

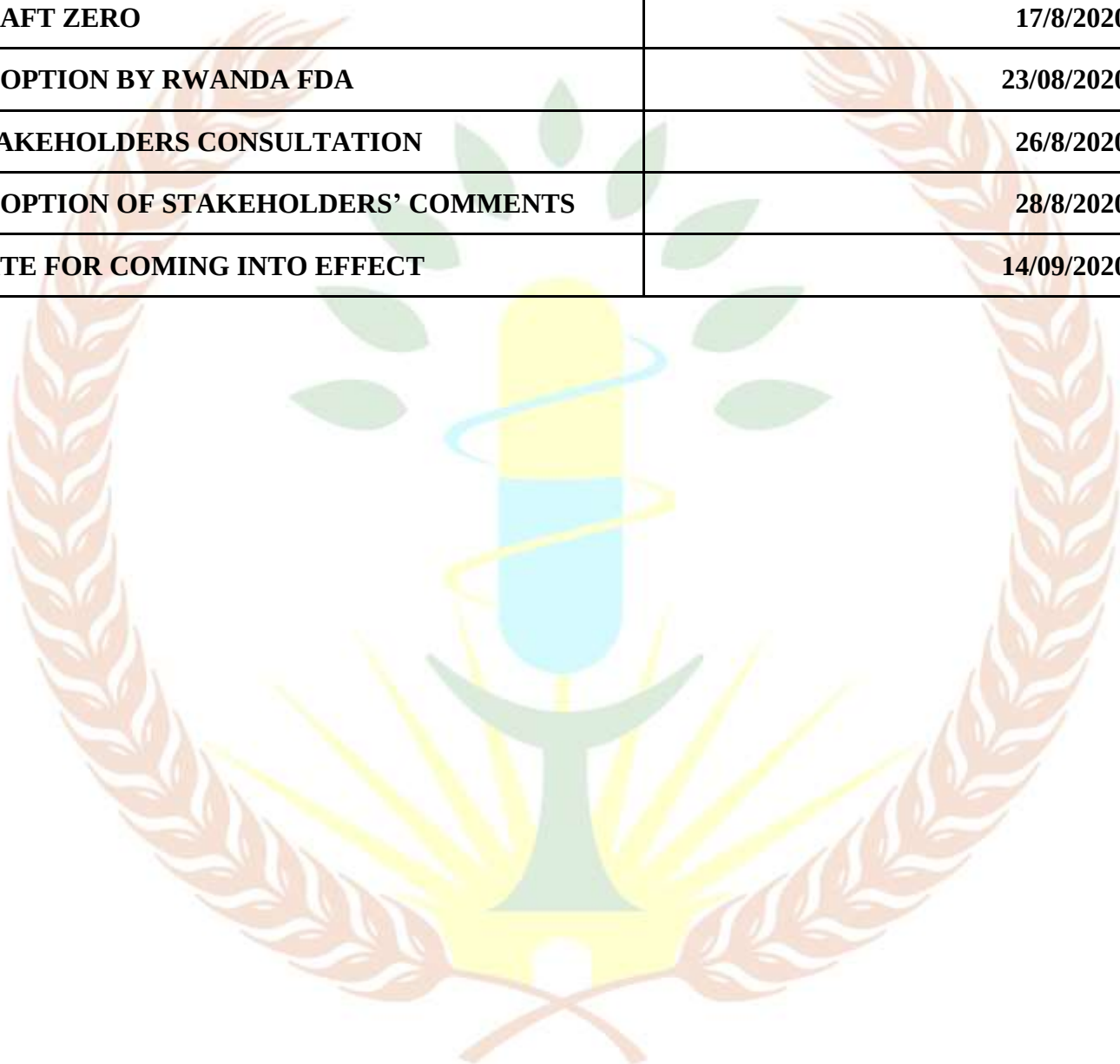


**REGULATIONS GOVERNING ONLINE PHARMACY
PRACTICE**

(Rwanda FDA law N°. 003/2018 of 09/02/2019, Article 9)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	17/8/2020
ADOPTION BY RWANDA FDA	23/08/2020
STAKEHOLDERS CONSULTATION	26/8/2020
ADOPTION OF STAKEHOLDERS' COMMENTS	28/8/2020
DATE FOR COMING INTO EFFECT	14/09/2020



RWANDA FDA
Rwanda Food and Drugs Authority

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 N° CBD/TRG/014 Rev. N° 0, governing online pharmacy practice, made this 14th day of September, 2020.

Dr. Charles KARANGWA
Ag. Director General



RWANDA FDA
Rwanda Food and Drugs Authority

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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 regulation of pharmaceutical products and provide a transparent and non-discriminatory process for authorization to operate online pharmacy.

Article 2: Citation

These Regulations may be cited as the “*Regulations CBD/TRG/014 Rev. N° 0, Governing online pharmacy practice*”.

Article 3: Application

These regulations shall apply to any establishment, company or individual involved in online pharmacy practice.

Article 4: Interpretation

In these regulations, unless the context otherwise requires:

“**Authority**” means Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Article 2 of the Law;

“**Authorization**” means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes licences, permits, and certificates.

“**Tariff/fees**” Includes any charge made or levied in connections with services rendered by the Authority;

“**Law N°. 003/2018**” means Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning;

“**Law N°. 47/2012**” means Law N° 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products

“**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 drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

“Pharmacist” means any person holding a second cycle university degree in pharmacy who is registered and licensed;

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

“Premises/Establishment” 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.

In these Regulations, the following verbal forms are used:

“*shall*” indicates a requirement;

“*should*” indicates a recommendation;

“*may*” indicates a permission; and

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

CHAPTER II: LICENSING REQUIREMENTS TO OPERATE AS AN ONLINE PHARMACY

Article 5: Obligation to obtain an Authorization

Any person shall not, without an Authorization issued by the Authority, operate an online pharmacy.

Article 6: Application for an Online Pharmacy Authorization

An online pharmacy authorization can be granted to an establishment willing to deal with human medicines, Veterinary medicines, medical devices, medical consumables, medicated cosmetics, and public health products.

An application for an authorization to operate online pharmacy shall be made using the standard form (*Doc. N° DIS/FOM/020-Application Form for online pharmacy*), and shall be accompanied by the following:

I. REQUIREMENTS FOR AN ONLINE PHARMACY

- a) Company profile, also indicating both physical and website addresses used for that purpose and all relevant information necessary to identify that the website offering the medicinal products contains at least:
 - i. the contact details of the owner.
 - ii. the company logo clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products and health commodities.
- b) Business registration certificate and full registration information of domestic company;
- c) Evidence of payment of prescribed fees;
- d) Notarized valid license for professional practice of the designated responsible pharmacist/veterinary doctor;
- e) Commitment letter from the designated pharmacist/veterinary doctor to respect the laws and regulations;
- f) Valid contract between the owner and the designated responsible pharmacist/veterinary doctor;
- g) Degree and curriculum vitae of the designated responsible pharmacist/veterinary doctor;
- h) Copy of the identity card or passport of both the owner and the designated responsible pharmacist/veterinary doctor;
- i) One recent passport-size photograph of the owner and designated responsible pharmacist/veterinary doctor;

- j) Contract between online pharmacy and physical pharmacies for supply of medicines and medical supplies.

Article 7: Authorized technical persons for supervising online pharmacy

- i. Online pharmacy for human medicines and medical supplies shall be supervised by pharmacist.
- ii. Online pharmacy for veterinary medicines shall be supervised by either veterinary doctor or pharmacist.

Article 8: Physical location of an online pharmacy

The online pharmacy shall have a designated physical address and adequate space for carrying out and supervision of the necessary operations;

Article 9: Documentation and related controls

- 1) All records including but not limited to invoices, purchase orders, sales and dispensing records, copy of prescriptions, for all pharmaceutical products, medical supplies and administrative records of the staff shall be properly kept for at least ten (10) years and be readily available for inspection or audit by the Authority.
- 2) All entries and dispensing of pharmaceutical products and medical supplies must be approved by the responsible pharmacist/veterinary doctor.
- 3) A copy of authorization for online pharmacy, license to practice for the responsible pharmacist/veterinary doctor shall be conspicuously displayed in the office and on the website.

Article 10: Authorized medicines for online pharmacy

The online pharmacy shall be authorized to deal with all medicines with exception of narcotics, psychotropic substances, precursors and Prostaglandin analogues.

Article 11: Transportation and Delivery

The transportation of pharmaceutical products and medical supplies shall maintain the storage conditions prescribed by the manufacturer. When necessary, the use of specialized shipping containers will be required to control drug temperatures in order to ensure drug quality, safety and efficacy. The pharmacy shall ensure that the transportation and delivery is done by trained personnel. The responsible

pharmacist/veterinary doctor shall ensure effective transportation and delivery of products. The online pharmacy shall notify Rwanda FDA of the transportation plan and safe delivery.

All the appropriate records of the online pharmacy transactions shall be kept with a verifiable audit trail of the medicines sold or supplied. These records shall be readily available for inspection and audit by Authority. The records shall include;

- a. the name, quantity, batch number and expiry date of the medicines supplied;
- b. the name and address of the person to whom the medicines were supplied;
- c. the purpose for which the drug was stated to be required (in case of a prescription, a copy of the prescription);
- d. the signature of the person to whom the medicine was delivered;
- e. the date of supply and the date of delivery.

Note that: The original prescription shall be returned and kept at the establishment within 3 days after delivery of medical products.

Article 12: Medicine Information

Prescription should be presented where necessary for ordered medicines and medical supplies.

It is the responsibility of the pharmacist/veterinary doctor to ensure that information related to the medicine delivered is given to the patient.

In the case of medicines liable to abuse, overuse or misuse, and ongoing monitoring is important, the pharmacist should assure that the prescriber is contacted in advance of issuing a prescription.

Article 13: Pharmacovigilance activities and safety monitoring

The online pharmacy shall provide the report of any non-compliance to the Authority. The responsible pharmacist shall comply with the provisions of pharmacovigilance activities and safety monitoring.

CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION

Article 14: Refusal to grant an Authorization

An authorization to operate online pharmacy shall not be granted where the Authority finds the applicant not complying with the minimum requirements prescribed in these Regulations.

Article 15: Validity of an Authorization

- 1) An authorization shall be valid for one-year renewable from the date it is issued, but may be suspended or revoked, if any of the conditions under which it was granted, is violated.
- 2) An authorization is issued to an applicant and shall not be transferable to another applicant.

Article 16: Administrative Functions

- 1) A **warning letter**, **Suspension letter**, or **revocation letter** may be issued to the applicant, any time when the Authority finds the applicant not complying with any of the requirements or conditions in these Regulations; or has ceased to be fit to carry on the business.
- 2) Monetary fines are provided in the Regulations No CBD/TRG/004 Related to regulatory service tariff/fees and fines.

CHAPTER IV: RENEWAL AND VARIATION OF AN AUTHORIZATION

Article 17: Renewal of an authorization

An authorization shall be renewed after one year from the date it was issued, upon submission of an application for renewal and after meeting all prescribed requirements. The application for renewal of authorization shall be done one month before its expiration.

Article 18: Variation of an authorization

- 1) Whenever the Authority varies, amends, or imposes any new conditions on the authorization requirements, the Authority shall communicate the return of such authorization to be duly endorsed within reasonable time.
- 2) An application shall be made to the Authority for review and approval of any variation made on the details of the issued authorization.

Article 19: Identification and Confidentiality

There shall be a system for authentication of patients through identity checks on people obtaining medicines.

The pharmacy shall establish a demonstrable system for data confidentiality, and personal data protection to avoid unauthorised access and use of patient data.

The pharmacy shall have a system for identifying requests for medicines that are inappropriate, including multiple orders to the same address or orders using the same payment details.

CHAPTER V: MISCELLANEOUS PROVISIONS

Article 20: Publication of authorized online pharmacies

Online Pharmacies that are granted authorizations shall be published regularly on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

End of Document



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