RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR RENEWAL OF REGISTERED HUMAN AND VETERINARY MEDICINAL PRODUCTS

JUNE 2021

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GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	06/05/2021
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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 medical products to protect public health and improve access to medical products in Rwanda.

Considering the provisions of the technical regulations No CBD/TRG/010 governing the registration of human medicinal products, the Authority has to issue these Guidelines **No DAR/GDL/041** on submission of documentation for Renewal of Registered Human and Veterinary Medicinal Products.

Keeping in mind that during the lifecycle of a medical product, there are current and emerging technical requirements which need to be met at all times. Therefore, it had been considered necessary to develop these guidelines to address existing gaps in terms of technical requirements during approval of applications for renewal.

Applicants are requested to adhere to these guidelines by providing all relevant information for renewal of registration of medical products. This will prevent queries that result in unnecessary delays and facilitate efficient and effective evaluation and approval process.

The Authority acknowledges all the efforts and contributions from our stakeholders that participated in the development and validation of these guidelines.

Dr. KARANGWA Charles
Acting Director General

1.0 TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

FPPs	Final Pharmaceutical Products
GMP	Good Manufacturing Practice
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
PIL	Package Information Leaflet
Rwanda FDA	Rwanda Food and Drugs Authority
SmPC	Summary of Product Characteristics

DEFINITIONS

The definitions provided below apply to the words and phrases used in these guidelines. The following definitions are provided to facilitate interpretation of these guidelines. Other terminologies can be found in the Rwanda FDA glossary of terms (*Refer to the Guidance No DAR/GDL/010H).*

Active pharmaceutical ingredient (API) means any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Applicant means the person by, or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the "Marketing Authorisation Holder".

Authority refers to the Rwanda Food and Drugs Authority, or its acronym "Rwanda FDA" established under Article 2 of Law Nº 003/2018 of 09/02/2018

Composition: In relation to a medical product means an ingredient of which it consists, proportions, degree of strength, quality, and purity in which those ingredients are contained.

Container means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, not being a capsule or other article in which the medical product is or is to be administered or consumed, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.

Container labelling means all information that appears on any part of a container, including that on any outer packaging of such as a carton.

Drug Master File Means a master file that provides a full set of data on an API. In some countries, the term may also comprise data on an excipient or a component of a medical product such as a container.

Excipient means any component of a finished dosage form which has no therapeutic value.

Expert report means a summary and interpretation of data, with conclusions, prepared by an independent expert on the subject.

Formulation means the composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.

Generic (multisource) products means products that are pharmaceutical equivalents or alternatives to innovator or reference products and which are intended to be therapeutically equivalent and can therefore be used interchangeably with the innovator or reference product.

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any medical product.

Marketing authorization (product license, registration certificate) is a legal document issued by the competent drug regulatory Authority that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its

ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

Manufacturer means a person or firm is engaged in the manufacture of medical product (s).

Manufacturing site means the location where the manufacturing process of a pharmaceutical products is undertaken.

Manufacture means all operations of receipt of materials, production, packaging and repackaging, labelling and relabelling, quality control, release, storage and distribution of pharmaceutical products and related controls.

Master formula A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

Mock-up is a copy of the flat artwork design in full colour, providing a replica of both the outer and immediate packaging, providing a two-dimensional presentation of the packaging/ labelling of the medicine. It is also referred to as a paper copy or computer-generated version**.**

On-going stability study is the study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected retest period (or shelf-life) of the API, or confirm or extend the shelf-life of the FPP.

Pharmaceutical product is any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses.

Retention fee means a fee paid annually to maintain marketing authorization.

Release specifications means the combination of physical, chemical, biological and microbiological test requirements that determine whether a drug product is suitable for release at the time of its manufacture.

Renewal of product registration: Applications for renewal of a registered product.

Specifications is a document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Shelf life specifications means the combination of physical, chemical, biological and microbiological test requirements that an active ingredient must meet up to its retest date or a drug product must meet during its shelf life.

Variation means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

1. INTRODUCTION

1.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) is established by the Law N° 003/2018 of 09/02/2018, especially in its article 8 and 9;

Considering the provisions of the technical regulations No CBD/TRG/010 governing the registration of human medicinal products, the Authority has issued **Guidelines No DAR/GDL/041 on submission of documentation for Renewal of Registered Human and Veterinary Medicinal Products.**

These guidelines provide guidance to applicants on format and content of minimum documents and information required for renewal of registration of medical products. It also guides the Authority in managing applications for Renewal of Registered Human and Veterinary Medicinal Products. Applicants and users are encouraged to familiarize with the guidelines when preparing and submitting/reviewing applications for Renewal of Registered Human and Veterinary Medicinal Products.

Renewal of registration is required as specified in the regulation to ensure all changes made with respect to the manufacture and quality control of Human and Veterinary Medicinal Products are updated, reported, and evaluated to ensure safety and quality. Changes include variations, both those notified and those not notified to Rwanda FDA.

These guidelines provide requirements to be fulfilled by applicants, including specific documents to be submitted for evaluation prior to renewal of Human and Veterinary Medicinal Products registration.

Applicants are required to read carefully these guidelines together with relevant regulations and guidelines for registration along with other references provided in this document.

It should be noted that the Authority has the right to request any further information or documents, with a commitment that such requests are justifiable, and will be for the purpose of ensuring quality, safety, and efficacy of the submitted product.

1.2 Scope

These guidelines shall apply to applications for Registered Human and Veterinary Medicinal Products, submitted to the Authority for renewal of registration.

2. SUBMISSION REQUIREMENTS AND ASSESSMENT

2.1 Mode of submission

An application for renew of product registration for either locally manufactured or imported, shall be made in writing via a cover letter and application form dated and signed by the applicant. The application should be submitted to the Authority through the authorized local technical Representative to the following address:

Director General
Rwanda Food and Drugs Authority
Nyarutarama Plaza, Rwanda
KG 9 Avenue, Kigali
P.O. Box 1948, Kigali, Rwanda.
E-mail: info@rwandafda.gov.rw

2.2 General Requirements

a. In accordance with laws and regulations in place, marketing authorisation holders must apply for renewal of registration to the Authority at least ninety (90) calendar days before its expiry. The Authority foresees a grace period for renewal of ninety (90) days after the specified expiry date. In the case where a MAH does not submit the renewal application, the MA will expire as specified in the Law.

b. It is the responsibility of the MAH to apply for renewal of the registration of the medical product.

c. The application should be submitted in **English**. All submitted documents that are in any language other than English must be accompanied by a certified or notarized **English translation**.

d. Data should be presented in readable format, font size 12, style Times New Roman. Every page shall be numbered sequentially (x of y). Extension sheets, tables, diagrams, and other supporting documents shall, where possible, be of the same size, clear, well annotated, numbered, and appropriately cross-referenced.

e. Proof of payment of the non-refundable renewal fee at the time of submission should be submitted with the application for renewal. Applicable fees are defined in the regulation Nº CBD/TRG/004 related to regulatory services tariffs/fees and fines. Any application not accompanied by the relevant proof of payment will not be considered. Note that the Authority reserves the right to determine the correct interpretation of the fee payable based on the published schedule.

f. Evidence of performance of the finished medical product manufacturing facility with current Good Manufacturing Practices (GMP) requirements as prescribed in GMP guidelines should be provided.

g. The MAH should provide a list of all countries where the product has been reviewed and approved over the registration period of the product, the registration numbers, and copies of registration certificates if available.

h. At renewal, the Authority will perform a new check of the samples across all marketed product presentations. Two (2) commercial samples with batch certificates of analysis should be provided to the Authority as part of the renewal application, for each strength, dosage form, and container type in the smallest marketed pack-size. In case the MAH plans to change the overall design and readability of the labelling and/or package leaflet at the time of renewal, submission of specimens of the previous product design will not be necessary.

i. Two CD-ROMs or external data drives: containing all information on safety, quality, and efficacy of the product (where applicable).

2.3 Technical Documentation Requirements

All applications for renewal of registration of human and veterinary medicinal products shall be accompanied by the following documentation/requirements:

2.3.1 Active Pharmaceutical Ingredient(s) [API(s)]

2.3.1.1 Names and complete addresses of all current suppliers of active pharmaceutical ingredient(s) along with manufacturing and GMP certificates of the active pharmaceutical ingredient(s) manufacturing facilities issued by competent regulatory authorities;

2.3.1.2 Copy of current signed, dated and numbered specifications and analytical procedures used for testing of the active pharmaceutical ingredient(s) by the finished product manufacturer;

2.3.1.3 Information on container-closure system used for storage of the API in FPP manufacturer's storage facilities, storage conditions specified for the API and re-test period/shelf life implemented for the respective API;

2.3.2 Finished Pharmaceutical Product (FPP)

2.3.2.1 Detailed description of qualitative and quantitative composition of the unit dosage form and of the commercial batch size(s) approved including colorants, coating agents in a manner provided for in section 3.2.P.1 of the main registration guidelines for human and veterinary medicinal products;

2.3.2.2 A copy of batch manufacturing record (BMR) for the largest production batch manufactured within six months before the date of submission of the renewal application;

2.3.2.3 Report on annual product quality review for all batches of the finished product manufactured in the past 36 months before the date of application of the renewal. At minimum the report should include the following:

a) A review of starting and primary packaging materials used in the FPP, especially those from new sources;
b) A tabulated review of quality control and in-process control results;
c) A review of all batches that failed to meet established specification(s);
d) A review of all changes carried out to the processes or analytical methods;
e) A review of the results of the stability monitoring programme and
f) A list of validated analytical and manufacturing procedures and their revalidation dates.

2.3.2.4 A copy of current signed, dated and version numbered release and shelf life specifications of the finished products along with standard testing procedures;

2.3.2.5 Information on container/closure system(s). Data should be submitted according to the requirements stipulated under section 3.2.P.7 of the main registration guidelines for human pharmaceutical products and 3.2.P.7 of the main Guidelines for Registration Veterinary Medicinal products;

2.3.2.6 Data on stability study. For pharmaceutical products previously registered with long term stability data which do not support stability of the product under zone IV b, data should be provided to demonstrate stability of the product under storage conditions of 30°C±2°C/75% ± 5% relative humidity. Studies should be conducted according to requirements stipulated under section 3.2.P.8 of the main Guidelines on Submission of Documentation for Registration of Veterinary Medicinal products and specific guidelines on Stability Testing Requirements for Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products for human pharmaceutical products;

2.3.2.7 List of all variations submitted to and accepted by the Authority over the registration period of the product.

Reference number	**Description of change**	**Date submitted**	**Approval/Rejection date and reference number of the letter**	**Implementation status**

2. 3.3 PRODUCT INFORMATION

2.3.2.1 Specimen of current package insert and copies of colored mock up labels of the product as per current requirements prescribed in section 1.5.4 of the main Registration Guidelines for Human Pharmaceutical Products and section 1.5 of the main Registration Guidelines for Veterinary Medicinal Products.

2.3.2.2 All prescription medicines should be accompanied by SmPC. Refer to Guidelines on Format and Content of Summary of Product Characteristics for Human Pharmaceutical Products and section 1.5.1 of the main Registration Guidelines for Veterinary Medicinal Products.

2.3.2.3 All Pharmaceutical preparations with potential for long-term use and self-administered injections and Over the Counter (OTC) medicines must contain a patient information leaflet. Languages used for PIL and labelling should be clearly expressed in English. Refer Guidelines on Format and Content of Patient Information Leaflet for Human Pharmaceutical Products.

2.3.2.4 Submission of periodic post-marketing surveillance and safety studies

2.4 Evaluation Process

2.4.1 Assessment Process

a. After receiving the product renewal application, the application will be scheduled for evaluation according to the first-in first-out (FIFO) rules. Priority assessment may be granted where the product is intended for treatment of rare disease conditions through an expression of interest (EOI DHT/FMT/032) or in the case of emergency situation.

b. A product dossier is assessed by two assessors to provide scientific and regulatory oversight regarding the quality, safety, and efficacy of the product under assessment.

c. During the evaluation, additional data and/or samples may be requested through an official communication letter. Once a query has been issued to the applicant, the assessment process stops until the Authority receives a written response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued in the official communication letter contains all outstanding information requested in one submission. Failure to comply with this condition, or if the queries have been reissued for a **second** time and the applicant provides unsatisfactory responses, will result in the MA suspension.

d. In the event that the responses to the queries are not submitted within thirty (30) calendar days from the date they were issued, the application will be considered withdrawn unless the applicant has requested for an extension of the deadline from the Authority. Thereafter, renewal for registration of the product may only be considered upon new submission of renewal application.

e. A final dossier assessment report shall be presented to Peer Review Committee (PRC) before making a final decision for granting or rejecting the renewal of the registered product. The renewal processes should be completed in maximum period of Ninety (90) days from the application date.

f. The assessment will consist of a benefit-risk balance re-evaluation, on the basis of a consolidated version of the file in respect of quality, safety, and efficacy, including evaluation of data contained in suspected adverse reactions reports, the Periodic Safety Update Report (PSUR) data, and any relevant new information affecting the benefit-risk balance for the product. A full re-evaluation of the whole dossier normally should not take place. Serious public health concerns should be addressed as part of the renewal process, and the product will not be renewed if serious public health issues remain at the end of the procedure, or if an existing suspension on the marketing authorisation cannot be lifted.

g. Inspection status, particularly regarding the pharmacovigilance system, as well as GMP compliance status of the manufacturer(s), and potential impact of the findings on the benefit-risk balance of the medicinal product, will be reviewed during the assessment of the renewal application.

h. At time of renewal, compliance by the MAH with the conditions imposed on the medicinal product will be evaluated. As a result, these conditions may be modified and/or new conditions may be imposed.

i. Review of whether the marketing authorisation holder complies or not, with their obligation to maintain up-to-date product information.

j. Where there are adequate and objective reasons not to renew the marketing authorisation in its existing terms, and changes are necessary to the SmPC, labelling, and/or PIL arising from the renewal evaluation, the marketing authorisation holder may submit additional information and/or change the product information as part of the renewal process to address the concerns raised. Such changes will not require a separate variation procedure.

k. Other issues arising from assessment and changes due to the revision of the SmPC guidelines, and/or other relevant guidelines impacting on the product information should be considered within the renewal process. Proposed changes to the SmPC, labelling, and PIL must be indicated on the renewal application form.

l. None of the changes introduced at renewal can substitute for the marketing authorisation holder's obligation to update the marketing authorisation throughout the life of the product by variation application as data emerge, provided that the implemented changes fall within the scope of application of the Authority regulations governing registration of medicinal products in article 19, concerning the application for variation of a registered medical product.

m. Major changes to the product, such as the introduction of new indications, and quality changes, such as an extension of shelf life, shall not be modified through the renewal procedure and must be assessed through the appropriate variation procedure.

n. Accordingly, no new studies should be submitted within the renewal unless this impact the benefit-risk balance of the medicinal product. However, any new data should be discussed in the addendum to the relevant overview.

3. REFERENCES

1. Law Nº 003/2018 OF 09/02/2018 establishing Rwanda food and drugs authority and determining its mission, organisation and functioning
2. Rwanda FDA regulations Nº CBD/TRG/010 governing registration of medicinal products; February 2020.
3. Rwanda FDA guidelines Nº DHT/GDL/001 on submission of documentation for registration of human medicinal products.
4. Rwanda FDA guidelines Nº DHT/GDL/022 on submission of documentation for registration of Veterinary medicinal products.
5. European Medicines Agency; Guidelines on the processing of renewals in the centralised procedure, July 2016
6. Tanzania Medicines, and medical devices Authority, Guidelines on submission of documentation for renewal of registration of human and Veterinary Medicinal products, March 2020.
7. Saudi Food & Drug Authority; Data Requirements for the Renewal of Marketing Authorizations for Herbal and Health Products; May 2012
8. European Medicines Agency Reflection Paper Criteria for requiring one additional five-year renewal for Centrally Authorised Medical Products, November 2007
9. WHO, Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: *A manual for National Medicines Regulatory Authorities (NMRAs). 2011*
10. NDA Guidelines for submission of renewal of registration of pharmaceutical product for human use, Uganda February 2020

4. REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change made
05/05/2021	Rev_0	DAR/GDL/041	First Issue

ANNEXES

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

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

Dear Sir/Madam,

Subject: Submission of Application Dossier(s) for renewal of Marketing Authorization Nº ..... of <Product Name(s), [strength(s)] of active pharmaceutical ingredient(s) and dosage form(s)

We are pleased to submit our Application Dossier(s) for renewal of Marketing authorization of registered Human Medicinal Products or Veterinary Medicinal Products (***please specify***) that details are as follows:
Name of the medicinal product(s): ……
Dosage form(s) and strength(s): ……..
INN/active Pharmaceutical ingredient(s): ……
Manufacturer name and Country of origin: ..……
Rwanda FDA Marketing Authorization No: ……

You will find enclosed the submission dossier as specified hereafter:

—
• Two CD-ROMs or external data drives: containing all information on safety, quality, and efficacy of the product (where applicable).
• The renewal fees for this application have been paid:

• A valid Certificate of cGMP compliance has been provided:
—
—

• Two (2) commercial samples with batch certificates of analysis have been provided

• I confirm that the Product Dossier information submitted including composition, formulation, strength, specifications and packaging is the same in all aspects as the product registered with the relevant SRA, WHO PQ and EAC (Only for Abridged Application)

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. Model letter on renewal of Marketing Authorization following a Periodic Review

Application number
The Managing Director
[Name of the company]
[Address]
[Date]

Attention: Regulatory Affairs Manager
Dear Sir/Madam
I refer to the application dated [date of application] for [marketing authorization or periodic review or variation] of

Proprietary name (trade name)
Approved generic name(s)
Strength(s) per dosage unit
Dosage form
Name of authorization holder*
[*Must be a person or company in the country in which marketing is being authorized. This letter should normally be addressed to the marketing authorization holder.]

Evaluation of the application has been completed. Approval under [name of legislation] is granted, subject to the conditions in this letter and its attachments. This letter and its attachments constitute the marketing authorization. The details of this renewed marketing authorization are as follows. Some of these details may have changed since the last marketing authorization of this product.

Marketing authorization number

Date from which marketing authorisation is renewed
Expiry date of this marketing authorization
The conditions which apply are as follows:

A. General conditions applying to all products

- The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence.
- No changes may be made to the product without prior approval, except for changes of the type listed in [name of regulatory authority]'s policy on "Changes to pharmaceutical aspects of registered products which may be made without prior approval". Conditions in that policy apply.

- The approved sites of manufacture are those in Attachment 1.
- The approved shelf-life is that in Attachment 2.
- The only Product Information (PI) that may be supplied with or for this product must be the approved PI. Attachment 3 is a copy of the approved PI.

The Product information may not be altered without prior approval, except for safety updates that further restrict use of the product. Any such safety-related changes must be notified to *[name of regulatory authority]* within five days of making the change.
The product information must include the marketing authorization number and the date from which marketing is authorized. This information must appear in the top right-hand corner of the first page of the Product information, in letters of at least 1.5 mm tall.
All advertising and promotion of the product(s) must be consistent with the agreed product information.

B. Additional specific conditions applying to this product:

[...for example, "Distribution is restricted to hospitals specializing in oncology" .]
[.....]
[.....]

If you have any doubt as to the meaning of this letter and its attachments, you should contact the undersigned prior to marketing the product.

Yours faithfully

[Name]
[Signature]
authorized person under [name of legislation]

Marketing authorization Attachment 1

Product

- Proprietary name (trade name)
- Approved generic name(s)
- Strength(s) per dosage unit
- Dosage form
- Name of authorization holder
- Marketing authorization number
- Date from which the marketing authorization is renewed
- Expiry date of this marketing authorization
- The approved manufacturers are as follows.

Production stage	Name of site	Street address of site	Manufacturing step
[Active pharmaceutical ingredient I			Production
[Active pharmaceutical ingredient II]			Production
Finished product			[For example, granulation]
			[For example, sterilization]
			[For example, packaging]
			[For example, quality control]

Marketing authorization Attachment 2

Product

- Proprietary name (trade name)
- Approved generic name(s)
- Strength(s) per dosage unit
- Dosage form
- Name of authorization holder
- Marketing authorization number
- Date from which the marketing authorization is renewed
- Expiry date of this marketing authorization

Shelf-life

The approved shelf-life of this product when packaged and labelled as detailed in the application and modified in subsequent correspondence is as follows.

Pack	Shelf-life	Storage conditions
[For example, PVC/Al blisters, 25 and 50 tablets per blister]	8 months	Store below 30ºC Protect from moisture
[For example, HDPE bottles]	3 year	Store below 30ºC Protect from moisture

Restrictions on sale or distribution

[Normally one of these, and possibly different restrictions for different strengths]

- Scheduled narcotic;
- Restricted prescription-only distribution (specify - for example, hospitals only);
- Prescription only;
- Pharmacy only;
- Over the counter (OTC).

Annex III: Application form for renewal of registration of a medical product

(For official use only) Application Reference No:

1.1 Registration number:
……..
1.2 Date of expiry of current registration:
……..
1.3 Name of Product……
1.4 Product Form……...
1.5 Physical description……...
……..
1.6 Are there any changes since product was registered?

No	
Yes	

If yes give descriptions of the changes and if they were approved by Rwanda FDA
……..
……..
1.7 Are there any reported adverse reactions?

No	
Yes	

If yes give descriptions of the adverse reactions and if they were reported to Rwanda FDA
……..
……..

2. Particulars of Registrant

Name: …….
Physical Address: ……

……..
Postal Address: ……
Country…….
Phone: ……Fax: ……Email: ……...
Status of applicant (tick where appropriate)

Manufacturer ☐ Importer ☐

3. Particulars of manufacturer

Name: ……..
Physical Address: ……
……..
Postal Address: ……
Country…….
Phone: ……Fax: ……..……Email: ……...……

4. Particulars of local agent or importer

Name: ……..
Physical Address: ……
……..
Postal Address: ……
Country…….
Phone: ……Fax: ……Email: …….

5. Declaration by the Applicant

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 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 reliable for appropriate action under the provisions of the Rwanda FDA regulation
Name:……..……
Position in the company:……
Signature……..……
Official stamp:……
Date:……

ENDORSEMENT OF GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Human Medicines, and Devices Assessment & registration	Head of Drugs & Food Assessment and Registration Department	Director General
Names	**Dr. Eric NYIRIMIGABO**	**Mr. Joseph KABATENDE**	**Dr. Charles KARANGWA**
Signature			
Date	11/06/2021	11/06/2021	11/06/2021