

**Zambia Medicines Regulatory Authority****GUIDELINES ON THE SAFE DISPOSAL OF UNFIT MEDICINES AND ALLIED
SUBSTANCES**

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1.0. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) regulates medicines and allied substances in accordance with the provisions of the Medicines and Allied Substances Act No. 3 of 2013, (hereinafter referred to as “the Act”) and the relevant Regulations made thereunder.

This guideline for the safe disposal of unfit medicines and allied substances is issued by the Authority pursuant to section 69 (2) (I) of the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The Authority may amend any part of this guideline from time to time.

While the expiry of medicines and allied substances is an inevitable occurrence, stakeholders are urged to adopt measures that minimize wastage and safeguard the environment from contamination.

Patients and medicine users are advised to adhere strictly to prescribed treatment regimens and follow the instructions provided by their Pharmacist. Importers are encouraged to plan and quantify their procurement in a manner that reduces the risk of expiry. Hospitals and healthcare facilities should promote rational use of medicines to ensure efficiency and prevent unnecessary losses through expiry.

This collective responsibility supports sustainable supply chain management, enhances patient outcomes, and strengthens compliance with regulatory standards aimed at protecting the environment.

2.0. OBJECTIVE

This guideline aims at protecting public and animal health and the environment by ensuring that all unfit medicines and allied substances are permanently removed from circulation and disposed of safely. The process prevents re-entry of such products into the supply chain, supports regulatory enforcement actions, ensures compliance with national laws, and promotes safe, accountable and environmentally sound fit medicines and allied substances management practices.

3.0. SCOPE OF THE GUIDELINE

This guideline is applicable to manufacturers, wholesalers, retail and hospital pharmacies, health shops, agro-veterinary shops, clinical trial sites, healthcare facilities, home based care providers, animal health facilities, companies and staff attached to waste disposal management facilities and any other facilities or persons dealing in medicines and allied substances as well as the general public.

4.0 DEFINITIONS

In this Guideline unless the context otherwise requires:

“Act” means the Medicines and Allied Substances Act No. 3 of 2013;



“Antineoplastic” means a medicine that is used for treatment of cancer;

“Applicant” means person(s) or institution(s) applying for authorization for the disposal of obsolete, expired or unwanted medicines or allied substances

“Authority” means Zambia Medicines Regulatory Authority;

“Certificate of disposal” means the document issued by the Authority as evidence and upon satisfaction of the safe disposal of unfit medicines and allied substances **pharmaceutical waste**.

“Cytotoxic” means toxic to living cells, preventing their replication and causing death;

“Disposal” means an action or process of getting rid of unfit medicines and allied substances using safe methods;

“Disposal process” includes the storing, handling, sorting, processing, treatment, utilisation, burial, deposit, discharge, recycling, dumping, pre-treatment, decommissioning of medical devices and equipment, placing or release, of waste into or onto air, land or water as directed by the Authority. This includes operations which do not lead to the possibility of resource recovery, recycling or reclamation, direct re-use or alternative uses;

“Disposal site” means the land on which unfit medicines and allied substances disposal facilities are physically located;

“Donor” means the giver or benefactor of medicinal products or allied substances;

“Encapsulation” means the disposal method of landfill approach to reduce the risk of medicine waste through immobilizing the medicine in a solid block within a plastic or steel drum;

“Hazardous Waste” means waste which is poisonous, corrosive, irritant, explosive, inflammable, teratogenic, carcinogenic, toxic or other substance or thing that is harmful to human beings, animals, plants or the environment;

“Incineration” means the disposal method of oxidation by burning at high temperatures of unfit medicines and allied substances so that it is rendered harmless or inert with or without the recovery of combustion heat generated;

“Inertisation” means the disposal method of removing the packaging materials, including, blister packs, paper, cardboard and plastic from the medicines or allied substances and then crushing and mixing medicines or allied substances with cement, lime and water, where applicable;

“Inspector” means a person duly appointed as an inspector under section 55 of the Act to monitor, inspect and enforce the provisions of the Act;



“Unfit medicines and allied substances” means obsolete, unwanted, expired, improperly sealed, damaged, improperly labelled, substandard, falsified, adulterated, prohibited or unauthorised medicines and allied substances.

“Substandard medical products” Also called “out of specification,” refers to an authorized medical product that fail to meet either its quality standards or specifications, or both.

“Falsified medical products” means a medical product that deliberately/fraudulently misrepresent its identity, composition, or source

“Responsible person” means a person duly qualified as a pharmacist, pharmacy technologist, veterinary surgeon, veterinary para-professional or such other person as the Authority may determine;

“Sewer” means a disposal method of flushing of diluted pharmaceutical waste effluent into the sewerage system after proper dilution and regulation;

5.0 APPLICATION PROCEDURE FOR DISPOSAL OF UNFIT MEDICINES AND ALLIED SUBSTANCES

5.1 A person who intends to dispose of unfit medicines and allied substances shall apply to the Authority in the prescribed manner and form upon payment of a prescribed fee

5.2 An application for the disposal of unfit medicines and allied substances shall be accompanied by:

- (a) List of the unfit medicines and allied substances with details (name of product, manufacturer, dosage form, strength, quantity, batch number and expiry date).
- (b) Documented authorization or proof of notification to dispose of from the Zambia Environmental Management Agency (ZEMA)
- (c) In relation to disposal through return to donor or manufacturer an export permit rather than an application to dispose shall be required, in addition to notifying ZEMA.

6 SORTING, STORING AND TRANSPORTING OF UNFIT MEDICINES AND ALLIED SUBSTANCES

6.1 Sorting of medicines and allied substances enables their categorization into different disposal methods which provides safety. It is essential to provide segregated temporary storage areas for these.

6.2 Sorting of unfit medicines and allied substances shall be done before choosing the appropriate disposal method.

6.3 Unfit medicines and allied substances that require disposal may have to be separated from their packaging.



- 6.4 In consultation with ZEMA, the Authority shall determine the optimal disposal method, and its inspector shall supervise and verify that sorting of unfit medicines and allied substances is done properly.
- 6.5 The institution requiring disposal shall assign personnel who are trained on sorting criteria, safety and risks associated with handling medicines and allied substances.
- 6.6 During the sorting and verification process, staff shall be supplied with personal protective equipment like gloves, boots, overalls and dust masks, by the institution requiring disposal.
- 6.7 Sorting shall be done in open air or at a well-ventilated covered area as close as possible to the stockpile.
- 6.8 The sorting process shall include verification of each item: quantity, type of packaging material and state of the product e.g. expired, damaged, spilled, unsealed or any other.
- 6.9 Sorting shall be done to separate the following unfit medicines and allied substances depending on the disposal method needed:
- (a) Controlled drugs or substances,
 - (b) Antineoplastics and other toxic medicines,
 - (c) Radiopharmaceuticals,
 - (d) Anti-infective medicines,
 - (e) Hazardous non-medicine products like antiseptics and disinfectants, and
 - (f) Other medicines or allied substances by dosage form:
 - Solids, semisolids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories, etc.);
 - Liquids (solutions, suspensions, syrups and ampoules); and
 - Aerosol canisters (propellant-driven sprays and inhalers).

6.9.1 Anti-infective drugs

Anti-infective drugs are unstable and are best incinerated, and if that is not possible encapsulated or inertized.

6.9.2 Controlled Substances

Controlled substances require the presence of a pharmacist/veterinary surgeon representing the institution and any other law enforcement officer as the case may be for purposes of supervision. They shall be disposed of by encapsulation or inertization and then dispersed among the municipal solid waste in a landfill, or incinerated.

6.9.3 Antineoplastics

These may be disposed of by returning to supplier, by high temperature incineration and by waste encapsulation.

It should be noted that antineoplastics have the potential of interfering with reproductive processes in various life forms. They therefore need to be handled with



care. Firstly, segregation from other unfit medicines and allied substances must be employed followed by storage in clearly marked containers with rigid walls.

(a) Return to supplier

Antineoplastic should be packaged safely and returned to the supplier.

(b) Incineration

This method requires a two-chamber incinerator which operates at a high temperature of at least 1200°C in the secondary chamber and is fitted with gas cleaning equipment. An after-burner (i.e. the secondary chamber) is important for the destruction of cytotoxic waste, as it is possible that antineoplastic solutions could become aerosolized following the initial combustion in the primary chamber. As a result, without a higher temperature secondary chamber, degraded antineoplastic material may be emitted from the chimney. The secondary combustion chamber consequently ensures that such antineoplastic substances are fully incinerated.

(c) Encapsulation for antineoplastics

For antineoplastics, sealable container/drum should be filled to 50% capacity with drugs, after which a well stirred mixture of lime, cement and water in the proportions of 15:15:5 (by weight), should be added and the drums filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. The container/drum should then be sealed and left to set for 7 to 28 days. This will form a firm, immobile, solid block in which the wastes are relatively securely isolated. The drums are then placed at the working face of a landfill which has been lined with an impermeable layer of clay or membrane.

6.9.4 Radiopharmaceuticals

These must be disposed of under strict radiation safety and pharmaceutical waste regulations, using segregation, decay-in-storage, authorized transfer to licensed facilities, or specialized incineration depending on isotope half-life and contamination type. Disposal follows IAEA guidance and national radiation protection authority rules to protect staff, patients, and the environment. Refer to Radiation Protection Authority guidelines

6.9.5 Disinfectants

Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly, large quantities should not be put into watercourses since the disinfectants will damage aquatic life.

Small quantities of diluted disinfectant may be disposed of by discharge to a sewer provided, the operation is supervised by a pharmacist, and the quantities are strictly controlled to set limits. The guideline control proposed is 50 litres total per day, with the disposal spread over the whole working day. If possible, disinfectants should be used, for example for toilet cleaning in hospitals. Other methods include disposal in chemical waste or incineration. In addition, reference should be made to safety data sheets for common disinfectants and pesticides

6.9.6 Aerosol canisters



Disposal should be in a landfill, dispersed among municipal solid waste. Burning or incineration are not advisable because high temperature causes explosion of disposable aerosol canisters and inhalers which can injure operators and damage the incinerator. The alternative methods require returning to the manufacturer or supplier

6.9.7 Ampoules

In handling ampoules, there is need for workers to put goggles, gloves, boots and work suits or aprons. The ampoules are first crushed on a concrete surface or hammered in a metal drum or bucket. The resulting crushed glass is then placed in a container and inertized, sealed and then disposed of in a landfill.

6.10 Storage and transportation of unfit medicines and allied substances

6.10.1 The container/ drums or cardboard boxes containing the sorted unfit medicines and allied substances shall be labelled and kept in a dry, secure and preferably a separate room.

6.10.2 Transporting sorted unfit medicines and allied substances to temporary storage places and disposal sites shall be done in closed motor vehicles to avoid pilferage.

7.0 RECOMMENDED METHODS OF DISPOSAL

The following are the recommended methods for the safe disposal of unfit medicines and allied substances:

7.1 Return to the donor or manufacturer

This method applies to donations, especially those that arrive past or with a shelf life of less than one year or those that present disposal problems.

It would be necessary to have a contractual agreement to return expired products prior to their procurement;

It should be noted that both local and foreign products would need an application for disposal.

Locally donated unwanted or expired products need an application for disposal in the prescribed manner and form;

For a foreign based facility, an export permit and cover letter would be required.

7.2. Open uncontrolled non-engineered dump

Unfit medicines and allied substances shall only be disposed of using this method after immobilisation by either encapsulation or inertization. It must then be covered rapidly with large quantities of municipal waste to prevent scavenging. This must be done with sufficient isolation from the aquifer or other watercourses to prevent pollution and contamination of water.

7.3. Engineered landfill



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

7.4 Highly Engineered Sanitary Landfill

This is a properly constructed and operated landfill site which protects the environment, the aquifer, other watercourses or air. It consists of an evacuated pit isolated from water courses and above the water table. The basement of highly engineered sanitary landfill shall be closed and sealed with impermeable materials to prevent gas emission to the open air and water leaching to the environment. The solid waste shall be compacted and covered with soil or coal ash to maintain sanitary conditions.

7.5 Waste immobilisation by Inertisation

- (a) Medicines or allied substances are mixed with cement, lime and water to form a homogenous paste at designated waste dump sites.
- (b) This process involves removing the packaging materials, paper, cardboard and plastics from the unfit medicines and allied substances.
- (c) Pills or tablets need to be removed from their blister packs.
- (d) The unfit medicines and allied substances (where applicable) are then ground and mixed with water, cement and lime added to form a homogenous paste.
- (e) The approximate ratios by weight used are as follows:
 - Unfit medicines and allied substances - 65%
 - Lime -15%
 - Cement- 15%
 - Water-5% or more to form a proper liquid consistence

7.6 Waste immobilisation by encapsulation

- (a) This involves immobilization of the unfit medicines and allied substances in a steel or plastic container/drum
- (b) The container/drum shall be filled to 75% capacity with the solid and semi solid medicines or allied substances, and the remaining space shall be filled with a medium such as cement, cement/lime mixture, plastic foam or bituminous sand.
- (c) The mixture of lime, cement and water added to fill the container/drums shall be in the proportions of 15:15:5 (by weight).
- (d) The sealed container/drums should be placed at the base of the landfill and covered with fresh municipal solid waste.
- (e) In-situ encapsulation may be employed in remote areas. This involves digging a pit, lining it with a container that prevents from reaching the environment and then making a homogenous paste of the unfit medicines and allied substances and finally covering it.

7.7 Sewer

- (a) Decantation into the sewer line where liquid materials are emptied into the sewer line and diluting with plenty of water at the same time.



- (b) The liquid dosage forms of medicines or allied substances are diluted to make them neutral and pH monitored (between 6 and 9) shall be done before flushing into the sewer line in small quantities over a period of time without serious public health or environmental effect.

7.8 High temperature incineration

- (a) Incineration is when materials are burnt in an incinerator at very high temperatures exceeding 1,200°C.
- (b) This is the most appropriate method of safe disposal of unfit medicines and allied substances.

7.9 Medium temperature incineration

- (a) This method is acceptable for treating solid dosage forms of medicines or allied substances using an incinerator that operates at medium temperature combustion process (850-1,000°C). The final ash shall not be left to open air and so requires encapsulation before disposal. It shall be collected and dumped into an approved landfill

7.10 Chemical decomposition

- (a) Chemical decomposition is another method of disposal that can be used in accordance with the manufacturer's recommendations, followed by landfill.
- (b) Chemical decomposition refers to breaking down hazardous or unwanted chemicals into less harmful or inert substances through controlled chemical reactions. This is often used when neutralization or transformation is safer than physical disposal. Used for non-radioactive pharmaceutical waste or chemical reagents.
- (c) However, this method is not recommended unless chemical expertise is readily available. This method is tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times.

7.11 Recycling

This method only applies to packaging materials such as cardboards, plastics and papers.

7.12 Domestic disposal

The general public may return the unfit medicines and allied substances to the health facility or animal health facility for appropriate disposal.

8.0 HANDLING AND DISPOSAL OF SF MEDICINES AND ALLIED SUBSTANCES



Handling and disposing of substandard and falsified (SF) medicines and allied substances requires immediate reporting to ZAMRA to initiate recalls. Substandard and falsified should not be disposed as regular waste. Disposal involves all the processes outlines above.

SF medicines and allied substances should not be destroyed independently because they are often considered evidence or hazardous waste, you must obtain permission from ZAMRA before disposing them. Maintain a strict paper trail to verify compliance and protect against legal liability.

9.0 PERSONNEL TO SUPERVISE AND INSPECT THE DISPOSAL EXERCISE

8.1 Mandatory personnel

- i. A representative from ZAMRA;
- ii. An inspector(s) from ZEMA;
- iii. An inspector(s) from the Local Authority;

8.2 OTHER PERSONNEL ATTENDING THE DISPOSAL EXERCISE

Optional personnel depending on the type of the unfit medicines and allied substances

- i. An officer from Zambia Police Service to witness and provide security;
- ii. Personnel representing the applicant;
- iii. Any other officers coming from relevant institutions;

10.0 GRANTING OF A CERTIFICATE OF DISPOSAL

- 10.1 The Authority shall upon receipt of the application to dispose of unfit medicines and allied substances conduct a review of the application and advise the applicant on the appropriate methods, dates and site (s) of safe disposal.
- 10.2 The Authority shall send inspector(s) to be present at the disposal site to inspect and supervise the final disposal of unfit medicines and allied substances.
- 10.3 The Authority shall issue the Certificate of Disposal within 14 days after the disposal has been done.

**11.0 Annex I. Summary of disposal methods**

No	Dosage form of Product	Recommended Methods of Disposal	Procedure	Place of Disposal
1.	Tablets/capsules	Inertization	Removing of tablets/capsules from blister pack/container. Mixing of tablets and capsules with cement, lime and water to form a homogenous paste at designated waste dump site.	Approved council waste disposal sites
2.	Injectables	Inertization	Crushing of vials, ampoules and bottles followed by mixing of broken bottle pieces and fluid with cement and lime. Burying and landfill of homogenous paste at designated waste dump site.	Approved council waste disposal sites
3.	Creams/ointments/solution	Inertization	Emptying the content of tubes/containers. Mixing of the contents with cement and lime. Burying and landfill at designated dump site.	Approved council waste disposal sites
4.	Syrups/suspensions/I.V. fluids/drops without anti-infectives	Sewer	Diluting with plenty of water and then emptying of the content of bottles into a recommended sewerage plant	Recommended sewerage plant
5	Syrups/suspensions/I.V. fluids/drops with anti-infectives	Inertisation	Mixing of the contents with cement and lime. Burying and landfill at designated dump site.	Approved council waste disposal sites.



6	Vacutainer, bandages, syringes, needles, catheter, sutures, blades and other sharps, plastic bottles and packs etc.	High Temperature Incineration	Burning in an incinerator at very high temperature.	Recommended sites for incineration within the province
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