RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON RECALL, TREATMENT AND DISPOSAL OF UNFIT PHARMACEUTICAL PRODUCTS

NOVEMBER, 2021

Doc. No.: DIS/GDL/034	Revision Date: 12/11/2021	Effective Date: 20/12/2021
Revision No.: 1	Approval Date: 08/12/2021	Review Due Date: 20/12/2024

GUIDELINES 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	05 February 2021
DATE OF REVISION	12th November 2021
APPROVAL DATE	08th December 2021
DATE FOR COMING INTO EFFECT	20th December 2021

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
05/02/2021	**0**	First issue
12/11/2021	**1**	1. The table of grossary was updated to include the definiation of unift pharmaceutical products and other definitions related to methods of disposal were included 2. Section 4.2 of Methods of Disposal was included 3. Provisions for safe disposal /destructions investigaltional products 4. The word Rwanda FDA was replaced by the Authority were applicable 5. Specific Section of requirement regarding safe disposal of unused investigational products 6. Chapter 5 was deleted 7. Application form for safe disposal of investigational product included 8. The form for disposal of unfit investigational products included 9. Necessary editorial changes and formatting were made;

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 the Authority as it is provided for the above law especially in its article 3 paragraph 9 and 11.

Considering the provisions of the regulations N°.:CBD/TRG/019, Governing Recall, Treatment and Disposal of Unfit Products, the Authority issues 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 against a suspected subsatandards and falsified products.

These Guidelines for recall, treatment and disposal of unfit pharmaceutical products intend to put in place a process for recall and to ensure that 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 re-entry of the product into the supply chain.

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

08/12/2021

Dr Emile BIENVENU
Director General

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA

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ABBREVIATIONS AND ACRONYMS

CRO	Contract reseach organization
GMP	Good Manufacturing Practice
HCPs	Health care providers
IP	Investigational product
MAH	Marketing Authorization Holders
PI	Principal investigator
Rwanda FDA	Rwanda Food and Drugs Authority

DEFINITIONS

"Authority" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under article 2 of the Law Nº 003/2018 of 09/02/2018.

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

''Investigational Product" 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.

"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

"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;

"Statutory recall" as used in this document refers to when the Authority requests or orders a product recall due to non-compliance to regulatory requirements.

"Unfit pharmaceutical products" means pharmaceutical products which have expired, improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labelled, substandard or

falsified, adulterated, counterfeit, prohibited or unauthorised or any other product that do not have the required quality standards even before the expiry date. It include also the Investigational products and placebos that are expired, damaged/unused and/or returned products which can no longer be used for research.

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

"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.

"High Temperature Incinerator" means an incinerator that generates at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment.

"Medium Temperature Incinerator" means a two-chamber incinerator with minimum temperature of 850^{o}C.

"Open Controlled landfill" means a landfill where medicines waste is covered with large amount of municipal wastes but it is still left open.

"Open uncontrolled landfill" means a landfill where medicines waste is not covered with large amount of municipal wastes and it is left open.

"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.

"Sewer" means a flushing of medicines wastes to the sewerage system after proper dilution and regulation.

"Waste Inertization" means a variant of encapsulation and involves removing the packaging materials including blister packs, paper, cardboard and plastic from the medicines and then crushing and mixing medicines with cement, lime and water.

"Waste Encapsulation" means a landfill approach to reduce the risk of medicine waste through immobilizing the medicine in a solid block within a plastic or steel

CHAPTER ONE: 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 the Authority.

A recall will be terminated when the Authority 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 requirements of treatment and disposal of unfit pharmaceutical products stipulated by these guidelines.

1.1 Scope

These Guidelines apply to all manufacturers, importers, exporters, distributors, CROs and clinical trial sites and retailers of pharmaceutical products that are found to be unfit, in order to explain and standardize the procedure for pharmaceutical products recall in order to ensure effective removal and safe disposal of unfit pharmaceutical products from the market including disposal of any unused quantities of investigational products and to provide guidance of handling in order to prevent its re-entry into the supply chain.

CHAPTER TWO: RESPONSIBILITIES & REQUIREMENTS

2.1. Responsibilities of Manufacturers, importers, Distributors and MAH

The Responsibilities of Manufacturers, importers, distributors and marketing authorization holders include the following:

a) maintaining records and establishing procedures which 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 defective product and recallas well as providing the corrective and preventive actions.
e) initiation of Voluntary Recall which is the recalling of a product at the 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

The requirements and responsibilities of the Authority include the following:

a) initiation of Statutory-Recall (Non-Voluntary): 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 may take appropriate actions to remove the product from sale or use. The recalling entity's recall does not preclude enforcement actions being taken by the Authority 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 given pharmaceutical product is ongoing;
    2. When the Authority receive reports on quality defect of pharmaceutical products which are suspected to harm the life of a consumer and need further investigations;
    3. Anytime the 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

The management of pharmaceutical products called for quarantine must comply with the following:

i. Where quarantine status is ensured by storage in separate areas, the 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;
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.

CHAPTER THREE: 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 may 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) reports of serious 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 issued by the Authority.

3.3 Management of recalled pharmaceutical products.

a) All recalled pharmaceutical products must be clearly recorded and returned to the local supplier within ten days after issuance of recall.
b) The 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.

3.4 Recall classification

The Authority shall assign a designation number, 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; and
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 consenquences
3. Contamination with no medical consequences (e.g. dirt or detritus among others).

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.
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 recall 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 among others;
b) All Class II recalls shall be executed up to the levels of wholesale and retail; and
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

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, the Market Authorization Holder (MAH) 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 of these guidelines.
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 the Authority.

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 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.

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 the Authority 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 the Authority

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.

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.

The Authority 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, the Authority 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.

3.15 Post recall notification to the Authority

After recall, the recalling entity immediately on becoming aware of the problem shall notify the Authority 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 the Authority 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;

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.

CHAPTER FOUR: TREATMENT AND DISPOSAL OF UNFIT PHARMACEUTICAL PRODUCTS

4.1 General requirements for treatment and disposal of Unfit products

The following are the general requirements for the treatment and disposal of unfit pharmaceutical products:

a) Disposal of any unfit product without permission and supervision from Authority is prohibited;
b) Approval of application and safe disposal of any unfit product shall be sought from the Authority;
c) Evidence of payment of the prescribed fee for destruction/disposal as per Regulations N° CBD/TRG/004 related to regulatory services tariff/fees and fines.
d) 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 Disposal Methods

Category	Disposal methods	Comments
Solids Semi-solids Powders	Landfill, Waste encapsulation, Medium and high temperature, Waste inertization and incineration (cement kiln incinerator).	
Liquids	Sewer, High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed in sewer.
Ampoules	Crush ampoules and flush diluted fluid to sewer	Antineoplastics shall not be disposed in sewer.
Anti-infective medicines	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to sewer discharged to sewer.
Antineoplastics	Waste encapsulation, Waste inertization, High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed into landfill unless encapsulated, and shall not be disposed by sewer or by medium temperature incineration.
Controlled substances	Waste encapsulation, Waste inertization, High temperature incineration (cement kiln incinerator)	Shall not be disposed into Landfill unless immobilized.
Aerosol	Landfill, waste encapsulation	Not to be burnt: may explode.

canisters		
Disinfectants	To sewer: small quantities of diluted disinfectants (max. of 50 liters per day under supervision)	No undiluted disinfectants shall be disposed to sewer.
PVC plastic, Glass	Landfill	Shall not be disposed by burning.
Paper cardboard	Recycle, burn or landfill	

4.3 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.

4.4 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.).

4.5 Specific Requirements for disposal of unfit pharmaceutical products

a) All applications for safe disposal/destruction of unfit products shall be submitted to the Authority's 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;
   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 team of inspectors 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 will ensure that the authorization from the Authority is obtained prior to the safe disposal of unfit products

e) The applicant mus arrange and agree with the Authority on a convenient date on which the destruction can be undertaken.

f) Authority shall after completion of the disposal exercise issue a certificate of destruction of the products.

4.6 Specific Requirements for safe disposal of unused investigational products

Any unfit stocks of investigational products shall be safely disposed of in order to prevent them of being abused. The safe disposal/destruction of unfit/unused investigational products is carried out after any discrepancies have been investigated, reconciliated, satisfactorily explained and accepted by the Athority and PI/Sponsor.

A safe disposal/destruction request of unfit/unused investigational products will be done using appropriate form according to these guidelines within 6 months of the conclusion or termination of the clinical trial. The safe dosposal request also apply to all 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 for their safe disposal

During the exercise of safe disposal of investigational products, PI or Sponsor will appropriately record in the IP accountability logs and request for disposal must be accompanied with the following information:

a) List of IP showing the official name, proprietary name (i.e., brand name) or other description of the IP, the identification number of the IP (e.g., the control number, lot number/batch number or serial number in a medical device), the quantity of IP disposed, exported
b) Copy of Clinical Trial Approval certificate
c) Copy of Import license (s) of IP issued by the Authority
d) Copy of signed and dated accountability logs
e) List of other non investigational products and their import license (if applicable)
f) Proof of payment of prescribed fees

The Authority will, upon receipt of the request for safe disposal of investigational products or of other non investigational products, appoint a team of inspectors to verify and authenticate the information submitted in relation to the products 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.

The PI or sponsor must ensure that the authorization from the Authority is obtained prior to the safe disposal of investigational or non investiation products and the IP accountability logs are properly recorded, updated accordingly and maintained after disposal.

The PI or Sponsor will arrange and agree with the Authority on a convenient date on which the destruction can be undertaken.

Authority shall after completion of the disposal exercise issue a certificate of destruction of investigational or non investiation products.

ENDORSEMENT OF THE GUIDELINES

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Signature			
Date	30/11/2021	30/11/2021	08/12/2021

ANNEXES

ANNEX I: REQUEST FORM FOR DISPOSAL OF UNFIT PRODUCTS

I/We.....of .....with 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……..

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

Name of the applicant undertaking clinical trial or the business of medical 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 the Authority? 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.....

REGISTER FORM FOR UNFIT PHARMACEUTICAL PRODUCTS

S/N	Date	Name of unfit 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

FORM FOR DISPOSAL OF UNFIT INVESTIGATIONAL PRODUCT

The Rwanda Food and Drugs Authority declares to have supervised the disposal of unused inverstigational products/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 is ……Kgs and market value is .....Rwf…

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:.....

.....

.....

.....

FORM FOR DISPOSAL OF UNFIT INVESTIGATIONAL PRODUCT

PROTOCOL TITLE:

PROTOCOL REF No:

PRINCIPAL INVESTIGATOR:

SITE NAME:

Name of IP/ Placebo	Quantity (Units)	Lot No.	Code Nomber	Exp. Date	Reasons for Disposal	Tentative date of Disposal	Observations

Add more raw as you want

DECLARATION:

☐ I hereby declare that the information and quantities of above listed unfit/unused or returned investigational products for safe disposal/destruction is true. I commit to update all accountability logs relating to the investigational products after the safe disposal. ***(To be completed by pharmacist or PI)***

Name: Signature: Date:

IP RECEIVED FOR DESTRUCTION

☐ **I accept this package for destruction. (To be completed by waste management company)**

Name: Signature: Date:

☐ **I accept this package into custody for destruction by an authorized agency. (To be completed by person responsible for sending the IP for destruction).**

Name: Signature: Date: