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RWANDA FDA Rwanda Food and Drugs Authority	Title: **SAFE DISPOSAL OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**	

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1.0 Purpose

This Standard Operating Procedure is to:

1.1 To ensure that safe disposal of detected substandard and falsified medical products is carried out as per regulations and guidelines

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all **substandard and falsified** medical products

3.0 Policy

3.1 Law No. 003/2018 of 09/02/2018 establishing Rwanda FDA, determining its mission, organization, and functioning states in:

Article 8 (1) ..." regulate pharmaceutical products, vaccines" and

3.2 Regulations No.:CBD/TRG/019 Rev_0Governing Recall, Treatment and Disposal of Unfit Products

3.3 Guidelines on Recall, Treatment and Disposal of Unfit Pharmaceutical Product

4.0 Abbreviation and Definitions

4.1 **"SF"** Substandard falsified
4.2 **"Medical products"** means medicines, vaccines, diagnostics and medical devices
4.3 **"Disposal"** means the process of rendering harmless any unwanted or unfit regulated product
4.4 **"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;
4.5 **"Quarantine"** The status of regulated products isolated physically due to suspicion on the quality or safety, while a decision is wait on their release, recall, and rejection or reprocessing. Quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to unauthorized personnel.

5.0 Responsibility

Food and Drugs Inspection and compliance Division is responsible for:
5.1 The Head of Food and Drugs Inspection and Safety Monitoring is responsible for:

5.1.1 Ensuring that all applications for safe disposal of SF medical products are processed according to this SOP.
5.2 The Division Manager of Food Inspections and Compliance is responsible for ensuring that all new applications and applications for renewal of premises licenses received are processed; and that the database is updated accordingly.
5.2.1 Maintaining the database of safe disposal of the SF medical products.

6.0 Distribution

6.1 Head of Food and Drugs Inspection and Safety Monitoring Department
6.2 Division Manager of Food Inspections & Compliance
6.3 Quality assurance analyst
6.4 Analysts
6.5 Specialists

7.0 Safety precautions

7.0.1 The inspectors should have the identification cards at all times during the supervision of the safe disposal of SF medical products

7.0.2 Inspectors should wear appropriate protective equipment including coveralls and boots at all times, and gloves, masks and caps when appropriate

8.0 Materials and Equipment

8.1 PV

8.2 Authorization letter for disposal of SF medical products issued by Rwanda FDA

8.3 List of SF Medical products to be disposed

8.4 Pens with indelible blue or black ink

8.5 Rwanda FDA Inspector's Identity cards

9.0 Procedures

9.0.1 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

9.0.2 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

9.0.3 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.

9.0.4 All recalled medical products should be clearly recorded and returned to the local supplier within ten (10) days after issuance of recall.

9.0.5 The local suppliers with recalled medical 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 medical products.

9.0.6 a) 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;

b) Follow-up communications should be sent to those who fail to respond to the initial recall communication

c) 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.

9.0.7 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 substandard and falsified medical 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 substandard and falsified medical products that possibly could cause temporary or medically reversible adverse health problem or mistreatment; Examples include but not limited to:

1. Mislabeling 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 substandard and falsified medical 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.)

9.0.8 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 medical 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 medical products

c) **Consumer level** includes patients and other consumers

9.0.9 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

9.0.10 After that substandard and falsified medical products are recalled, they have to be disposed and it is the duty of the recalling entity to gather all remaining quantity of the recalled product and apply for disposal at Rwanda FDA whereby they make an application to destroy substandard and falsified medical products.

9.0.11 The recalling entity should make a proper application including motivation letter showing the weight of total products to be destroyed with attached list of all products to be destroyed and prescribed fees

9.0.12 Application for disposal of substandard and falsified medical products shall be submitted to the Rwanda FDA.

9.0.13 Secretariat shall stamp "received", file the application and direct it to the Head food and drugs inspection and safety monitoring department.

9.0.14 The Head food and drugs inspection and safety monitoring department shall forward the application to the Division manager drug and food inspection and compliance

9.0.15 The Division Manager of drug and food inspection and compliance shall forward the application to the assigned analyst or specialist for assessment. If not satisfied, then he/she shall inform the applicant for clarification of the application.

9.0.16 Rwanda FDA provides a feedback letter authorizing the recalling entity to dispose substandard and falsified medical products

9.0.17 Recalling entity notifies the authority the date and venue of disposal

9.0.18 The assigned Analyst or specialist from Rwanda FDA will inspect the sorting of substandard and falsified medical products into categories for which different disposal methods are required.

9.0.19 It is the duty of assigned Analyst or specialist from Rwanda FDA to verify whether the list provided during the application is the same in quantity and number of products.

9.0.20 Controlled substances (e.g. narcotics and psychotropics) require tight security and control. In some countries, scavenging of material from landfills is a frequent problem, and, disposed drugs may be recovered and sold by the scavengers. In this case, Immobilization is the best method of preventing pilfering from a store or landfill.

9.0.21 **Summary of disposal methods and medical products involved the following:**

Disposal methods	Types of medical product
Return to donor or	All bulk waste pharmaceuticals,
manufacturer, transfrontier	particularly antineoplastics.
transfer for disposal	
High temperature incineration	Solids, semisolids, powders,
with temperatures greatly in	antineoplastics, controlled substances.
excess of 1200°C	
Medium temperature	In the absence of high temperature
incineration with two-chamber	incinerators, solids, semi-solids,
incinerator with minimum	powders. Controlled substances.
temperature of 850°C. Cement	
Immobilization	
Waste encapsulation	Solids, semi-solids, powders, liquids,
	antineoplastics, controlled substances.
Inertization	Solids, semi-solids, powders,
	antineoplastics, controlled substances.
Landfill	
Highly engineered sanitary	Limited quantities of untreated solids,
Landfill	semi-solids and powders. Disposal of
	waste pharmaceuticals after
	immobilization preferable. PVC plastics.
Engineered landfill	Waste solids, semi-solids and powders,
	preferably after immobilization. PVC
	plastics.
Open uncontrolled non-	As last resort untreated solids, semi-
engineered dump	solids, powders - **must** be covered
	immediately with municipal waste.
	Immobilization of solids, semi-solids,
	powders **is preferable**.
Sewer	Diluted liquids, syrups, intravenous
	fluids, small quantities of diluted
	disinfectants (supervised).
Fast-flowing watercourse	Diluted liquids, syrups, intravenous
	fluids; small quantities of diluted
	disinfectants (supervised).
Burning in open containers	As last resort, packaging, paper,
	cardboard.
Chemical decomposition	Not recommended unless special
	chemical expertise and materials
	available.

9.0.22 after the disposal of substandard and falsified medical products, assigned analyst or specialist from Rwanda FDA will fill and sign the disposal form and the PV de constant to

document the products destroyed, the quantity and mention whether all products were destroyed

9.0.23 The assigned analyst or specialist shall submit the filled in and signed Disposal form to Rwanda FDA Head Quarters so that Certificate of Destruction can be prepared.

9.0.24 The Rwanda FDA responsible officer shall enter disposal details into a disposal register and prepare a Certificate of Destruction.

9.0.2 Storage of SF Medical products

9.0.2.1 All recalled medical products should be placed in quarantine upon receiving. The status of the goods should be clear. Precautions should be taken to prevent access and distribution until a decision has been taken with regard to their disposition

9.0.2.1.1 All recalled products should be secure, segregated, transported and stored under appropriate conditions. These should be clearly labelled as recalled products. The particular storage conditions applicable to the product should be maintained.

9.0.2.1.2 The recalled products should be stored in the restricted area

9.0.2.2 The particular storage conditions applicable to the medical products should be maintained

9.0.2.3 Medical products returned should be destroyed unless it is certain that their quality is satisfactory after they have been critically assessed in accordance with a written and authorized procedure.

9.0.2.4 The nature of the medical product, any special storage conditions it requires, its condition and history and the time lapse since it was issued, should all be taken into account in this assessment. Where any doubt arises over the quality of the medical product, it should not be considered suitable for reissue or reuse. Any action taken should be appropriately recorded

10.0 References

10.1 Guidelines on Recall, Treatment and Disposal of Unfit Pharmaceutical Product

10.2 Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, WHO/EDM/PAR/99.2

11.0 Records

Inspection reports follow up inspection reports, inspection checklists, disposal form inspection memorandum forms, certificates, and general correspondences shall be maintained at the registry and the department for five years and then destroyed appropriately.

12.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

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