

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

(Rwanda FDA law No. 003/2018 of 09/02/2018, Article 9)

# REGULATION DEVELOPMENT HISTORY

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| **STAKEHOLDERS CONSULTATION**  | 18 February 2019  |
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| **DRAFT COMING INTO EFFECT** |  |

# DOCUMENT REVISION HISTORY

| Date of revision | Revision number | Changes made and/or reasons for revision |
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| 14/07/2021 | 1 | 1. Article 19.Validity of an Authorisation |
| …/…./2022 | 2 | 1. Addition of the obligation to obtain an import Licence for importation of investigational products in Article 6
2. Addition of article 19: Establishment of Advisory committee
3. Addition of article 21: Administrative sanctions
4. Addition of article 22: Appeal and review
5. Addition of article 23: Powers to issue guidelines
6. Addition of Regulations development history section
7. Addition of Document revision history Section
8. 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
9. Correction of typographic errors and formatting.
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# ADOPTION AND APPROVAL OF THE REGULATIONS

*In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article No 9 of the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulations No. CBD/TRG/002 Rev. No. 2, Governing Control of Importation and Exportation of Pharmaceutical Products and Medical Devices, made this …../…./2022.*

**Dr. Emile BIENVENU**

**Director General**

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# CHAPTER I: GENERAL PROVISIONS

## Article 1: 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, medical devices, and their respective raw materials in a transparent, non-discriminatory manner.

## Article 2: Citation

These Regulations may be cited as the *“Regulations No DIS/TRG/002 Rev.\_2, 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, medical devices, and their respective raw materials for the public, private, non-profit organizations, and individuals as stipulated in Article 3 of Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.

## Article 4: Definitions

In these regulations, unless the context otherwise requires:

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

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

**“Authority”** means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Article 2 of the Law No 003/2018 of 09/02/2018

**“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 import visas, import/export licenses, permits, and certificates.

***Import Visa*** means an authorization/permit issued to the importer after confirmation by the Authority that manufacturer(s)/suppliers of pharmaceutical products or medical devices or their respective raw materials to be imported comply with international and national standards. The Import visa gives the right to the importer to confirm an order of the products and to apply for import license.

***Import License*** means an authorization/permit issued to the importer by the Authority, authorizing him/her to import pharmaceutical products or medical devices or their respective raw materials into the country after complying with the importation requirements;

***Export License*** means an authorization/permit issued to an eligible exporter by Authority, authorizing him/her to export pharmaceuticals or medical devices or their respective raw materials from the country;

***“To Whom it may concern”*** means a special authorization/permit issued to an eligible importer/exporter by Authority, authorizing him/her to import/export pharmaceuticals or medical devices or their respective raw materials for specifics reasons;

**“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.

**“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 Authorisation, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control.

**“Manufacturer”** means a person or corporation, or other entity engaged in the business of manufacturing pharmaceutical products and/or medical devices;

**“Pharmaceutical product”** means any substance in its finished dosage form, or as a starting material for use in such a dosage form, capable of preventing, or 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 farmhouses.

**“Pharmacy”** means any licensed/authorized location used for the practice of the pharmacy profession.

**“Premises”** means any plot of land, buildings or boats, aircraft, 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.

**“Medical device”** means any instrument, machine, appliance, or material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery, for human or animal health protection;

**“Investigational product”** means any drug, biological product, device, or placebo being tested or used in a clinical trial/research.

**“Raw material”** refers to any unfinished substance used to manufacture medical devices or pharmaceutical products including vaccines.

In these Regulations, the following verbal forms are used:

**“shall”** indicates a requirement;

**“may”** indicates a permission; and

**“can”** indicates a possibility or a capability.

**CHAPTER II: IMPORTATION / EXPORTATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES AND THEIR RESPECTIVE RAW MATERIALS**

**Article 5**: Obligation to obtain an import Visa

Any person intending to import any pharmaceutical product or medical device or their respective raw materials and investigational products shall apply for an Import Visa for each consignment, issued by the Authority in accordance with these Regulations.

## Article 6: Obligation to obtain an import/export Licence

Any person intending to import/export any pharmaceutical product, medical device or their respective raw materials and investigational products shall apply for an import/export license for each consignment, issued by the Authority in accordance with these Regulations.

## Article 7: Special circumstances

In special circumstances including but not limited to products for personal use, disasters, emergency and outbreaks officially declared by competent Authority the article 5 and/or 6 shall not be applied.

## Article 8: Eligibility to import pharmaceutical products or medical devices

Eligible applicants to import pharmaceutical products, medical devices, and their respective raw materials for their manufacture include:

1. A manufacturer of pharmaceutical products or medical devices;
2. A wholesaler of pharmaceutical products or medical devices;
3. A retailer of pharmaceutical products and medical devices can import the products based only on medical prescription in case the products are not available on the local market;
4. A beneficiary of pharmaceutical products or medical devices donation;
5. Government institutions (examples: Ministries, Teaching and Referral Hospitals, Universities, etc.)
6. Public and Private Health Facilities with justified reasons
7. Research institutions/researchers with clinical trial or research approval in the country;
8. UN agencies, international organizations intervening in health sector, Non-governmental organizations (NGOs) with MOU with Ministry of Health (MOH) or Government of Rwanda;
9. A tourist, a visitor in the country or any other person with justified reasons;
10. Hatcheries

## Article 9: Eligibility to export pharmaceutical products or medical devices

Eligible applicants to export pharmaceutical products, medical devices and raw materials include:

1. A manufacturer of pharmaceutical products or medical devices;
2. A wholesaler of pharmaceutical products or medical devices;
3. A donor of pharmaceutical products or medical devices;
4. Government institutions (examples: Ministries, Teaching and Referral Hospitals, Universities, etc.) with justified reasons
5. Public and Private Health Facilities with justified reasons
6. Research institutions/researchers with clinical trial or research approval in the country;
7. Non-governmental organizations (NGOs) with MOU with Ministry of Health (MOH) or Government of Rwanda;
8. UN organizations and other international organizations intervening in Health sector;
9. A tourist, a visitor in the country or any other person for justified reasons.

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## Article 10: Authorisation for importation/exportation of narcotic drugs and psychotropic

##  substances.

Any person intending to import/export any narcotic drugs or psychotropic substances shall apply for an official certificate of importation/exportation of controlled substances, issued by the Authority in accordance with these Regulations.

The Authority shall issue an official certificate of importation/exportation of controlled substances where it is satisfied that the applicant meets the requirements and any applicable national and/or international laws.

Any person granted an authorization to import/export a narcotic drug or psychotropic substance shall provide quarterly reports to the Authority.

**Article 11**: **Authorisation for importation/exportation of vaccines**

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 the Authority in accordance with these regulations.

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 12: Physical inspection of pharmaceutical products or medical devices or raw materials by the Authority

All imported consignments of pharmaceutical products and medical devices shall be subjected to physical inspection at port of entry or at importer’s premise for the consignments released under seal before being used to ensure that they comply with claimed specifications. The Authority may take samples for quality control testing.

Consignments to be exported shall be subjected also to physical inspection.

Where the Authority rejects imported pharmaceutical products/medical devices/raw materialsfor reasons other than their quality, the importer of the rejected product shall re-export them in the country of origin, within a period of thirty (30) days from the date of the rejection. The cost related to this exercise is paid by the importer.

Where the Authority rejects imported pharmaceutical products/medical devices/raw materials, due to reasons of poor quality, they shall be destroyed at the cost of the importer within three (3) months from the date of rejection following the procedures for safe disposal.

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

##  Article 13: Gazetted/approved ports of entry and exit

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

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

**Article 14: Validity of an Authorization**

1. An import Visa shall be valid for 6 months from the date of its issuance.
2. An import/export License shall be valid for 6 months from the date of its issuance
3. An official certificate of importation/exportation of controlled substances shall be valid for 12 months from the date of its issuance
4. An authorization is issued to an applicant, to cover only one consignment, and shall not be transferable.

**Article 15: Refusal to grant an Authorization**

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

**Article 16: Suspension or withdrawal of an authorization**

An authorization may be suspended or withdrawn where the Authority finds that the applicant 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 suspension or withdrawal shall be issued by the Authority to the applicant.

# CHAPTER IV: RENEWAL AND VARIATION OF AN AUTHORIZATION

## Article 16: Renewal of an import license

An import License shall be renewed after six months from the date it was issued in case it has not been used by the applicant upon submission of an application for renewal.

## Article 18: Variation of an authorization

Whenever the Authority varies, amends, or imposes any new condition on the authorization requirements, the Authority shall communicate the return of such authorization to be duly endorsed within a reasonable time.

An application shall be made to the Authority for review and approval of any variation made on the details of the issued authorization.

# CHAPTER V: MISCELLANEOUS PROVISIONS

## Article 19: Establishment of Advisory Committee

1. The Authority shall establish Import and Export Control Advisory Committees with clear terms of reference;

2. The committees shall be composed of internal and external multidisciplinary experts with specialization in relevant fields to assess all safety and quality issues on importation and exportation of Pharmaceutical products, medical devices and their respective raw materials.

## Article 20: Compliance with other requirements

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

## Article 21: Administrative sanctions

Any person who imports or exports, sells, distributes unapproved or not inspected and fraudulent pharmaceutical products/medical devices/ raw materials or fails to comply with the conditions of the authorization issued to him or her; commits an administrative fault and shall be guilty of an offense. He/she shall be liable for administrative fines equivalent to double the value of condemned products plus tests related costs, when testing is compulsory, as stipulated in the regulations related to regulatory service tariff/fees and fines.

The Authority may cause the prosecution of offending parties as the case may be.

## Article 22: Appeal and review

1. Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (**30**) days from the date of notice.
2. The Authority shall, within thirty (**30**) days from the date of receiving the application, review, reject or vary its own decision.
3. If a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

## Article 23: Power to issue guidelines

The authority shall issue Guidelines, Standards Operating Procedures, forms and formats necessary for the implementation of these Regulations.

## Article 24: 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 25: Commencement and repealing

These regulations come into force on the date of signature and publication by the Authority.

All provisions contrary to these regulations are hereby repealed.

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