled according to the pharmacovigilance reporting system established by the Authority;

2. Without prejudice to the established pharmacovigilance and quality management systems provided in these Regulations, all manufacturers and MAHs shall directly report to the Authority any adverse reactions or events suspected to be associated with the use of their products notified/reported to them by healthcare professionals, patients or consumers;

3. The adverse events reports shall include reports that arise from post-marketing experience, unsolicited and solicited sources, clinical trials and non-interventional post-registration studies and other post-marketing studies and programs;

4. All manufacturers and MAHs shall regularly monitor domestic and international literature, on-going safety and efficacy studies for any identification of adverse reaction reports or relevant safety findings regarding their products.

Article 22: Signal detection and identification

1. The Safety signals shall be detected from a wide range of sources, such as spontaneous reports, Active surveillance, clinical trials, pharmaco-epidemiology studies, non-clinical studies and scientific literature;

2. The Authority and MAHs shall have mechanisms in place for signal detection and perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the risk-benefit balance.

Article 23: Signal Management

1. The Authority and MAHs shall put in place a process of signal management to determine whether there are new risks associated with a particular pharmaceutical product or medical devices, or whether known risks associated with a particular product has been changed;

2. The MAHs shall have mechanisms in place for early signal detection, evaluation, validation, prioritization, minimisation and communication of risks associated with pharmaceutical products and medical devices throughout their lifecycle;

3. The safety monitoring activities shall include a review of cumulative cases in order to allow for a comprehensive review of potential safety issues.

Article 24: Safety information and communication

1. The Authority shall put in place mechanisms to communicate safety information to healthcare providers, patients and other relevant stakeholders;

2. The Authority shall ensure that safety information to be communicated is presented objectively, based on scientific evidences, provided timely, targeting appropriate audience and is not misleading;

3. The MAHs shall obtain approval from the Authority on any information intended for the healthcare providers and public on pharmacovigilance concerns in relation to the safety, quality, and rational use of pharmaceutical product and medical devices;

4. The Authority and MAHs shall ensure that safety information is communicated using appropriate communication channels.

Article 25: Confidentiality and data Management

1. The Authority, Health facilities, Public Health programs and Marketing Authorization Holders shall maintain and control the records and reports of all activities relating to pharmacovigilance operations;

2. The Authority, Health facilities, Public Health programs and Marketing Authorization Holders shall maintain and keep all pharmacovigilance data with fully confidentiality;

3. The pharmacovigilance data shall be appropriately stored in way that is traceable, retrievable, and secure with access restricted only to authorized personnel.

Article 26: Pharmacovigilance data and Regulatory actions

1. Without prejudice to other applicable laws and regulations, the Authority may, as part of control measures, impose different regulatory actions based on carefully analysed safety information in order to prevent injury to the health or safety of patients, users or other persons;

2. The incriminated pharmaceutical product or medical devices shall be put on hold or quarantined pending further investigations, recalled, destroyed, change of conditions under which a particular product is marketed, withdrawal from the market registration;

3. The Authority may, upon proof of scientific information received relating to safety of pharmaceutical products or medical devices from other regulatory Authorities or relevant international bodies, take a regulatory decision;

4. The regulatory decision may include any corrective or preventive action to protect the public from any eminent safety concerns that may likely arise.

Article 27: International collaboration for pharmacovigilance activities

1. The Authority shall work closely with other regulatory Authorities at regional and international level, development partners and WHO-UMC (Uppsala Monitoring Centre) for sharing information on safety issues, anticipated regulatory action and communication;

2. The Authority shall also participate in the harmonization initiatives to strengthen pharmacovigilance and safety monitoring activities of pharmaceutical products and medical devices marketed in and outside of Rwanda.

Article 28: Reliance

1. The Authority shall rely on Pharmacovigilance decisions from other national regulatory Authorities, regional and international regulatory bodies when deemed necessary;

2. The Authority shall establish the procedures, circumstances, collaborative and mutual agreement for reliance.

CHAPTER III: MISCELLANEOUS PROVISIONS

Article 29: Power to issue guidelines for pharmacovigilance

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

Article 30: Appeals and review

1. 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;

2. The Authority shall, within thirty (30) working days from the date of receiving the application, review, reject or vary its own decision.
   However, if a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

Article 31: Administrative sanctions

Any person who contravenes any of the provisions of these Regulations will be liable to administrative sanctions attached to this regulation as **Annex I**.

Article 32: Commencement

These regulations shall enter into force on the date of its signature and publication. All prior contrary provisions to these regulations are hereby repealed.

End of Document

Annex I: Administrative sanctions

No	Fault	Administrative sanctions
1	Failure to submit the PSUR/PBRER/DSUR or RMP reports as per prescribed timelines	Warning letter
2	Failure to submit local serious cases as per the prescribed timelines	Warning letter
3	Failure to nominate Qualified personnel in pharmacovigilance (QPPV)	Warning letter
4	Failure to notify the emerging safety issues/signals impacting the quality of life	Warning letter
	Failure to notify regulatory actions taken by other regulatory agencies	Warning letter
5	Failure to implement required regulatory actions as part of the risk minimization	Suspension of Marketing authorization
6	Critical findings from GVP inspections	Suspension of Marketing authorization
7	Failure to communicate and implement risk minimization measures for a potential or confirmed risk	Withdrawal of market authorization