REVOLUTIONARY GOVERNMENT OF ZANZIBAR

Guidelines for Medicines and Medical Equipment Donations and Guidelines for Safe Disposal of Unwanted Pharmaceuticals.

Ministry of Health and Social Welfare
In collaboration with:

World Health Organization

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Foreword

The goal of the National Drug Policy is to provide right drugs to the right patients in the right quantity at the right time and affordable prices. The Ministry of Health and Social Welfare (MOH&SW) has been making effort to achieve this goal through various ways including receiving donations from various donors during emergency situation or as development aid.

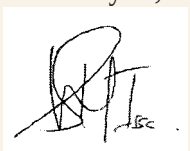
Unfortunately, there have been no official guidelines to assist the donors and recipients on Good Donation Practices. Consequently, there has been accumulation of pharmaceutical waste which threatens people health and environment of our country.

Therefore, the MOH&SW has decided to lay down this guideline which will be used as a guiding document for both donors and recipients so that Zanzibaris can benefit as much as possible from the donation. These guidelines have been prepared for the purpose of optimizing the benefits of the donations and not to hinder the donations.

The implementation of these guidelines requires mutual cooperation between both parties, donors in one hand and recipient in another.

I therefore, make sincerely call to all stakeholders to take their respective responsibilities toward good donation practice laid down in this document for the betterment of the health of our people and environment.

Thank you,



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Hon. Sultan M.Mugheiry
Minister for Health and Social Welfare.
ZANZIBAR.

Acknowledgement

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The Ministry would like to thank all those who have contributed to the development of this version. The principal contributors for the edition were;

Mr. Habib Ali Sharif	–	Chief Pharmacist, MOHSW
Mr. Mberik Rashid said	–	Registrar, Pharmacy Board
Mr. Burhani Othman Simai	–	Chief Drug Inspector, Zanzibar Pharmacy Board
Mrs. Salma Mohd Said	–	Assistant Chief Drug Inspector, Zanzibar Pharmacy Board
Mrs. Lydia John Zungufya	–	Pharmacist, Central Medical Store
Mrs. Mayassa Ali Salum	–	Pharmacist, Drug Management Unit
Mr. Mohd Omar Mohd	–	Pharmacist, ZMPC
Mr. Haji Juma Haji	–	Pharmacist, MMH
Mr. Shija Joseph Shija	–	Pharmacist, Pharmacy Board
Mr. Zahran Ali Hamad	–	Pharmacist In charge Pemba
Dr. Mkasha Hija Mkasha	–	Coordinator, MOH&SW Pemba
Dr. Hassan Ameir Haji	–	Member, Pharmacy Board
Mr. Haji Ameir Bonde	–	Acting Chief Government Chemist
Mr. Talib Mahadhi	–	Pharmacist, Private
Mr. Hamad O. Juma	–	Head, Pollution Control Dept of Environment
Mr. Ali Hassan Suleiman	–	Planning Officer, MOH&SW
Mr. Jaffar Abdullah Mussa	–	Chief Supplies Officer, MOH&SW

Mr. Abdulrazak Juma Fakih deserves special thanks for typing and editing the contents of this work.

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Glossary of Terms

For the purpose of these guidelines, the following definitions may apply:

1. Active ingredient

Is a substance or compound that is intended to be used in the manufacture of pharmaceutical product as therapeutically active compound (ingredient).

2. Chemical decomposition

Is the fragmentation of pharmaceutical wastes into elements or smaller compounds using chemicals in accordance to manufacturer's recommendations followed by a landfill.

3. Container

Is a box, drum or any receptacle, which is to contain pharmaceutical waste to be administered for safe disposal.

4. Engineered landfill

A landfill which have some features to protect from loss of chemicals into the aquifer.

5. Highly Engineered landfill

A properly constructed and operated landfill site which offers a relatively safe disposal route of municipal solid wastes, including pharmaceutical wastes.

6. High temperature incineration

An incinerator which operates at very high temperature, have a long combustion retention times and disperse exhaust gases via a tall chimney, often to high attitudes. e.g. – cement kiln, coal fired thermal power stations and foundries.

7. Label

Any tag, brand, mark, pictorial or other descriptive matter, written, stenciled, marked, embossed or impressed on or attached to a container.

8. Landfill

A place whereby pharmaceutical wastes are directly disposed in a landsite without prior treatment or preparation.

9. manufacturer

Is a person or firm that is engaged in the manufacture of a product.

10. Medium temperature incineration

A two chamber incinerator designed to handle more than1% halogenated compounds and meets strict emission control standards.

11. Pharmaceutical wastes

All Pharmaceuticals expired or not expire with damaged seals or otherwise declared eliminated in the world market which should never be used by human unless otherwise indicated to be used in other institutions.

12. unwanted pharmaceuticals

Pharmaceutical products, whether expired or unexpired, regarded to be not useful or unnecessary for the purpose intended.

13. Waste encapsulation

Immobilizing the pharmaceuticals in a solid block within a plastic or steel drum.

14. Waste Inertization

Is a variant of encapsulation whereby, the packing materials (e.g. papers, cardboard and plastic) are removed from the pharmaceuticals, Pills are removed from their blisters, then the pharmaceuticals are grounded, mixed with water, cement and lime to form paste which is then disposed to a landfill.

List of Abbreviations

DMU	-	Drug Management Unit
DRA	-	Drug Regulatory Authority
INN	-	International Nonproprietary Name
MMH	-	Mnazi Mmoja Hospital
MDTC	-	Ministerial Drug and Therapeutical Committee
NGOs	-	Non Governmental Organizations
NSEL	-	National Standard Equipment List
MOH&SW	-	Ministry of Health and Social Welfare
RGoZ	-	Revolutionary Government of Zanzibar
STGs	-	Standard treatment Guidelines
WHO	-	World Health Organization
ZEML	-	Zanzibar Essential Medicines List
ZFDB	-	Zanzibar Food and Drug Board
ZFDCA	-	Zanzibar Food, Drug and Cosmetics Act
ZMCP	-	Zanzibar Malaria Control Programme
ZNDP	-	Zanzibar National Drug Policy
ZMED	-	Zanzibar Medicines and Equipments Donations

Contents

1.0 Introduction

Like many other developing countries, Zanzibar has been receiving many donations of pharmaceutical products from various donor agencies. In most cases, the donations have been in the form of medicine, medical supplies and equipments that may be released in acute emergencies or as part of government aid in non-emergency situations. The recipients of these donations have been RGoZ, religious organizations, local NGOs and individual health facilities.

Despite of the donors' good intentions, Zanzibar has been experiencing several problems associated with donations. Examples include receiving expired medicines or medicines with short shelf life, medicines which do not comply with the Zanzibar National Drug Policy (ZNDP), Zanzibar Essential Medicine List (ZEML) and Standard Treatment Guidelines (STGs), medicine not relevant for emergence situations, medicine labeled in a language which is not understandable to Zanzibaris, medicine not appropriate for the level of a prescriber at the intended health facility and alike.

In order to alleviate problems associated with the donations and achieve good donation practice, the Ministry of Health and Social Welfare has decided to develop official guidelines based on the existing Zanzibar National Drug Policy, WHO's Guidelines for Drug Donations and Zanzibar Food Drugs and Cosmetics Act (ZFDCA).

1.1 The Need for Guidelines

- Donors intend well, but often do not realize the possible inconveniences and unwanted consequences at the receiving end.
- Zanzibar may need donor support and therefore it is important to specify on what kind of assistance is needed.
- Pharmaceutical products and medical equipment needs may vary from time to time according to existing circumstances. Medicine donation must be based on sound analysis of the need, and their selection and distribution must fit within the existing policies and administrative system of the ministry responsible for health.
- The quality of pharmaceutical products and medical equipments must meet the required standards which need to be certified by the recipient.

- Pharmaceutical products and medical equipments may be harmful if misused; therefore they need to be easily identified through labels and written information. Expiry dates, handling and storage conditions must be specified because medicines may expire and need to be destroyed, an exercise which is costly.

In view of what has been described above, the Ministry of Health and Social Welfare has therefore decided to develop these guidelines to serve the interests of both donors and recipients.

1.2 Aims of the Guidelines

- To create awareness to both donors and recipients on the standards which have to be met on medicine, medical supplies and equipments to be received as donations.

- To promote good pharmaceuticals and medical equipments donation practice.

- To stop importation and minimize the accumulation of unwanted pharmaceutical products, medical supplies and equipments in Zanzibar.

1.3 Core Principles

- Medicine donation should benefit Zanzibar to the maximum extent possible. This implies that all donations should be based on expressed need and that unsolicited medicine donations are to be discouraged.

- A donation should be made with full respect for the wishes and the authority of Zanzibar government and be supportive of the Zanzibar's health policies and administrative arrangements

- There should be no double standards in quality of the donated item; this means if the quality of an item is unacceptable in the donor country it is also unacceptable as a donation to Zanzibar.

- There should be effective communication between the donors and the RGoZ; this means donations should be based on expressed need of the RGoZ and should not be sent without prior consent of the technical authority of the Ministry responsible for Health.

2.0 Guidelines for Medicine and Medical Supplies Donation

2.1 Selection of Medicine and Medical Supplies

i. The Zanzibar Food and Drug Board (ZFDB) is the only responsible body to allow importation of donated medicine and medical supplies to both public and private sectors.

The contact person to be addressed for any information pertaining to sending donations to Zanzibar is:

The Registrar,
Zanzibar Food and Drug Board
P.O. Box 236, ZANZIBAR

Telephone Number: +255-777-414455
Email Address: bsimai@yahoo.com

ii. Donated medicine and medical supplies should be only those, which are indicated in the Zanzibar essential medicine list and relevant to the disease patterns.

iii. Restricted pharmaceutical products such as narcotics must be specifically and separately declared to Zanzibar Food and Drug Board.

iv. Drug samples are not allowed for donation.

v. Large bulk of liquid containers should not be used, they are not suitable for dispensing purposes and they increase the risk of further contamination of the products, because of need for repacking.

vi. The strength and formulation of donated medicine and medical supplies should, as much as possible be similar to those commonly in Zanzibar.

vii. Obsolete pharmaceutical products will never be allowed into the country.

JUSTIFICATION/EXPLANATION

The Ministerial Drug and Therapeutic Committee (MDTC) is the prime responsible body for specifying the needs of medicine and medical supplies to be donated. It has the mandate to prevent unsolicited donations, unannounced donations and unwanted donations.

The provision is intended to ensure medicine and medical supplies donations comply with the National Drug Policy and Zanzibar essential medicine list. It aims at maximizing the positive impact of the donation, prevent the donations of medicine and medical supplies which are unnecessary in Zanzibar.

POSSIBLE EXCEPTIONS

i. In acute emergencies, the need for prior consent by the Revolutionary Government of Zanzibar may be waived, provided the medicine and medical supplies are amongst those from the WHO – Model list of essential medicines that are in the United Nations list of emergency relief.

ii. An exception can be made for medicines and medical supplies needed in sudden outbreaks of uncommon or newly emerging diseases since such medicine and medical supplies may not be approved for use in Zanzibar.

2.3 Quality Assurance of Medicine and Medical Supplies

i. Donated medicine and medical supplies should have a shelf life of not less than twelve months from the date of arrival of the consignment.

ii. Donated medicine and medical supplies must be of good quality and obtained from reliable sources.

iii. WHO Certification Scheme on Quality of Pharmaceutical Products moving in International Commerce should be used wherever possible.

iv. No medicine and medical supplies should be donated if were already dispensed to patients, but were returned to Pharmacies or collected in donor countries for the purpose of donating them to others.

v. Medicine and medical supplies will be subjected to inspection at the port of entry. If these guidelines are not met, the donation will be rejected.

vi. Medicine and medical supplies must be registered by ZFDB.

JUSTIFICATION/EXPLANATION

1. In order to prevent double standards, medicine and medical supplies of unacceptable quality in the donor country should not be donated in Zanzibar. Donated medicine and medical supplies should be authorized for sale in the country of origin and manufactured in accordance with International standards of Good Manufacturing Practice (GMP).

2. Unused medicine and medical supplies which have been returned by patients to the pharmacy in the donor country should not be donated in Zanzibar. In additional to quality issues, returned medicine and medical supplies are very difficult to manage because of broken packages and the small quantities involved.

POSSIBLE EXCEPTIONS

1. In acute emergences, the use of WHO Certification Scheme may not be practical, therefore a justification should be given by the donor country.

2. In acute emergences, short-shelf life medicines less than one year can be donated but prior information and agreement between donor country and RGoZ should be made.

2.4 Information and Management

i. The Ministerial Drug and Therapeutic Committee (MDTC) should be informed of all Public medicine and medical supplies donations that are being considered, prepared or actually under way to be imported in Zanzibar.

ii. The ZFDB should be informed of all private medicine and medical supplies donations that are being considered, prepared or actually under way to be imported in Zanzibar.

iii. MDTC is responsible for informing the drug donors on the quantity required for Public sector in Zanzibar.

iv. The country donating medicine and medical supplies should declare the value of drugs based upon the wholesale price of its generic equivalent in Zanzibar. If such information is not available, the wholesale World market price for its generic equivalence should be applied.

v. Costs of transportation and handling from the donor country to the port of entry should be paid by the donor, unless specifically agreed otherwise with the Revolutionary Government of Zanzibar (RGoZ) in advance.

vi. The permit for importation for medicine and medical supplies will be issued by ZFDB after the donor has submitted a Donation Information Form (see annex 1 for sample of Form).

JUSTIFICATION/EXPLANATION

1. Detailed advance information on all medicine and medical supplies donations must be provided in order to plan for the receipt of the donations and to coordinate the donations with other sources of supply. The information should at least include;

- the type and quantities of donated medicine and medical supplies
- the International Nonproprietary Name (INN) or generic name.
- strength and dosage form
- manufacturing and expiry date
- expected date of arrival and port of entry
- identity and contact address of the donor

2. In order to prevent medicine and medical supplies donations being over valued, price value should be based upon the wholesale price in Zanzibar.

3. The provision that the donor country covers all costs of transport, and handling the medicine and medical supplies could help the RGoZ to spend effort and money in other services.

POSSIBLE EXCEPTIONS

In case of medicine and medical supplies which have no generic equivalent, the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

2.5 Packing and Labelling

i. Donated medicine and medical supplies must be well packed in suitable containers and well labeled in their International non-proprietary names, and labeling must be in English or Swahili.

ii. Packing unit of larger quantity (as per 100 or 1000 units) is preferred for ease transport and use.

iii. Preferably, donated drug should be presented in larger quantity units and hospital packs.

iv. Donated drugs should be packed in accordance with International shipping regulations and be accompanied by a detailed packing list.

The list must specify the contents of each numbered carton by:

- The type and quantities of donated drugs.
- The International Nonproprietary Name (INN) or generic name.
- Strength and dosage form.
- Manufacturing and expiry date.
- Batch number.
- Volume.
- Weight.
- Special storage conditions.

The weight per carton should not exceed 50Kgs and drugs should not be mixed with other supplies in the same carton.

JUSTIFICATION/EXPLANATION

1. Donated drugs should be labeled with their INN or the official generic name; this will help to avoid confusion for health workers. In case of injections, the route of administration must be indicated.

2. The maximum weight of 50Kgs ensures that carton can be handled without special equipment.

2.6 Other Ways Of Medicine And Medical Supplies Donations

The new emergency health kit.
In the acute phase of an emergency, it is better to send a standardized kit of drugs and medical supplies which is specifically designed for this purpose.

A financial contribution should be considered instead of a drug donation since it may be cheaper to buy the drugs locally.

A technical support to ensure that victims receive effective services.

2.7 Implementation and Management of Medicine and Medical Supplies Donations in Zanzibar

The two governing boards for importation of medicine and medical supplies donations in Zanzibar are;

i. MDTC
ii. ZFDB

Responsibilities of MDTC are:

i. To define and prioritize the needs of medicine and medical supplies donations for Public sector.

ii. To communicate with donors on the quantity and quality of medicine and medical supplies donations before importation.

iii. To prevent unsolicited, unannounced and unwanted donations to enter in the country.

Responsibilities of ZFDB are:

- The MDTC is responsible for defining and prioritizing the needs. The Drug Management Unit is responsible for coordinating all PD. The documents which are needed when a donation is planned include ZNDP, STGs, ZEML, ZMED and ZFDCA. The donation will be received by the MOHSW.

- When for good reasons medicine and medical supplies donations do not fulfill guidelines, an advance communication should be made prior to the arrival of the donation. Information must specify:

  - the aim of the donations
  - contents of the donations

Inspection of the donated pharmaceutical products will be made by the ZFDB.

- The ZFDB will accept the donated pharmaceutical products if standards are attained according to the guidelines.
- In case the standards of donation guidelines are not met, the ZFDB will reject the pharmaceutical products.
- Once the pharmaceutical products have arrived, the Central Medical Store will coordinate reception, storage and distribution.
- Donated pharmaceutical products will be recorded into CMS's ledger and reported accordingly.
- In case inappropriate donated pharmaceutical products have been identified, the ZFDB and the environmental department will coordinate a safe disposal under the donors' cost.

3.0 Guidelines for Medical Equipment Donations

These guidelines are intended to be used for those accepting and making donations on medical equipment.

Donations of equipment are made as a result of;

- A genuine desire to help.
- A response to a request by recipient.
- A desire to utilize functional equipment not necessarily required by donor.
- A need for financial gain.

However problems arise when;

- Donors of medical equipment may have no background in health issues, or an understanding of the structure of health service of the recipient.
- New but inappropriate equipment is donated as a means of promoting and marketing.
- Companies, hospitals or private doctors donate out-modeled, outdated equipment as it provides them with tax exemptions or as a means of getting rid of redundant equipment.
- Potential donors with patronizing attitudes towards recipients regard them as beggars desperate for any equipment and therefore don't consider it worthwhile to consult them.

The recipient may compound this problem by feeling obliged to accept any donation, even though the equipment is unnecessary, or where charges such as import taxes and transport costs, are prohibitive.

3.1 Rationale

Although donations of equipment and materials may improve the efficiency of health facilities, experience has shown that equipment donation may cause the recipient more problems than benefit. That is why the Revolutionary Government of Zanzibar (RGoZ) has developed these guidelines which should be followed by donors. The RGoZ will define the equipment requirements which would be shown to donors who should respect them. Before a donation agreement is settled, donors and RGoZ should make a thorough evaluation of the requirements of both parties. The final choice of equipment will be limited by cost, environmental and operational conditions, the availability of spare parts and the quality of maintenance services.

What can be done?

- The donor and the recipient should communicate as equal partners to workout how the effort and goodwill involved in making donations can be put to best use.
- MDTC to coordinate all equipment donations.

3.2 Responsibilities of Recipients in Zanzibar

3.2.1 To select and Standardize equipment

Equipping a medical unit is more than simply obtaining the equipment. Maintenance is vital, and maintaining a vast array of different equipment can be problematic.

The MDTC shall select and standardize the equipment to be used in Zanzibar based on the available National Standard Equipment List. The list will be reviewed periodically. Before making any request, the institution should first check whether the equipment requested is on the National Standard Equipment List (NSEL)

This list is useful because;

a) Equipment included in the list can be fully supported in terms of spare parts, maintenance and operation instructions.

b) Installation and operation arrangements for users and maintenance procedures for technical personnel are simplified.

c) Lower prices due to bulk purchasing are possible, and planning for storage space is easier.

Important issues to consider with regard to standardization include:

MDTC should consider the following when standardizing the NSEL: -

- Staff experience and training required for installation, operation and maintenance. Consider both the clinical staff and the technical service staff required to operate the equipment.
- Location for the equipment including site accessibility and space available.
- Climatic and environmental conditions, such as heat (temperature), humidity, dust, ventilation, etc.
- Utilities: power supply (electric, generator, etc), reliability of supplies (fluctuating power, interruptions, rationing, etc), type of power (voltage, frequency, phase, AC/DC); type of water (polluted, salty, hard, soft, etc.) and the means of delivery (piped, stored, etc).
- Support services required for operation, procedures, and clinical use of the equipment.

- Maintenance costs in terms of spare parts, downtime during normal servicing and level of expertise of technical staff required.

- Availability of consumables; some equipment may require consumables which are not available locally, for example, special papers, films, filters, etc. these are recurrent costs items and their availability must be assured.

- Other specific requirements related to the equipment. For example whether a new addition will conform to existing equipment, whether a cold room is required for computerized equipment, or especially solid walls for x-ray machines, or a boiler for autoclaves, or power stabilizers for electronic equipment etc.

- Experience of others with similar equipment, brands or sources. Check whether equipment is manufactured locally or imported on a regular basis.

This list may not be exhaustive. It aims at providing criteria to help define equipment that is technologically and clinically appropriate to the use in Zanzibar. By following this list, the final choice of equipment is likely to be of high quality, solid and robust and of a standard that will withstand both environmental and operational conditions in Zanzibar.

3.2.2 Involve technical department

In preparing the equipment request, the technical personnel must be involved. As experts, they will consider and advise upon:

- All aspects of the requirements for installation, operation, and maintenance
- Essential spare parts and other special requirements, their availability, and costs
- Availability of technical personnel and level of training required.
- Estimated lifespan of the equipment based on the model, year of manufacture and whether it is new or reconditioned.
- Appropriateness of equipment in terms of running costs and design.
- If a financial contribution would be more appropriate than a donation of equipment.

The request list must be approved by the MDTC.

3.2.3 Specify clearly items to accompany the equipment.

- All equipment must be provided with a full set of technical documents. That is, documentation for installation, for user operation, for repair and maintenance (manuals), a list of spare parts and diagrams and technical data should be available. These documents should be in English or Swahili.

- All equipment must be accompanied by a reasonable quantity of spare parts and consumable items. This should take into account the "lead period" (i.e. period between placing an order and receipt of spare parts). A legal expert should assist in reading and interpreting the conditions if necessary.

3.2.4 Make a check-list

The recipient shall compile a checklist which will include consideration of all issues discussed above. This ensures that the donor receives all the information required in order to make an appropriate donation. (See annex 2).

3.2.5 Communicate alternative preferences

If a financial donation to allow local purchase would be more appropriate and convenient, the recipient should state this information clearly. Issues on which the donor is unable to comply can then be discussed.

The solution should be understood and agreed upon by both parties. As a result, the donors will not substitute items believing that such alternatives would be equally suitable.

3.3 Donor Responsibilities

Donated equipment will only be useful if it is properly installed, operated, maintained, and appropriately used.

The donors have the following responsibilities to ensure donated equipment properly operates: -

- Communicate with the recipient

  Before supplying any equipment, the donor must request for a comprehensive description of the equipment required by the recipient (including their checklist). Ensure that the conditions that cannot be fulfilled are communicated to the recipient. An agreement on all conditions should be reached before shipping the equipment.

- Understand relevant regulations.

  Donors should understand and follow the existing relevant laws, regulations, and policies of Zanzibar with respect to importation and donation of Medical Equipment

- Supply fully functional equipment

  Equipment whether new or reconditioned, should be tested and all essential parts, accessories and working materials included before shipment. A basic list of all components must be provided to the recipient. Second-hand equipment should be fully rebuilt or reconditioned. It should be established that the manufacturer continues to produce spare parts, and the "life expectancy" of the equipment should be indicated.

Old, broken, outmoded, and redundant equipment for which spare parts and consumables are no longer available, or equipment which is no longer supported by the manufacturer, will not be accepted.

- Supply all technical documents

These include all installation, operation, maintenance, repair manuals and technical diagrams. The technical documents should be supplied in English and/or Kiswahili language. The need for these documents applies even when expatriate staffs are provided to help in the initial stages.

- Supply an initial requirement of consumables and spare parts

Equipment should be supplied with an initial consignment of consumables and spare parts expected to last at least three years, and a full list of spare parts. The list must clearly indicate the part name and number, and full name and address (including phone, fax number and e-mail address, if possible) of the manufacturer or authorized dealer.

- Ensure proper packaging and shipment

The consignment is likely to endure long periods in ships, trains and motor vehicle. The packaging must be strong and sturdy to withstand rough handling and to minimize damage during transportation. It should also;

- include a clear packing list identifying all components
- be of a size that can be handled using simple mechanical devices and manual labour.

- Supply shipping documents promptly

Prompt submission of shipping documents is essential and should be sent by express mail. If possible, send advance copies by fax.

- Offer technical assistance

Where possible, promote, recommend and provide training for the use and maintenance of the equipment. (If possible on-site)

- Compliance with electrical supply system

The donor should ensure that electric equipment comply with Zanzibar electrical supply system.

- Cost of donation

Ensure all cost of donation (freight, taxes, insurance, clearance and forwarding, etc.) is the responsibility of donors unless otherwise compromised by both parties.

3.4 Criteria for Accepting Donation of Medical Equipment

1) Usefulness,

2) Quality and safety,

3) Preferably current and popular model,

4) Economically in terms of running costs,

5) There should be a need of that equipment,

6) Should fulfill all conditions for donation mentioned in Zanzibar Guideline for Medicines, Medical supplies and Medical equipment Donations.

3.5 Criteria for Rejection of Donation

Any donation, which does not follow the above, mentioned criteria will be rejected.

Procedures for rejected donation:

a) Before arrival:

- If guidelines are not followed, donor should stop exporting procedures of the donation.
- There could be some negotiations of looking for alternatives.

b) After arrival:

- Immediate return at donor's cost.

4.0 Guidelines for Safe Disposal of Unwanted pharmaceutical

Disposal of unwanted or expired medicine and medical equipments is necessary in order to ensure that all pharmaceutical waste is safely disposed of. This aims at preventing accumulation of pharmaceutical waste which could lead to other major problems to human as well as to the environment.

There several factors which can contribute accumulation of pharmaceutical waste:

- Poor infrastructure leading to poor transportation system.
- Poor storage conditions
- Expiration due to drop of acute emergencies which could lead to low utilization of drugs
- Unplanned drug donations.
- Inadequate quantification etc

Donations are usually provided as part of humanitarian assistance to save lives and alleviate suffering. Some donations were given with good intentions but due to lack of proper communication between donors and recipient, such donations may cause problems.

Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs, unrecognizable because they are labeled in a foreign language or may have been sent in unwanted quantities. Donations with long shelf life may be mismanaged, particularly in the confusion during and after armed conflict or a natural disaster. Staff and storage space may be lacking and pharmaceutical management system in disarray. Smaller quantities of pharmaceutical waste may accumulate due to inadequacies in stock management and distribution, and due to lack of routine system of disposal. Safe disposal of these unwanted or expired drugs often creates a major problem.

In 1984 Zanzibar Government revealed the existence of various forms of chemical wastes in various parts of the islands.These included agro-chemicals, pharmaceuticals, and industrial chemicals as well as laboratory reagents. Most of these chemical wastes were brought in the country in the form of donations by different donors.

The chemicals posed a big threat to the environment and human lives as well.These chemicals became obsolete because:-

- They were brought in the country without prior consultations with the government technical authorities.

- Some of them were not correctly labeled and with no proper instruction for use.
- Some of the chemicals were not even relevant for their use in Zanzibar.

An inventory of all the chemicals including pharmaceuticals was made and a special task force was formed to advise the government on proper disposal system. Many donors were approached to provide financial assistance for the disposal but the response was until 1995 when the Netherlands government offered 1.5 million USD for the whole exercise which involved repacking, recollection in special centers and finally to remove the chemicals including pharmaceuticals to be incinerated in the UK. Rechem Company was contracted to do the job and 400 tons were removed in 1995. But after all those effort of removing the chemical waste the current situation show that there are more than 12 metric tones of pharmaceutical wastes accumulated since 1995 in the Ministry of Health alone waiting for disposal.

Due to this very detrimental environmental hazard experienced during this period by Zanzibar islands, with very sensitive and fragile ecosystem the Ministry of Health and Social Welfare in collaboration with WHO decided to develop these official and very comprehensive guidelines based on the National Drug Policy, WHO guidelines and the Zanzibar Food, Drugs and Cosmetics Act No 2/2006.

Therefore these guidelines give appropriate measures of safe disposal to minimize the risks that could happen due to pharmaceutical waste.

Prevention of waste from pharmaceutical donations

Donor must adhere to the Zanzibar medicine, medical supplies and medical equipment donation guidelines so that donations will address the expressed needs of the Zanzibar and that the date of expiry should not be less than one year unless there is a clear evidence from Zanzibar that there is clear logistics and managerial capacity to store and distribute shorter dated drugs efficiently.

The cost of disposal of waste pharmaceuticals

Pharmaceuticals are ideally disposed of by high temperatures (i.e. above 1200^{o}C) incineration. Such incineration facilities, equipped with adequate emission control, are mainly found in industrialized world. The costs for such disposal in Zanzibar have not yet been determined.

4.1 Purpose of the guidelines

These guidelines are meant to provide guidance on the recommended method of destruction of pharmaceutical waste.

A number of methods for safe disposal of pharmaceutical waste are described in this document and involve those with minimal risks to public health and the environment taking into consideration the limited resources and equipment available.

The adoption of these guidelines by the ministry of health and social welfare, ministry responsible for environment and other relevant ministries, and their practical application, will contribute to the safe and economical elimination of stock piles of unusable pharmaceuticals in Zanzibar.

The best environmental option for pharmaceutical waste destruction is to use high temperature incineration with adequate flue gas cleaning. However, this is not the only method that can be used to achieve adequate disposal. In deed many countries including Zanzibar do not possess such facilities. It is for this reason that these guidelines are developed as a practical alternative to be applied for safe disposal of unwanted pharmaceuticals in Zanzibar.

4.2 What the guidelines do not cover

These guidelines do not cover the management of other waste generated by health institutions e.g. infectious waste, photographic chemicals, solvents, waste with high contents of heavy metals (e.g. mercury and cadmium), chemical laboratory waste and radioactive waste.

4.2.1 Steps to be taken

A number of steps need to be taken when disposing of unwanted pharmaceuticals and they are briefly summarized below:

- Decision

  The pharmaceutical personnel in a health facility or organization with pharmaceutical programs shall decide when action needs to be taken, because of accumulation of unwanted pharmaceuticals which are unfit for human consumption. This also applies for veterinary products. A list of all the pharmaceuticals which need to be disposed of should be prepared and submitted to the DRA for approval.

- Approval

  In the public sector, the pharmaceuticals to be disposed of will be written off, by the stock verification committee. Approval and sanctioning of disposal of pharmaceuticals for both public and private sectors must be sought from the Drug Regulatory Authority (DRA) which then communicates with the ministry responsible for environment for disposal.

- Planning

  Planning, in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal option will be required. This will be done in collaboration between the drug regulatory authority and the ministry responsible for environment and any other relevant institutions.

- Work team

  The work of disposal will be conducted by a team consisting of a supervising pharmacist, personnel from the ministry responsible for environment, general medical workers preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel, the owner of the pharmaceuticals to be disposed (private sector) and any other personnel who may be needed for the completion of the task.

  - The size of the team, and the ratio of experts to workers, will be determined by the volume and composition of the stockpiles, and working conditions at the sites.

  Health and safety of work team

  Workers should be provided with appropriate equipment including washable overalls, tough boots, gloves, safety glasses, masks and caps. The disposable protective gear should be disposed appropriately where as the reusable should be washed and safely kept. Particular care should be taken when handling antineoplastics.

- Sorting

  The objective of sorting is to separate pharmaceuticals into different categories for which different disposal methods are required. Each health facility should identify and separate pharmaceutical waste according the appropriate disposal methods recommended in these guidelines.

- Disposal

  Disposal options vary considerably between situation, and the ideal solution may not be feasible. The aim of these guidelines is to propose the simplest, safest and most practical alternatives.

- Security

  Controlled substances (e.g. narcotics, psychotropics and precursor chemicals) require tight security and control. Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from landfills. Immobilization is the best method of preventing pilfering from a store or landfill. If as a last resort, pharmaceuticals must be discarded direct to the landfill then they must be covered immediately with a large quantity of municipal waste.

4.3 Consequences of improper disposal or non-disposal of pharmaceuticals

Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby community. Expired drugs may come into the hands of scavengers and children if landfill is insecure. Pilfering from a stockpile of waste drugs or during sorting may results in expired drugs being diverted to the market for resale and misused.

Most expired pharmaceuticals become less efficacious and a few may develop a different adverse drug reaction profile. There are some categories of expired drugs their disposal practices may carry a public health risk.

The main health risks and their respective precaution measures are summarized bellow:-

- Contamination of drinking water might occur. Therefore landfill must be sited and constructed in a way that minimizes the possibility of leachate entering an aquifer, surface water or drinking water system.

- Bacteria necessary for the treatment of sewage may be killed by non-biodegradable antibiotics, antineoplastics and disinfectants if disposed of into sewage system. Also antineoplastics may damage aquatic life. Similarly large quantity of disinfectant may impair ecosystem if large quantities are discharged into a sewage system or watercourse. Therefore antineoplastics should not be disposed of into sewer system and disinfectant must be well diluted before they are introduced into the sewer system.

- Release of toxic pollutants into the air may occur by burning pharmaceuticals at low temperatures or in open container. Therefore this should be avoided.

- Drugs beyond their expiry dates may be diverted for resale to the general public by inefficient, insecure sorting and unsafe disposal. Also scavenging in unprotected, insecure landfills may result in causing health hazard. Therefore efficient, secure sorting and safe disposal should be properly performed and landfills must be properly secured.

- Expired pharmaceuticals waiting for the disposal may pose a risk of diversion if stored in the original packing. Therefore they must be securely stored in appropriate containers preferable in drums with pharmaceutical immobilization.

4.4 Public information

The public should be informed about the problem of safe disposal of expired pharmaceuticals. Key points to present to the media are:-

- The vast majority of pharmaceuticals are donated with the intention to help; there are only rare occurrences of " dumping" by unscrupulous companies to gain tax relief or off-load unwanted stock;

- When pharmaceutical pass their expiry date they do not automatically become hazardous, they simply become less efficacious.

- Most pharmaceuticals are relatively harmless to the environment, they do not present a serious threat to the public or environment unless handled recklessly.

- Applying safe disposal methods can minimize the risk from disposal of pharmaceutical waste.

- Pharmaceutical disposal should be undertaken at minimum financial cost and with minimum risk to public health and the environment considering the local circumstances.

- Disposal of pharmaceuticals should be carried out under the supervision of DRA, who organize it according to strict criteria; individuals must not carry it out.

Information on pharmaceutical disposal must be carefully handled as it may be politicized and sensationalized. If the public and media are not kept judiciously informed of the efforts to dispose of expired pharmaceuticals safely, the disposal work might be severely hampered by misinformation propagated by uninformed journalists and politicians. Good public relations, including comprehensive dissemination of information, are, therefore, an important element in achieving satisfactory safe disposal.

5.0 Methods of Disposing Pharmaceutical Wastes

There are two major categories of unwanted pharmaceuticals for disposal:

5.1 Medicine, Medical supplies and Medical equipments still at the port of entry.

- All products arrived without complying with guidelines for donations, after rejection, should be immediately returned to the donor country under their costs.

Justification/Explanation

- Donated medicine and medical equipments which were declared or specified by the donors to be fulfilling all guidelines and still at the port of entry, which have been confirmed to be of poor quality, will automatically be rejected and subsequently be immediately returned to the donor country under their costs.

- All donated medicines and medical equipments that exceeded the amount as specified in the needs or prioritizations by the MDTC/ZFDB will be rejected.

These above provisions are to ensure that unsolicited, unannounced and unwanted donations are not disposed in Zanzibar.

5.2 Medicine, Medical supplies and Medical equipment which have already entered in Zanzibar

These are all products already in circulations system within Zanzibar. However, for one reason or another have expired, or damaged during transportation or eliminated in the world market, they will be considered as Pharmaceutical wastes.

Pharmaceutical wastes include:

- All expired pharmaceuticals.
- All unsealed syrups or eye drops (expired or unexpired).
- All cold chain damaged unexpired pharmaceuticals (e.g. Insulin, gamma globulins and vaccines).
- Loose tablets and capsules whose original packaging is broken.
- All unsealed tubes of creams, ointments etc (expired or unexpired).

6.0 Sorting of Pharmaceuticals Wastes

This is a process of identifying and separating all pharmaceutical wastes for safe disposal. Sorting should start immediately after collection of all pharmaceutical wastes identified from different premises.

The objective of sorting:

To separate pharmaceutical wastes into categories that requires different disposal methods. All pharmaceutical wastes have to be segregated temporarily in storage areas or containers for each sorted categories.

6.1 Points to be considered During Sorting Process

- A thoroughly overall evaluation of stockpile and subsequent division of pharmaceuticals into those suitable for use and those to be discarded should be conducted in selected premises.
- All pharmaceutical wastes to be discarded should be separated from their packing as late in the process as possible, except those which are not allowed to be separated from their packing for disposal e.g. antineoplastics (i.e. should be disposed with their packing).
- All pharmaceutical wastes found to be suitable for use should remain in their packing and should be stored in safe storage conditions.

6.2 Stage in Process of Sorting

- Identifying the item.
- Making a decision on whether it is usable.
- If usable, leave package and boxes intact and store in good condition then a decision on whether to distribute to other institution for use.
- If NOT usable, separating their packing prior to definitive disposal.
- If NOT usable, making a judgment on the optimal method of disposal and sorting accordingly.

6.3 Optimum Conditions for Sorting

- Sorting should be done in the open air or a well ventilated and covered structure in a designated area.
- Sorting should be done as close as possible to the stockpile with all sorted material clearly labeled and separated at all times.
- Personnel who work with sorting process must wear protective equipments such as gloves, boots, overalls, safety glasses and masks etc.
- Personnel must be trained on sorting criteria, safety and risks associated with handling materials.
- A pharmacist must supervise all sorting process.

Once pharmaceutical wastes have been sorted out, they should be packed carefully in appropriate containers such as sturdy cardboard boxes, with the contents clearly marked on the outside of the container. These materials should be kept in a dry secure and preferably separate room to avoid being confused with products still in use, until disposal is carried out.

6.4 Sorting Categories

The top priority of sorting process should be to separate out all pharmaceutical wastes categorized as Controlled substances, {e.g. narcotics, antineoplastics, any other hazardous non-pharmaceutical products etc}. These must all be stored in separate, secure designated areas prior to their safe disposal.

The remaining unwanted pharmaceuticals must be further sorted into different categories by Dosage form {e.g. capsules, powder, solutions, suppositories, syrups, tablets etc}.

The following categories and subcategories are suggested: -

A. Pharmaceuticals and other materials which can still be used.

A lager proportion of the volume of a typical stockpile of waste drugs is not occupied by the pharmaceutical themselves, but rather by other items (non-pharmaceuticals). Therefore, the first step is to remove and dispose non-drug, non-chemical items. All such items should be clearly separated from pharmaceuticals and chemicals.

Non-pharmaceutical useful materials

Such as medical equipments, beds, wheelchairs, dressing, clothing, laboratory glassware etc.

These can either:
- Be utilized by other institution or by other facilities.
- Recycled
- Cannibalized for spare parts or disposed to a landfill.

Useful Pharmaceuticals

If feasible, pharmaceuticals within expiry date and useful should be separated out and immediately used by the institution or reallocated according to the needs as instructed by the DMU. All necessary details of information must be produced and circulated to others who can use the materials. (e.g. type of the item available, quantity and expiry date).

Chemicals

Acids, alkalis, reagents, phenols-based chemicals used for cleaning floors, disinfectants etc can be put into good use. If large quantities of these items are found, a list may be prepared and detailed information circulated to other potential users.

B. Expired or unwanted pharmaceuticals

These should never be used and should always be considered as pharmaceutical wastes.

Special disposal method is needed for the following:-

- Controlled substances such as narcotics, psychotropic substances etc
- Anti-infective substances
- Antineoplastics
- Antiseptics and disinfectants

All other pharmaceuticals

- **Solids, semi-solids and powders**
  e.g. tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories etc.

- **Liquids**
  e.g. solutions, suspensions, syrups etc.

- **Aerosol canisters**
  e.g. Propellant-driven sprays and inhalers.

Hazardous or potentially hazardous non-pharmaceutical materials
All non-pharmaceuticals, potentially dangerous waste such as chemicals, cleaning solutions, batteries and waste oil must be dealt with on a case-by-case basis by hazardous waste expert. Pharmaceutical team must collaborate with hazardous waste expert for safe disposal of such waste.

The waste requires separate and careful labeling and storage until disposal

Recyclable materials

Recycling is recommended for some kind of materials which can be recycled if facilities are available.

Depending on the type of material and its proposed reuse, appropriate treatment, such as cleaning or disinfection must be done.

The kind of materials to be recycled includes:

- Waste paper, cloth, packing materials, glass bottles and wood materials etc.
- Materials which are not recyclable should be burnt or disposed of as normal waste to a landfill.
- Materials to be recycled must be separated from those which are to be disposed of.

7.0 Types of Disposal Methods

7.1 Return to donor or manufacturers.

Zanzibar lacks special facilities for destruction and disposal of pharmaceutical wastes. The option of returning of unwanted pharmaceutical wastes should be explored in col laboration with the donor or manufacturer.

Wherever practical, all unwanted pharmaceuticals especially those which arrive past or unreasonably near their expiry date shall be returned to the donor or importer for disposal at their own costs.

7.2 Landfill

Despite being the oldest method of disposing of solid pharmaceutical wastes, this method could be applied wherever possible with the conditions that all unwanted pharmaceuticals are first treated before disposal to minimize environmental pollution.

Types of Landfill which can be applied for safe disposal of Pharmaceutical waste.

a. Engineered landfill

This method can be applied if all conditions to prevent penetration of chemicals into water sources are guaranteed. Pharmaceutical wastes must be treated before disposal.

b. Highly engineered sanitary landfill

This method can be applied provided the landsite is properly constructed and managed. The top priority is to protect water sources. Upgrading an uncontrolled wastes disposal to a reasonable standard should be considered. An appropriate (concrete pit) landfill consists of an evacuated pit isolated from water sources and above the water table. Each day's solid waste is compacted and covered with soil to maintain sanitary conditions.

7.3 Waste immobilization:

a. Encapsulation

This method involves immobilization of pharmaceutical waste into a solid block within a container. A container should be cleaned prior to use and should not contain explosive or hazardous materials previously.

The container should be filled up to 75% capacity with solid and semi-solid pharmaceutical waste, pouring in medium cement, lime mixture, plastic form or bituminous sand and water should fill the remaining space.

The mixture of lime, cement and water should be in proportions of 15:15:5 (by weight), then the container if filled with water to capacity.

A lager quantity of water may be required sometimes to attain the satisfactory liquid consistency.

For disposal, a sealed container should be placed at the base of a landfill and covered by municipal solid waste.

Encapsulation of antineoplastics requires a slightly different technique.

b. Inertization

This is another variant of encapsulation and involves the removing of the packing materials, paper, cardboard and plastic from their pharmaceuticals. Pills need to be removed from their blister packs.

The pharmaceuticals are then grounded and mixed with water, cement and lime to form homogeneous paste. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer and supplies of cement, lime and water.

The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted in the normal urban waste.

This is one of the relatively inexpensive process which can be carried out with unsophiscated equipment.

The approximate ratios by weight used are as follows:

- Pharmaceutical waste 65%
- Lime 15%
- Cement 5%
- Water 5%

  or more to form a liquid consistency.

7.4 Sewer

This method can be applied to some pharmaceuticals e.g. syrups and intravenous (IV) fluids.

The fluids can be diluted with water and flushed into a sewer in small quantities over a period of time without a serious public health or environmental effects.

Small quantities of well-diluted liquid pharmaceuticals or antiseptics can be flushed in fast flowing watercourses.

7.5 Burning in open containers

Papers and cardboard packing which are not recyclable may be burnt at high temperature in open containers.

However, this method should be applied to dispose only very small quantities of pharmaceutical waste.

Polyvinyl chloride (PVC) plastic must not be burnt.

7.6 Medium temperature incineration

The medium temperature incinerators can be used to treat pharmaceutical waste at a medium temperature of 850^{0}C with combustion retention time of at least two seconds in to the second chamber. The chimney of the incinerator should not be less than 10 metres high. It is recommended to dilute pharmaceutical waste with large quantities of municipal waste (approximately 1:1000).

Such incinerators are not designed to incinerate halogenated compounds safely.

7.7 High temperature incineration

Currently, in Zanzibar, there are no high temperature incinerators (Two chamber incinerators) such as cement kilns, coal fired thermal power stations or foundries operating at temperature exceeding 850^{0}C.

The incinerators have long combustion retention and disperse exhaust gases via tall chimneys, often to high altitudes.

Cement kiln can be particular suitable for disposal of expired pharmaceutical waste .The process involves introducing pharmaceutical waste into a furnace as reasonably small proportions of the total fuel feed.

It is suggested that not more than 5% of the fuel fed into the furnace at any one time. It is necessary to remove packing materials and to grind the pharmaceuticals to avoid clogging and blocking the fuel feed mechanisms.

This kind of incinerator can be used for disposal of halogenated compounds such as x-rays contrast media and povidone iodine.

7.8 Chemical decomposition

This method can be applied as an alternative if an appropriate incinerator is not available. There should be chemical expertise to provide technical assistance.

The process is tedious and time consuming and stock of chemical used must be available all times.

However, for disposal of small quantities of antineoplastics (not more than 50 Kg), this method may be practical.

8.0 Recommended Disposal Methods

8.1 Solids, semisolids and powders

Anti-infective drugs, controlled drugs and antineoplastics

When unwanted pharmaceuticals of above category need to be disposed of, the following disposal methods are recommended: -

- Return to the manufacturer;
- Incineration using medium and high temperature
- Encapsulation or inertization followed by discharge to a landfill.

If it is not possible to return these to the manufacturer, or adequate incineration is unavailable, then Encapsulation or inertization method is recommended.

Anti-infective drugs and antineoplastics should be encapsulated to delay release to the environment and avoid high concentration.

Controlled drugs should be immobilized under supervision of Drug Regulatory Authority.

8.2 Other drugs

Small quantities of solid and semi-solid unwanted pharmaceuticals can be disposed of by suitable and adequate method available. If such adequate facilities are not in place, quantities which are not more than 1% of the total daily wastes can be disposed of directly in landfill with large volume of municipal solid wastes.

In situations where the stockpile is large, then 5-10% of the total daily municipal waste would be an acceptable daily disposal figure, where municipal waste disposal would be more than 50 metric tones per day. Such disposal should be for a fixed period of time, and the landfill should be managed.

Destruction by high temperature incineration is highly recommended for large quantities of solid and semi-solid unwanted pharmaceuticals. Medium temperature incineration can be practiced for solid form of unwanted pharmaceutical, provided that the bulk is first diluted in large quantities of municipal wastes.

Procedure for disposal

Solids, semi-solids and powders should be removed from their outer packaging but remain in their inner packaging and placed in clean plastic or steel drums, for treatment according to the encapsulation method. Removing outer packaging dramatically reduces the volume for disposal for methods such as encapsulation. Small quantities of pharmaceuticals still within their packaging may be discharged into a landfill as described above. They should be immediately covered with municipal waste. Outer packaging should be disposed of as non-drug, non-chemical materials by recycling or burning.

The separation of materials should be as follows:

- Tablets and capsules in plastic/foil blisters should be removed all outer packaging but not from blisters;
- Tablets and capsules in bottles should be removed from outer packaging but not bottles;
- Tablets and effervescent in tubes should be removed from outer packaging but not from tubes;
- Powders in sachets or bottles should be removed from outer packaging but not from sachets or bottles.

Any large quantities of a single type of drug should be checked by the supervising Pharmacist to ensure that the drug is not an anti-infective drug, antineoplastics or controlled substance. If the drug is an anti-neoplastic, it should be treated according to the procedures for antineoplastics. Controlled substances should be treated with normal solids, but with supervision according to Zanzibar laws and the Act governing controlled substances.Very large quantities of loose tablets should be mixed with other medicines in several different steel drums to avoid very high concentrations of single drug in any one drum.

8.3 Liquids

Pharmaceuticals with no or low toxicity

Pharmaceuticals that can be classified as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers.

Other liquid pharmaceuticals (except controlled drugs, antineoplastics or anti-infective drugs)

Small quantities of other liquid pharmaceuticals, which are not controlled substances, anti-infective drugs, or antineoplastics, can be flushed into sewers. If there are no sewers or

there is no functioning sewage treatment plant, liquid pharmaceuticals can be first diluted with large volumes of water and poured into large watercourses, provided they are immediately dispersed and diluted by flowing water.

Liquid pharmaceuticals waste may be disposed of using the cement encapsulation procedure.

It is not acceptable to discharge liquid pharmaceuticals, diluted or not, into slow moving or stagnant surface waters.

8.4 Ampoules

These can be crushed on a hard impermeable surface (e.g. concrete) or in metal drum or bucket using a stout block of wood or a hammer. Workers doing this should wear protective equipment, such as eye protection, boots, clothing and gloves. The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill.

Ampoules should not be burnt or incinerated as they will explode, possibly furnace or incinerator may be damaged. Melted glass will also clog up the grate of a furnace if the operating temperature is above the melting point of glass.

8.5 Anti- infective drugs

Anti-infective drugs should not be discarded in an untreated form. Generally they are unstable and are best incinerated, and if that is not possible, encapsulated or inertized. Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.

8.6 Controlled substances

Controlled substances must be destroyed under supervision of Drug Regulatory Authority. Such substances must not be allowed into the public domain as they may be abused. They should be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

8.7 Antineoplastics

Antineoplastics drug waste, previously called cytotoxics or anti-cancer drugs, have the ability to kill or stop the living cells. They are used in the chemotherapy of cancer which is usually performed in the specialized treatment centers. It is extremely unlikely that they would form part of an aid donation in emergencies. However, if unwanted and discharged into the environment they can have very serious effects, such as interfering with reproductive processes in various life forms. Their disposal must therefore be handled with care.

Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. They should ideally be safely packaged and returned the supplier for disposal.

Antineoplastics waste should never be disposed of in a landfill unless encapsulation or inertization has been done. Work team handling these drugs must avoid crushing cartons or removing the product from its packages. They may only be discharged in a sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.

8.8 Special treatment for antineoplastics

For antineoplastics drums 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 drums filled to capacity. A larger quantity of water may be required sometimes to attain satisfactory liquid consistency. The drums should then be sealed by seam or spot welding and set for 7 to 28 days. This will form a firm, immobile, solid block in which the waters 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.

Table 1. Antineoplastics drug disposal

Methods of disposal:	1. Return to supplier/donor; 2. High temperature incineration; 3. Waste encapsulation'
Methods of disposal of antineoplastics **not** to be used	1. Low and medium temperature incineration; 2. Disposal to sewers and water courses; 3. Directly to landfill.

8.9 Disinfectants

In general disinfectants do not have an expiry date. They can be stored and gradually used over time so there is no real need to dispose of them. 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 water courses since the disinfectants will damage aquatic life. Small quantities f diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits. Control proposed volume is 50 litres per day, with the disposal spread over the whole working day.

If possible, disinfectants should be used, foe example for toilet cleaning in hospitals. Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an expiry date. If this date has past, the material can still be used for general disinfectant purposes at an appropriate dilution decided by a pharmacist.

The World Health Organization (WHO) publishes chemical safety sheet for common disinfectants and pesticides. The sheet provides data on the chemical composition of the substance and indicates suitable methods of disposal. Such sheets may be obtained from WHO.

8.10 Aerosol canisters

Disposal aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/ or damage to the furnace or wastes.

Table 2: Summary of pharmaceutical categories and disposal methods

Categories	Disposal methods	Comments
Solids, semisolids and powders	✓ Engineered landfill ✓ Waste encapsulation ✓ Waste inertization ✓ Medium & high temperature incineration (Cement kiln incinerator) minimum temp. 850^{0}C.	- Not more than 1% of the municipal waste should be disposed daily in an untreated form (non-immobilized) to a landfill. - antineoplastics best incinerated at high temperatures
* untreated solids	* highly engineered sanitary landfill	
Liquids	✓ Sewer ✓ High temperature incinerator (cement kiln incinerator).	Antineoplastics not to sewer.
Ampoules	✓ Crush ampoules and flash diluted fluids to sewer.	Antineoplastics not to sewer.
Anti-infective drugs	✓ Waste encapsulation ✓ Waste inertization ✓ Medium & high temperature incineration (Cement kiln incinerator).	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer.
Antineoplastics	✓ Return to the donor or manufacturer. ✓ Waste encapsulation ✓ Waste inertization ✓ Medium & high temperature incineration ✓ (Cement kiln incinerator, chemical decomposition).	- Not to landfill unless encapsulated. - Not to sewer. - No medium temperature incinerator.
Controlled drugs	✓ Waste encapsulation ✓ Waste inertization ✓ Medium & high temperature incineration (Cement kiln incinerator)	- Not to landfill unless encapsulated
Aerosol canisters	✓ Landfill ✓ Waste encapsulation	- Not to be burnt may explode.
Disinfectants	✓ Use ✓ To sewer or fast flowing watercourses, small quantities diluted disinfectants (maximum 50 litres per day under supervision)	- No diluted disinfectants to sewer or water courses. - Maximum 50 litres per day diluted to sewer or fast –flowing watercourses.
PVC, plastics and glasses.	Highly engineered sanitary landfill	- Not for burning in open containers
Paper and cardboards	Recycle, burn or to landfill	

Annex 1: DONATION INFORMATION FORM

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

Medicine Information

Name of medicine (INN):
Brand Name:
Strength:
Formulation:
Is medicine in ZEML:
Is medicine Registered in Tanzania or Zanzibar:
Date of Manufacture:
Expiry date:
Name and address of Manufacturer :
Label language:

Donor information

Name and address of donating agency/organization
……...……
……...……
Contact person and address
……...……
……...……

Recipient Information

Name and address of Recipient: ……....……...
……...……
……...……

Contact person and address: ……...……..
……...……
……...……

Shipping information

Mode of shipment of donation
Expected Date of arrival

Send this form to:

The Registrar,
Zanzibar Food and Drug Board
P.O. Box 236
ZANZIBAR
Fax Number:
Telephone Number: +255-777-414455
Email Address: bsimai@yahoo.com

Annex 2: An example of an equipment checklist

1. **Name of equipment**

2. **Description of equipment**

3. **Equipment type included on National Standard Equipment List (NSEL).**

4. **Technical specifications**

5. **Functions required**

6. **Special requirements**

7. **Staff available for;**
   a) Installation
   b) Operation
   c) Maintenance
   d) Other (specify)

8. **Location:**
   a) Site
   b) Size
   c) Accessibility
   d) Type of building
   e) Other factors (specify)

9. **Climate;**
   a) Temperature range – Day/Night
   b) Humidity- maximum/minimum
   c) Ventilation system
   d) Other factors (specify)

10. **Utilities;**
    a) Power supply
    b) Fuel type
    c) Voltage
    d) Phase
    e) Frequency
    f) Water system
    g) Water type
    h) Other issues (specify)

11. **Any other comments**