RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES FOR DONATION OF MEDICAL PRODUCTS

JUNE, 2021

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GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	06/05/2021
ADOPTION BY RWANDA FDA	07/05/2021
STAKEHOLDERS CONSULTATION	8/06/2021
ADOPTION OF STAKEHOLDERS' COMMENTS	9/06/2021
DATE FOR COMING INTO EFFECT	14/06/2021

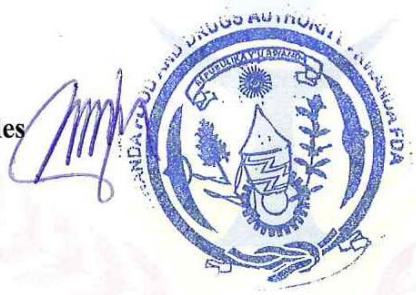
FOREWORD

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, safety and efficacy of medicinal products, medical devices and IVDs in order to protect public health by increasing their access and availability.

Considering the provisions of the technical regulations No CBD/TRG/010 governing the registration of human medicinal products, regulations No CBD/TRG/011 governing control of medicated cosmetics; Regulations No CBD/TRG/012, governing registration of medical devices, Regulations No CBD/TRG/013, governing the registration of pesticides, laboratory and cleaning chemicals; The Authority has developed guidelines No. DHT/GDL/040 for donation of medical products to promote a more efficient approach for regulatory oversight, access to quality-assured, effective and safe donated medical products.

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

Dr. KARANGWA Charles
Acting Director General



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DEFINITIONS

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

- **Applicant:** In this context refers to a manufacturer, the donor, or by an importer of the medical products. Such an applicant would be responsible for the product and all issues relating to the product, including any information accompanying the product.
- **Authority** refers to Rwanda Food and Drugs Authority, or its acronym "Rwanda FDA" established under Article 2 of Law Nº 003/2018 of 09/02/2018
- **Medical products:** in this context refers to medicinal products, medical devices and IVDs.
- **Local Applicant:** An applicant that is resident in Rwanda.
- **Local Agent:** A local agent is a person resident in Rwanda or a corporate body registered in Rwanda, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters relating to the donation.
- **Non-Resident applicant:** An applicant applying for permit to donate products to Rwanda but not a resident of Rwanda.
- **Recipient:** refers to governmental or non-governmental institutions, private institutions or individuals that voluntarily receive medical products as donation.

1. INTRODUCTION

1.1 Background

Medical products are essential in the delivery of effective health care. The safety, quality and efficacy of medical products are thus of importance in the regulatory framework. These guidelines are hereby made for information, guidance and strict compliance by all concerned parties on the procedure and requirements for the donation of medical products in Rwanda. They are applicable to medicinal products, medical devices, IVDs for both in humans and veterinary use.

Donations may come from governmental, non-governmental institutions, private institutions or individuals. All donated medical products must be based on a prior expressed need by the recipient.

The objectives of this guideline are:

- To protect the public health from unsafe, poor quality and ineffective medical products by ensuring Good Donations Practices.
- To facilitate the regulatory process and help ensure that medical products are distributed and reach to those in need.
- To ensure that the medical products donated are safe, effective and are authorized for use.
- To make sure that donated medical products are in compliance with the need of the country.

These guidelines must be read and used in conjunction with other relevant regulations in place issued by the Authority.

1.2 Scope

These guidelines shall apply to applications for donation of Medical Products, submitted to the Authority for compliance verification.

Submission of applications

All applications for processing of medical products donations shall be made by submitting a letter addressed to:

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. REQUIREMNTS

2.1 Principles of Good Donation

The four underlying principles, which form the core of *Good Donation Practice*, are:

1. Medical products donations should benefit the recipient to the maximum extent possible.
2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.
3. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
4. There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties with an official agreement between them.

2.2 General Requirements

1. All donations should be based on an expressed need and be relevant to the disease pattern in Rwanda. These should be based on National essential medicines Lists and other relevant National Standards Treatment Guidelines.
2. The specifications of donated items should be similar to those of items commonly used in Rwanda.
3. All product intended for donation shall have at least 2/3 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 importation.
4. Products requiring refrigeration or freezing for stability must specifically indicate storage requirements, both on labels and containers as well as on the documents and be shipped in special containers to ensure that the cold chain is maintained.
5. Labels and leaflets for all donated medical products must be in both English and French or in one of them. The label on each individual container must at least contain the international Non-proprietary name (INN) or generic name, batch number, dosage form, name of manufacturer, pack size, storage conditions and expiry date.
6. In accordance with regulations No. CBD/TRG/016 governing Pharmacovigilance of Pharmaceutical products and medical devices, the recipient has to ensure that a Qualified Person for Pharmacovigilance actively monitor and report all adverse events experienced accordingly to the Authority.
7. Donations must be from GMP compliant plants

2.3 Specific Requirements

1. A non-resident applicant would be required to appoint a local agent with the requisite mandate to represent the said applicant. For donation of medical products, the local agent

may be the recipient of the donated medical products. The agent would be required to produce the relevant documentation including, but not limited to, a power of attorney or any other documentation, confirming his/her appointment as an agent.

2. Where the medical product to be donated has been registered in Rwanda by the Authority, the recipient of the donated item would be required to liaise with the Company that holds the market authorization in Rwanda. This would be for the purposes of monitoring the safety of the medical product.
3. Where the medical product is not registered in the country, the donation would be permitted only after the medical product has been duly registered in reference to the relevant guidelines for registration.
4. Donations for products that can be locally manufactured they cannot be imported for donations.
5. An application for medical product donations should include the packing list of the products. The packing list should include the Name of the Product, Manufacturer, Strength of the product, dosage form and the expiry dates of the items to be donated.

2.4 Fees

1. All fees in connection with the registration of drugs are specified in the current regulation N° CBD/TRG/004 related to regulatory services tariffs/fees and fines.
2. No fee is Charged for processing applications for donation for registered products.
3. For non-registered products, the Authority will define the applicable registration fee for donated products considering the status of need and/or emergency of the products

3. TIMELINES

A minimum period of 1(one) month is to be allowed for the completion of the process.

4. REFERENCES

1. Ghana FDA Guideline for Donation OF Drugs number: FDA/DRI/DER/GL-DOM/2019/01
2. Rwanda FDA Guidelines on submission of Documentation for Registration of human medicinal products N°: DHT/GDL/001

5. REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change made
05/05/2021	Rev_0	DAR/GDL/040	First Issue