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TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR RECALL, HANDLING AND DISPOSAL OF UNFIT MEDICINAL PRODUCTS

Third Edition

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TABLE OF CONTENT

ABBREVIATIONS

ADR	-	Adverse Drug Reactions
CAPA	-	Corrective Actions and Preventive Actions
CROs	-	Clinical Research Organisations
DMC	-	Director, Medical Product Control
DMO	-	District Medical Officer
LGAs	-	Local Government Authorities
LTR	-	Local Technical Representative
MAH	-	Marketing Authorization Holder
MSD	-	Medical Stores Department
NEMC	-	National Environmental Management Council
NGOs	-	Non Governmental Organisations
PMS	-	Post Market Surveillance
RCA	-	Root Cause Analysis
RMO	-	Regional Medical Officer
TMDA	-	Tanzania Medicines and Medical Devices Authority

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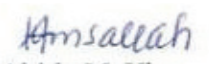

Akida M. Khea
Acting Director, Medical Products Control

FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219 to regulate among others, the quality, safety and efficacy of medicines manufactured locally, imported and distributed for use by the general public. To attain this function, various measures and strategies were introduced to detect and remove from the market unfit medicinal products such as substandard, falsified and expired medicines so as to protect public health.

These guidelines have been prepared to provide improved guidance on conducting withdraw and recall of unfit medicinal products based on relative health risks and adverse events that may occur to patients. These guidelines have also over-emphasized the need for appropriate handling and disposal of unfit medicinal products which includes those recalled from the market. The guidelines intend to elaborate step by step procedures for enforcing the provisions stipulated under the Act and TMDA *Recall, Handling and Disposal of Unfit Medicines and Cosmetics Regulations, 2015.*

Generally, improper recall and or unsafe disposal of unfit medicinal products could present a serious health risks to the general public or to the environment. For example, falsified medicinal products may come into hands of unscrupulous dealers and diverted to the market for resale and cause health risks. Also, improper disposal may be hazardous to individual and enviroment if it leads to contamination of water supplies. Furthermore, unsafe disposal of non-biodegradable antibiotics, anti-neoplastic and disinfectants may kill microbes necessary for the treatment of sewage. Additionally, burning of medicinal products at low temperatures or in open containers could result in release of toxic pollutants into the air and affects both the environment and human being.

Therefore, these guidelines sets out vital procedures and actions which should be adhered by the entire community and other players or stakeholders such as manufacturers, pharmaceutical dealers, public

and private health facilities, LGAs, NGOs and drug inspectors during implementation of recalls at different levels. Handling or managing of recalled products during safe disposal have also been highlited so as to protect the public from consuming harmful products.

It is anticipated that, our esteemed stakeholders will acquaint and make use of these guidelines to meet the overall objective of protecting the public and the environment. The TMDA will make use of its zone offices and other staff to create awareness to stakeholders regarding requirements of these guidelines so as to enhance smooth implementation. Any comments or inputs that will improve this document in future are highly welcomed.

Adam M. Fimbo
Director General

DEFINITION OF TERMS

For the purpose of these guidelines the following terms are defined as follows:-

Act
Means Tanzania Medicines and Medical Devices Act, Cap 219;

Authority
Means Tanzania Medicines and Medical Devices Authority or its acronym "TMDA";

Disposal
Means the process of rendering the unfit medicinal products for the duration of its biological and chemical activity such that it is harmless;

Environmental Inspector
Means an inspector appointed under or designated pursuant to the section 82 of the Environmental Management Act, Cap 191;

Inspector
Means TMDA inspector appointed, authorized or recognized under section 105 of the Act;

Importer
Means person or institutions authorized under the Act to import medicinal products in the Country;

Marketing Authorization Holder (MAH)
Means a person resident or domicile to Tanzania or a foreigner who holds authorization to place a medicinal product in the country and is responsible for that product;

Medicinal Product
Means any substance or mixture of substances manufactured, sold presented for use in:-

a) diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in man or animal;

b) restoring, correcting or beneficial modification of organic or mental functions in man or animal;
c) disinfection in premises in which medicinal products are manufactured, prepared or kept, hospitals, equipment and farm houses; or
d) articles intended for use as a component of any articles specified in clause (a), (b) or (c); but does not include medical devices or their components, parts or accessories.

Recall
Means the removal of specific batch or batches of a medicinal product from the market for reasons related to deficiencies in the quality, safety or efficacy;

Superintendent
Means a pharmacist in-charge who supervises a pharmacy business and registered as such under the Pharmacy Act, Cap 311 or Veterinarian who is registered under the Veterinary Act No. 16 of 2003;

Unfit Medicinal Product
Means products that have expired, improperly sealed, damaged, unexpired but improperly stored, improperly labeled, substandard, falsified and adulterated, prohibited or unauthorized;

Mock Recall
Means an exercise carried out by the manufacturer to challenge the effectiveness of the defined product recall procedures;

Controlled drugs
Means any narcotic drug, psychotropic substance and precursor chemical as described under section 77(2) of the Act;

Anti-neoplastic
Means medicinal products previously called cytotoxins or anti-cancers that have the ability to kill or stop growth of living cells;

Withdraw
Means total removal of medicinal product from the market;

Recall implementing agents
Means manufacturers, market authorization holders, local technical representatives or any other authorized importer.

1.0 INTRODUCTION

Medicinal products play a major role in saving lives and alleviating suffering, while at the same time when these products are regarded unfit may present serious hazardous effects on public health and environment especially if their quality, safety and efficacy have been compromised, hence have to be recalled from the market.

To reinforce effective and efficient recall operations and guarantee safe disposal of unfit medicinal product, the Authority has reviewed its guidelines by clearly outlining procedures for executing the recall, which have taken on board the levels of recall, roles and responsibilities of key actors. To ensure public and environmental safety a detailed guidance on safe handling of unfit medicines has been provided. Several modes of destruction have been outlined specifying disposal modes for controlled drugs, anti-neoplastic, cytotoxic and anticancer drugs.

These guidelines are divided into three (3) major parts which are recall of unfit medicinal product, handling of unfit medicinal product and disposal of unfit medicinal products.

The Authority expect that good implementation of these guidelines will help to prevent unnecessary accumulation and protect the public from unfit medicinal products marketed in Tanzania.

2.0 RECALL OF UNFIT MEDICINAL PRODUCTS

2.1 Initiation of recall

Recall of unfit medicinal products may be initiated by the following agents or firms:-

a) Authority;
b) Marketing Authorization Holder (MAH) ;
c) Manufacturer; or
d) Any other authorized importers.

Where the recall has been initiated by MAH, manufacturer or any other authorized importer the Authority should be informed in writing prior to execution of the recall.

2.2 Factors which may lead to initiation of recall

The following factors may trigger the Authority, MAH, manufacturers or authorized importer to initiate recall of any medicinal product:-

a) Complaints from users or general public;
b) Reports of Adverse Drug Reactions (ADRs);
c) Results of ongoing stability studies;
d) Results of Post Market Surveillance (PMS);
e) Incorrect labeling of the products;
f) Proof that a medicinal product has caused or is about to cause injury to the health or safety of patients or other users; or
g) Proof that a medicinal product does not meet specifications;
h) Any other defect related to quality, safety and efficacy of the medicinal product.

The costs associated with recall shall be borne by the initiator namely Manufacturer, MAH or Local Technical Representative (LTR).

2.3 Recall Procedures

2.3.1 Information to be submitted to the Authority

Prior to implementation of recall; Manufacturer or MAH or LTR or authorized importer should submit to the Authority the following information of the product(s) to be recalled:-

a) Proprietary name and generic name;
b) Dosage form;
c) Strength;
d) Batch or lot number;
e) Pack size;
f) Name and address of the manufacturer;
g) Manufacturing date and expiry date;
h) Reason(s) for the recall;
i) Nature of the defectiveness or possible defectiveness;
j) Date on and circumstances under which the defects or possible defects were discovered;
k) Total quantity of the product to be recalled originally in possession of the manufacturer, MAH or importer;
l) Date on which distribution of the product began;
m) Total quantity of the product to be recalled that had been distributed up to the time of the recall;
n) Area of distribution of the product;
o) List of customers to whom product was distributed; and
p) Quantity of the product still in possession of the manufacturer, registrant or importer.

The received information shall be evaluated or assessed by the Authority followed by issuance of official directive to carry out the recall.

2.3.2 Submission of weekly progress and final recall reports

After start of the recall process as directed by the Authority, the recall implementing agents should submit weekly progress reports to the

Authority and upon completion of the recall, the recalling agent shall submit the following to the Authority:-

a) Final report which includes reconciliation between distributed and recovered quantities of the product.

b) A thorough investigation report detailing causes of the defect and Corrective Actions and Preventive Actions (CAPA) undertaken.

2.4 Recall classification and recall timeline

There shall be three (3) classes of recalls based on relative health risks or adverse events to patients as described below;

a) Class I refers to recall of defective, dangerous or potentially life threatening medicinal products that predictably or probably could result into serious health risk or adverse events or death;

b) Class II refers to recall of medicinal products that possibly could cause temporary or medically reversible adverse health problem or mistreatment; and

c) Class III refers to recall of medicinal products which are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements of the Act, in terms of the requirements of printed packaging material, product specification or labeling.

The maximum time for recall shall be fourteen days for Class I, twenty one days for Class II and thirty days for Class III from the date of instruction. The Authority shall have the final decision on the maximum time for recalling of any medicinal product.

2.5 Levels of Recall

For purpose of ensuring that the general public is protected from consuming unfit medicinal products, there shall be three (3) levels of

recall based on recall classes stipulated in 2.4

a) Level A

Level A refers to recall designed to reach all suppliers of medicinal products throughout the supply chain (i.e. all public and private drug outlets and health facilities) and individual customers or patients through media release such as radio, television and websites. Communication to inform facilities and individuals or customers under this level shall be made urgently via media release and issuance of letters at the same time.

b) Level B

Level refers to recall designed to reach public and private drug outlets and health facilities. Communication to inform facilities (wholesalers and retailers) under this level shall be made urgently by sending letters.

c) Level C

Level C refers to recall designed to reach wholesaler and retailer levels. Communication to inform the concerned outlets could be achieved by means of a representatives calling on wholesalers and/ or retail outlets. If it is known where the product in question had been distributed; specific telephone calls or recalls letters requesting for the return of the product could be made.

2.6 Roles and responsibilities of key actors in the recall process

During implementation of recall there shall be involvement of different players with the following roles and responsibilities:-

2.6.1 The Authority

a) Receive, evaluate and assess information related to unfit medicinal product(s) present in the market.
b) Instruct recall of unfit medicinal product depending on classification of recall and levels.
c) Monitor recall progress on weekly basis until completion of the recall.
d) Document recalled medicinal product in the 'DMC Quality and Safety Issues Register'.
e) Issue public notice where applicable.
f) Assess the CAPA submitted from the Manufacturer or MAH.
g) Provide timely feedback to individuals who reported incidents related to quality and safety of medicinal products.
h) Official closure of the recall process.

2.6.2 Manufacturer/MAH/Authorized importer

a) Take the prime responsibility for implementing recall processes.
b) Voluntarily initiate recall after detection of any problem related to quality, safety and efficacy of a medicinal product.
c) Handle product recall according to TMDA established recall procedures.
d) Maintain records and establish procedures for conducting recall.
e) Have in place a documented procedure for conducting mock recall.
f) Conduct Root Cause Analysis (RCA) on the identified defect.
g) Timely submission of CAPA to the Authority for assessment.
h) Submit to the Authority, recall progress and final reports.

2.6.2 Consumers

a) Report to the Authority, health facilities or any other law enforcing agencies issues related to quality, safety and efficacy of medicinal products.
b) Remain vigilant during purchase and use of medicinal product.
c) Provide cooperation with Authority and other law enforcing agencies.

2.6.3 Inspectors

a) Make prompt follow up to the MAH, manufacturer and any other authorized importers regarding recall progress.
b) Close monitoring the effectiveness of recall progress and intervene by conducting inspection whenever necessary.
c) Prepare and submit recall report to supervisors.
d) Foster cooperation with LGAs and other law enforcing agencies on behalf of TMDA.

2.6.4 Local Government Authorities (LGAs)

a) Report incidents of presence of unfit medicinal products.
b) Cooperate with the Authority in implementing recalls.
c) Conduct inspection on the market to remove unfit medicinal products as instructed by the Authority.
d) Submit recall report to the Authority.

3.0 HANDLING OF UNFIT PRODUCTS

3.1 Premises for handling unfit medicinal products

Unfit medicinal products may be found in the following premises:-

a) Manufacturers

b) MAH/LTR
c) Authorized Importers
d) Importing wholesalers
e) Wholesalers
f) Retailers
g) Health facilities
h) Clinical Research Organizations (CROs)
i) Households
j) Laboratories

3.2 Requirements for safe handling unfit medicinal products

3.2.1 Handling of unfit medicinal products at facility level

The following requirements should be adhered in handling unfit medicinal products at the facility level;

a) Stored in a secured and designated area conspicuously marked in red or stored in containers such as boxes which are clearly marked in red ink with words "unfit for intended use" or "Hazifai kwa Matumizi".

b) Kept in different medicinal categories by dosage forms such as;
   (i) Solids, semi-solids and powders: capsules, powders for injection, tablets, granules, creams, gels suppositories;

   (ii) Liquids: solutions, suspension, syrups, mixtures, lotions, aerosol and inhalers.

c) Facility should maintain a register book for unfit medicinal products (Annex III) detailing name of the product and manufacturer, strength and dosage form, quantities, market value of each products.

d) Medicinal products which fall under controlled drugs, anti-neoplastic, radio-pharmaceuticals, antibiotics and any other hazardous medicines should be kept separately.

3.2.2 Handling of unfit medicinal products at household level

Unfit medicinal products at household level should be stored in a secure place, separate from in-use medicinal products and should be kept away from reach of children. However, for purpose of not accumulating unfit medicinal products at household level, the household may return them to nearest TMDA offices or government health facilities.

4.0 DISPOSAL OF UNFIT MEDICINAL PRODUCTS

Unfit medicinal products may present a serious threat to public health or to the environment if not safely destructed as they may come into hands of scavengers and children and cause health risks such as death or contaminate the environment. Therefore, the following decision levels may initiate the disposal process for unfit medicinal products:-

a) The Authority;
b) Regional, District or Hospital pharmacists;
c) Owner or In-charge of facility or premises;
d) Superintendent;
e) Inspector.

4.1 Procedures for Disposal of Unfit Medicinal Products

4.1.1 Application for disposal

a) Application for disposal of unfit medicinal products shall be made to the Director General by filling in Form No. TMDA/DMC//F/010 whose template is attached as **Annex I**.

b) The form shall be available in the TMDA website www.tmda.go.tz or from TMDA offices, RMOs or DMOs offices and applicant shall submit the filled form to Zone offices where the applicant is located.

c) The application shall be accompanied by a list of products to be disposed off, for each item the following shall be clearly stated:-

i. Trade name and generic name;
ii. Strength and dosage form where applicable;
iii. Type of packaging material and pack size;
iv. Quantity;
v. Manufacturer;
vi. Expiry dates;
vii. Batch or lot number;
viii. Market declared value;
ix. Reasons for disposing.

d) Subject to requirements stipulated in a) above; disposal of unfit medicinal products for Governmental institutions, shall be accompanied by an approval from Accountant General declaring that the products have been written off and that are subject to disposal as required by the Public Finance Act, Cap 348.

e) After submission of an application, the TMDA zone manager shall officially inform the applicant its intention to conduct verification of the consignment or inform the applicant to communicate with respective LGAs where applicable for verification of the consignment on behalf of TMDA.

f) After verification by use of verification form (TMDA/ DMC/F /001), **Annex II** TMDA inspector or LGA as the case may be, shall order the applicant to liaise with

National Environment Management Council (NEMC) or his representative in the Region or Council or any other institution responsible for environment management on the proposed mode of destruction and issuance of condemnation certificate as per National Environment Management Act, Cap 191.

g) The applicant shall submit to the Authority condemnation certificate from NEMC and shall liaise with the incineration company and LGA or any other institution approved by NEMC for safe disposal, cost and agreed date of conducting destruction.

4.1.2 Transportation and supervision during destruction process

It will be the responsibility of the applicant to provide vehicle for transportation of the consignment from the consignee premises to the disposal site, the transportation shall be supervised by the following officers:-

a) An Inspector (TMDA or LGAs Inspector);
b) Environmental Health inspector;
c) Policeman;
d) Any other authorized officer; and
e) The owner of the consignment (applicant) or company representative.

During destruction of the consignment, the officers stipulated in above (a) – (e) shall be present at the disposal site to witness the destruction. After completion of the disposal, all supervisors present and owner of the consignment or representative shall sign the TMDA disposal form (TMDA/DMC/F/026) whose template is attached as **Annex IV**.

4.1.3 Issuance of Certificate of Destruction

The Authority shall issue a certificate of destruction No. TMDA/DMC/MCIE/CF/003 whose template is attached as **Annex V** after

receiving the signed disposal form verifying and assured that the consignment was destructed as per laid down procedures.

4.1.4 Destruction costs

The cost of destruction shall be borne by the owner of the consignment. In case of unfit consignments confiscated or seized (not voluntarily surrendered) by the Authority, the consignee shall be liable to pay TMDA a 25% penalty of the total market value of the consignment as disposal fee as stipulated in the TMDA Fees and Charges Regulations, 2015 or as it may be revised from time to time.

4.1.5 Destruction of controlled drugs

Destruction of controlled drugs at health facilities and MSD shall be made under the supervision of a pharmacist. In case of narcotics including used empty ampoules, the destruction shall be preceded by careful verification, tallying and ensure correctness of procured and consumption records such that any discrepancy should be recorded and reported officially to higher Authorities as per laws and regulations.

The destruction of narcotics shall be witnessed by other accountable officers such as facility health secretary, medical officer in-charge and matron or Quality Assurance Manager and Logistics in-charge for the case of MSD and report submitted to the Authority.

4.1.6 Destruction of anti-neoplastic or cytotoxic or anti–cancer drugs

Anti–neoplastic have very serious effect if discharged into environment as they may interfere with reproductive processes in various life forms. Hence, their disposal must be handled with care. Their methods of destruction shall involve return to supplier or use of high temperature incineration at temperature not less than 1200^{O}C

in the secondary chamber and or waste encapsulation only. Anti-neoplastic drugs or waste should never be disposed off in landfill other than encapsulation or incineration.

Work teams handling these drugs must avoid crushing cartons or remove the product from its cartons. Anti-neoplastic may only be discharged into sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.

4.1.7 Recommended methods for destruction of medicinal products

The recommended modes of destructions of unfit medicinal products include; incineration, landfill, immobilization (encapsulation or inertization), sewer, burning in open containers, medium and high temperature incineration, chemical decomposition or any other method as may be approved by the NEMC.

5.0 ANNEXES

Annex I: Application Form for Disposal of Unfit Medicines

TMDA Tanzania Medicines & Medical Devices Authority	APPLICATION FORM FOR DISPOSAL OF UNFIT MEDICINES	*TMDA/DMC/F/010* *Rev #: 00*

(Made under Regulations 10(1))

I/We…….of(postaladdress)…… with premises registration number……of 20……..hereby apply for the disposal of unfit medicinal 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 TZS)……..

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: Unfit Products Verification Form

TMDA Tanzania Medicines & Medical Devices Authority	UNFIT PRODUCTS VERIFICATION FORM	*TMDA/DMC/F/001* *Rev #: 00*

(Made under regulation 12(2) of the Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Unfit Medicines and Cosmetics) Regulations, 2015 and regulation 62(2) of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015)

1. Name of applicant…… of postal address…… undertaking the business of medicinal products or medical devices as per attached list.
2. Physical address of the Premises ……..
3. Weight (Kg)……
4. Market value (in TZS)……
5. Does the actual product(s) tally with the list of product(s) submitted to TMDA?

   YES [ ] NO [ ]
6. Other observation(s)……...…
7. Suggested mode of destruction ……
8. Name of applicant representative:……

Signature:……

9. Date of verification: ……

……..……

10. Names of Inspectors **Signature**

…….. ……

…….. ……..

Annex III: Register of Unfit Medicines

TMDA Tanzania Medicines & Medical Devices Authority	REGISTER OF UNFIT MEDICINES *(Made under Regulation 13(2))*	*TMDA/DMC/MCIE/R/014* *Rev #:02*

Sn	Date	Name of Product		Strength (where applicable)	Dosage form	Pack size	Quantity	Batch No.	Value (TZS) where applicable	Reason	Date of disposal

Annex IV: Disposal Form

TMDA Tanzania Medicines & Medical Devices Authority	DISPOSAL FORM	*TMDA/DMC/F/026* *Rev #:01*

(Made under Regulation 14(2))

The Tanzania Medicines and Medical Devices Authority declares to have supervised the disposal of unfit product(s) (as per attached list) belonging to M/S……of postal address……

The destruction exercise was conducted at (location, site) ……on this date ……... by the following method(s) (state clearly):-

1……

2……

3……

The total weight of the products destroyed is …..…Kgs and market value is ……TZS

Name and signature of owner/representative of the organization:

…….
…….

(Name) (Signature)

Names, titles and signatures of Inspector(s), other supervisor(s) and witness of the disposal exercise:-

Name: Title/Position:
Signature &Date:

1……. …….
……..

2……. …….
……..

Annex V: Certificate of Destruction

TMDA Tanzania Medicines & Medical Devices Authority	CERTIFICATE OF DESTRUCTION	*TMDA/DMC/MCIE/CF/003* *Rev #:01*

(Made under Regulation 14(3))

Ref.No:……..
Date:…….

I, being the person in-charge with the administration of the law relating to the control of Products to which the Tanzania Food, Drugs and Cosmetics Act, Cap 219 apply, hereby certify the destruction of unfit Medicines being the property of M/S .....
of Postal Address ..... which took place on..... (date).
The said consignment was destroyed by (method) at .... (location/site) under the witness and supervision of Inspector, Environmental Officer, Health Officer and Police as specified in the attached disposal form with S.No. ....
The weight of the consignment disposed was …….. Kg(s) and its market value was …….TZS.

Name of Director General

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