RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING RECALL, TREATMENT AND DISPOSAL OF UNFIT REGULATED PRODUCTS

(Rwanda FDA Law Nº 003/2018 of 09/02/2018, Article 8)

DECEMBER, 2021

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Date of revision	Revision number	Changes made and/or reasons for revision
03/02/2021	**0**	First issue
12/11/2021 & 07/12/2021	**1**	1. List of definitions updated to include the definition of investigational products and definition unfit product was updated; 2. Rwanda FDA is replaced with Authority were necessary; 3. Article regarding the safe disposal of investigational product was included; 4. Provisions related to the disposal/destruction of unfit/unused investigational products were included; 5. Article on reasons for recall was included; 6. Article on types of recalls was included; 7. Article on monitoring and recalls audit; 8. Article regarding penalties was changed to administrative sanctions; 9. Article regarding the implementation of these regulations was included; 10. The table of revision history was included; 11. Necessary editorial changes and formatting were made in the entire document.

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/019 Rev_1 governing the Recall, Treatment and Disposal of Unfit regulated products on this 14th December 2021.

14/12/2021

Dr. Emile BIENVENU
Director General

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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 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 regulations 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 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 Nº CBD/TRG/004 Governing service tariff/fees and fines;

2. **"Authority"** means the Rwanda Food and Drug Authority, established under Article 2 of the law Nº 003/2018 of 09/02/2018;

3. **"Disposal"** means the process of rendering harmless any unwanted or unfit regulated product;

4. **"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;

5. **''Investigational Product (IP)"** Any regulated products being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

6. **"Unfit products"** means:
    a) Pharmaceutical Products that are expired, improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labelled, substandard or falsified, adulterated, prohibited or unauthorised.
    b) Investigational products and/or placebos that are expired, damaged/unused and/or returned products which can no longer be used for research.
    c) Any product that does not meet regulatory requirements or when consumed or used can be injurious to the health of the consumer.
    d) Any product regulated under the law that has in or on it, a poisonous or harmful substance.
    e) Any regulated product that consists in whole or part of a filthy, putrid, rotten, decomposed or diseased substance.

7. **"Regulated product"** means any human and veterinary drugs, human and animal vaccines and other biological products used in clinical as drugs or investigational products, 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; laboratory and cleaning chemicals and pesticides, and raw materials used in the manufacture of regulated products.

8. **"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.

9. **"Product defect"** is a non-conformity to a specification confirmed by laboratory analysis or a suspected deficiency which may produce an impact either directly or indirectly on the continuing safety, efficacy or quality of the product.

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 limited to only authorized personnel.

CHAPTER TWO: GENERAL REQUIREMENT

Article 5: Prohibition

It is prohibited for everyone to:

a) possess or sell any regulated product which is referred as unfit regulated products
b) 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.
c) manufacture, import, export and distribute unfit regulated products subjected to be recalled
d) No person shall dispose off any unfit regulated product unless she/he has requested the Authority and secured an approval to proceed with disposal procedure.

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

The Authority shall issue Alert notice, a call for quarantine while the investigation on quality and safety of regulated product is ongoing. Quarantine status is ensured by storage in separate dedicated- areas, clearly marked and access restricted only to authorized personnel.

The Authority may, if satisfied that any regulated product 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.

In the event of recall, Authority 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.

The Authority shall monitor the progress and effectiveness of a recall procedures and ensure that no recalled product cannot re-enter to the Rwandan market through different market authorization holders.

Article 7: Reasons for recall

The reasons for the recall of unfit product shall include:

a) incorrect labelling of the product;
b) incorrect formulation of a product;
c) unfavourable result of ongoing stability studies;
d) evidence of poor storage and handling;
e) microbial contamination of sterile product;
f) contamination with another chemical with serious health consequences;
g) non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution;
h) wrong active ingredients;
i) product registration cancellation;
j) Any other reason that may compromise the safety, efficacy or quality of the product.

CHAPTER THREE: RECALL OF UNFIT REGULATED PRODUCT

Article 8: Initiation of recall

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 or supplier, Marketing Authorization Holder, importer, distributor as the case may be.

Before or while undertaking a recall, the manufacturer or supplier, Marketing Authorization Holder, importer, and distributor of confirmed/suspected unfit regulated 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, 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 confirmed or possible defectiveness, the date on and circumstances under which the confirmed or possible defects were discovered;
d) The total quantity of the product being recalled originally in possession of the manufacturer, Marketing Authorization Holder 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, Marketing Authorization Holder or importer and distributor.

The manufacturer, Marketing Authorization Holder, importer, distributor of regulated product 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 consumers.

The manufacturer, Marketing Authorization Holder, importer, distributor of regulated products who voluntarily initiates a recall shall be required to comply with the requirements stipulated under these regulations.

Article 9: Classification of recall

The Authority shall assign each recall a classification in the form of Class I, Class II, or Class III, depending on the nature and degree of health risk or adverse events of the product being recalled or considered for recall:

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;

b) **Class II** is unfit regulated products that possibly could cause temporary or medically reversible adverse health problem or mistreatment;
c) **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.

The maximum time for recalling class I, II and III shall be three (3) working days, ten (10) working days and thirty (30) working days respectively.

Notwithstanding the article 9 of these regulations, the Authority reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

Article 10: 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 according to the recall levels which shall include wholesale, retail and consumer or user level.

More details on recall requirements and processes shall be provided in the relevant guidelines issued by the Authority.

Article 11: Types of Recall

Based on defect in quality, efficacy and safety of any product or batch of regulated product, Authority shall recognize the Voluntary Recall and Statutory Recall.

The voluntary recall is a recall initiated by a market authorization holder as a result of a defective report from the manufacturer or market complaints. The Statutory recall also called non-voluntary recall is initiated by the Authority after a notification that a batch (es) or a product is identified as unfit regulated product.

Article 12: Notification of Product defect

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 notified as a result of test carried out by the quality control laboratory of the Authority on samples of a product obtained from post-marketing sampling or based on request from international companies or health authorities.

Article 13: Initiation of Voluntary and Statutory Recall

The manufacturer, marketing authorization holder, or local technical representative or importer shall initiate the voluntary recall of unfit product and shall notify the Authority in writing within twenty-four (24) hours.

In case of the statutory recall or non-voluntary recall, the Authority upon the establishment of the reason for recall of unfit product shall notify the manufacturer, marketing authorization holder, or local technical representative or importer and other stakeholders.

In all cases, the notification shall include the following details:

a) product proprietary name;
b) product non-proprietary name (active pharmaceutical ingredients), dosage form, strength, pack size or type;
c) batch number,
d) manufacturing date and expiry date,
e) names and address of manufacturer/distributors and contact telephone numbers and email address;
f) number of batch manufactured,
g) quantity released or imported into Rwanda;
h) local distribution list;
i) identified defect,
j) quantity of the recalled product still in possession of the manufacturer, MAH or importer
k) reason for recall
l) product recall protocol
m) overseas distribution list of products exported from Rwanda;
n) whether the product is meant to be sterile
o) any other information as may be prescribed by the Authority to make informed decision.

The manufacturer, marketing authorization holder, or local technical representative or importer shall notify all the distributors of the product recall, reason for recall and the recall structures. In case of voluntary recall, manufacturer, marketing authorization holder, or local technical representative or importer shall bear the cost of the voluntary recall of unfit regulated product.

Article 14: Reporting of Recalls

The manufacturer, marketing authorization holder, or local technical representative or importer of a suspected product shall submit to the Authority, a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between delivered and recovered quantities of the product.

The manufacturer, marketing authorization holder, or local technical representative or importer shall submit to the Authority an investigation report detailing causes of the defect, stock reconciliation report and corrective and preventive actions undertaken within fourteen (14) calendar days after termination of a recall.

The Authority shall assess the performance of the recall and conduct the recall Audit if deemed necessary.

Article 15: Recall Strategy

The recall strategy shall specify the proposed level in the distribution chain to which the recall will be extended to, the duration for the recall, recall communication strategy and key personnel appointed to coordinate the recall until the completion of the exercise.

In case the recall is not applied to all levels, manufacturer, marketing authorization holder, or local technical representative or importer shall indicate the reasons for not extending the recall to all distribution levels.

The manufacturer, marketing authorization holder, or local technical representative or importer shall provide a proposed disposal plan of the recalled products and inform the Authority before product disposal.

Article 16: Communication to the public

In case of recall communication, the manufacturer, marketing authorization holder, or local technical representative or importer shall prepare letters/notices containing reasons for the recall of the product and specific details that can allow the product to be easily identified. The recall letter shall contain also the method of return, disposal or correction and refund mechanism of the product.

The Authority shall prepare an alert notice to warn the public that a product being recalled presents a serious hazard to health.

The letter/alert may be sent by mail to all clients or by press release either electronic or print and posted on the website. The text of the recall letter shall include the description of unfit regulated product, the hazard associated with the product and instruction for recall of the product.

Article 17: Responsibilities of Marketing Authorization Holders and Importers

In the exercise of recall of unfit products, manufacturer, marketing authorization holder, or local technical representative or importer shall**:**

a) voluntary recall a product if any evidence appears casting doubts on its quality, efficacy or safety and inform the Authority within twenty-four (24) hours of initiating such voluntary recall;
b) recall every batch or every product of suspected unfit product from the circulation in Rwanda within specified timeframe;
c) collaborate with the Authority on action taken to avoid or reduce risks posed by the specific batch(es) or product;
d) liaise with the manufacturer of the product to investigate the reasons for the reported quality or safety issues to carryout corrective and preventive actions;
e) Put in place clear procedures for handling and monitoring of recalls;
f) store any stock of recalled unfit products in a safe, separate and lockable demarcated area

g) dispose recalled unfit products according to the provisions of these regulations and relevant guidelines issued by the Authority;
h) maintain records of recalled products related to the production, import or export, distribution, storage or disposal records.
i) rectify issues that lead to the defects if intend to reinstate a product that had its registration cancelled due to permanent withdrawal of the product.

Article 18: Refund Mechanism

The manufacturer, marketing authorization holder, or local technical representative or importer, distributor and any other supplier of recalled products must refund all persons affected by the recall. He/she shall put in place clear refund mechanism for the recalled products.

Article 19: Post-recall

The manufacturer, marketing authorization holder, or local technical representative or importer is expected to provide the Authority with a report on the progress of the recall within fifteen (15) days of initiation of the recall. This interim report shall contain the following information:

a) Number of organizations or persons to whom the defective product has been supplied;
b) Date and means of notifying the recall to them;
c) Number of responses received from them;
d) Names of the non-responders;
e) Quantity of stock returned;
f) Quantity of stock that has been taken off shelves pending return to Licensee; Estimated timeframe for the completion of the recall.

Article 20: Monitoring and Recall Audit

The Authority shall closely monitor the effectiveness of recall procedures and 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

The Authority shall analyse the report submitted by the manufacturer, marketing authorization holder, or local technical representative or importer, distributor and any other supplier to check whether recalled regulated products were not sold and make reconciliation of recalled quantities.

The Authority shall plan and conduct recall audit at premises that bought the recalled products.

Article 21: Implementation of Remedial Action

The manufacturer, marketing authorization holder, or local technical representative or importer shall identify the root cause of the problem and implement the remedial action taken and corrective action and preventive action (CAPA).
All costs associated with the recall of a product and its safe disposal shall be for the account of the manufacturer, marketing authorization holder, or local technical representative or importer.

Article 22: Submission of Analytical Report

After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the Marketing Authorization Holder shall submit analytical report(s) of the new batch tested by external accredited laboratory to the Authority as a proof of product quality.

The submitted report(s) shall be evaluated by the Authority and inform the manufacturer, marketing Authorization Holder, or local technical representative or importer whether the submitted reports are satisfactory.

In addition to the documents and report, samples of the product manufactured or imported that is subjected to the recall shall be tested in the quality control laboratory of the Authority or at another qualified laboratory. The certificate of analysis shall be used as supporting document for informed regulatory decision making.

Article 23: Termination of Product Recall

A recall shall be terminated when Authority and manufacturer, marketing authorization holder, or local technical representative or importer are in agreement that the product which was subjected to the recall has been removed from the market and proper disposal has been accomplished, the Authority shall issue a recall termination letter.

Article 24: Health risk evaluation

The Authority shall conduct the evaluation of the health risk presented by a product being recalled or considered for recall and takes into account to the following factors:

a) whether any disease or injuries have already occurred from the use of the product;
b) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health risk;
c) any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health risk determination;

d) assessment of risk to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the risk to those individuals who may be at greatest risk;
e) assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;
f) assessment of the likelihood of occurrence of the risk; and
g) assessment of the consequences (immediate or long-range) of occurrence of the risk.

CHAPTER FOUR: TREATMENT AND DISPOSAL OF UNFIT PRODUCTS

Article 25: Treatment of unfit products

All regulated products which are unfit for intended purpose shall be quarantined and kept in a separate place clearly labelled *"Unfit for intended use"* to prevent their unintended use.

In order to properly manage unfit products at a facility level, the following requirements shall be adhered to:

a) Maintain an updated inventory register of unfit products
b) Keep and segregate them into different categories according to their type, with special regard to unfit products which fall under controlled drugs, antineoplastic, antibiotics and any other hazardous substances
c) Store in containers according to their dosage forms to facilitate verification and sorting exercise for proper selection of disposal method.
d) Maintain safe custody of unfit products in registered or approved premises or facility until they are disposed-off according to the provisions of these regulations

Article 26: Restriction of unauthorized disposal of unfit products

It is restricted for everyone to dispose off any unfit product unless she/he has notified the Authority and has obtained approval to proceed with the disposal.

The request and approval for safe disposal of any unfit product shall be sought from the Authority and shall be done in accordance with relevant guidelines.

Article 27: 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 28: Request for disposal of unfit products

A request for disposal of unfit products shall be made to the Authority according to the requirements prescribed in relevant guidelines and standards operating procedures for better implementation of these regulations.

The applicant shall pay a prescribed fee according to the Regulations N° CBD/TRG/004 related to regulatory service tariff/fees and charges. In case the application for disposal is varied by addition of other

products after verification of the previously submitted list, the applicant shall pay an additional fee accordingly.

A request for disposal of unfit products shall be accompanied by a list of products to be safely disposed 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 and market value of each product.

In the case of a pharmaceutical product, the strength and dosage form, where applicable, are not stated, the reason(s) for which the products are declared unfit shall be clearly stated.

Article 29: Safe disposal of investigational products

All unused investigational product/placebo shall be safely disposed of in order to prevent them of being abused.

In all circumstances, the sponsor shall:

a) ensure that the authorization from the Authority is obtained prior to the safe disposal of investigational product(s) and/or placebo to the sponsor;
b) ensure that any unused or returned investigational products is disposed within six (6) months of the conclusion or termination of the clinical trial;
c) ensure that all other unused non-investigational products such as concomitant medications, standard care medications, diagnostics, laboratory reagents and medical devices used in the context of a clinical trial are well kept before disposal according to the provisions of these regulations and relevant guidelines issued by the Authority;

The application of safe disposal of investigational products shall be accompanied by the signed, dated and balanced investigational product accountability logs in addition to the provisions stated in article 28 of these regulations.

The principal investigator and sponsor shall retain records of shipment, receipt, disposal, and returned investigational product.

Article 30: Approval to dispose of unfit products

The Authority shall, upon receipt for request for disposal appoint inspectors to verify and authenticate the information submitted in relation to the list of unfit products to be disposed-off according to the provisions of the article 28 of these regulations.

The safe disposal/destruction of unfit/unused investigational products shall be carried out for a given trial site or a given trial period only after any discrepancies have been investigated and satisfactorily explained and the reconciliation has been accepted.

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 safe mode of disposal and issue a disposal permit.

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.

The cost of destruction shall be covered by the owner of the unfit products

Article 31: Disposal of unfit products

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 safe disposal/ destruction exercise.

The Authority shall notify the applicant of the need for and terms for supervision of the safe disposal/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.

The Authority shall, upon completion of the exercise issue a Certificate of Disposal Destruction of the products.

Article 32: Implementation of these regulations

The Authority shall issue guidelines and standards operating procedures (SOPs), forms and checklists for proper implementation of these regulations.

Article 33: Administrative sanctions

The Authority may take following regulatory actions based the outcome of recall investigation /disposal report and associated risk to public health:

a) warning letter;
b) request for payment of prescribed administrative fines;
c) suspension or cancellation of product marketing authorization;
d) suspension or cancellation of the manufacturing/Wholesale license;
e) permanent withdrawal of marketing authorization;

f) temporary ban of import permit of incriminated unfit product;
g) suspension or cancellation of production lines;
h) payment of prescribed fees for supervision of safe disposal;

Any person who imports, sells, distributes, stores substandard, counterfeit/falsified, fraudulent products, shall be sanctioned with the fines amounting to double the value of condemned products plus all costs related to the compulsory laboratory tests.

Any manufacturer, marketing authorization holder, or local technical representative or importer who fails or refuses to recall unfit product from the market as requested by the Authority shall be sanctioned with fines amounting to triple the value of condemned products plus all costs to related to the compulsory laboratory tests.

The Authority may constitute legal proceedings against offenders, if administrative measures alone are not sufficient in comparison to the magnitude of the offence;

Article 34: Appeals to the Authority

Any person aggrieved by a decision of the Authority during the implementation of these regulations may appeal to the Authority for the review of the decision showing grounds for dissatisfaction within thirty days (30) calendar days from the date of notice of the administrative sanction;

In case the applicant is not satisfied by the decision of the Authority, he/she may appeal to the supervising Authority in accordance with relevant laws.

Article 35: 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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