



**GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR
REGISTRATION OF PUBLIC HEALTH LABORATORY
CHEMICALS**

AUGUST, 202

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality and safety of public health laboratory chemicals in order to protect public health by increasing access and availability of quality and safe public health laboratory chemicals.

Considering the provisions of the technical regulations N° CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals, the Authority has developed the Guidelines N° DD/CHCR/GDL/005 on submission of documentation for registration public health laboratory chemicals.

These guidelines were developed in reference to a number of stringent regulatory authorities' regulations such as Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency. We also referred to the EU regulations on chemicals, food additives and labelling and classification of substances, and the National Institute of Health striving for Registration, Evaluation, Authorization and Restrictions of chemical substances.

These guidelines have been developed to provide guidance to the applicants and the authority in managing applications for registration of public health laboratory chemical products.

Applicants are encouraged to familiarize with the guidelines and follow it when preparing and submitting applications for registration of laboratory chemical product.

Adherence to these guidelines will ensure that all relevant information is provided for registration of public health laboratory chemical products. This will facilitate efficient and effective evaluation as well as public health laboratory chemical products market authorization approval process. It will also help to avoid queries which result in unnecessary delays in approving documents.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

First issue date	29/11/2022
Effective date of this version	Refer to the approval date

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
29/11/2022	0	First version
Refer to the approval date	1	<ol style="list-style-type: none"> 1. Changes to IRIMS has been included to ensure that the system meet the current requirements 2. Chemical substances categories that are not part and not concerned of these guidelines have been moved from objectives to the scope. 3. The application should be written in English is replaced by the application should be written in official language in Rwanda 4. The PDF documents should be in optical character recognition (OCR), selectable and searchable in section 1.5 d is removed 5. Categories of certificate for the laboratory chemical products is removed 6. Original hard-copy of application is removed in all sections 7. Documents requirements for variation are removed and referred to the guideline for variations 8. Receiving of new applications for product registration is reformulated and timeline for applicant to respond queries is moved from assessment procedure to timeline section. 9. Requirements for registration of local manufactured and foreign manufactured products are separated 10. Requirement to provide Flow chart and narrative description of the manufacturing process is removed 11. Time line for new application dossier processing has been reduced from 6 months to 3 months 12. Application for renew has been fixed to 2 months 13. Annual Retention on the Register has been removed

TABLE OF CONTENT

FOREWORD.....	2
GUIDELINES DEVELOPMENT HISTORY	3
DOCUMENT REVISION HISTORY	3
TABLE OF CONTENT.....	4
ABBREVIATIONS AND ACRONYMS	6
GLOSSARY	7
CHAPTER I: INTRODUCTION	9
I.1 Background	9
I.2 Scope	9
I.3 Submission of applications.....	10
I.3.1 Submission of technical dossier	10
I.3.2 Submission of commercial samples for registration	10
I.4 Types of Applications	10
I.4.1 New applications for registration.....	10
I.4.2 Renewal application for registration.....	11
I.4.3 Variation application.....	11
I.5 Receiving of applications for product registration	11
I.6 Timelines for public health laboratory chemical product registration	11
I.7 Compliance to Good Manufacturing Practices (GMP)	11
I.8 Reliance	12
I.9 Rwanda FDA Peer Review Committee for CHC Product Registration.....	12
I.10 Validity of issued registration certificate	12
CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION.....	13
II.1 Requirements for locally manufactured products	13
II.1.1 Section A: Administrative Requirements	13
II.1.1.1 Cover letter.....	13
II.1.1.2 Application form	13
II.1.1.3 Manufacturing License	13
II.1.1.4 Contract Manufacturing Agreement (where applicable)	13
II.1.1.5 Samples of the product.....	13
II.1.1.6 One coloured artwork/Label of the product.....	13
II.1.2 Section B: Technical Requirements	13
II.1.2.1 Details on the product characteristics	13
II.1.2.1 Information related to molecular and structural formula of product	13
II.1.2.2 Composition of each substance.....	14
II.1.2.3 Physicochemical properties and use product	14
II.1.2.4 Labelling	14
II.1.2.5 Safety data sheet (SDS).....	15
II.1.2.6 Certificate of analysis.....	15
II.1.2.7 Composition of each substance.....	15
II.1.2.8 Commitment letters (if applicable)	16
II.2 Requirements for foreign manufactured products	16
II.2.1 Section A: Administrative requirements.....	16
II.2.1.1 Cover letter.....	16
II.2.1.2 Application form	16

*Guidelines on Submission of Documentation for Registration of Public Health Laboratory
Chemicals*

II.2.1.3 Valid Manufacturing license	16
II.2.1.4 Contract Manufacturing Agreement (if Applicable).....	16
II.2.1.7 Samples of the product.....	16
II.2.1.8 One coloured artwork/Label of the product.....	17
II.2.1.9 Commitment letters (if applicable)	17
II.2.2 Technical data requirements	17
II.2.2.10 Identifier of each substance.....	17
II.2.2.11 Information related to molecular and structural formula of each substance:.....	17
II.2.2.12 Composition of each substance.....	17
II.2.2.13 Physico-chemical description and use (s) of the laboratory chemical/substance(s)	17
II.2.2.14 Labelling	18
II.2.2.15 Safety data sheet (SDS).....	18
II.2.2.16 Certificate of analysis.....	19
ENDORSEMENT OF THE GUIDELINES	21
ANNEXES.....	22
ANNEX I: COVER LETTER	23
ANNEX: II SAFETY DATA SHEET (SDS) TEMPLATE.....	25
ANNEX III: APPLICATION FORM FOR NEW REGISTRATION OF PUBLIC HEALTH LABORATORY CHEMICAL PRODUCTS	32

DRAFT

ABBREVIATIONS AND ACRONYMS

cGMP	: Current Good Manufacturing Practice
CHC	: Cosmetics and Household Chemicals
CHCR	: Cosmetics and Household Chemicals Registration
EC	: Economic Commission
EINES/ELINCS	: European Inventory of Existing Chemical Substances /European List of Notified Chemical Substance
EP	: Essential Principles
GMP	: Good Manufacturing Practice
IRIMS	: Integrated Regulatory Information Management System
IUPAC	: International Union of Pure and Applied Chemistry
NLP	: No-Longer-Polymer
PRC	: Peer Review Committee
QMS	: Quality Management Systems
REACH	: Registration, Evaluation, Authorization, and Restriction for Chemicals
Rwanda FDA	: Rwanda Food and Drugs Authority

DRAFT

GLOSSARY

For the purpose of these guidelines, the following definitions shall be applied:

1. **“Applicant”**: Is a person or a company who applies for registration of any kind of laboratory chemical products to Rwanda FDA, which may be the owner of the marketing authorization of the product. He/she may be a manufacturer or person whose order or permission is provided by the laboratory chemical product manufacturer. The applicant shall therefore be responsible for signing the application form/cover letter. In the event that the applicant wants another person or company to register the laboratory chemical product on his/her behalf, the power of attorney copy, duly notarized in the country of origin, a local registered company with registrar of companies in Rwanda shall be provided. Once the product is registered, the applicant shall be the Marketing Authorization Holder.
2. **“Authority”**: means “Rwanda FDA”,
3. **“Batch number (or lot number)”**: a distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, etc.
4. **“Distributor”**: means any natural or legal person established within Rwanda, EAC, any other place around the world such as EU etc, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties.
5. **“Fee”**: means the fee prescribed in Regulations No. ODDG/RES/TRG/001 Version 5 governing tariff/fees and charges on services rendered by Rwanda food and Drugs Authority
6. **“Import”**: means the physical introduction into the customs territory of Rwanda.
7. **“Importer”**: means any natural or legal person who is responsible for import public health laboratory chemicals and permitted by the authority,
8. **“intended use/purpose”**: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.
9. **“Label”**: means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a laboratory chemical substance.
10. **“Labelling”**: is all labels and other written, printed, or graphic matter (l) upon any article or any of its containers or wrappers.
11. **“Law”**: means Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
12. **“Local Technical Representative (LTR)/Agent”**: Any applicant who is not resident in Rwanda shall appoint a registered chemical wholesale or retail company or an accredited manufacturer’s technical representative in Rwanda to deal with their public health laboratory chemical products as an agent/ local technical representative (LTR). The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarized in the country of origin.

*Guidelines on Submission of Documentation for Registration of Public Health Laboratory
Chemicals*

13. “**manufacture**”: means production or extraction of substances in the natural state. Or, all operations that involve preparation, processing, filling, transforming, packaging, repackaging and labelling of public health laboratory chemicals;
14. “**manufacturer**”: means any natural or legal person who manufactures a substance. In other words, a person or a firm that is engaged in the manufacture of public health laboratory chemicals.
15. “**Packaging material**”: means any material, including printed material, used in the packaging of a laboratory chemical substance, excluding any outer packaging used for transportation or shipment.
16. “**Packaging**”: means all operations, including filling and labelling, that a laboratory chemical substance has to undergo.
17. “**Public Health Laboratory Chemical**”: refers to standard chemical reagents or simple chemicals directly applied to public health or applied in manufacturing of public health chemicals vector control products, public health antiseptics and disinfectants, and any ingredient used in formulation of cosmetic products.
18. “**Radioactive substances**”: are substances that contain one or more radionuclides of which the activity or concentration cannot be disregarded as far as radiation protection is concerned. Radioactive substances are covered by specific legislation and therefore exempted these guidelines.
19. “**Reactant**”: A substance that is consumed in the course of a chemical reaction.
20. “**Regulatory Reliance**”: is the act whereby the regulatory Authority in one jurisdiction may take into account and give significant weight to regulatory work performed by another regulatory or trusted institution for purposes of reaching its own regulatory decisions.
21. “**Signal word**”: means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label and if a hazard is generally more severe or less severe. The label should include the relevant signal word in accordance with the classification of the hazardous chemical product or mixture.
22. “**Substance**”: means a chemical element and its compounds in the natural state or obtained by any manufacturing process.

CHAPTER I: INTRODUCTION

I.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) is established by Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of public health laboratory chemicals in order to improve access to quality and safe public health laboratory chemicals in Rwanda.

Considering the provisions of the technical regulations ref. Doc. N°: CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals, the authority has developed these “Guidelines on Submission of Documentation for Registration of public health laboratory chemicals”. These guidelines illustrate the procedures and requirements for the implementation of laboratory chemical products registration.

Any public health laboratory chemical classes on their own, in mixtures or in articles shall not be manufactured or imported or placed on the Rwandan market unless they have been registered in accordance with these guidelines. Unless otherwise, any manufacturer or importer of public health laboratory chemical, shall submit an application for registration of the public health laboratory chemical product to the national regulatory authority.

Adherence to these guidelines by the manufacturers/importers/applicants will timely facilitate assessments and approvals of the concerned public health laboratory chemical products/substances application dossiers by the authority for pre-marketing evaluation, marketing authorization/registration and post-marketing review.

I.2 Scope

These guidelines provide the appropriate requirements to the applicants and guidance to place their respective public health laboratory chemicals on the Rwandan market. According to the application and exemption, the following chemical substances categories are not part and concerned of these guidelines:

- a) **Radioactive chemical substances:** in relation to basic safety standards for the protection of public health and the general public against the dangers arising from radioactive materials, these chemicals are not concerned by these guidelines.
- b) **Blasting chemicals:** These are chemical substances applied for demolishing rock, concrete, or structures, often through a controlled expansion process. For security reasons, these products are also not concerned by these guidelines.
- c) **Common chemicals in Universities/School Laboratories and other research-based Laboratories:** These chemicals are also not concerned by these guidelines.

I.3 Submission of applications

I.3.1 Submission of technical dossier

An application for public health laboratory chemical substance registration for either locally manufactured or imported shall be made in writing and supported by an official cover letter (Annex...) and application form (Annex...) duly dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative (LTR). The LTR shall be a registered wholesale company or an accredited manufacturer's representative company registered in Rwanda.

All application documents shall be in one of the official languages used in Rwanda. Any document which is in any language other than official language must be accompanied by a certified or notarized document translated in official language. The application dossier shall be submitted to Rwanda FDA through Integrated Regulatory Information Management System (IRIMS) available at <https://irims.rwandafda.gov.rw/portal/#/public/app-home>

I.3.2 Submission of commercial samples for registration

The submission of samples for registration shall be in the final package proposed for marketing of the product in Rwanda and shall have at least 60% of its shelf-life remaining. This notwithstanding, products with a shelf life of less than 24 months shall have at least 80% of its shelf life remaining at the time of submission. Two commercial samples must be directly submitted to Rwanda FDA headquarter on the addresses below:

Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali
Nyarutarama Plaza, KG 9 Avenue

The additional samples may be requested once deemed required during the registration process. Where it's not possible due to big pack size (above 5L or 5kg), the applicant shall be requested to avail the necessary commercial sample size simulated and equivalent (1L or 1Kg) to the big commercial samples for further assessment procedures. The simulated and equivalent commercial samples shall never be placed on the market. A hard copy of the latter should be brought with samples for reception acknowledgement by the Authority.

I.4 Types of Applications

For the purposes of submission of laboratory chemical substances dossier to Rwanda FDA, applications are classified into three categories as follows:

I.4.1 New applications for registration

An application for registration of a public health laboratory chemical product that is intended to be placed on the Rwanda market for the first time or product which was on the market without a registration certificate.

I.4.2 Renewal application for registration

Applications for renewal of the marketing Authorization of product that has been previously registered. The application dossier shall be submitted to the Authority at least 3 months before the expiry of existing marketing Authorization Certificate.

I.4.3 Variation application

Variation application refers to the application for any change in the registered products. An application for variation shall be submitted as per the requirements set out in the guidelines for variation of registered cosmetics, vector control product and public health laboratory chemical products.

I.5 Receiving of applications for product registration

An application for product registration is submitted as electronic documents and received through IRIMS. The application is screened through the system and the applicant is queried for any document that is not fulfilling the application requirements. The reference number assigned to the product during the application is used in all subsequent correspondences relating to the application. An acknowledged receipt of application will be issued by the system.

A separate and complete application for registration of products shall be submitted for each public health laboratory chemical product with different commercial name, ingredients, formulation, intended use, forms and/or site of manufacturer.

I.6 Timelines for public health laboratory chemical product registration

Product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. New applications, the assessment process shall be processed within three (3) months from the date of submission, with feedback provided to the applicant. Regarding the renewal and variation application of the registered products, the assessment shall be processed within two (2) months from the date of submission, with feedback provided to the applicant. The applicant will be required to provide any requested additional data within sixty (60) calendar days. Assessment of submitted additional data or query responses shall be processed within thirty (30) calendar days from the day of submission with feedback provided to the applicant.

I.7 Compliance to Good Manufacturing Practices (GMP)

Applicant shall submit a valid GMP Certificate or ISO certificate or other applicable internationally recognized Management System certification for foreign manufacturers. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA. More information on GMP requirements and application for GMP inspection is detailed in the Rwanda FDA Guidelines on Good Manufacturing Practice and its annexes accessible *via* Rwanda FDA Website.

I.8 Reliance

The Authority may rely on other regulatory agencies from regional, international and other Stringent Regulatory Authorities' decisions in regard to product market authorization when it deems necessary. The Authority may apply reliance procedures for granting Marketing Authorization in the following situations:

1. The product should have been evaluated and listed on register of EAC countries, WHO and other Stringent Regulatory Authorities or Regulatory Authorities with ML3/4 with signed MoU with Rwanda FDA.
2. The product should have been evaluated through work sharing (Joint) or regional reliance mechanisms.

I.9 Rwanda FDA Peer Review Committee for CHC Product Registration

A final dossier assessment report shall be presented to CHCR Peer Review Scientific Committee before making final decisions for granting or refusing Market Authorization.

When there are deficiencies related to safety, quality and/or efficacy to be resolved as per the decision of the CHCR Peer Review Scientific Committee, application shall remain pending until the raised queries are resolved.

I.10 Validity of issued registration certificate

The Market Authorization issued by Rwanda FDA shall be valid for five (5) years from the date of its approval and it is renewed.

CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION

II.1 Requirements for locally manufactured products

II.1.1 Section A: Administrative Requirements

All administrative documents should be provided in part of administrative requirements as follow:

II.1.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I)

II.1.1.2 Application form

A dossier application must include a completed application form available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.1.1.3 Manufacturing License

The applicant should submit a valid manufacturing license issued by Rwanda Food and Drugs Authority.

II.1.1.4 Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures any product on the order of another party) is required. If a product is manufactured on contract, evidence of the contract shall be included in the documentation submitted, and this shall be clearly stated on the label of the product.

II.1.1.5 Samples of the product

Two (2) samples of the product(s) shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.1.1.6 One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.1.2 Section B: Technical Requirements

II.1.2.1 Details on the product characteristics

- a) Name(s) in the IUPAC nomenclature or other international chemical name(s)
- b) Other names (Usual name, trade name, abbreviation)
- c) CAS number
- d) EC number (if applicable)
- e) Other identity code (if available)

II.1.2.1 Information related to molecular and structural formula of product

- a) Molecular structure

- b) Molecular weight
- c) Information on optical activity and typical ratio of stereo- isomers (if applicable and appropriate)

II.1.2.2 Composition of each substance

- a) Degree of purity
- b) Nature of impurity (%), including isomers and by-products (if applicable)
- c) Percentage of (significant) main impurities
- d) Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

II.1.2.3 Physicochemical properties and use product

- a. Physical properties (Form, colour, physical state, odour, density, etc).
- b. Intended use (s)
- c. The hazard classification of the substance (s)
- d. Guidance on safe use

Note: For each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification

II.1.2.4 Labelling

(a) Product information content

Public Health Laboratory chemical products manufacturers, importers, or distributors must ensure that each container of laboratory chemical product is labelled, tagged or marked with the following information:

- a) Name, address of the manufacturer, or responsible party.
- b) Product name
- c) Manufacturing date and Expiry date
- d) Net content (weight/volume)
- e) Purity/concentration
- f) Density (if applicable)
- g) Lot or batch number
- h) List of ingredients used (if applicable)
- i) Instructions for use
- j) Storage conditions
- k) Country of origin

(b) Hazard and safety information

Public Health Laboratory chemical products manufacturers, importers, or distributors must ensure that each container of public health laboratory chemical product is labelled, tagged or marked with the following information related to hazard:

- a) Product identifier
- b) Signal word and hazard symbol;

In case your laboratory chemical PRODUCT displays a more severe hazard, the label should bear the signal word ‘**danger**’, and in case of less severe hazards, it should bear the signal word ‘**warning**’

- c) hazard statement(s);
- d) precautionary statement(s)
- e) GHS pictogram(s)

II.1.2.5 Safety data sheet (SDS)

The applicant of registration of public health laboratory chemical substances shall submit to the authority a safety data sheet compiled according to the Global harmonization system. The SDS to be submitted should contain the detailed information as required by the Global harmonization system for hazard communication standard. Specifically, the SDS containing the following sections is recommended:

Section 1. Product Identification: Brand name and chemical name

Section 2. Hazards identification and analysis

Section 3. Composition and information on ingredients

Section 4. First Aid Measure

Section 5. Firefighting measures

Section 6. Accidental release measures

Section 7. Handling and storage

Section 8. Exposure control/Personal protection

Section 9. Physical and chemical properties

Section 10. Stability and reactivity

Section 11. Toxicological information

Section 12. Ecological information

Section 13. Disposal information

Section 14. Transport information

Section 15. Regulatory information

Section 16. Other information

II.1.2.6 Certificate of analysis

The duly signed and dated certificate of analysis bearing its unique identification number, batch number, date of manufacturing and expiry date, tested parameters, specifications, methods and test results should be submitted.

II.1.2.7 Composition of each substance

- a. Degree of purity
- b. Nature of impurity (%), including isomers and by-products (if applicable)
- c. Percentage of (significant) main impurities
- d. Spectral data (infra-red, nuclear magnetic resonance), (ultra-violet, mass spectra: if applicable)
- e. HPLC, Gas Chromatography chromatogram (volatile compound): if applicable
- f. Elemental analysis data
- g. Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

II.1.2.8 Commitment letters (if applicable)

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be available. The authority reserves its total rights to request the applicant to submit the commitment letter wherever it is applicable

II.2 Requirements for foreign manufactured products

II.2.1 Section A: Administrative requirements

II.2.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I).

II.2.1.2 Application form

A Dossier application must include a completed application form (refer to the annex III, document No DD/CHCR/FORM/005) which is also available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.2.1.3 Valid Manufacturing license

The applicant should also submit a valid certificate of public health laboratory chemical product manufacturing license granted by the competent authorities in the country of manufacturing.

II.2.1.4 Contract Manufacturing Agreement (if Applicable)

Once a public health laboratory chemical product is manufactured under the manufacturing contract, evidence of the updated contract shall be produced in the submitted documentation. And this shall be clearly stated on the product label/artwork.

II.2.1.5 Valid GMP or other applicable internationally recognized Management System certification

For all foreign products, all key manufacturing and/or processing steps in the production of finished products must be performed in plants that comply with GMP or ISO. Regarding to the quality and safety concern of the product, applicant may be requested to apply for GMP inspection to Rwanda FDA.

II.2.1.6 Appointment of local technical representative

Appointment letter of the LTR with original copy of Power of attorney must be enclosed in the product dossier. The LTR shall be a wholesale company registered in Rwanda FDA or manufacturer's representative company registered in Rwanda.

II.2.1.7 Samples of the product

Two (2) samples of the product shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.2.1.8 One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.2.1.9 Commitment letters (if applicable)

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be available. The authority reserves its total rights to request the applicant to submit the commitment letter wherever it is applicable.

II.2.2 Technical data requirements

II.2.2.10 Identifier of each substance

- a. Name(s) in the IUPAC nomenclature or other international chemical name(s)
- b. Other names (Usual name, trade name, abbreviation)
- c. CAS number
- d. EC number (if applicable)
- e. Other identity code (if available)

II.2.2.11 Information related to molecular and structural formula of each substance:

- a) Molecular structure
- b) Molecular weight
- c) Information on optical activity and typical ratio of stereo- isomers (if applicable and appropriate)

II.2.2.12 Composition of each substance

- a. Degree of purity
- b. Nature of impurity (%), including isomers and by-products (if applicable)
- c. Percentage of (significant) main impurities
- d. Spectral data (infra-red, nuclear magnetic resonance), (ultra-violet, mass spectra: if applicable)
- e. HPLC, Gas Chromatography chromatogram (volatile compound): if applicable
- f. Elemental analysis data
- g. Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

II.2.2.13 Physico-chemical description and use (s) of the laboratory chemical/substance(s)

- a. Physical properties (Form, colour, physical state, odour, density, etc).
- b. Intended use (s)
- c. The hazard classification of the substance

Note: For each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification

II.2.2.14 Labelling

(a) Product information content

Public health laboratory chemical products manufacturers, importers, or distributors must ensure that each container of laboratory chemical product is labelled, tagged or marked with the following information:

- a. Name, address of the manufacturer, or responsible party.
- b. Product name
- c. Manufacturing date and Expiry date
- d. Net content (weight/volume)
- e. Purity/concentration
- f. Density (if applicable)
- g. Lot or batch number
- h. List of ingredients used
- i. Instructions for use
- j. Storage conditions
- k. Country of origin

(b) Hazard and safety information

- a. Product identifier
- b. Signal word and hazard symbol; In case your laboratory chemical PRODUCT displays a more severe hazard, the label should bear the signal word '**danger**', and in case of less severe hazards, it should bear the signal word '**warning**'
- c. hazard statement(s);
- d. precautionary statement(s)
- e. GHS pictogram(s)

II.2.2.15 Safety data sheet (SDS)

The applicant of registration of laboratory chemical substances shall submit to the national regulatory authority a safety data sheet compiled according to the Global harmonization system. The SDS to be submitted should contain the detailed information as required by the Global harmonization system for hazard communication standard. Specifically, SDS containing the following sections is recommended:

Section 1. Product Identification: Brand name and chemical name

Section 2. Hazards identification and analysis

Section 3. Composition and information on ingredients

Section 4. First Aid Measure

Section 5. Firefighting measures

Section 6. Accidental release measures

Section 7. Handling and storage

Section 8. Exposure control/Personal protection

Section 9. Physical and chemical properties

Section 10. Stability and reactivity

Section 11. Toxicological information

Section 12. Ecological information

Section 13. Disposal information

Section 14. Transport information

Section 15. Regulatory information

Section 16. Other information

II.2.2.16 Certificate of analysis

The duly signed and dated certificate of analysis bearing its unique identification number, batch number, date of manufacturing and expiry date, tested parameters, specifications, methods and test results should be submitted.

II.2.2.17 Stability data

The proposed shelf life should be justified by submission of stability data. The applicant shall provide stability data supporting the proposed shelf life. The stability studies shall be conducted in the container in which it will be marketed in Rwanda. Stability study report critically examine the method used to determine the established product shelf life including:

1. Study design (protocol);
2. Test conditions (humidity and temperature), testing interval;
3. Duration:

Storage conditions	Duration	Testing interval (Months)
Long term stability studies at 25±5°C/60% RH	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at 40°C/75% RH	6 months	0,3,6

4. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);
5. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product.

III GENERAL REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION

An application for Market Authorization renewal shall be made ninety (90) calendar days before expiration of the last registration

III.1. Cover letter

Signed and dated cover letter addressed to the DG of Rwanda FDA must be submitted.

III.2. Application form

Signed and dated application form for renewal of registered antiseptic or disinfectant for public health products (*refer to the annex IV, document No. DD/CHCR/FORM/005*)

III.3. Copy of previous registration certificate

The applicant shall submit the copy of previous registration certificate issued by Rwanda FDA.

III.4 Supporting documentation for any variations since the product was last registered

During the renewal of the product, the applicant must submit the data for the variations that have been reported and also the variations which were not reported yet (variation that happened in the last year of certificate validity).

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	Division Manager/CHCR	Head of Drugs Department	Division Quality Assurance Management	Director General
Names	Dr. Janvier MUKIZA	Dr. Védaste HABYALIMANA	Mrs. Marie Ange UWASE	Prof. Emile BIENVENU
Signature				
Date				

DRAFT

ANNEXES

DRAFT

ANNEX I: COVER LETTER

Letter header of the applicant/manufacturer/LTR

< Applicant>
< Address>
<Postal Code>
< Town>
<Country>
<Date>

<Rwanda FDA>
<P.O.BOX 1948> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of application for registration of public health laboratory chemical product <Brand Name(s), Common Name (s) and product form(s)>

We are pleased to submit our Application Dossier(s) for a registration of public health laboratory chemical product that details are as follows:

Name of the public health laboratory chemical product as follow:

Brand name (s):
Proprietary (Common Name (s):
Name and strength/purity of active ingredient(s):
.....
Product form:
Intended use(s):
Manufacturer:

You will find enclosed the submission dossier as specified hereafter:

- The relevant fees for this application have been paid
- Two commercial samples of the product
- The electronic submission contains the following sections:

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

We confirm that the electronic submission has been checked with up-to-date and state-of-the-antivirus software.

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

*Guidelines on Submission of Documentation for Registration of Public Health Laboratory
Chemicals*

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

DRAFT

ANNEX: II SAFETY DATA SHEET (SDS) TEMPLATE

SDS must be generated in accordance with Globally Harmonized System (GHS) compliant requirements before shipping or transporting the chemical away from the supplier. Use the SDS template to make a GHS compliant SDS.

The SDS includes information such as the properties of each chemical; the physical, health, and environmental hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The person preparing the SDS must ensure the information accurately reflects the scientific evidence used in making the hazard determination.

For solutions or mixtures of chemicals it is best practice to list 100% of the ingredients, regardless if they are hazardous or not.

Bellow SDS template is based but not limited on the Washington State Department of Labor & Industries hazard communication standard [WAC 296-901-14028 Appendix D-Safety data sheets](#). If no relevant information is found for any given item within a section, the SDS must clearly indicate that no applicable information is available

When SDS is completed delete the instructions in *red italics*.

In addition to the SDS, chemical containers must be labeled according to [WAC 296-901-14026 Appendix C-Allocation of label elements](#).

SAFETY DATA SHEET

Section 1: Identification

(a) Product identifier used on the label

(b) Other means of identification

(c) Recommended use of the chemical and restrictions on use

(d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

(e) Emergency phone number

Product Name:

Chemical Name/Synonyms:

Company:

In emergency call:

For information about this SDS, use this contact phone#:

Section 2: Hazard(s) Identification

(a) Classification of the chemical in accordance with WAC 296-901-14008

(b) Signal word(s), hazard statement(s); symbol(s) and precautionary statement(s) in accordance with WAC 296-901-14012. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, e.g., flame, skull and crossbones)

(c) Describe any hazards not otherwise classified that have been identified during the classification process

(d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$ and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required

Hazard Classification:

Signal Word(s):

Hazard Statements:

Pictograms:

Delete

pictograms

that

don't

apply!



Precautionary Statements:

Description of other hazards:

Section 3: Composition/ Information on Ingredients

For Substances

(a) Chemical name

(b) Common name and synonyms

(c) CAS number and other unique identifiers

(d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance

For Mixtures

In addition to the information required for substances:

(a) The chemical name and concentration (exact percentage) of all ingredients which are classified as health hazards in accordance with WAC 296-901-14008 and

(1) are present above their cut-off/concentration limits; or

(2) present a health risk below the cut-off/concentration limits.

(b) The concentration (exact percentage) must be specified.

Chemical Name	Synonym	CAS#	Conc.

Section 4: First-Aid Measures

- (a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion*
- (b) Most important symptoms/effects, acute and delayed*
- (c) Indication of immediate medical attention and special treatment needed, if necessary*

After skin contact:
After eye contact:
After inhalation:
After swallowing:

Section 5: Fire-Fighting Measures

- (a) Suitable (and unsuitable) extinguishing media*
- (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products)*
- (c) Special protective equipment and precautions for fire-fighters*

Suitable extinguishing agents:
Special protective equipment for firefighters:

Section 6: Accidental Release Measures

- (a) Personal precautions, protective equipment, and emergency procedures*
- (b) Methods and materials for containment and cleaning up*

Personal precautions:
Measures for environmental protection:
Measures for cleaning/collecting:

Section 7: Handling and Storage

- (a) Precautions for safe handling*
- (b) Conditions for safe storage, including any incompatibilities*

Handling:
Storage:

Section 8: Exposure Controls/Personal Protection

- (a) DOSH permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available*
- (b) Appropriate engineering controls*
- (c) Individual protection measures, such as personal protective equipment*

Chemical Name	OSHA PEL	OSHA PEL (ceiling)	ACGIH OEL (TWA)	ACGIH OEL (STEL)

General protective and hygienic measures:

Breathing equipment:

Protection of hands:

Eye protection:

Section 9: Physical and Chemical Properties

- (a) Appearance (physical state, color, etc.)*
- (b) Odor*
- (c) Odor threshold*
- (d) pH*
- (e) Melting point/freezing point*
- (f) Initial boiling point and boiling range*
- (g) Flash point*
- (h) Evaporation rate*
- (i) Flammability (solid, gas)*
- (j) Upper/lower flammability or explosive limits*
- (k) Vapor pressure*
- (l) Vapor density*
- (m) Relative density*
- (n) Solubility(ies)*
- (o) Partition coefficient: n-octanol/water*
- (p) Auto-ignition temperature*
- (q) Decomposition temperature*
- (r) Viscosity*

Form:

Odor:

Odor threshold:

pH:

Melting point/melting range:

Boiling point/boiling range:

Flash point:

Evaporation rate:

Flammability:

Upper/lower flammability or explosive limits:

Auto ignition temperature:

Danger of explosion:

Vapor pressure:

Vapor density:

Relative density:

Solubility in/Miscibility with water:

Section 10: Stability and Reactivity

(a) Reactivity

(b) Chemical stability

(c) Possibility of hazardous reactions

(d) Conditions to avoid (e.g., static discharge, shock, or vibration)

(e) Incompatible materials

(f) Hazardous decomposition products

Reactivity:

Chemical stability:

Conditions to avoid:

Incompatible materials:

Hazardous decomposition products:

Section 11: Toxicological Information

Description of the various toxicological (health) effects and the available data used to identify those effects, including:

(a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact)

(b) Symptoms related to the physical, chemical and toxicological

Characteristics

(c) Delayed and immediate effects and also chronic effects from short and long-term exposure

(d) Numerical measures of toxicity (such as acute toxicity estimates)

(e) Whether the hazardous chemical is listed in the National

Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by

DOSH

Acute toxicity:

Potential routes of exposure/potential health effects

Skin:

Eye:

Inhalation:

Ingestion:

Carcinogenic effects:

Mutagenic effects:

Reproductive toxicity:

Sensitization:

Target organs:

Section 12: Ecological Information (non-mandatory)

(a) Ecotoxicity (aquatic and terrestrial, where available)

(b) Persistence and degradability

(c) Bioaccumulative potential

(d) Mobility in soil

(e) Other adverse effects (such as hazardous to the ozone layer)

Ecotoxicity:

Mobility:

Biodegradation:

Bioaccumulation:

Section 13: Disposal Considerations (non-mandatory)

Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging

Section 14: Transport Information (non-mandatory)

(a) UN number

(b) UN proper shipping name

(c) Transport hazard class(es)

(d) Packing group, if applicable

(e) Environmental hazards (e.g., Marine pollutant (Yes/No));

(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)

(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

DOT regulations:

- **Hazard class:**
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:**
- **Maritime transport IMDG:**

Air transport ICAO-TI and IATA-DGR:

- **ICAO/IATA Class:**

Section 15: Regulatory Information (non-mandatory)

Safety, health and environmental regulations specific for the product in question

US Federal Regulations

SARA Section 355 (extremely hazardous substances):

SARA Section 313 (specific toxic chemical listings):
Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs):
TSCA (Toxic Substances Control Act):
Etc.

Section 16: Other Information

The date of preparation of the SDS or the last change to it

SDS date of preparation/update:

DRAFT



Doc No: DD/CHCR/FORM/007

Revision No: 002

Effective Date:/05/2025

ANNEX III: Application form for new registration of public health laboratory chemical products

1. ADMINISTRATIVE INFORMATION	
1.1	Name(s) and complete physical address(es) of the manufacturer(s) Company name: Physical address: Postal address: Country: Telephone: Telefax: E-mail:
1.2	Particulars of Applicant/ Registrant Name: Physical Address: Postal Address: Country: Phone: Fax: Email: Status of applicant (tick where appropriate): Manufacturer: Importer: Exporter: Other:
1.3	Particulars of Local Technical Representative/ Distributor (if applicable) Name: Physical Address: Postal Address: Country: Phone: Fax: Email:
1.4	Marketing Authorisation 1.4.1 Have you applied for Marketing Authorization of public health laboratory chemical product containing the same chemical substance (s) in the Rwanda FDA? Yes <input type="checkbox"/> No <input type="checkbox"/> If Yes state: Product name (s): CAS number: EC number:

<p>Other reference number (EINES, ELINCS/ NLP):</p> <p>Strength/percentage</p> <p>Purity:</p> <p>Product form (s):</p> <p>Use(s):</p>
<p>1.4.2 Have you applied for Marketing Authorization of public health laboratory chemical product containing the same formulation with different excipients/composition/mixture (s) in the Rwanda FDA? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If Yes state:</p> <p>Product name (s):</p> <p>CAS number.....</p> <p>EC number:</p> <p>Other reference number (EINES, ELINCS/ NLP):</p> <p>Strength/percentage</p> <p>purity:</p> <p>product form (s):</p> <p>Use(s):</p> <p>Short description of difference.....</p> <p>.....</p> <p>.....</p>
<p>1.4.3. Product Marketing Authorisation in the country of manufacture of the same public health laboratory chemical product.</p> <p>Product name:</p> <p>CAS number.....</p> <p>EC number:</p> <p>Other reference number (EINES, ELINCS/ NLP):</p> <p>Authorised Country:</p> <p>Date of authorisation (dd-mm-yyyy):</p> <p>Authorisation number:</p> <p>If not registered/licensed state reasons:</p> <p>Date of refusal (dd-mm-yyyy):</p> <p>Reason for Refusal:</p>
<p>1.4.4. Product Marketing Authorisation in the country of manufacture of the same public health laboratory chemical product. (Withdrawn by applicant after authorisation)</p> <p>Withdrawn Country:</p> <p>Date of withdrawal: (dd-mm-yyyy):</p> <p>Product name:</p> <p>CAS number.....</p> <p>EC number:</p> <p>Other reference number (EINES, ELINCS/ NLP):</p> <p>Reason for withdrawal:</p>

	<p>1.4.5. Product Marketing Authorisation in the country of manufacture of the same public health laboratory chemical product. (Suspended/revoked/banned by competent authority)</p> <p>Suspended/revoked/banned</p> <p>Country:</p> <p>Date of suspension/revocation/ban (dd-mm-yyyy):</p> <p>Product name:</p> <p>CAS number.....</p> <p>EC number:</p> <p>Other reference number (EINES, ELINCS/ NLP):</p> <p>Reason for suspension/revocation/ban:</p>	
	2. Product information	
2.1	Proprietary name of the product and Brand name (exactly as shown on label):	
2.2	<p>Name and strength/purity of chemical substance(s).....</p> <p>CAS number.....</p> <p>EC number:</p> <p>Other reference number (EINES, ELINCS/ NLP):</p>	
2.3	a. Class of laboratory chemical product	
	Hazard Class and category	Specify
	Acute toxicity, category 1,2, and 3	
	Acute toxicity, category 4	
	Skin corrosion/irritation, category 1, sub-categories: 1A, 1B, 1C and Category 2	
	category 1: Sub-category: 1A....., 1B....., 1C....	
	Category 2	
	Serious damage to eyes/eye irritation, category 1 and 2	
	Category 1	
	Category 2	
	Respiratory/skin sensitization	
	Germ cell mutagenicity category 1A and 1B	
	category 1A	
	category 1B	
	Germ cell mutagenicity category 2	
	Carcinogenicity category 1A, 1B and 2	
	category 1A	
	category 1B	
	category 2	
	Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	
	category 1A	
	category 1B	

	category 2				
	Specific target organ toxicity (STOT)-Single exposure, category 1 and 2				
	category 1				
	category 2				
	Specific target organ toxicity (STOT)-Repeated exposure, category 1 and 2				
	category 1				
	category 2				
	Aspiration Hazard				
	Hazardous to the aquatic environment-Acute, category 1				
	Hazardous to the aquatic environment-Chronic, category 1				
	Hazardous to the aquatic environment-Chronic, category 1, 2,3 and 4				
	category 1				
	category 2				
	category 3				
	category 4				
	Hazardous for the ozone layer				
2.4	Packing type:				
2.5	Intended use:				
2.6	Pack size:				
2.7	Visual description:				
2.8	Proposed shelf life:				
2.9	Proposed shelf life (dilution if any):				
2.10	Proposed shelf life (after first opening container):				
2.11	Proposed storage conditions:				
2.12	Proposed storage conditions after first opening:				
2.13	Other sister products registered or applied for registration				
2.14	Distribution category: <input type="checkbox"/> Institutional <input type="checkbox"/> Industrial <input type="checkbox"/> General public. <input type="checkbox"/> Other.....				
2.15	Country of (origin) manufacture:				
2.16	Qualitative and Quantitative composition (chemical substance (s) and excipient(s))				
	No	Name of ingredient	Quantity/unit (ml, g)/ batch	Reasons of inclusion	Manufacturer and/or Supplier's full address
	1				
	2				
	3				
	4				
		Etc			
2.17	Submitted Spectral data (if applicable):				

	Ultra-violet: Yes <input type="checkbox"/> No <input type="checkbox"/> Infra-red: Yes <input type="checkbox"/> No <input type="checkbox"/> Nuclear magnetic resonance: Yes <input type="checkbox"/> No <input type="checkbox"/> Mass spectrum: Yes <input type="checkbox"/> No <input type="checkbox"/>
2.18	Do you hold Marketing Authorization (s) of this product from other regulatory authorities? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes state; Market Authorization Number: Market Authorization issuance date: Name of Regulatory Authority issued the Market Authorization: Country:
3	Type of Formulation 3.1. Solids <input type="checkbox"/> Powder <input type="checkbox"/> Wettable Powder <input type="checkbox"/> Soluble Powder <input type="checkbox"/> tablet <input type="checkbox"/> Pellet <input type="checkbox"/> Cake <input type="checkbox"/> Other (specify) 3.2. Liquids <input type="checkbox"/> Emulsifiable Concentrate <input type="checkbox"/> Flowable Concentrate 3.3. Other <input type="checkbox"/> Suspension <input type="checkbox"/> Gel <input type="checkbox"/> Aerosol <input type="checkbox"/> Emulsion <input type="checkbox"/> Gaseous <input type="checkbox"/> Powder: <input type="checkbox"/> Paste <input type="checkbox"/> Others (Specify).....
4. LABELLING 4.1. Brief description of the type and properties of packaging material and the seal and its liner (if any) and provide justification for the suitability of the packaging material and the seal and its liner used. 4.2. Recommended storage conditions (where applicable) including any relevant information after the product is opened for use or reconstituted: 4.3. Mode of use	

5. Declaration by the Applicant/ Registrant

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to Rwanda Food and Drugs Authority.

It is hereby confirmed that fees have been paid according to the Rwanda Food and Drugs Authority fees and regulation.

I understand that if any information given here above is found false or incorrect, I will be reliable for appropriate action under the provisions of the Rwanda Food and Drugs Authority regulation.

Name:
Position in the company:
Signature:
Official stamp:
Date:

DRAFT



Annex IV: Application form for renew of registration of cosmetic, vector control products, public health antiseptic and disinfectant and public health laboratory chemical products

1. Product information

- 1.1 Registration number.....
- 1.2 Date of issue of current Market Authorization.....
- 1.3 Date of expiry of current registration.....
- 1.4 Brand Name of Product:
- 1.5 Product category:.....
- 1.6 Physical description.....
- 1.7 Product Form:
- 1.8 Name and Strength of the Active ingredient(s):.....
- 1.9 Intended use of the product.....
- 1.10 Are there any changes since product was registered? No Yes

If yes, give descriptions of the changes and if such variation was approved by Rwanda FDA

.....
.....

2. Are there any reported adverse reactions?

No Yes

If yes, give descriptions of the adverse reactions and if were reported to Rwanda FDA

.....
.....

3. Particulars of Applicant/ Registrant

Name of company:

Physical Address:

Postal Address:

Country:

Phone:

*Guidelines on Submission of Documentation for Registration of Public Health Laboratory
Chemicals*

Fax:

Email:

Status of applicant (tick where appropriate)

Manufacturer Importer Other

If other, please specify:.....

4. Particulars of manufacturer

Name:

Physical Address:

Post Address:.....

Country.....

Phone: Fax: Email:

5. Particulars of Local Technical Representative (if applicable)

Name:

Physical Address:

Postal Address:

Phone Number..... Fax: Email:

Declaration by the Applicant

I.....undersigned certify that all the information filled on this form and accompanying documentation are correct, complete and true to the best of my knowledge. I also agree that I shall carry out vigilance to monitor the safety of the product on the market and provide safety update reports to Rwanda FDA. It is hereby confirmed that fees have been paid according to the Rwanda FDA fees and regulation. I understand that if any information given here above is found false or incorrect, I will be liable for appropriate action under the provisions of the Rwanda FDA regulations.

Name:.....

Position:.....

Signature:.....

Officials Stamp:.....

Date:.....