RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING CONTROL OF IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

First issue date	**11/06/20218**
Effective date of this revision	

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
09/07/2020	0	First issue
12/07/2021	1	Article 19.Validity of an Authorization
14/10/2022	2	1. Addition of the obligation to obtain an import License for importation of investigational products in Article 6 2. Article 14: Validity of an Authorization 3. Addition of article 19: Establishment of Advisory committee 4. Addition of article 21: Administrative sanctions 5. Addition of article 22: Appeal and review 6. Addition of article 23: Powers to issue guidelines 7. Addition of Regulations development history section 8. Addition of Document revision history Section 9. Removal of articles about Requirements for pharmaceutical products and/or medical devices import/export authorization, packaging of imported products, container closure system and procedures for re-export of pharmaceutical products and medical devices not allowed into Rwanda 10. Correction of typographic errors and formatting
15/02/2026	3	1. Removal of Import Visa and corresponding requirements 2. Eligibility criteria for both import and exporter have been summarized 3. Removal of the definition of Authority, since not supported by the law

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations No.: DD/DIEC/TRG/001 Version 4 governing control of importation and exportation of pharmaceutical products and medical devices on this [DD/MM/YYYY].

Names and signature
Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article one: Purpose of these Regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient control of importation and exportation of pharmaceutical products and medical devices and provide a transparent, non-discriminatory process of their importation and/or exportation.

Article 2: Citation

These Regulations may be cited as the "Regulations No DD/DIEC/TRG/001 Version 4, Governing Control for Importation and Exportation of Pharmaceutical products and Medical Devices."

Article 3: Application

These regulations shall apply to the authorization of importation or exportation of pharmaceutical products and medical devices, and their respective raw materials for public, private and non-profit organizations, including donated products, as stipulated in Article 3 of Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

a. "**Fee**" means the income prescribed in the Fees Regulations in accordance with Article 9 and Article 32 of the Law No 003/2018 of 09/02/2018;

b. "**Pharmacy**" means any licensed or authorized location used for the practice of the pharmacy profession;

c. "**Medical device**" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
   iii. investigation, replacement, modification, or support of the anatomy, or of a physiological process;
   iv. supporting or sustaining life;
   v. control of conception;
   vi. cleaning, disinfection, or sterilization of medical devices;
   vii. providing information by means of in vitro examination of specimens derived from the human body;

   and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

d. "**In-vitro diagnostic (IVD)"** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or

compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

e. "**Investigational product**" means any drug, biological product, device, or placebo being tested or used in a clinical trial;

f. "**Good Manufacturing Practice**" means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorization, Clinical Trial Authorization or product specification. Good Manufacturing Practice is concerned with both production and quality control;

g. "**Premises**" means any plot of land, buildings or boats, aircrafts, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed;

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

i. **"Law No. 47/2012"** means Law No 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products;

j. "**Pharmacist**" means any person holding a second cycle university degree in pharmacy who is registered and licensed;

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

l. "**Manufacturer**" means a person or corporation, or other entity engaged in the business of manufacturing pharmaceutical products and medical devices;

m. "**Authorization**" means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes licenses, permits, and certificates;

In these Regulations, the following verbal forms are used:

a. "**shall**" indicates a requirement;
b. "**should**" indicates a recommendation;
c. "**may**" indicates a permission; and
d. "**can**" indicates a possibility or a capability.

CHAPTER II: IMPORTATION OR EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS

Article 5: Obligations of importer/exporter

Any person intending to import/export any pharmaceutical products, medical devices including in vitro diagnostics, and investigational products or their respective raw materials, shall:

a. Apply for import/export license or other form of authorization issued by Rwanda FDA in accordance with these Regulations. The requirements to apply for import/export license are provided in the guidelines for importation and exportation of pharmaceutical products or medical devices including in vitro diagnostics. However, the import/export license is not required for products declared as personal effects. The requirements to import products for personal use are provided in the guidelines for importation and exportation of regulated products declared as personal effects;

b. Ensure the safety and quality of products they intend to import/export and ensure they are properly preserved during transport, distribution, storage, and sale;

c. ensure that only safe Products are placed on the market;

d. Notify Rwanda FDA upon the arrival of imported products for physical inspection.;

Article 6: Eligibility to import pharmaceutical products or medical devices

a. All pharmaceutical products and medical devices including in-vitro diagnostics (IVDs) must be imported by eligible importers as defined in the Guidelines for importation and exportation of Pharmaceutical Products or Medical Devices;

b. Any pharmaceutical products or medical devices registered by Rwanda FDA shall be imported only by an eligible company/institution appointed by the marketing authorization holder;

c. Any Investigational products shall be imported only by an eligible company/institution that received an approval to conduct a clinical trial.

Article 7: Authorization for importation of narcotic drugs and psychotropic substances.

a. Any entity intending to import/export any narcotic drugs or psychotropic substances shall apply for an official certificate of importation/exportation of controlled substances, issued by Rwanda FDA in accordance with these Regulations;

b. Rwanda FDA shall issue an official certificate of importation of controlled substances if the client meets the requirements and any applicable national and/or international laws;

c. Any entity granted an authorization to import/export a narcotic drug or psychotropic substance shall provide reports in accordance with the requirements set by Rwanda FDA.

Article 8: Authorization for importation/exportation of vaccines

a. Any person intending to import/export any vaccine and/or its active substance including master and working cell banks shall apply for importation/exportation authorization issued by Rwanda FDA in accordance with these regulations;

b. These regulations therefore concern import/export of either finished vaccine in its final form or any product essential for its manufacturing; this includes the active substance (commonly called drug substances or bulk, intermediates, master and working cell banks), the vaccine in a bulk packaging, the vaccine in its primary and /or secondary packaging.

Article 9: Physical inspection of pharmaceutical products, medical devices or raw materials

a. All imported consignments of pharmaceutical products and medical devices shall be subjected to physical inspection at port of entry or at importer's premises (for the consignments released under seal) before being used to ensure that they comply with claimed specifications. Rwanda FDA may take samples for quality testing. Consignments to be exported shall be subjected also to physical inspection;

b. The products which do not conform to importation requirements shall be rejected. Where Rwanda FDA rejects imported product for reasons other than their quality, the product shall be re-exported to the country of origin or to a third-party country on special request and special clearance from the National Regulatory Authority of the country where the product is being re-exported, within a period of ninety (90) calendar days from the date of the rejection;

c. Where Rwanda FDA rejects imported pharmaceutical products/medical devices/raw materials, due to reasons of poor quality, they shall be destroyed at the cost of the importer following the procedures for safe disposal;

d. When justified and for valid reasons, Rwanda FDA may authorize the release of an imported consignment under seal, pending importer's compliance with the importation requirements or the completion of further analysis prior to full approval for use;

e. No person shall obstruct or hinder Rwanda FDA staff in the exercise of their powers or performance of their duties during inspection as provided for in the Law.

Article 10: Points of entry and exit

Pharmaceutical products, medical devices or raw materials shall be imported or exported only through Gazetted points of entry and exit.

CHAPTER III: VALIDITY, REFUSAL, SUSPENSION, AND WITHDRAWAL OF AN IMPORT/EXPORT AUTHORIZATION

Article 11: Validity of license

a. An import/export license shall be valid for 6 months from the date of its issuance;

b. An official certificate of importation/exportation of controlled substances shall be valid for 12 months from the date of its issuance;

c. A license is issued to an importer/exporter, to cover only one consignment, and shall not be transferable.

Article 12: Refusal to grant a license

An authorization to import/export shall not be granted where Rwanda FDA finds that the client is not complying with the importation /exportation requirements.

Article 13:Withdrawal or suspension of a license

A license may be withdrawn or suspended where Rwanda FDA finds that the client violated any of the conditions under which authorization was granted for or has ceased to be fit to carry out the business. The notice of withdrawal shall be issued by Rwanda FDA to the client.

CHAPTER IV: RENEWAL AND AMENDMENT OF AN AUTHORIZATION

Article 14: Renewal of a license

Upon submission of an application for renewal, a license shall be renewed in case it has not been fully used.

Article 15: Amendment of an authorization

Whenever there is a justified reason, Rwanda FDA may amend the issued authorization upon client's request.

CHAPTER V: MISCELLANEOUS PROVISIONS

Article 16: Establishment of Advisory committee

a. Rwanda FDA shall establish Drugs Import and Export Control Advisory Committee with clear terms of reference;

b. The committee shall be composed of internal multidisciplinary experts with specialization in Pharmaceutical products and medical devices.

Article 17: Compliance with other requirements

A company that has been granted an authorization shall comply with any other requirements as may be specified by Rwanda FDA.

Article 18: Administrative sanctions

Any person who contravenes the provisions of these regulations, shall be liable to the administrative measures and sanctions as per the following table:

#	**Fault**	**Administrative sanction**
1	Importation of regulated products without fulfilling some of the requirements for the first time including certificate of compliance and/or certificate of analysis for import license	Warning letter
2	Importation of regulated products without fulfilling some of the requirements for the second time including certificate	Refusal to grant import authorization

	of compliance and/or certificate of analysis for import license	
3	Importation of unauthorized regulated products without special approval by Rwanda FDA	Rejection of the consignment and order the re-export of the product at the cost of the importer
4	Importation, sale, or distribution of substandard, unapproved, falsified, expired or fraudulent regulated products	50% of the product value found in violation
5	Obstruction of Rwanda FDA staff during the inspection process.	100,000 Frw for each day of obstructions
6	Failure to re-export consignment that were recommended a re-exportation within the recommended timelines	10, 000 Frw for each extra day but not exceeding 300,000Rwf.

Article 19: Appeal and review

a. Any person aggrieved by a decision of Rwanda FDA may appeal for review of the decision showing grounds for dissatisfaction within thirty (30) days from the date of notice;

b. Rwanda FDA shall review the appeal within thirty (30) days and thereafter revises or maintains its initial decision.

c. If a person is dissatisfied with the decision after review, he/she may appeal to the Minister of Health whose decision shall be final.

Article 20: Power to issue guidelines

Rwanda FDA shall issue guidelines, guidance, SOPs, forms necessary for the implementation of these Regulations.

Article 21: Revision of these Regulations

The revision of these regulations shall be done at least after three (3) years from the date of their publication, except in case of special circumstances. Amendments shall be communicated to the public in due time.

Article 22: Commencement and repealing

a. These regulations come into force on the date of signature and publication by Rwanda FDA;

b. All Provisions contrary to these regulations are hereby repealed.

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