RWANDA FDA
Rwanda Food and Drugs Authority

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

DRAFT ZERO BY CONSULTANTS	11/06/2018
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STAKEHOLDERS CONSULTATION	13/10/2022
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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 Authorisation
14/10/2022	2	1. Addition of the obligation to obtain an import Licence for importation of investigational products in Article 6 2. Article 14: Validity of an Authorisation 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.

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 24/11/2022.

ARRANGEMENT OF THE REGULATIONS

CHAPTER I: 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, medical devices, and their respective raw materials in a transparent, non-discriminatory manner.

Article 2: Citation

These Regulations may be cited as the *"Regulations N° 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:

"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 determining its mission, organization and functioning.

"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/purchase 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 documentary 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 pharmaceutical products or medical devices or their respective raw materials for specific reasons including but not limited to products for disasters, emergency and outbreaks officially declared by competent authority;

"Fee" means the regulatory service charge 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.

"Unapproved regulated products" refers to regulated products not yet released by the authority including but not limited to imported pharmaceutical products, medical devices and their respective raw materials that are uninspected (not yet physically inspected at ports of entry or at importer's premise for consignments released underseal) or unauthorized for use by the Authority.

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. The requirements to apply for import visa are provided in the guidelines for importation and exportation of pharmaceutical products and medical devices.

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. The requirements to apply for import/export license are provided in the guidelines for importation and exportation of pharmaceutical products and medical devices.

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. The requirements to apply for import/export permit of products for personal use are provided in the guidelines for importation and exportation of regulated products declared as personal effects.

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

NB: Registered pharmaceutical products or medical devices by Rwanda FDA shall be imported only by the marketing authorization holder's Local Technical Representative (LTR) or by any other company appointed by the marketing authorization holder or by the manufacturer in case he/she is the marketing authorization holder**.**

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.

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.

The products which do not conform to importation requirements shall be rejected. Where the Authority rejects imported pharmaceutical products/medical devices/raw materials for reasons other than their quality, the importer of the rejected product shall re-export them to the country of origin, within a period of ninety (90) 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 ninety (90) days from the date of rejection following the procedures for safe disposal.

The Authority reserves the right, when deemed necessary and for justified reasons, to release underseal an imported consignment while waiting for the client to comply with importation requirements and/or to obtain a full release of the imported products for their intended use.

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/approved 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: Withdrawal of an authorization

An authorization may be 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 17: 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 contravenes the provisions of these Regulations, shall be liable to the administrative
measures and sanctions under **Annex A**:

1°. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.
2°. Importation/Exportation of unregistered or unauthorized regulated products without special approval given by the Authority
3°. Obstruction of inspectors from Rwanda Food and Drugs Authority
4°. Failure to re-export consignment that were recommended for re-exportation within the recommended timeline

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.

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.

End of Document

ANNEX A: FAULTS AND ADMINISTRATIVE SANCTIONS

Fault	**Administrative sanction**
1. Importation of regulated products without fulfilling some of the requirements for the first time including certificate of compliance for import visa 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 of compliance for import visa and/or certificate of analysis for import license.	Refusal to grant import authorization/ Application letter
3. Importation of unregistered or unauthorized regulated products without special approval by the Authority	Rejection of the consignment and order the re-export of the product at the cost of the importer
4. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.	25% to 50% of the product value found in violation
5. Obstruction of inspector from Rwanda Food and Drugs Authority	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