REGULATIONS GOVERNING RECALL, TREATMENT AND DISPOSAL OF UNFIT PRODUCTS

(Rwanda FDA law N^{o} 003/2018 of 09/02/2018, Article 8)

FEBRUARY 2021

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY CONSULTANTS	20th May 2018
ADOPTION BY RWANDA FDA	10th July 2020
STAKEHOLDERS CONSULTATION	13th October 2020
ADOPTION OF STAKEHOLDERS' COMMENTS	25th November 2020
DATE FOR COMING INTO EFFECT	03rd February 2021

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.: CBD/TRG/019 Rev_0 governing the Recall, treatment and Disposal of Unfit products on this 03rd February 2021.

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Ag. 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 regulation of recall, treatment and disposal of unfit regulated products and providing an open transparent and non-discriminatory process for the treatment and disposal of unfit regulated products.

Article 2: Citation

These regulations may be cited as "the regulation governing recall, treatment and disposal of unfit regulated products" and shall come into operation from the date of publication.

Article 3: Application and scope

These regulations shall apply to all regulated products that are manufactured, imported, distributed, stored, sold and used in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

1. **"Appropriate fee"** means the fee prescribed in the regulation N^{o} CBD/TRG/004 Rev_1 Governing service tariff/fees and fines
2. **"Authority"** means the Rwanda Food and Drug Authority, established under Article 2 of the law N^{o} 003/2018 of 09/02/2018
3. **"Rwanda FDA"** means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of the Law N^{o} 003/2018 of 09/02/2018
4. **4"Disposal"** means the process of rendering harmless any unwanted or unfit regulated product.
5. **"Law"** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning;
6. **"Recall"** means the removal of specific batch or batches of human and veterinary drugs; human and animal vaccines and other biological products used in clinical as drugs; processed food for humans and animals, food supplements and fortified foods, poisonous substances; herbal medicines; medicated cosmetics; human and veterinary medical devices; tobacco and tobacco products from the market for reasons relating to deficiencies in the quality, safety or efficacy;
7. **"Unfit regulated products"** means:
    a. Products regulated under the law that are expired, improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labelled, substandard or falsified, adulterated, prohibited or unauthorised.
    b. Any product regulated under the law that does not meet regulatory requirements or when consumed or used can be injurious to the health of the consumer.
    c. Any product regulated under the law that has in or on it a poisonous or harmful

substance.

d. Any regulated product that consists in whole or part of a filthy, putrid, rotten, decomposed or diseased substance

8. **"regulated product" means any human and veterinary drugs, human and animal vaccines and other** biological products used in clinical as drugs, processed food for humans and animals, food supplements and fortified foods; poisonous substances; herbal medicines; medicated cosmetics; human and veterinary medical devices; tobacco and tobacco products;
9. **"Product License Holder"** is the person or business which could be the manufacturer, importer, distributor or the registration certificate holder of regulated products and has the primary responsibility for the supply and distribution of regulated product in Rwanda;
10. **"Quarantine"** The status of regulated products isolated physically due to suspicion on the quality or safety, while a decision is awaited on their release, recall, and rejection or reprocessing. Quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to unauthorized personnel.

CHAPTER II: GENERAL REQUIREMENT

Article 5: Prohibition

It is prohibited for everyone to:

1. possess or sell any regulated product which is referred as unfit Regulated products
2. distribute, offer or expose for sale, procure for sale, or administer to any person or animal, any regulated product which is unfit for its intended purpose.
3. manufacture, import, export and distribute unfit regulated products subjected to be recalled

Article 6: Powers to seize, forfeit, condemn, destruct and recall unfit products

1. The Authority should issue a call for quarantine while the investigation on quality and safety of regulated product is ongoing. Quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel.
2. The Authority may, if satisfied that any product regulated under the Law is unfit for the intended use, seize, forfeit, condemn and recall such product and declare it unfit for intended use and shall order that product to be destroyed at the owner's cost.

3. In the event of recall, Rwanda FDA expects the holder of registration certificate and the importers to take full responsibility of products recalls including follow-up, checks to ensure that the recalls are successful.

CHAPTER III: RECALL OF UNFIT REGULATED PRODUCT

Article 7: Initiation of products recall

1. The Authority may at any time when it is of the opinion that any regulated products, for reasons relating to deficiencies in the quality, safety or efficacy, order recall of such product from the market at the cost of the manufacturer, registrant , importer ,distributer as the case may be.

2. Before or while undertaking a recall, the manufacturer, registrant, importer, and distributer of confirmed unfit products shall provide to the Authority with the following:
    a. Proprietary name , generic name, dosage form, strength, batch or lot number, pack size, the name and address of the manufacturer, manufacturing date and expiry date;
    b. For food products shall provide brand name/commercial name batch or lot number, pack size, the name and address of the manufacturer, manufacturing date and expiry date;
    c. The reason for the recall, the nature of the defectiveness or possible defectiveness, the date on and circumstances under which the defects or possible defects were discovered;
    d. The total quantity of the product being recalled originally in possession of the manufacturer, registrant or importer and distributor
    e. The date on which distribution of the product began;
    f. The total quantity of the product being recalled that had been distributed up to the time of the recall;
    g. Area of distribution of the product;
    h. List of customers to whom product was distributed,
    i. The quantity of the recalled product still in possession of the manufacturer, registrant or importer and distributor
3. The manufacturer, registrant, importer, distributor of regulated products may voluntarily initiate a recall after receiving complaints from users or upon proof after investigation that such product has caused or is about to cause injury to the health or safety of patients, users or other persons.

4. The manufacturer, registrant, importer, distributor of regulated products who voluntarily initiates a recall shall be required to comply with the requirements stipulated under this regulation (article 7,3)

Article 8:Classification of recall

1. There shall be three classes of recall as provided in these Regulations depending on the nature of the health risk or adverse events.

a) **A Class I** is for defective, dangerous or potentially life threatening unfit regulated products that predictably or probably could result into serious health risk or adverse events or death; Examples include but not limited to:

   i. Wrong product (label and content are different products);
   ii. Correct product but wrong strength;
   iii. Microbial contamination of sterile product;
   iv. Contamination with another chemical with serious health consequences
   v. Wrong active ingredient
   vi. Product mix up

b) **A Class II** is unfit regulated products that possibly could cause temporary or medically reversible adverse health problem or mistreatment; Examples include but not limited to:

c) Mislabelling e.g. wrong or missing text or figures
d) Missing leaflets or incorrect information on the leaflets
e) Microbial contamination of non injectables, non-ophthalmic sterile product with medical consequences
f) Chemical/physical contamination (significant impurities, cross contamination, particulates matters)
g) Mix up of products in containers
h) Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
i) Insecure closure with serious medical consequences (e.g.cytotoxins, child resistant containers, potent products, toxic chemicals)
j) **A Class III** is for unfit regulated products that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements for the printed packaging material, product specification or labelling. Examples include but not limited to:

   1) Faulty packaging e.g. wrong or missing batch number or expiry date
   2) Faulty closure not resulting in any medical consequences

2. Contamination with no medical consequences (dirt or detritus, etc.) The maximum time for recalling class I, II and III shall be 3 days, 10 days and 30 days respectively.
3. Notwithstanding regulation (article 8,2), the Authority reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

Article 9: Levels of Recall

The Authority shall determine the level of recall. The determining factors shall include the level of hazard, the level to which the distribution has taken place and channels through which the products have been distributed.

a. *Level A*, wholesale level involves all the parties involved in manufacturing, importation, and wholesale

b. *Level B*, retail level involves:
   i. All public and private hospital pharmacies
   ii. Retail pharmacies
   iii. Clinical investigators and the institutions in which clinical investigations are performed;
   iv. Medical, dental, veterinary and other health care practitioners;
   v. Nursing homes and other related institutions;
   vi. Other retail outlets e.g. medicine shops, agrochemicals shops, pesticides shops, laboratory chemicals shops, supermarkets and food shops

c. *Level C*, consumer level involves patients and other consumers;

Article 10: Notification of Product problem

The recall might be initiated as a result of complaints by consumers on its quality, safety or efficacy of the product. It might also be as a result of test carried out by the quality control laboratory of the Rwanda FDA on samples of a product obtained from post marketing sampling or based on request from international companies or health authorities.

Article 11: Initiation of Recall and Information Required for Assessment of Recall

The Authority must be notified by the product license holder with the following information:

1. Details of the Problem
   - Name, telephone number of the person reporting the problem;
   - Date of report;
   - Physical location of the problem;
   - Nature of the problem;
   - Number of similar reports received;
   - Results of tests and other investigations on suspect or other samples

2. Details of the Product
   - Name of the product and description including active Ingredients, dosage form, strength, registration number, pack size or type;
   - Batch number(s) and expiry date;
   - Manufacturer/distributors and contact telephone numbers and email address;
   - Date manufactured, date released or imported into Rwanda;
   - Quantity of the batch, date and amount manufactured, released or imported into Rwanda;
   - Local distribution list;
   - Overseas distribution list of products exported from Rwanda;
   - Whether the product is meant to be sterile

3. Health hazard evaluation and proposed action
    - Type of hazard, and evaluation of health hazard to user;
    - Action proposed by the Product license holder;
    - Proposed recall classification and level; and
    - Availability of alternative product

Article 12: Recall Strategy

In the recall strategy, the Product license holder should mention the following:

- Indicate the proposed level in the distribution chain to which the recall is extending
- If the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;
- In case of consumer level recall, additional information should be mentioned:
    i. Indicate the location of recall spots for consumers, their operation time and duration
    ii. Indicate the hotlines number(s) for enquiry and the corresponding operating hours;
    iii. Indicate the proposed refund mechanism at the recall spots, the conditions of refund (applicable to opened products, expired products or parallel-imported products) and methods of refund (by means of money, credit notes or product replacement etc.);
    iv. Indicate the method of notification (e.g. mail, phone...)
    v. Indicate how the message of recall will be delivered to customers e.g. press release or recall letters etc;
    vi. If the Product license holder has a website, it should consider posting the recall notification on it as an additional method of recall notification;
    vii. Report on what the customer has been instructed to do with the recalled product;
    viii. It is necessary for recalling firms to know the name and title of the recall contact person for each of its consignees. Addressing a recall letter to a recall contact person will expedite the recall process and reduce the potential for the recall letter to get misdirected;
    ix. If product is to be returned, explain the mechanics of the process;
    x. Explain if the recall will create a market shortage that will impact on the consumer;
    xi. Determine and provide the course of action for out-of-business distributors;
    xii. Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to overseas manufacturer; and
    xiii. Inform the Authority before product disposal, such disposal shall be in accordance with guidelines approved by the Authority.

Article 13: Communication to the public

- The product license holder shall prepare letters with a factual statement of the reasons for the recall of the product, together with specific details that will allow the product to be easily identified.
- The letter may be sent by mail to the clients or by press release either electronic or print and it should use company letterhead or by press release either electronic or print; include date and name and title of authorized or responsible person.

- The text of the recall letter must include:

  i. Description of unfit product
  ii. Hazard associated with the product
  iii. Instruction for recall of the product

Article 14: Responsibilities of Product License Holders

Product license holder has responsibilities in relation to recall of unfit products in two general areas:

a. In maintaining records and establishing procedures which will assist in facilitating recall if such action become necessary;

b. In taking the prime responsibility for implementing recall in the situation where it is necessary.

Article 15: Refund Mechanism

The manufacturer, importer, distributor and any other supplier of recalled products should set up a refund mechanism for the recalled products.
Refund mechanism should be done by means of money, credit notes or product replacement etc.

Article 16: Post-recall

The Licensee is expected to provide Rwanda FDA with a report on the progress of the recall within fifteen (15) days of initiation of the recall. This interim report should contain the following information:

i. Number of organizations or persons to whom the defective product has been supplied;
ii. Date and means of notifying them of the recall;
iii. Number of responses received from them;
iv. Names of the non-responders;
v. Quantity of stock returned;
vi. Quantity of stock that has been taken off shelves pending return to Licensee; Estimated timeframe for the completion of the recall.

Article 17: Evaluation of the Recall

The Rwanda FDA shall evaluate the recall in two different ways;

a) A check on the effectiveness of the recall
b) An investigation of the reason for the recall and remedial action taken to prevent a recurrence of the problem.

Article 18: Implementation of Remedial Action

The Product license holder shall identify the root cause of the problem and implement the remedial action taken and corrective action and preventive action (CAPA).

Article 19: Submission of Analytical Report

1. After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the Product license holder shall submit analytical report(s) of the new batch tested by external accredited laboratory to the Authority as a proof of product quality.
2. The submitted report(s) will be evaluated by Food and Drug Inspection Department of the Authority after evaluation; the Authority would inform the Product license holder whether the submitted reports are satisfactory.
3. In addition to the documents submitted above, samples of the product manufactured or imported after the recall will be sampled for analysis at the quality control laboratory of the Authority or at another qualified laboratory (WHO prequalified or ISO/IEC 17025 accredited). The product can be put on the market only upon approval.

Article 20: Termination of Product Recall

A recall will be terminated when Rwanda FDA and the recalling firms are in agreement that the product which is the subject of the recall has been removed from the market and proper disposal has been made.

Article 21: Appeals to the Authority subjected to recall

1. Any person aggrieved by a decision of the recall may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) days from the date of recall;
2. The Authority shall, within fifteen (15) days from the date of receiving the application, review, reject or vary its own decision of recall;
3. If the applicant is not satisfied by the decision of the Authority, he/she may appeal to the supervising Authority.

Article 22: Health risk evaluation

1. An evaluation of the health risk presented by a product being recalled or considered for recall shall be conducted by the Authority.
2. After health risk evaluation the Authority shall assign the recall classification in the form of Class I, Class II, or Class III, to indicate the relative degree of health risk of the product being recalled or considered for recall.

CHAPTER IV: TREATMENT AND DISPOSAL OF UNFIT PRODUCTS

Article 23: Treatment of unfit products

1. All regulated products which are unfit for intended purpose shall be quarantined and kept in a separate place clearly labelled *"Unfit for intended use".*
2. Unfit goods shall themselves be clearly labelled as such to prevent their unintended use
3. The safe custody of unfit products shall be maintained on registered or approved premises until they are safely disposed of in terms of these Regulations.
4. The handling of unfit products shall include:
    a. Maintaining a register for unfit products in form prescribed in the schedule of these Regulations
    b. Keeping and segregating them into different categories according to their type, with special regard to products that fall under controlled substances or hazardous substances

Article 24: Restriction of unauthorized disposal of unfit products

1. It is restricted for everyone to dispose of any unfit product unless he has notified the Authority and has obtained approval to proceed with the disposal.
2. Approval of application and safe disposal of any unfit product shall be sought from the Authority

Article 25: Decision to initiate disposal of unfit products

The decision to initiate disposal shall be made by the Authority, the owner or responsible person of a facility or premises after getting the approval from the Authority.

Article 26: Request for disposal of unfit products

1. A request for disposal of unfit products shall be made to the Authority in form prescribed in the Annex of the guidelines implementing this regulation.
2. The applicant shall pay a prescribed fee as per Regulations No CBD/TRG/004 related to regulatory service tariff/fees and charges, for consideration of the application for disposal, if after verification, the submitted list is varied by addition of other products, the applicant shall pay an additional fee, as required.
3. A request for disposal of unfit products shall be accompanied by a list of products to be disposed of which shall state clearly the registered or approved details of the product including

any trade name, brand name, type of packaging material and pack size, quantity, manufacturer, batch or lot number. In the case of a pharmaceutical product, the strength and dosage form, where applicable, shall also be stated. The reason(s) for which the products are declared unfit shall be clearly stated.

Article 27: Approval to dispose of unfit products

1. The Authority shall, upon receipt for request for disposal appoint inspectors to verify and authenticate the information submitted in relation to the consignment to be disposed of.
2. Verification to be made in terms of Article 25,3 shall be made in the form prescribed in the annex of the guidelines implementing these regulations
3. Upon verification the Authority shall inform the applicant to liaise with the appropriate waste management agency or any other institution responsible for environment management on the proposed mode of disposal and issuance of a disposal permit.
4. After receiving the disposal permit, the applicant shall liaise with the appropriate local government agency for identification of disposal site, appropriate conveyance to disposal site, cost and date of destruction.
5. The cost of destruction shall be borne by the owner of the consignment.

Article 28: Disposal of unfit products

1. Subject to the provisions of these Regulations, the Authority shall prescribe the conditions for transportation of the consignment from the premises to the disposal site for the destruction exercise.
2. The Authority shall notify the applicant of the need for and terms for supervision of the destruction, where necessary, the Authority shall prescribe that representative from the waste management agency, environment management agency, police, customs and excise be present as witnesses.
3. The Authority shall, upon completion of the exercise issue a Certificate of Destruction of the products.

Article 29: Penalties

Where non-adherence to these regulations results in exposure of consumers to a safety risk, Rwanda FDA will impose Administrative Charges and Sanctions as per Regulations No CBD/TRG/004 related to regulatory service tariff/fees and charges.

Article 30: Commencement

These regulations shall enter into force on date of its signature and publication. All prior contrary provisions to these regulations are hereby repealed.

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