



**GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR  
REGISTRATION OF PUBLIC HEALTH ANTISEPTIC AND  
DISINFECTANT PRODUCTS**

**APRIL, 2026**

## **FOREWORD**

Rwanda Food and Drugs Authority 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, safety and efficacy of antiseptic and disinfectant products for public health in order to improve access to quality and safety antiseptic and disinfectant products for public health available on Rwandan Market.

Considering the provisions of the technical regulation No DD/HMDR/TRG/001 Rev\_3 governing registration of medicinal products especially in its article 32; Rwanda FDA has to issue this Guidelines No DD/CHCR/GDL/003 on submission of documentation for registration of antiseptic and disinfectant products for public health.

These guidelines have been developed to provide guidance to the applicants and Rwanda FDA in managing applications for registration of antiseptic and disinfectant products for public health.

Applicants are encouraged to familiarize with the guidelines and follow it when preparing and submitting applications for registration of antiseptic and disinfectant products for public health.

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

Rwanda FDA acknowledges all the efforts of key stakeholders who participated in development and validation of these Guidelines.

**Prof. Emile BIENVENU**  
**Director General**

## **GUIDELINES DEVELOPMENT HISTORY**

First issue date	20/05/2020
Effective date of this version	Refer to the approval date

## **DOCUMENT REVISION HISTORY**

Date of revision	Version number	Changes made and/or reasons for revision
20/05/2020	1	First version
Refer to the approval date	2	<ol style="list-style-type: none"> <li>1. Time line for new application dossier processing has been reduced from 6 months to 3 months;</li> <li>2. Timeline for submitting addition data has been increased from three (3) months to six (6) months;</li> <li>3. Timeline for processing addition data has been increased from one (1) month to two (2) months;</li> <li>4. Timeline for processing renewal application has been fixed to 2 months;</li> <li>5. The registration requirements for local manufactured products has been separated from the registration requirements for foreign manufactured products taking into consideration to the process of manufacturing license issued to local premises;</li> <li>6. The requirements on raw materials has been amended;</li> <li>7. Changes to IRIMS has been included to ensure that the system meet the current requirements;</li> <li>8. The manufacturing process data for foreign manufacturers has been waived as a result of relying on international standards compliance or being subject to Rwanda FDA GMP when it is deemed necessary due to quality and safety concern;</li> <li>9. Further changes were made to align the format with the requirement of the SOP on document control as per current approved revisions;</li> <li>10. Information required for packaging material have been revised and improved;</li> <li>11. Statement for reliance have been added in Guidelines;</li> <li>12. Annual Retention on the Register has been removed;</li> </ol>

## **TABLE OF CONTENTS**

FOREWORD .....	2
GUIDELINES DEVELOPMENT HISTORY .....	3
DOCUMENT REVISION HISTORY .....	3
TABLE OF CONTENTS .....	4
GLOSSARY .....	7
CHAPTER I: INTRODUCTION .....	9
I.1. Background .....	9
I.2 Scope .....	9
I.3. Submission of application .....	9
I.4 Types of applications.....	10
I.5 Receiving of applications for product registration .....	10
I.6 Timelines for product dossier assessment .....	11
I.7 Compliance to Good Manufacturing Practices (GMP) .....	11
I.8 Reliance .....	11
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 .....	12
II.1. Requirements for local manufactured products .....	12
II.1.1. Section A: Administrative requirements .....	12
II.1.1.1. Cover letter.....	12
II.1.1.2 Application form .....	12
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. Data on raw materials .....	13
II.1.2.2 Data on Final Product .....	13
II.2 Requirements for foreign manufactured products .....	14
II.2.1. Section A: Administrative requirements.....	14
II.2.1.1. Cover letter.....	14
II.2.1.2 Application form .....	14
II.2.1.3 Contract Manufacturing Agreement (where applicable) .....	14
II.2.1.4 Valid Manufacturing license .....	14
II.2.1.5 Valid GMP Certificate or other applicable internationally recognized Management System certification .....	15
II.2.1.6 Appointment letter of the Local technical representative .....	15
II.2.1.7 Samples of the product.....	15
II.2.1.8 One coloured artwork/Label of the product.....	15
II.2.1.9 Commitment letter (where applicable) .....	15
II.2.2. Section B: Technical requirements .....	15
II.2.2.1 Data on raw material .....	15
II.2.2.2 Data on final product.....	16

CHAPTER III: GENERAL REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION .....	17
III.1 Cover letter .....	17
III.2 Application form.....	17
III.3 Copy of previous registration certificate .....	17
III.4 Supporting documentation for any variations since the product was last registered.....	18
III.5 Samples of the product in the final package .....	18
ENDORSEMENT OF THE GUIDELINES .....	19
ANNEXES.....	20
ANNEX I: COVER LETTER .....	21
ANNEX II: EXPLANATORY NOTES ON INTENDED USES .....	23

## **ACRONYMS AND ABBREVIATIONS**

<b>eGMP</b>	Current Good Manufacturing Practice
<b>CHC</b>	Cosmetics and Household Chemicals
<b>CHCR</b>	Cosmetics and Household Chemicals Registration
<b>GMP</b>	Good Manufacturing Practice
<b>IRIMS</b>	Integrated Regulatory Information Management System
<b>LTR</b>	Local Technical Representative
<b>PRC</b>	Peer Review Committee
<b>QMS</b>	Quality Management Systems

## **GLOSSARY**

“**Active ingredient**” means a biologically or chemically active substance or compound that is intended to be used in the manufacture of a product as an active compound (ingredient).

“**Antiseptic**” means a product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane (mouth washes only).

“**Applicant**” means a person who applies for registration of antiseptic or disinfectant products to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the “Marketing Authorisation Holder”.

“**Batch number or Lot**” means the number or a combination of numbers and letters specifically given to an antiseptic or disinfectant product which is linked to the manufacturing history of the product.

“**Container**” means any form of packaging of an antiseptic for public health product for sale as a single item whether by completely or partially enclosing the antiseptic for public health and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

“**Disinfectant**” means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.

“**Distributor**” means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an antiseptic and disinfectant for public health product available on the Community market.

“**Fee**” means the fee prescribed in Regulations No. ODDG/RES/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority.

“**Importer**” means any person or body corporate permitted and authorized under the laws and regulation in Rwanda pertaining to import antiseptic or disinfectant products.

“**Ingredients**” means any substance that is one of the components of an antiseptic or disinfectant for public health and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the antiseptic and disinfectant for public health but that are not present in the final product as a result of the chemical process.

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

“**Manufacturer**” means a person or firm that is engaged in the manufacture of antiseptic or disinfectant product(s).

“**Marketing authorization**” refers to an official approval of the antiseptic and disinfectant for public health product to be marketed or distributed in Rwanda mainland.

“**Package**” refers to any box, packet or any other article in which one or more containers of antiseptic or disinfectant for public health are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof.

“**Package labelling**” includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package.

“**Registrant (Market Authorization Holder)**” means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Rwandan market.

“**Sanitizer**” means a product that reduces the level of microorganisms present by significant numbers, e.g. 99.9% or more, or to acceptable levels.

“**Specifications**” means the combination of physical, chemical, biological and microbiological test requirements that determine whether an antiseptic or disinfectant product is suitable for the intended use.

## **CHAPTER I: INTRODUCTION**

### **I.1. Background**

The Authority was given the power to regulate different products including antiseptics and disinfectants for public health available on the Rwandan market to ensure their safety, efficacy and quality. In that regard, Rwanda FDA developed the guidelines which are involved while submitting an application for registration of the mentioned products. The Marketing Authorization Certificate will be granted to the products that meet Quality, Safety and Efficacy requirements.

Antiseptics are antimicrobial substances that are applied to living tissue/skin to reduce the possibility of infection, sepsis, or putrefaction, while disinfectants are substances that are applied to non-living objects to destroy microorganisms.

The most commonly used antiseptic and/or disinfectant groups includes alcohols, quaternary ammonium compounds, chlorhexidine and other diguanide, antibacterial dyes, chlorine and hypochlorite, inorganic iodine compounds, metals, peroxides and permanganates, Air disinfectants, Aldehydes, Oxidizing Agents, Phenolic Acids, Silver, Copper, Alloy Surfaces, halogenated phenol derivatives and quinolone derivatives preparations with the appropriate strength & formulations containing active ingredients listed in annex I are products eligible for approval under the antiseptics and disinfectants for public health category. Other active ingredient internationally recognized and not harming life can be accepted in antiseptic or disinfectant products.

### **I.2 Scope**

These guidelines shall provide guidance for dossier applications for registration of antiseptics and disinfectants for public health, renewal of registered antiseptic and disinfectant for public health products.

### **I.3. Submission of application**

#### **I.3.1 Submission of technical dossier**

An application for product registration for either locally manufactured or imported, shall be submitted along with a dated and signed letter of application addressed to Rwanda FDA. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. 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 an 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>. Applicant shall therefore have account in IRIMS.

### **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 60% of its remaining shelf-life. This notwithstanding, products with a shelf life of less than 24 months shall at least have 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 necessary during the registration process. Where it's not possible due to big pack size (above 5L or 5kg), the applicant shall contact Rwanda FDA for further guidance. A hard copy of the latter should be brought with samples for reception acknowledgement by Rwanda FDA.

### **I.4 Types of applications**

For the purpose of submitting the antiseptic and disinfectant for public health dossier application for registration with Rwanda FDA, applications are categorized into three distinct groups as outlined below:

#### **I.4.1 New applications for registration**

An application for registration of a 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**

For applications for renewal of the marketing Authorization of product that has been previously registered, application dossier shall be submitted to Rwanda FDA at least 3 months before the expiry date of existing marketing Authorization Certificate.

#### **I.4.3 Variation application**

Variation application refer 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 antiseptics and disinfectant for public health, vector control products and laboratory reagents for public health.

### **I.5 Receiving of applications for product registration**

An application is electronically submitted as documents through IRIMS accessible via the following link: <https://www.irims.rwandafda.gov.rw/portal/>. Application of product registration 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 a 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 antiseptic and disinfectant for public health products with different commercial name, ingredients, formulation, intended use, forms and/or site of manufacture.

After receiving the product application, Rwanda FDA shall proceed with screening of the dossier for completeness. In the event that the dossier is incomplete, it will not be scheduled for assessment and the applicant will be notified within 30 calendar days and requested to comply with requirements in writing. In case of a positive outcome during the screening, the application will be scheduled for assessment according to the First in First out (FIFO) rules.

### **I.6 Timelines for product dossier assessment**

Product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. For new applications, assessment process shall be processed within three (3) months from the date of submission, with feedback provided to the applicant. Regarding the renewal 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 six (6) months. Assessment of submitted additional data or query responses shall be processed within sixty (60) calendar days from the day of submission with feedback provided to the applicant.

Once a query has been issued to the applicant, the assessment process stops until Rwanda FDA receives a response to the raised queries. Further processing of the application may only be undertaken if responses to issued queries, contain all outstanding information requested in one submission. If the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application shall be rejected. In the event that the responses to the queries are not submitted within specified timeline from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested for extension of deadline to Rwanda FDA. Thereafter, registration of the product may only be considered upon submission of a new application.

### **I.7 Compliance with Good Manufacturing Practices (GMP)**

The 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**

Rwanda FDA 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. Rwanda FDA may apply reliance procedures for granting Marketing Authorization in the following situations:

- a. 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.
- b. 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, unless otherwise revoked, shall be valid for five (5) years from the date of its approval and it is renewed.

## **CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION**

This chapter provides guidance of components expected in the application for registration of antiseptic and disinfectant products for public health products.

Data requirements for a new application contains two parts with each part having administrative requirements and technical data requirements. Part 1 relates to the requirements for local manufacturers while part 2 relates to the requirements for foreign manufacturers.

### **II.1. Requirements for local 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**

Dossier application must include a completed application form N<sup>o</sup>: DD/CHCR/FOM/003 for new registration of Antiseptic and Disinfectant Products for Public Health 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**

A technical data requirement is a document that includes various pieces of information about final product.

### **II.1.2.1. Data on raw materials**

The applicant should submit the Safety Data Sheet (SDS) for each raw material (ingredients) that describing all sections.

### **II.1.2.2 Data on Final Product**

#### **a. Certificate of analysis (CoA)**

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

#### **b. Packaging and labelling information**

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...). This shall be made of substances/materials which are safe and suitable for the product. Products labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- i. Brand name,
- ii. Manufacturer's name and physical address,
- iii. Lot or batch number,
- iv. Net content (weight/volume),
- v. intended use of Antiseptic or disinfectant product,
- vi. Instructions for use,
- vii. Country of origin,
- viii. Storage conditions,
- ix. Warnings and cautions if any.

**c. Commitment letters**

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be available. Rwanda FDA 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**

Dossier application must include a completed application form N°: DD/CHCR/FOM/003 for new registration of Antiseptic and Disinfectant Products for Public Health 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 Contract Manufacturing Agreement (where applicable)**

An agreement between two parties (the party who manufactures any product on the order of another party) is submitted. 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.2.1.4 Valid Manufacturing license**

Applicant should submit valid Manufacturing License from the manufacturer granted by competent authorities.

### **II.2.1.5 Valid GMP Certificate 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 other applicable internationally recognized Management System certification. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA.

### **II.2.1.6 Appointment letter of the 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 or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA or any manufacturer's representative company registered in Rwanda.

In case the LTR is not wholesale or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA, a contract with company owning Rwanda FDA licensed premise for cosmetics or household chemicals or pharmaceutical products together with valid premise license shall be submitted, and this contract shall highlight that the imported public health antiseptics and/or disinfectant will be stored in the above-mentioned premise.

### **II.2.1.7 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.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 letter (where applicable)**

For ongoing stability studies, the applicant must submit the commitment letter indicating when the final data on stability will be available.

## **II.2.2. Section B: Technical requirements**

A technical data requirement is a document that includes various pieces of information about the raw materials and the final product.

### **II.2.2.1 Data on raw material**

The applicant should submit the Safety Data Sheet (SDS) for each raw material (ingredients) that include all sections.

### **II.2.2.2 Data on final product**

#### **a. Certificate of analysis (CoA)**

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

#### **b. Method of analysis**

Method of analysis for the finished product shall include the equipment, reagent and analytical method.

#### **c. Product efficacy data**

The applicant shall submit information on:

- i. Effectiveness studies data in regards with the claimed intended use of the product.
- ii. Nature of the application area and method of use;
- iii. Standards Methods used for evaluating the efficacy

#### **d. Packaging and labelling information**

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...). This shall be made of substances/materials which are safe and suitable for its intended use. Products labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- i. Brand name,
- ii. Manufacturer's name and physical address,
- iii. Lot or batch number,
- iv. Manufacturing date and Expiry date/best before,
- v. Net content (weight/volume),
- vi. List of ingredients used,
- vii. Intended use of Antiseptic or disinfectant products product,
- viii. Instructions for use,
- ix. Country of origin,
- x. Storage conditions,
- xi. Warnings and cautions if any.

#### **e. 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:

- i. Study design (protocol);
- ii. Test conditions (humidity and temperature), testing interval;
- iii. Duration:

<b>Storage conditions</b>	<b>Duration</b>	<b>Testing interval (Months)</b>
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

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

**f. Materials safety data sheet (SDS)**

The applicant should submit the SDS that include **all sections** (Human health data sheet, Environmental safety information and Toxicity...).

**CHAPTER 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. Rwanda FDA foresees a grace period for renewal of ninety (90) days after the specified expiry date. Failure to renew the marketing authorization within the grace period, the application shall be considered as new.

**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 N°: DD/CHCR/FORM/006 for renew of registration of cosmetic, vector control products, public health antiseptic and disinfectant and public health laboratory chemical products shall be completed, and this form is available on Rwanda FDA website.

**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).

#### **III.5 Samples of the product in the final package**

The applicant must submit two samples of the product supporting along with the artwork/label.

**ENDORSEMENT OF THE GUIDELINES**

	<b>Prepared by</b>	<b>Checked by</b>		<b>Approved by</b>
<b>Title</b>	<b>Division Manager for Cosmetics and Household Chemicals Registration</b>	<b>Head of Drugs Department</b>	<b>Division Manager for Quality Management System</b>	<b>Director General</b>
<b>Names</b>	Dr Janvier MUKIZA	Dr Vedaste HABYALIMANA	Ms. Marie Ange UWASE	Prof. Emile BIENVENU
<b>Signature &amp; Date</b>				

**ANNEXES**

**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 antiseptic/disinfectant 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 antiseptic/disinfectant product that details are as follows:

**Name of the public health antiseptic/disinfectant 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

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

## **ANNEX II: EXPLANATORY NOTES ON INTENDED USES**

### **A. INTENDED USES OF ANTISEPTICS OR DISINFECTANT**

**Washes:** Antiseptic or disinfectant wash products, also known as antibacterial soaps, are intended for use with water and are rinsed off after use, and include hand washes /soaps and body washes.

**Rubs:** Rubs are leave-on products, or hand “sanitizers,” as well as antiseptic or disinfectant wipes. These products are intended to be used when soap and water are not available, and are left on and not rinsed off with water.

**Handwashing:** chlorhexidine gluconate and povidone iodine solutions are often used in hand scrubs and hand rubs in hospital settings.

**Pre-operative skin antiseptics or disinfectants:** applied to the operation site to reduce the resident skin flora. Caution should be used in facial use of solutions containing chlorhexidine, as these can injure the eye causing keratitis.

**Mucous membrane antiseptic or disinfectant:** irrigations may be instilled into the bladder, urethra or vagina to treat infections or cleanse the cavity prior to catheterisation.

**Preventing and treating infected wounds and burns antiseptic:** preparations are available over-the-counter from your pharmacist to treat minor cuts, abrasions and burns.

**Alcohol:** Used as a skin disinfectant

**Quaternary ammonium compound:** Used as skin disinfectant, irrigation, and to preserve eye drops

**Chlorhexidine and other diguanide:** Used as pre-operative skin disinfectant, to treat wounds, and for bladder irrigation

**Antibacterial dye:** Used as a skin disinfectant and to treat a wound or burn

**Peroxide and permanganate:** Used as wound cleanser, gargle and mouthwash, for irrigation and as a skin disinfectant

**Halogenated phenol derivative:** Used as a skin disinfectant and in medicated soap and solution

**Quinolone derivative:** Used to treat wounds, in throat lozenges and as a skin disinfectant

**Miscellaneous:** Bleach baths

## **B. INTENDED USES OF DISINFECTANTS**

**Air disinfectants:** Air disinfectants are typically chemical substances capable of disinfecting microorganisms suspended in the air.

**Alcohols:** Alcohol and alcohol plus Quaternary ammonium cation based compounds comprise a class of proven surface sanitizers and disinfectants approved by the EPA and the Centers for Disease Control for use as a hospital grade disinfectant.

**Aldehydes:** Aldehydes, such as formaldehyde and glutaraldehyde, have a wide microbicidal activity and are sporicidal and fungicidal.

**Oxidizing agents:** Oxidizing agents act by oxidizing the cell membrane of microorganisms, which results in a loss of structure and leads to cell lysis and death. A large number of disinfectants operate in this way. Chlorine and oxygen are strong oxidizers,

**Peroxy and peroxy acids:** Peroxycarboxylic acids and inorganic peroxy acids are strong oxidants and extremely effective disinfectants.

**Phenolics:** Phenolics are active ingredients in some household disinfectants. They are also found in some mouthwashes and in disinfectant soap and handwashes

**Quaternary ammonium compounds:** Quaternary ammonium compounds ("quats"), such as benzalkonium chloride, are a large group of related compounds. Some concentrated formulations have been shown to be effective low-level disinfectant.