RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING THE GOOD MANUFACTURING PRACTICES OF MEDICAL PRODUCTS

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

REGULATION DEVELOPMENT HISTORY

First issue date	08/10/2022
Effective date of this revision	01/06/2026

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
8/ 10/2022	0	First Issue
14/01/2022	1	**Addition of three articles;** 1. Article 9: Describing Virtual/remote inspections and the criteria for applicants to be considered for these types of inspections 2. Article 177: Describing the establishment of a scientific and advisory Committee 3. Article 182: Describing frequency of publication of GMP compliant facilities

28/08/2022	2	1. Streamlined regulation as per the recommendation from SOP on Document control ODG/QMS/SOP/001 2. Editorial Changes were done 3. Requirements for different articles were removed from the Regulations governing GMP of Medical Products and moved to the various guidelines. 4. Article 10: The article for reliance was renamed reliance/recognition since the criteria for both activities were similar. Also the word Stringent Regulatory Authority was replaced by the new terminology WLA (WHO Listed Authority) 5. Articles 11 and 12: Desk review and Virtual inspection: The criteria for Desk review and Virtual inspections were removed and inserted into the relevant guidelines. 6. Article 14: Certificate and Validity. Here the validity of the GMP certificate for both domestic and foreign sites was aligned. 7. Definition: added definition for Active Pharmaceutical Ingredient. **Added Articles:** 8. Article 5: obligation of manufacturer to get GMP certificate 9. Article 6: Language: This article describes the language of official documents for GMP applications. 10. Article 7: Authenticity of Documents This article describes the responsibility of the applicant to provide reliable documents and the authority of Rwanda FDA to reject documents considered not to be authentic 11. Article 8: Safe custody and confidentiality of information: This article describes the responsibility of the Authority to safeguard applicants' information. 12. Article 9: Assessment of GMP application. This article describes how applicants' dossiers are assessed and how communication is done between the Authority and the applicant. 13. Article 13: This article describes the criteria for considering applicants for

		temporary waivers of onsite inspection during emergency states 14. Article 145: Warnings, suspensions, and revocations: This article details when the Authority can take these actions against an applicant. 15. Article 146: restoration of a suspended or revoked GMP certificate. This article details when the Authority can take such actions against a suspended or revoked GMP certificate. 16. Article 89: on Transport and delivery validation was added.
23/03/2023	3	1. Article 4: Definitions: included the following definitions; "Marketing Authorization", "Packaging", "Packaging Material", "Production", "Qualification" and "Suspension/revocation" 2. Article 16: Exemption. This was included to detail manufacturers of medical products that are excluded from GMP certification. 3. Article 17: Guidelines and Guidance's: This was included to give powers to the guidelines and guidance. 4. Article 147: Warnings, suspensions and revocations: Expanded conditions for issuing warnings, suspension and revocations of GMP certificate. 5. Editorial changes

24/04/2026	4	1. Comprehensive review and restructuring of the GMP Regulations to improve regulatory clarity, readability, and implementation. 2. Reorganization and reduction of chapters and articles to distinguish legal provisions from technical implementation requirements contained in GMP guidelines. 3. Strengthening of provisions on GMP reliance and recognition, including reliance on WHO Listed Authorities (WLA), PIC/S participating authorities, WHO Prequalification Programme, EAC regulatory frameworks, and authorities with cooperation agreements with Rwanda FDA. 4. Inclusion of detailed provisions for substantial modifications requiring prior Rwanda FDA approval before implementation. 5. Strengthening of provisions related to inspection powers, conduct of inspections, seizure, sampling, access to records, and inspectors' responsibilities. 6. Expansion and clarification of enforcement measures including warning letters, suspension, revocation, administrative sanctions, fines, and restoration of GMP certificates. 7. Inclusion of provisions for publication of GMP compliant facilities and inspection summary reports on the Rwanda FDA website. 8. Revision and harmonization of definitions including critical, major and minor deficiencies, marketing authorization, GMP, manufacture, substantial modification, and related regulatory terminology. 9. Updating of certificate validity provisions to specify validity for three (3) years from the last inspection date. 10. Alignment of the Regulations with current Rwanda FDA operational structure, WHO GMP standards, reliance principles, and international best regulatory practices. 11. Editorial revisions, formatting updates, harmonization of terminology, and correction of structural inconsistencies throughout the document.

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.: DD/PIL/TRG/005 Version 4 Governing Good Manufacturing Practices of Medical Products on this …./06/2026

Prof. Emile BIENVENU
Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article One: Citation

These regulations are cited as the "Regulation DD/PIL/TRG/005 Version 4, Governing Good Manufacturing Practices of Medical Products" herein after abbreviated as (GMP) of Medical Products.

Article 2: Purpose of these Regulations

The purpose of these regulations is to enforce the legal and regulatory framework to ensure effective and efficient GMP of manufacturers of medical products.

Article 3: Scope

These regulations shall apply in all regulatory controls related to GMP inspections of medical products and shall apply to all persons and premises involved in any aspect of the manufacturing of medical products.

The Rwanda Food and Drugs Authority, hereinafter abbreviated as "Rwanda FDA", ensures that manufacturers of medical products that are involved in the manufacture, import, export, distribution, storage and sale of medical products within and outside Rwanda comply with GMP to prevent exposure of the public to substandard and falsified products.

Article 4: Definitions

In these regulations, unless the context otherwise requires, the following terms are defined as follows:

"Authorization" means the certification of a manufacture medical product

"Authorized Person" means an individual recognized by the Rwanda FDA as having the necessary relevant scientific and technical background and experience.

"Applicant" means any legal or natural person/entity submitting the application to the Authority, established within or outside Rwanda, seeking to obtain or having obtained the authorization to manufacture or register medical products in Rwanda

"Active Pharmaceutical Ingredient (API or Drug Substance)" means any substance or mixture of substances intended to be used in the manufacture of pharmaceutical dosage form which becomes an active ingredient to provide pharmacological activity, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

"Conflict of interest" means any interest in any business related to medicines declared or undeclared by the inspector or staff that may affect or reasonably perceived to affect the quality or the result of his/her work or remediation;

"Critical deficiency" means;
-A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.
-A "Critical" deficiency also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.
-A "Critical" deficiency may consist of several related deficiencies, none of which on its own may be "Critical", but which may together represent a "Critical" deficiency, or systems' failure where a risk of harm was identified and should be explained and reported as such.;

"Finished pharmaceutical product (FPP)" it's a pharmaceutical product that has undergone all stages of production including packaging in its final container and labeling, ready for distribution of supply.

"Good manufacturing practices or its acronym "GMP" means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specifications;

"Good Manufacturing Practice inspector" is an inspector appointed by the Authority who possesses qualifications and experience in pharmaceutical manufacturing, quality control, and quality assurance to conduct an inspection or assessment to verify GMP compliance of a manufacturing site on behalf of Rwanda FDA.

"Major deficiency" A deficiency that is not a "Critical" deficiency, but which:
- has produced or may produce a product which does not comply with its Marketing Authorisation, Clinical Trial Authorisation, product specification; pharmacopoeia requirements or dossier;
- does not ensure effective implementation of the required GMP control measures;
- indicates a major deviation from the terms of the manufacturing authorisation;
- indicates a failure to carry out satisfactory procedures for release of batches or failure of the authorised person to fulfil his/her duties;
- consists of several "Other" related deficiencies, none of which on its own may be "Major", but which may together represent a "Major" deficiency or systems failure and should be explained and reported as such.

"Manufacture" means all operations of purchase of materials and products, production, packaging, quality control, release, storage, shipment of medical products, and their related controls;

"Manufacturer" means a person or a firm that is engaged in the manufacture of medical products;

"Marketing Authorization" approval from the Rwanda FDA necessary to market and sell a product in Rwanda. This is a legal document that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

"Medical product" includes medicines, vaccines, in-vitro diagnostics and medical devices

"Minor deficiency" A deficiency that is not classified as either "Critical" or "Major", but indicates a departure from Good Manufacturing Practice (GMP). A deficiency may be judged as "Other" because there is insufficient information to classify it as "Critical" or "Major".

"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 to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises where food and drugs are manufactured, prepared, or stored, cleaning hospitals, equipment, and farmhouses;

"Production", means all operations involved in the preparation of a medical product, from receipt of materials, through processing, packaging, labelling, to completion of the finished product.

"Rwanda FDA" means Rwanda Food and Drugs Authority established under Law N° 003/2018 of 09/02/2018.

"Suspension/Revocation of GMP certificate" means an annulment of GMP certificate issued to manufacturer of medical products due to violation of conditions of issue.

"substantial modification" means a change to the premises, equipment, personnel, procedures and processses that is likely to have significant impact and affect the quality, safety and intergity of the products manufactured, stored, distributed and used.

"WHO Listed Authority (WLA)**"** means a regulatory authority or a regional regulatory system (RRS) that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process.

CHAPTER II: GOOD MANUFACTURING PRACTICE INSPECTION

Article 5: Obligation to obtain GMP certificate

Every person intending to manufacture or market their medical products on the Rwandan Market within as per the scope of this regulation shall comply with applicable GMP requirements prior to commencement.
Premises for manufacturing of medical products within the country shall require prior premise registration and only be carried out in premises holding a valid GMP certificate issued by the Rwanda FDA. Manufacturing License for domestic manufacturers shall only be issued after issuance of a valid GMP certificate by Rwanda FDA.
Rwanda FDA shall conduct inspection for confirmation of the compliance to this Regulation and relevant GMP guidelines. A GMP certificate shall not be granted where the Authority finds the applicant not complying with GMP requirements as detailed in the applicable Rwanda FDA Guidelines.

Article 6: Certificate and Validity

Rwanda FDA shall issue a Certificate of GMP, when a manufacturer meets all the stipulated requirements. This certificate shall be valid for a period of three (3) years from the last date of inspection and shall apply to both foreign and domestic manufacturing sites.
Application for renewal of GMP certificate shall be made to Rwanda FDA within six months before the end of validity period.
Any changes to the information as contained in the issued GMP certificate or circumstances affecting its validity must be reported to Rwanda FDA within fifteen (15) working days of the implementation of change.

Article 7: Approval of a substantial modification

Rwanda FDA may conduct an inspection of the premises before approving any substantial modification.
The applicant must inform Rwanda FDA of any substantial changes or modification which may affect the quality, safety or efficacy of medical products for approval purposes, and must wait for written approval from Rwanda FDA before implementing the proposed changes.
The types of substantial modifications are outlined in the relevant Rwanda FDA guidelines on GMP.

Article 8: Application for GMP

Any person intending to apply Good Manufacturing Practice (GMP) inspection must submit an application addressed to the Director General of the Rwanda FDA. The application must include all required documents, as specified in the applicable GMP guidelines.
Notwithstanding the provisions of the preceding paragraph, no GMP inspection shall be conducted for facilities that have not submitted an application for Market Authorization and manufacturing license where applicable.

Article 9: Language

All applications and supporting documents must be submitted in English, French, or Kinyarwanda. If any documents are presented in a language other than these, the applicant must provide certified translations prepared by approved translators to facilitate the review process.

Article 10: Authenticity of submitted documents

All documents submitted to Rwanda FDA must be authentic and approved by the applicant or an authorized representative.
Rwanda FDA reserves the right to reject an application for GMP inspection of a medical product manufacturer if it determines that the submitted documents are not authentic or if the integrity of the data is deemed questionable.

Article 11: Safe custody and confidentiality of submitted information

Rwanda FDA shall ensure the secure custody of all information related to GMP applications for manufacturing sites submitted by applicants. All submitted information shall be treated as confidential and shall not be disclosed to any third party without the prior written consent of the applicant.

Article 12: Assessment and Additional requirements for GMP applications

Rwanda FDA shall, upon being satisfied with the submission of an application, conduct an assessment to verify its compliance with Good Manufacturing Practice (GMP) requirements.

1º Rwanda FDA may, during the dossier assessment, require the applicant to provide additional documents, information, data, or clarifications to support the GMP inspection application.

2º If Rwanda FDA requests additional documents, information, data, or clarifications pursuant to paragraph 1º of this Article, the processing of the application shall be put on hold until the applicant submits the required information.

3º Where the applicant fails to submit the requested information as outlined in paragraph 2º of this Article within ninety (90) working days from the date of the request, the application shall be considered withdrawn, and a new application shall be required.

4º An applicant may request an extension of time to submit the additional documents, information, data, or clarifications required by Rwanda FDA, provided the request is submitted in writing and includes valid justifications.

5º If the applicant fails to provide satisfactory responses to the requested information as outlined in paragraph 2º of this Article for the third time, the application shall be rejected, and a new application shall be required.

6º Applications withdrawn pursuant to paragraph 3º and applications rejected pursuant to paragraph 5º of this Article shall only be considered for GMP inspection upon the submission of a new application in accordance with the requirements of these Regulations.

Article 13: Reliance of GMP regulatory decisions

1º Rwanda FDA may rely on GMP decisions issued by:
a) Regulatory authorities that are members of the Pharmaceutical Inspection Co-operation Scheme;
b) WHO Listed Authorities;
c) World Health Organization Prequalification Program, including prequalified manufacturing facilities;
d) Regional regulatory frameworks where Rwanda is a member, such as East African Community; and
e) Authorities with which the Rwanda FDA has established mutual recognition agreements, memoranda of understanding, or other cooperation arrangements.

2º Upon receipt of a duly completed GMP application, Rwanda FDA may conduct a desk assessment based on the documentation submitted, including valid GMP certificates, recent inspection reports, site master files, and relevant quality system documentation. Such desk assessments shall be conducted at the discretion of the Authority using a risk-based approach.

3º Notwithstanding the provisions of paragraphs 1º to 2º of this Article, Rwanda FDA may require an on-site inspection using a risk-based approach.

5º Reliance under this Article shall not constitute automatic recognition of external regulatory decisions. Rwanda FDA shall retain full regulatory independence and may accept, partially accept, or reject any external decision based on its own scientific and regulatory assessment.

6º The criteria, procedures, and documentation requirements governing the application of reliance, including eligibility for desk assessments and recognition of manufacturing sites, shall be specified in the relevant guidelines.

7º The validity of a GMP certificate issued through reliance shall not exceed the validity period of the reference certificate.

Article 14: Virtual Inspections

Upon receipt of a duly completed application, the Authority may conduct a voluntary virtual interactive or remote inspection of facilities where medical products are manufactured, processed, or packed. This type of inspection may be conducted under the following circumstances:

1º The Authority determines, based on its assessment, that a virtual inspection is appropriate;
2º A force majeure event prevents the conduct of physical inspections.

Virtual interactive or remote inspections shall be conducted at the discretion of the Rwanda FDA The criteria for selecting facilities eligible for such inspections shall be outlined in the relevant guidelines.

Article 15: Temporary Waivers of Onsite Inspection During Emergency Situations

Manufacturers who have applied for new or renewed GMP inspections but do not meet the criteria for desk reviews or virtual inspections may be considered for temporary waivers on a short-term basis during emergency situations.
The criteria for applicants to be considered for temporary waivers shall be outlined in the relevant guidelines.

Article 16: Exemption

Provisions of Article 5 shall not apply to:

1º Manufacturers of medical products granted Authorization for Emergency Use by the Rwanda FDA during a declared public health emergency;
2º Manufacturers or entities whom the Rwanda FDA deems necessary to exempt from GMP certification.

The Authority may, in writing, exempt, subject to such conditions as it may specify, any medical product or substance from the operation of any or all of the provisions of this regulation. Before any decision regarding exemption from onsite GMP inspection is made, the history of valid onsite GMP inspection approvals by other National Medicines Regulatory Authorities (NMRAs) and Notified Bodies shall be reviewed.

CONDUCT OF INSPECTIONS

Article 17: Inspection and Compliance with GMP Regulations

Rwanda FDA shall conduct inspections as per relevant GMP guidelines to ensure that:
1º Manufacturers comply with the requirements set forth in these Regulations; and
2º Non-conformances with these Regulations are resolved

Article 18: Appointment of inspectors

Rwanda FDA shall appoint qualified inspectors to conduct inspections of both domestic and overseas manufacturing facilities where medical products intended for use in Rwanda are produced.
Inspectors shall possess the necessary qualifications, including relevant academic education, training, and experience, to effectively perform inspections of medical product manufacturing facilities.
The list of GMP inspectors may be made available to the public upon formal request to the Rwanda FDA.

Article 19: Conflict of Interest

To prevent any conflict of interest, all inspectors shall declare any potential conflict of interest upon their appointment.

Article 20: Powers of inspectors

For the purpose of enforcing compliance with these Regulations, an inspector duly appointed under these provisions shall, upon presentation of official identification or written authorization, have the power, at all reasonable times, to:

1º Enter any premises, place, vehicle, vessel, or aircraft where any medical product, substance, device, or related activity subject to these Regulations is located, or is reasonably suspected to be located.

2º Entry into premises used solely as a private dwelling shall only be permitted where the inspector has reasonable grounds to believe that evidence of a contravention exists therein and in accordance with applicable regulations.

3º Conduct inspections, examinations, tests, and analysis of any medical product, substance, device, or related process at such premises or locations as deemed necessary.

4º Require the production of, inspect, and take copies of or extracts from any book, document, record, or data, in any format, including electronic records and computerized systems accessible from the premises.

5º Take samples for examination and analysis, and seize any medical products, substances, devices, articles, or any books, documents, or records which appear to provide evidence of a contravention of these Regulations.

6º Question any person present at the premises whom the inspector reasonably believes may have relevant information.

7º Require any person to:

- Provide necessary assistance in relation to matters under their control; and
- Provide access to facilities, equipment, or resources reasonably required for the performance of inspection duties.

Provided that no person shall be compelled to produce any document protected by legal professional privilege.
Where an inspector enters premises that are closed or unoccupied:

1º The inspector shall be accompanied by:

- A representative of the local administration; and
- A representative from the public investigation body (RIB).

2º During the inspection, a written record shall be prepared, including:

- Identification of the premises
- Confirmation of its condition (closed/unoccupied)
- Signatures of accompanying officials
- Photographic evidence, where necessary

3º Where premises are unoccupied, the inspector shall ensure that such premises are secured upon exit to the same extent as they were found.

Documentation of Seizure and Sampling

1º Where any item is seized, a detailed inventory shall be prepared and:

- Provided to a responsible person at the premises; or
- Left in a prominent location where no such person is present.

2º Where samples are taken:

The Authority may arrange for analysis by an authorized laboratory.

Article 21: Establishment of a scientific and advisory committee
Rwanda FDA may establish a scientific and advisory committee consisting of internal and/or external experts from various fields and scientific research to provide guidance on matters related to Good Manufacturing Practices (GMP) inspections.

Article 22: Joint Inspection
Rwanda FDA may participate in joint inspections with regulatory authorities from other countries. Unless otherwise notified, these Regulations shall apply during such joint inspections.

CHAPTER III: FINAL PROVISIONS

Article 23: Administrative sanctions

The administrative sanctions provided in this regulation are in two categories:

1. Administrative fines
2. Warning letter, suspension and revocations

Article 24: Administrative fines

Any person who contravenes the provisions of these regulations shall be liable to the administrative measures and fines under Annex A.

Article 25: Warning letter, suspension and revocations

Rwanda FDA may issue a warning letter, suspend, or revoke a GMP certificate if the applicant is found to be non-compliant with any of the requirements or conditions set forth in these Regulations and relevant guidelines.

Conditions for Issuing a Warning Letter:

1º If the information on which the approval was granted is later found to be false;
2º If the circumstances under which the GMP certificate was granted no longer exist and Rwanda FDA was not informed.

Conditions for Suspension:

Rwanda FDA may suspend a GMP certificate under the following circumstances:
1º The site is no longer GMP compliant;
2º Manufacture of authorized products has been discontinued;
3º The manufacturer has submitted an application notifying the Authority of the decision to discontinue manufacture, along with reasons for the discontinuation;
4º Market complaints about products manufactured at the site are serious, with fatal consequences or failure to meet manufacturing specifications for quality, safety, and efficacy;
5º GMP inspectors are unable to access the manufacturing site to conduct the necessary GMP inspections.

Conditions for Revocation:

Rwanda FDA may revoke a GMP certificate under the following circumstances:
1º Repeated violations of regulatory sanctions or administrative decisions;
2º It appears to the Authority that failure to revoke the GMP certificate would create an imminent risk of manufacturing medical products that are not in conformity with specifications;
3º The manufacturer has requested in writing the cancellation of the GMP certificate;
4ºThe manufacturer has requested in writing the cancellation of the GMP certificate;

5º The manufacturing site has failed to comply with the conditions under which the GMP certificate was issued.

Notification and Enforcement:

Where the GMP certificate is suspended or revoked, Rwanda FDA shall issue a notice to the management of the facility. Rwanda FDA shall take further steps, including suspension of registered medicinal products or facility closure, to ensure that manufacturing activities cease until a final decision is made by the Authority.

Measures to enforce this Article may include the publication of the Rwanda FDA's actions on its website and through other relevant media channels.

Where the GMP certificate is revoked, the applicant must wait the period specified in the relevant guidelines before becoming eligible to reapply for GMP certification. Reinstatement of the GMP certificate will only be possible if the applicant meets the relevant requirements.

Other administrative sanctions:
Rwanda FDA shall take the following regulatory actions, as recommended by the inspectors, when determining the outcome of inspections:

1º Minor Non-Compliances:

a) Corrective action within a specified timeframe;
b) Request for a compliance report.

2º Major Non-Compliances:

c) Issue a warning letter and/or impose an administrative fine in accordance with the applicable laws;
d) Request corrective action within a specified timeframe;
e) Temporarily withdraw or suspend marketing authorization and impose an administrative fine in accordance with the applicable laws;
f) Request a comprehensive compliance report;
g) Conduct a follow-up inspection to verify the implementation of corrective actions within a specified timeframe.

3º Critical Non-Compliances:

h) Permanent withdrawal of marketing authorization for registered products and/or impose an administrative fine in accordance with the applicable laws;
i) Suspension or import or export license of medical products to Rwanda
j) Suspension of marketing authorization for registered products and/or impose an administrative fine in accordance with the applicable laws;
k) Denial of marketing authorization for new applications

<u>Article 26:</u> Restoration of a Suspended or Revoked GMP Certificate

Pursuant to Article 27, the Authority may restore a suspended or revoked GMP certificate if it is satisfied that the reasons for suspension or revocation have been addressed or if it determines that the grounds for suspension or revocation were unfounded.

Article 27: Appeals

Any person aggrieved by a decision of the Authority may submit a formal written request for a review of the decision, outlining the grounds for dissatisfaction, within thirty (30) days from the date of notification of the decision.

Rwanda FDA shall review the request and either reject, vary, or uphold its decision within thirty (30) working days from the date of receiving the application.

The Rwanda FDA Guidelines on appeals and complaints shall be followed in addressing any lodged appeals.

Article 28: Circulars, Guidelines and Guidance

Rwanda FDA may, from time to time, issue circulars, guidelines and guidance necessary for the implementation of these Regulations and shall be adhered to by the applicant(s) and to the members of the general public, as part of the GMP compliance process.

Article 29: Publication on Rwanda FDA website

List of GMP compliant facilities and inspection summary reports shall be published regularly on the Rwanda FDA website, and on any other media, as the Rwanda FDA may decide from time to time.

Article 30: Commencement

These Regulations shall enter into force upon their approval and publication on the Rwanda FDA website.

End of Document

Annex- A: Faults and Administrative fines

Fault	**Administrative Fines**
1º Any person who resists, or obstructs an inspector, in the exercise of his/her functions under this regulation shall be guilty of an offence and liable to a fine not exceeding	100, 000 FRW
2º Any person who tampers with any sample taken in terms of this regulation with intent to defraud or to frustrate the proper testing of the sample, shall be guilty of an offence and liable to a fine not exceeding	1,000,000 FRW