



**GUIDELINES ON RECALL, TREATMENT AND DISPOSAL OF
UNFIT PHARMACEUTICAL PRODUCTS**

RWANDA FDA
Rwanda Food and Drugs Authority

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GUIDELINES DEVELOPMENT HISTORY

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Rwanda Food and Drugs Authority

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FOREWORD

Rwanda Food and Drug Authority is a regulatory body established by the law N°003/2018 of 09/02/2018, whereby the management of unfit Pharmaceutical products, drugs post marketing surveillance and safety monitoring are among the functions of Rwanda FDA as it is provided by the above law especially in its article 3 paragraph 9 and 11.

Considering the provisions of the regulations No.:CBD/TRG/019 Rev_0, governing Governing Recall, Treatment and Disposal of Unfit Products. The authority issue these *Guidelines on Recall, Treatment and Disposal of Unfit Pharmaceutical Product*.

When pharmaceutical products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, and are particularly suspected to be Substandard and Falsified or unregistered / unlicensed they may be subjected to a recall. Recall is therefore, an effective method of removing specific batch or batches of pharmaceutical products from the market due to the public health protection.

These guidelines for recall, treatment and disposal of unfit Pharmaceutical products intend to ensure that a recall is necessary, the recall procedures are effectively and efficiently carried out. They also provide guidance to all stakeholders handling pharmaceutical products to ensure safe disposal of unfit pharmaceutical products and prevent it's re-entry into the supply chain.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Charles KARANGWA
Ag. Director General



Rwanda FDA
Drugs Authority

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ABBREVIATIONS AND ACRONYMS

GMP Good manufacturing practice
HCPs Health care providers
Rwanda FDA Rwanda Food and Drugs Authority



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DEFINITIONS

“Authority” means Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under the article 2 of the Law N° 003/2018 of 09/02/2018.

“Disposal” means the process of rendering harmless any unwanted or unfit pharmaceutical product.

“Recall” means the process of removing a pharmaceutical products from the distribution chain because of defects of the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be unfit for intended use . The product is removed from further sale, distribution or use.

The definition of "recall" does not include a "product withdrawal".

“Recall strategy” means a planned specific course of action to be taken in conducting a specific recall, which addresses itself to matters such as the depth of recall, need for public warnings, and extent or effectiveness checks for the recall

“Recalling entity” as used in this document refers to the legal party that initiates or is instructed to initiate a recall. It is usually the entity that has primary responsibility for the manufacture, importation, distribution, or is the marketing authorization holder.

“Pharmaceutical products” 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 in which food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses

“Statutory recall” as used in this document refers to when Rwanda FDA requests or orders a product recall due to non-compliance to regulatory requirements.

“Unfit pharmaceutical products” means:

- a) Pharmaceutical products that are expired,improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labeled, substandard or falsified, adulterated, prohibited or unauthorized.
- b) Any pharmaceutical product that does not meet regulatory requirements or when consumed or used can be injurious to the health of people.

“Voluntary Recall” as used in this document refers to when a manufacturer, importers, distributor, or marketing authorization holder requests a product recall after discovery of safety issues, product defects or non-compliance to regulatory requirements.

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“Withdrawal or cancellation of registration” means the total removal of a medical product from the market that could be due to an irreversible quality, safety or efficacy concern due to published research findings or non-compliance to Good Manufacturing Practices.

“Quarantine”: The status of pharmaceutical products isolated physically due to suspicion on the quality and safety, while a decision is awaited on their release, recall, rejection or reprocessing. Quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to unauthorized personnel.



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CHAPTER 1. INTRODUCTION

Ensuring the safety, efficacy and quality of pharmaceutical products is a prime responsibility of the manufacturers and distributors of pharmaceutical products. The responsibility is shared with the Rwanda Food and Drugs Authority (Rwanda FDA).

When pharmaceutical products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information must be reported to Rwanda FDA.

A recall will be terminated when Rwanda FDA and the recalling entities are in agreement that the pharmaceutical product which is the subject of the recall has been removed from the market and proper disposal has been made following all requirement of treatment and disposal of unfit pharmaceutical products stipulated by these guidelines

1.1 Scope

These guidelines apply to all manufacturers, importers, exporters, distributors and retailers of pharmaceutical products that are found to be unfit, so as to explain and standardize the procedure for pharmaceutical products recall in order to ensure effective removal and disposal of unfit pharmaceutical products from the market and to provide guidance of handling unfit pharmaceutical products in order to prevent its re-entry into the supply chain

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CHAPTER 2. REQUIREMENTS AND RESPONSIBILITIES

2.1. Responsibilities of Manufacturers, importers, distributors and marketing authorization holders include:

- a) maintaining records and establishing procedures which will assist in facilitating the recall;
- b) taking the prime responsibility in implementing the recall, if it becomes necessary;
- c) having written procedures in place which are consistent with the Guidelines and which are applicable to their own operations;
- d) further investigating the case of a product defect and recall and providing the corrective and preventive actions.
- e) initiation of Voluntary Recall which is the recalling entity's sole responsibility to request and implement the recall process by contacting all companies and facilities to whom the recall products have been distributed and ensuring the physical removal of the products from the market to the level required. In such cases prior notice should be given to the Authority.

2.2. The requirements and responsibilities of the Authority include:

- a) initiation of Statutory (Non-Voluntary) Recall: The Authority shall be responsible for requesting/ordering a product recall when the registration of a product is cancelled for safety reasons, or when the product does not meet regulatory requirements and communicate to the general public.
- b) in such instances, the Authority shall monitor the effectiveness of the recalling entity's actions and provide scientific, technical and operational advice where necessary.
- c) if the recalling entity's actions are deemed inadequate, the Authority will take appropriate actions to remove the product from sale or use. The recalling entity's recall does not preclude enforcement actions being taken by Rwanda FDA, as deemed appropriate, either during or following the completion of a recall.
- d) The Authority shall issue a call for quarantine due to the following reasons:
 1. while the investigation on quality and safety of Pharmaceutical product is ongoing;
 2. When Authority receive reports on quality defect of pharmaceutical products which should harm the life of consumer and need deep investigation;
 3. Anytime Authority is conducting deep investigation on quality and safety of pharmaceutical products due to suspicion of poor quality of products and due to serious adverse drug events associated to the use of pharmaceutical products.

2.3 Management of Pharmaceutical products called for quarantine

- i. Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access;

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- ii. All pharmaceutical products that were called for quarantine must be quarantined at the level where they were when the call for quarantine was issued. Quarantined Pharmaceutical products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is made.



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CHAPTER 3 RECALL

Any product / batch (es) not meeting the defined quality standards have to be recalled from the market. Recall can be of two types; Voluntary recall and Statutory recall.

3.1 Voluntary Recall

Voluntary recall can be triggered by any incident that affects the quality, safety and efficacy of the batch/product in question such as

- a) Batch(es) not complying with regulatory specifications during the post marketing stability study
- b) Batch (es) found to be defective during investigation of market complaint.
- c) During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc.)
- d) If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation
- e) If the post marketing surveillance reports /pharmacovigilance reports indicates that there is serious safety risk associated with the product

3.2 Statutory recall (Non-Voluntary)

Statutory recall of products or batch (es) from the market by the Authority may be triggered by the:

- a) Product/batch identified to be in violation of requirements, such as substandard, falsified
- b) Serious reports of adverse drug reactions not included in the package insert
- c) Unexpected frequency of adverse reaction stated in the package insert
- d) Presence of products banned by the Authority
- e) Products for which the marketing authorization has been withdrawn/cancelled
- f) Labelling and/or Promotional materials that are considered to be in violation of regulations.

3.3 Management of recalled pharmaceutical products.

- a) All recalled pharmaceutical products should be clearly recorded and returned to the local supplier within ten days after issuance of recall.
- b) The local suppliers with recalled pharmaceuticals products shall report to the Authority within 10 days, the quantities imported per product, quantities distributed, quantities returned and final stock on hand of recalled Pharmaceutical products.

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3.4 Recall classification

The Authority shall assign numerical designation, i.e. I, II or III, to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. The following classifications shall apply:

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

1. Wrong product (label and content are different products);
2. Correct product but wrong strength;
3. Microbial contamination of sterile product;
4. Contamination with another chemical with serious health consequences
5. Wrong active ingredient
6. Product mix up

Class II: is for unfit pharmaceutical products that possibly could cause temporary or medically reversible adverse health problem or mistreatment; Examples include but not limited to:

1. Mislabelling e.g. wrong or missing text or figures
2. Missing or incorrect information- leaflets or inserts with packing
3. Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
4. Chemical/ physical contamination (significant impurities, cross contamination, particulates)
5. Mix up of products in containers
6. Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
7. Insecure closure with serious medical consequences (e.g. cytotoxins, child resistant containers, potent products, toxic chemicals)

Class III: is for unfit pharmaceutical 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 labeling. 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
3. Contamination with no medical consequences (e.g. dirt or detritus, etc.)

3.5 Levels, depth and action for the recall

The level (or depth) of recall of a product/batch shall be determined based on recall classification and level to which distribution has taken place. There are three levels of recall namely, consumer/user, retail and wholesale levels.

- a) **Wholesale level** includes all parties involved in wholesale distribution of Pharmaceutical products

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- b) **Retail level** includes all public and private hospitals; retail pharmacies; clinical investigators and the institutions in which clinical investigations are performed; medical, dental and other health care practitioners; nursing homes and other related institutions; other retail outlets dealing with pharmaceutical products
- c) **Consumer level** includes patients and other consumers

Recall level	Depth	Action
Wholesale Level	Recall is designed to reach wholesale level and other distribution points. This can be achieved by means of representatives calling on Wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or recalls letters to arrange for the return of the product could be made	Recall letter to manufacturers, importers/wholesalers
Retail Level / User facilities	Recall is designed to reach wholesalers, hospital pharmacies (private / public hospitals), retail outlets	Recall letter to manufacturers / importers and HCPs
Consumer or User Level	Recall is designed to reach all suppliers of Medicines (all distribution points) i.e. wholesalers, hospitals pharmacies (private / public hospitals), retail outlets, and individual customers or patients through media release (TV, radio, print media, social media etc.)	Recall letter to manufacturer/importer to be initiated at all levels of distribution Plus media release.

3.6 Recall timelines

- a) All Class I recalls shall be executed to the levels of Wholesale/Distributors, retail, and consumer. In such cases, public announcements shall be made using print/electronic media, Newspapers, Television, Radio, etc.
- b) All Class II recalls shall be executed up to the levels of wholesale and retail.
- c) All Class III recalls shall be executed up to the levels of wholesale.

The following timelines shall apply to product recalls, the timeline for initiating and stopping sale/distribution of defective product.

Recall Class	Initiation Timeline	Physical Recall Timeline
Class I	24 Hours	72 Hours
Class II	48 Hours	Up to 10 Days
Class III	72 Hours	Up to 30 Days

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3.7 Procedure for Rapid Alert and Recall System

The following steps shall be taken when a recall is initiated:

- a) In case of voluntary recall, as soon as the product/batch (es) to be recalled is/are identified, Market Authorization Holder or local agent in charge shall review the information related to the defective product/batch(es) and decide about recall as per the procedure established in section 3.1
- b) The decision on recall of the defective product/batch shall be made within 24 Hours up to maximum of 72 Hours for Class I recall upon receipt of the recall information.
- c) Within 24 Hours of the decision taken for the recall of the product/batch(es), the communication shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, social media, text (SMS) etc. to the entire supply chain.
- d) The Marketing Authorisation Holder/Local Agent where the product is marketed shall inform the concerned regulatory authorities where the product batch (es) in question was distributed immediately after the decision of recall has been taken.
- e) It is the responsibility of the recalling entity (Marketing Authorisation Holder/ Local agent) immediately after discovering the problem to officially notify distributors to suspend sale and/or further distribution of the product in question. Details of notification shall include but not limited to:
 - i. Name, strength, batch and any other pertinent descriptive information of the product;
 - ii. Reason for the recall;
 - iii. Suggested action to be taken and its urgency;
 - iv. Provide specific instructions on what should be done with the recalled product;
- f) Follow-up communications should be sent to those who fail to respond to the initial recall communication
- g) Records of the recall notice, available stock and returned stock from various outlets shall be maintained by the recalling entity and shall be made available for verification by Rwanda FDA.

3.8 Recall Communication

A recalling entity is responsible for promptly notifying each of its affected distribution outlets about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product and the strategy developed for that recall.

Recall communication should convey:

- a) That the product in question is subject to a recall;
- b) That further distribution or use of any remaining product should cease immediately;
- c) Instructions regarding what to do with the product.

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3.9 Implementation

As determined by the recall strategy, a recall communication can be accomplished by: Telephone, SMS, email, social media and announcement.

3.10 Communication to the public by recall letters

In the event of a recall, the recalling entity may prepare letters with a factual statement of the reasons for the recall of the product, together with specific details that will allow to be easily identified.

The recall communication cannot contain any material that can be viewed as promotional in nature. The letter can be sent by standard means of communication such as mail, Proof of delivery or acknowledgement of receipt.

The recall letter needs prior approval by Rwanda FDA unless the matter is urgent and there is immediate hazard or risk to the consuming public.

The recall letter should use the company/Authority letter head, include the date, name and title of signatory.

The contents may include:

- a) A description of the medical product:** name of the product, name of manufacturer, Manufacturing date, registration details, pack size, dosage form, batch number(s) and expiry date(s).
- b) Hazard and risk associated with the product:** The reason for the recall should be concisely explained. It should be explained that further distribution or use of the product should cease immediately.
- c) Instruction for recall of the product:** The method of return, disposal and refund mechanism.

If safety of the public is involved and distribution is limited, the recalling entity may disseminate the information above by telephone which can then be followed by a recall letter.

3.11 Press release approved by Rwanda FDA

Rapid alert to the public is usually reserved for hazards classified as Class I, and where appropriate, Class II, or situations where other means of controlling the hazard appear inadequate. Rapid alerts to the public may be issued through appropriate channels which may include a press release approved by the Authority.

All press release statements associated with a product defect and recall must be approved by the Authority prior to publication or release in the press to avoid unnecessary panic to the public and consumers; or miscommunications.

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Information that should be included in the press statement is:

- a) A clear outline of the problem;
- b) Clear product information identifying product use;
- c) Possible effects (without alarming or causing fear to the consumer);
- d) What the consumer should do;
- e) Company information and contact details of the responsible person(s).

3.12 Evaluation of the recall

The evaluation consists of a check on the effectiveness of the recall and an investigation of the reason for the recall as well as the remedial action taken to prevent a recurrence of the problem.

3.13 Effectiveness Checks

It is the responsibility of the recalling entity to ensure that the recall is effective. The purpose of effectiveness checks is to verify that all affected distribution outlets identified have received notification about the recall and have taken appropriate actions. The check on the level of effectiveness of the recall shall be conducted by the recalling entity as follows:

- a) Consumer/user Level - 100 percent of the total number of distribution outlets to be contacted;
- b) Retail Level- Some percentage of the total number of distribution outlets to be contacted greater than 10% but less than 100% - which percentage is to be determined on a case by case basis.
- c) Wholesale Level - 10 percent or less of the total number of distribution outlets to be contacted, which percentage is to be determined on a case-by-case basis.

Rwanda FDA may carry out its own effectiveness checks as part of monitoring the recalling entity's performance. This is a separate exercise which must not be considered as part of, or supplement to, the recalling entity's responsibilities for adequate effectiveness checks.

If a recall is found to be ineffective, Rwanda FDA will request the recalling entity to take additional actions.

3.14 Investigation of the reasons for the recall and initiation of remedial action

On completion of a recall, the recalling entity shall provide a report of the investigation of the problem and details of the remedial action proposed to prevent a recurrence of the problem which gave rise to the recall. Where the nature of the problem and appropriate remedial action are not apparent, investigation and in some cases site inspections e.g. GMP inspections may be necessary.

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3.15 Post recall notification to Rwanda FDA

After recall, the recalling entity immediately on becoming aware of the problem shall notify the FDA in writing with the recall information including:

- a) Name, strength, Dosage form, Batch(es), Manufacturing and Expiry Dates, manufacturing company, address and any other means of identification;
- b) The total quantity of the product imported or manufactured;
- c) The total quantity of the product being recalled originally in possession of the company;
- d) The total quantity of the product that had been distributed up to the time of the recall;
- e) The total quantity of the product being recalled that had been distributed at the time of the recall;
- f) The distribution record of the recalled product;
- g) Report on investigation conducted to identify root cause and relevant corrective actions;
- h) Number of organizations or persons to whom the defective product has been supplied;
- i) Date and means of notifying them of the recall;
- j) Number of responses received from them;
- k) Names of the non-responders;
- l) Quantity of stock returned;
- m) Quantity of stock that has been taken off shelves pending return to Licensee;
- n) Estimated timeframe for the completion of the recall.

3.16 Termination of product recall

After all recalled pharmaceutical products returned to the supplier, a recall will be terminated. When Rwanda FDA and the recalling entity are in agreement that the product which is the subject of the recall has been removed from the market, proper disposal has been done and the refund mechanism for the recalled products has been done.

Refund mechanism shall be done by means of money, credit notes or product replacement etc.

3.17 Health risk evaluation

An evaluation of the health risk presented by a product being recalled or considered for recall shall be conducted by the Authority and takes into account, but need not be limited 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. 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;

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- c) 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;
- d) Assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;
- e) Assessment of the likelihood of occurrence of the risk; and
- f) Assessment of the consequences (immediate or long-range) of occurrence of the risk.

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.



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CHAPTER 4: TREATMENT AND DISPOSAL OF UNFIT PHARMACEUTICAL PRODUCTS

4.1 General requirements for treatment and Disposal of Unfit products

- a) Disposal of any unfit product without permission and supervision from Rwanda Food and Drugs Authority (Rwanda FDA) is prohibited.
- b) Approval of application and safe disposal of any unfit product shall be sought from Rwanda FDA.
- c) The applicant shall pay a prescribed fee for destruction as per Regulations N° CBD/TRG/004 related to regulatory services tariff/fees and fines.
- d) The applicant shall arrange with the appropriate Waste Management Agency to assist in the destruction and also be responsible for conveyance of the unfit products to the site of destruction

4.2 Treatment of unfit pharmaceutical product

- a) All regulated pharmaceutical products which are unfit for intended purpose shall be quarantined and kept in a separate place clearly labeled “*Unfit for intended use*”.
- b) The safe custody of unfit pharmaceutical product shall be maintained on registered or approved premises until they are safely disposed of in terms of these Regulations.

4.3 The handling of unfit pharmaceutical products

- a) Maintaining a register for unfit pharmaceutical products in Form prescribed in the Regulation governing the recall, treatment and disposal of unfit pharmaceutical products;
- b) Keeping and segregating them into different categories according to their type, with special regard to pharmaceutical products that fall under controlled substances or hazardous substances;
- c) Keeping unfit products into different categories by dosage forms (e.g. solids, liquids, etc.).

4.4 Specific Requirements for disposal of unfit pharmaceutical products

- a) All applications for destruction of unfit products shall be submitted to Rwanda FDA office through a letter addressed to the Director General.
- b) The letter shall be accompanied by a filled application form prescribed in regulations governing recall, treatment and disposal of unfit products and the list of products in both hard and soft copy (excel format) with the following details:
 - i. Product description
 - ii. Quantities
 - iii. Unit cost
 - iv. Total commercial values

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- v. Reason (s) for which the products are declared unfit
 - vi. Batch (applicable to recalled products)
- c) The authority shall, upon receipt of the request for disposal, appoint a regulatory officer to verify and authenticate the information submitted in relation to the consignment to be disposed. If after verification, the submitted list is varied by addition of other products, the applicant shall be made to pay an additional fee as required.
- d) The applicant shall arrange and agree with Rwanda FDA on a convenient date on which the destruction can be undertaken.
- e) The Authority shall after completion of the disposal exercise issue a certificate of destruction of the products.



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CHAPTER 5: PENALTIES

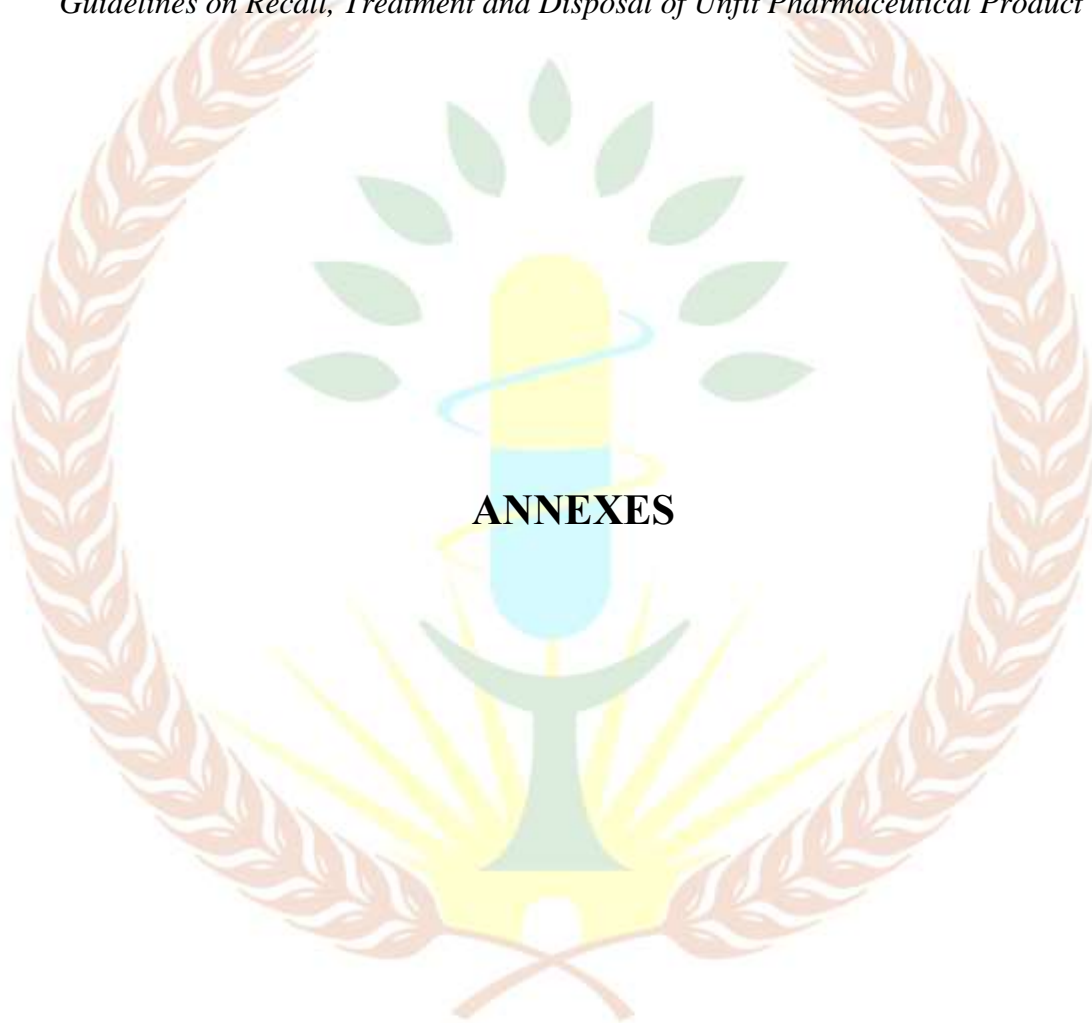
Where non-adherence to these guidelines results in exposure of consumers to a safety risk, Rwanda FDA will impose Administrative charges and sanctions in accordance with Regulations N° CBD/TRG/004 related to regulatory services tariff/fees and fines.

ENDORSEMENT OF THE GUIDELINES

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Title	Division Manager of Pharmacovigilance & Food Safety Monitoring	Head of Food & Drugs Inspections & Safety Monitoring Department	Director General
Names	NTIRENGANYA Lazare	GISAGARA Alex	Dr Charles KARANGWA
Signature	 Digitally signed by Rwanda FDA (DM PVSM) Date: 2021.02.02 15:42:31+02'00'	 Digitally signed by Rwanda FDA (HoD FDISM) Date: 2021.02.03 09:59:57+02'00'	
Date	02/02/2020	02/02/2020	02/02/2020

RWANDA FDA
Rwanda Food and Drugs Authority

Doc. No.: DIS/GDL/034	Revision Date: 29/01/2021	Review Due Date: 05/02/2024
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ANNEXES

RWANDA FDA
Rwanda Food and Drugs Authority

Doc. No.: DIS/GDL/034	Revision Date: 29/01/2021	Review Due Date: 05/02/2024
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QMS N°: DIS/FOM/027
Rev. N°: 0
Effective date: 25/01/2025
Ref. Doc.: DIS/GDL/034

ANNEX I: REQUEST FORM FOR DISPOSAL OF UNFIT PRODUCTS

I/We.....ofwith premises registration Number.....hereby apply for the disposal of unfit products as per attached list.

Physical address of the Premises.....

Name of the superintendent/in charge.....Registration number (*if applicable*).....

Reason(s) for disposal.....

Weight (Kg).....

Market value (in Rwf).....

Declaration:

I certify that the information provided in the application form is true and correct. Date of application.....

Signature of applicant.....Stamp.....

For Official use only:

Received by.....signature.....

Stamp.....Date.....

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QMS N°: DIS/FOM/028
Rev. N°: 0
Effective date: 25/01/2021
Ref. Doc.: DIS/GDL/034

ANNEX II: VERIFICATION FORM FOR A REQUEST FOR DISPOSAL OF UNFIT PRODUCTS

Name of applicant undertaking the business of medicinal products, food products, cosmetics as per attached list

Full address of the applicant.....

Full address of the premises.....

Weight (Kg).....

Market Value (Rwf).....

Does the products tally with the list submitted to Rwanda FDA? Yes/No or other observation.....

Suggested mode of disposal.....

Name of Applicant and signature.....

Date of Verification.....

1. Name of Inspector and Signature.....

2. Name of inspector and signature.....

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QMS N°: DIS/FOM/029
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 Ref. Doc.: DIS/GDL/034

REGISTER FORM FOR UNFIT PHARMACEUTICAL PRODUCTS

S/N	Date	Name of product		Strength (where applicable)	Dosage form	Pack size	Quantity	Batch No.	Value (Rwf)	Reason for unfitness	Date of disposal
		Trade Name	Generic Name								

Done By:

Approved By

Doc. No.: DIS/GDL/034	Revision Date: 29/01/2021	Review Due Date: 05/02/2024
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QMS N°: DIS/FOM/030
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 Ref. Doc.: DIS/GDL/034

FORM FOR DISPOSAL OF UNFIT PHARMACEUTICAL PRODUCTS

The Rwanda Food and Drugs Authority declares to have supervised the disposal of unfit products as per attached list belonging to Mr/Mrs.....
 Postal Address.....
 The destruction exercise was conducted at (location, site) on this date.....by the following method(s) (state clearly):.....
 The total weight of the products destroyed isKgs and market value isRwf...
 Name and signature of owner/representative of the organization:.....
 Names, titles and signatures of Inspector(s), other supervisor(s) and witness of the disposal exercise:.....

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