

TANZANIA FOOD AND DRUGS AUTHORITY



***Guidelines for safe disposal of unfit
medicines and cosmetic products***

(made under section 99 of the Tanzania Food, Drugs and Cosmetics Act, 2003)

First Edition

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These guidelines have been developed to provide guidance to all key players in medicines and cosmetics sector to ensure safe disposal of unfit medicines and cosmetic products.

The guidelines were prepared by a team of experts of the Tanzania Food and Drugs Authority (TFDA) namely, Mr. Emmanuel Alphonse, Ms. Ollympia Kowero, Mr. Adonis Bitegeko, Mrs Agnes S. Kijo, Mr. Damas Matiku, Mr. Erasto Mosha, Mrs. Anitha Mshigati, Mr. Florent L. Kyombo, Mrs Grace M. Shimwela, Mrs. Donesta Simon, Ms. Oliva Andrew and Mr. Dedan Jonas from the Ministry of Health and Social Welfare. I am highly indebted to the team for their effort and contribution for drafting the guidelines.

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FOREWORD

For quite a long time, disposal of unfit medicines and cosmetic products in the country has not been done systematically and professionally due to lack of appropriate guidance. This has resulted to accumulation of unfit medicines and cosmetic products in drug outlets in the country. The accumulation of these products has been mainly contributed by lack of adequate knowledge on procedure for safe disposal of unfit medicines and cosmetics products among the dealers.

The Tanzania Food and Drugs Authority (TFDA), established under section (4) of the Tanzania Food, Drugs and Cosmetics Act, 2003, is responsible for among other things protecting consumers against hazards associated with unfit medicines and cosmetic products.

Hazards associated with unfit medicines and cosmetic products may result from improper or non-disposal and handling activities carried out by all actors in the medicines and cosmetics business. In view of unique nature of these products, Section 99 of the Tanzania Food, Drugs and Cosmetics Act, 2003 provides for proper disposal of unfit medicines and cosmetics or any substance used for the manufacture of pharmaceuticals.

In general, improper disposal of unfit medicines and cosmetics presents a serious threat to public health. Some of the health risks are;

- Contamination of drinking water.
- Non-biodegradable antibiotics, antineoplastics and disinfectants may kill bacteria necessary for the treatment of sewage.
- Burning medicines and cosmetics at low temperatures or in open containers results in release of toxic pollutants into the air which should ideally be avoided.
- Inefficient and insecure sorting and disposal may allow medicines and cosmetics beyond their expiry dates to be diverted for resale to the general public.
- In the absence of suitable disposal sites, if stored in their original packing there is a risk of diversion.

In order to protect the entire Tanzanian population, medicines and cosmetics manufacturers, dealers, private health facilities and institutions, Local Authorities, Non-Governmental Organizations (NGOs), drug inspectors and the general public are required to adhere to set procedures as stipulated in these guidelines.

Therefore, it is anticipated that these guidelines will help to overcome the problems, which the dealers have been facing for many years while dealing with unfit medicines and cosmetics products.

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DIRECTOR GENERAL
TANZANIA FOOD AND DRUGS AUTHORITY

1. INTRODUCTION

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act 2003 to provide for comprehensive regulation of all matters related to quality, safety and effectiveness of food, drugs, cosmetics and medical devices. In order to achieve this mission various measures are required to be put in place including having proper means or strategies of managing unfit medicines and cosmetic products.

TFDA has developed these guidelines to provide guidance to medicines and cosmetics dealers on how to dispose off medicines and cosmetic products safely. The guidelines have been developed in line with the current development in science and technology of medicines and cosmetics formulations based on the World Health Organization (WHO) Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies.

The guidelines is divided into four sections which define unfit medicines and cosmetics products and gives guidance on handling of unfit medicines and cosmetic products at a facility, procedure for application for disposal of unfit medicines and cosmetic products and the actual destruction exercise. The last part contains annexes which provide formats of application form, verification form, disposal methods, disposal form and disposal certificate.

The Authority anticipates that good implementation of these guidelines shall help to prevent unnecessary accumulation of unfit medicines and cosmetic products on the market.

2. PROCEDURES FOR HANDLING AND DISPOSAL OF UNFIT MEDICINES AND COSMETIC PRODUCTS

2.1 Unfit medicines and cosmetic products

Medicines and Cosmetic products shall be considered as unfit when they are: -

- 2.1.1 expired
- 2.1.2 improperly sealed
- 2.1.3 damaged, unexpired and improperly stored
- 2.1.4 improperly labeled
- 2.1.5 counterfeit, substandard and adulterated
- 2.1.6 prohibited
- 2.1.7 unauthorized

2.2 Handling of unfit medicines and cosmetic products at facility level

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

- 2.2.1 Maintain a register book (**Annex I**) for unfit medicines and cosmetic products.
- 2.2.2 Keep them into different categories by dosage form such as:-
 - a) Solids, semi-solids and powders: capsules, powders for injection, tablets, granules, creams, gels, suppositories etc.
 - b) Liquids: Solutions, suspension, syrups, mixtures, lotions, aerosol, inhalers etc.
- 2.2.3 Keep separately medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicines or cosmetic products.
- 2.2.4 Keep in containers according to their dosage forms to facilitate verification exercise, sorting and selection of disposal method.
- 2.2.5 Demarcate an area for keeping containers of unfit medicines and cosmetic products which shall be labeled conspicuously with words “Expired medicines/ cosmetic products – Not for Sale” or “Unfit medicines/cosmetics – Not for sale” or “Dawa/Vipodozi hivi muda wake wa matumizi umekwisha – visiuzwe” au “Dawa/Vipodozi hivi havifai kwa matumizi – zisiuzwe” in red ink.
- 2.2.6 Maintain safe custody of unfit pharmaceutical products in registered premises until they are disposed off to avoid pilferage.
- 2.2.7 The decision of when to initiate disposal of unfit medicines and cosmetic products shall be made by regional, district or hospital pharmacist, owners, in-charge of facility, dispensers, and inspectors (including inspectors at ports of entry) to avoid accumulation of such products.

2.2.8 Application for disposal of unfit medicines from Government 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 law under Section 256 of the Public Finance Regulations, 2001.

2.3 Procedures for application to dispose off unfit medicines and cosmetic products

Any person who intends to dispose off unfit medicines or cosmetic products shall adhere to the following procedures:

2.3.1 Request in writing to the Director General of TFDA by using application form **(Annex II)** which is available at TFDA headquarter offices, TFDA zone offices, Regional and District Medical officer's offices and TFDA website: www.tfda.ac.tz.

2.3.2 A request shall be accompanied with a list of products to be disposed of and should state clearly trade name, generic name and strength (where applicable), dosage form, pack size, quantity, manufacturer, batch number and market value of product.

2.3.3 Once the request has been received by TFDA, the Authority shall acknowledge and inform the applicant through a letter to contact Directorate of Medicines and Cosmetics to arrange or TFDA zone offices for verification of the product. In case of regions where there are no TFDA zone offices, applicant shall be informed to contact the Regional or District Medical officer's offices for the same.

2.3.4 TFDA-HQ or TFDA zone office/Regional/District Medical officer's offices shall send inspectors to the premises to verify and authenticate the information submitted.

3. SORTING AND VERIFICATION EXERCISE

3.1 During verification exercise, the drug inspector shall supervise sorting exercise of unfit medicines and cosmetics products before determination of disposal method. Some of the examples of category of products and their recommended disposal methods are highlighted on the table below:

S/N	Category	Disposal methods
1.	Solids, semi-solids and powders	Landfill, incineration and waste immobilization
2.	Liquids	Sewer, high temperature incineration and treated waste
3.	Antineoplastics	Treated waste and landfill, high temperature incineration and return to manufacturer
4.	Controlled drugs	Treated waste and landfill, high temperature incineration
5.	Aerosols and inhalers	Landfill without waste inertization
6.	Disinfectants	Sewer or fast-flowing watercourse
7.	PVC plastics, glass (ampoules, bottles and vials)	Landfill and re-cycling
8.	Paper, cardboard	Recycle, burn, landfill

3.2 Sorting should be done in an open or in a well ventilated area/building as close as possible to the stock pile in an orderly manner. After verification exercise is completed, a verification form (**Annex III**) shall be filled and signed by both parties. Verification process shall involve the following stages:

3.2.1 Identification of the product.

3.2.2 Separate medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicinal or cosmetic products.

3.2.3 Sort according to Destruction Method (**Annex IV**)

3.3 Staff involved in sorting exercise shall be provided with protective gears such as gloves, boots, overalls and dust masks and shall be briefed on the sorting exercise, health and safety risks associated with handling the materials.

3.4 Sorted medicines and cosmetics shall be carefully packed into steel drums or cardboard boxes or jute bags and information to be indicated outside the container shall include; dosage form(s) and proposed mode of destruction. The materials should be kept in a dry secure and preferably separate room to avoid being confused with in-date medicines or cosmetics until disposal is carried out.

3.5 After verification the applicant shall be informed by either TFDA-HQ or TFDA zone office, Regional or District Authorities through a letter on the

proposed mode of destruction and shall be directed to arrange with the respective local authority e.g Municipal/ District Medical Officer/ Pharmacist to determine disposal site, cost and date of destruction.

- 3.6 The cost of destruction shall be born by the owner of the product as stipulated under Section 99 of Tanzania Food, Drugs and Cosmetics Act of 2003.

4. DESTRUCTION OF UNFIT MEDICINES AND COSMETIC PRODUCTS

Destruction of unfit medicines and cosmetic products shall involve the following procedures:

- 4.1 A Drug Inspector, Health Officer, Environmental Officer and Policeman shall supervise the transport of consignment from the owner's premises to the disposal site for destruction exercise.
- 4.2 The destruction exercise shall be supervised by Health Officer, Environmental Officer, Policeman and Drug Inspector.
- 4.3 Unfit medicines and cosmetic products shall be transported in a closed motor vehicle to avoid pilferage.
- 4.4 Supervisors shall wear protective gears such as overalls, gloves, masks, caps and boots during the exercise.
- 4.5 Upon completion of the exercise, a Drug Disposal Form (**Annex V**) shall be duly filled in and signed by the supervisors and owner/owner's representative.
- 4.6 Drug Disposal Form shall be sent to TFDA headquarter offices.
- 4.7 Once TFDA has received the form, a certificate of destruction of unfit medicines and cosmetic products (**Annex VI**) shall be prepared and sent to the consignee.
- 4.8 Particular care shall be taken while handling anti cancer drugs, narcotic drugs and penicillins to avoid associated hazards.

5. ANNEXES

Annex I

Format of Register Book of unfit Medicines/ cosmetic products

S/N	Name of product		Strength (where applicable)	Dosage form	Pack size	Quantity	Batch Number	Value (TZs)
	Trade Name	Generic Name						

Annex II

Model of Application Form for Disposal of unfit Products

Form No.....

To: Director General
Tanzania Food and Drugs Authority
P.O Box 77150
Dar-es-Salaam

I/We
of (postal address)... .. undertaking the business
of (specify).....

..... hereby apply for disposal of unfit (specify type of
products) License Number.....issued
on.....

Location of Business.....

Name of Incharge of the business.....Registration
Number (if applicable)

Reason for disposal.....

Weight (in Kg).....

Value (in Tshs)

Attached herewith is the list of products to be disposed off.

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.....

Annex III

Model of Verification Form

Form No.....

TANZANIA FOOD AND DRUGS AUTHORITY

P.O. BOX 77150, DAR ES SALAAM
Email: info@tfda.or.tz
Telephone :255 22 2450512, 2450751
DirectLine :255 22 2450979
Fax No : 255 22 2450793

Name of applicant.
of (postal address)... .. undertaking the business
of (specify).....

Location of Business.....

Weight (in Kg)

Value (in Tshs)

Does the actual product(s) tally with the list of product(s) submitted to TFDA?
YES/NO

Other observation (s).....
.....

Suggested mode of destruction.....
.....

Name of Applicant.....Signature.....

Date of verification.....

- 1. Name of Drug Inspector.....Signature.....
- 2. Name of Drug Inspector.....Signature.....

Disposal Methods

1. Landfill

This is a disposal method, which involves placing unfit medicines and cosmetic products directly into a land disposal site without prior treatment. The method is used in disposing off solid waste.

Small quantities of unfit medicines and cosmetic products produced on a daily basis may be land filled provided that they are dispersed in large quantities of general waste.

Cytotoxic, narcotic drugs and cosmetic products containing heavy metals such as mercury should not be land filled, even in small quantities.

Three types of landfill methods are recognized as outlined below:

1.1 Landfill for untreated unfit medicines and cosmetic products

The method is applicable to small quantities of unfit medicine and cosmetic products. It involves placing untreated waste medicine and cosmetic into an uncontrolled, non-engineered open dump. The unfit medicine and cosmetic products should be covered immediately with large quantities of other type of waste or soil/sand to prevent scavenging by unscrupulous people.

Discarding of untreated unfit medicine and cosmetics into such a site is not recommended except as a last resort. They should preferably be discharged after immobilization by encapsulation or inertization. It should be noted that discarding in open uncontrolled dump with insufficient isolation from the aquifer or other watercourses can lead to pollution, with the risk of drinking water contamination in the worst cases.

The disposal exercise should be done amid tight security by Police and be supervised by technical personnel.

This method is applicable to solids, semi-solids, powders, medicines, waste dosage forms and cosmetics.

1.2 Engineered landfill

Such landfill has some features to protect from loss of chemicals into the aquifer. Direct deposit of medicines and cosmetics is second best to discharging immobilized unfit medicines and cosmetic products into such a landfill.

1.3 Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer relative safe disposal route for unfit medicines and cosmetic products. An appropriate landfill consists of

an evacuated pit isolated from watercourses and which is above water table. Once unfit medicine and cosmetic products are thrown into the pit, they are compacted and covered with soil to maintain sanitary environment.

The term 'safe sanitary landfill' means a site that is adequately situated, constructed and managed. Limited quantities of untreated medicines and cosmetics waste in form of solids, semi-solids and powders are disposed of by this method.

1.4 Landfill for treated unfit medicines and cosmetics (medicines and cosmetics waste immobilization)

Immobilization of unfit medicine and cosmetics can be done in the following ways:

1.4.1 Encapsulation

In this process waste medicines and cosmetics are immobilized in a solid block within a plastic or steel drum. The drum should be cleaned before using them and they should not have contained explosive or hazardous materials previously.

The exercise starts by filling the drum to 75% of their capacity with solid and semi-solid waste medicines and cosmetics. The remaining space is filled by pouring in a medium such as cement or cement-lime mixture, plastic foam or bituminous sand.

For ease and speed of filling, the drum lids should be cut open and bent back. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15: 5 (by weight) is added and drum filled to capacity.

Steel drum lids should then be bent back and sealed by seam or spot welding. The sealed drum lids should be placed at the base of a landfill site and covered with fresh municipal solid waste.

The method is applicable to solids waste, semi-solids, powders, and liquids.

1.4.2 Inertization

The method involves removing the packaging materials (inner and outer container). The unfit medicines and cosmetics are then ground and a mix of water, cement and lime added to form a homogenous paste. The paste is then transported in liquid state by concrete mixer truck to a landfill site and decanted into a normal municipal waste. The paste then sets as a solid mass dispersed within the municipal solid waste.

The main tools required for the operation are a grinder or road roller to crush the medicines/cosmetics, concrete mixer, cement, lime and water.

Medicines or cosmetics waste, lime, cement and water are mixed in the following ratios by weight 65%, 15%, 15% and 5% respectively. Water can be

added more than the required amount when need arises to have satisfactory liquid consistency.

The method is applicable to solids, semi-solids, powders, antineoplastics controlled drugs of that nature and cosmetics containing heavy metals (e.g. mercury).

1.4.3 Sewer

This is a method used whereby waste medicines and cosmetic products in liquid form e.g. syrups, lotions and intravenous fluids are diluted with water and flushed into a proper functioning sewerage system/sewers in small quantities over a period of time without causing serious public health or environmental effect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid medicines/cosmetics or antiseptics.

1.4.4 Medium temperature incineration

This method involves the use of medium temperature incinerators. Unwanted solid pharmaceuticals may be destructed by using a two-chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber. It is recommended that prior to destruction; pharmaceutical waste should be diluted with large quantities of municipal waste (approximately 1:1000).

Medium temperature furnaces may be used in absence of medium temperature incinerators. This type of incinerator is not suitable for incineration of halogenated compounds, as they need a more high temperature incinerator. The method is applicable to solids, semi-solids, powders and controlled drugs of that nature.

1.4.5 High temperature incineration

This involves the use high temperature incinerator, which operates at a temperature well in excess of 850°C. Our country does not possess such expensive and sophisticated incinerators so the uses of industrial plant such as cement kilns serve the purpose. Cement kilns can reach temperatures of 1450°C – 2000°C that is suitable for total destruction of organic waste component. These have long combustion retention times and disperse exhaust gases via tall chimneys, often to high altitudes thus reducing the risk of environmental effect.

It may be necessary prior to incineration to remove packaging materials to avoid clogging and blockage of incinerator or kiln.

1.4.6 Burning in open containers

Paper and cardboard packaging materials, if they are not to be recycled, may be burnt. Polyvinyl Chloride (PVC) plastic however must not be burnt. Unfit medicines and cosmetics should not be destroyed by burning at low temperatures in open containers, as toxic pollutants may be released into the

air. It is strongly recommended that only very small quantities of unfit medicines and cosmetics be disposed of in this way.

1.4.7 Return to donor or manufacturer

Wherever practical the possibility of returning unfit medicines and cosmetic products for safe disposal by the manufacturer should be explored; particularly medicines and cosmetics which present problems, such as antineoplastics and heavy metals. For unwanted, unrequested donations, especially that arrive with past or unreasonably expiry dates, it may be possible to return them to the donor for disposal.

Model of Disposal Form

Form No.....

(Pursuant to Section 99 of the Tanzania Food, Drugs and Cosmetics Act, 2003)

The Tanzania Food and Drugs Authority declares to have supervised the disposal of unfit product (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 Kg and value is Tshs.

Name and signature of owner/in charge/representative of the organization:

.....

(Name)

(Signature)

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

Name:	Title/Position:	Signature & Date:
1.....
2.....
3.....
4.....
5.....

Annex VI

Model of Certificate of Destruction

Ref. No:.....

Date:

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT, 2003

CERTIFICATE OF DESTRUCTION

I, being the person in-charge with the administration of the law relating to the control of Pharmaceutical Products to which the Tanzania Food, Drugs and Cosmetics Act, 2003 apply, hereby certify the destruction of expired pharmaceutical products belonging to of (Postal Address) which took place on

The said consignment was destroyed by at under the witness and supervision of **Drug Inspector, Environmental Officer, Health Officer and Police** as specified in the attached disposal form with S.No.

The weight of the whole lot disposed is Kg and its value is T.Shs.

.....
Name and Signature of Director General