

#### REPUBLIC OF LIBERIA

#### LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY

(LMHRA) P.O. Box 1994

2<sup>nd</sup> and 3<sup>rd</sup> floors, Sekou Toure Avenue Mamba Point

Monrovia, Liberia



# GUIDELINE FOR PHARMACEUTICAL WASTES MANAGEMENT

#### 1.0. INTRTODUCTION

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) were established under the LMHRA 2010 Act. The LMHRA exist to implement the provision of LMHRA Act by employing good regulatory practices to ensure that medicines and health products used in Liberia conform to the highest standards of quality, safety, and efficacy. In order to achieve this mission, various measures are required to be put in place including proper means or strategies of managing unfit medicines and health products.

LMHRA has developed these guidelines to provide guidance to medicines and health products dealers on how to dispose of medicines and health products safely. The guidelines have been developed based on the World Health Organization (WHO) guidelines for safe disposal of unwanted pharmaceuticals.

The guidelines are divided into four sections which define unfit medicines and health products at a facility, procedure for application for disposal of unfit medicines and health products and the actual destruction exercise. The last parts provide formats of application, verification form disposal methods, and disposal form and disposal certificate.

The Authority anticipates that good implementation of these guidelines shall help to present unnecessary accumulation of unfit medicines and health products.

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

Hazards associated with unfit medicines and health products may result from improper or non-disposal and handling activities carried out by all actors in the medicines and health products business. In view of the unique nature of these products, the LMHRA 2010 Act Part III Count 2 states, "to protect the Liberian public from the harmful effects of unfit medicines and health products".

## 2.0. In general, improper disposal of unfit medicines and health products presents a serious threat to public health. Some of the health risks include:

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

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

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

## 3.0. Prevention of waste from Pharmaceutical donations, Sale, and/ or purchase

- a. Appropriate donations: this is ensured by adhering to the interagency or National Donation Guidelines. The key principles are that medicines and health products donated shall address the expressed needs of the recipients and that the date of expiration on arrival shall be no less than one year, unless there is clear evidence from the recipients that they have the logistic and managerial capacity to store, distribute and consume shorter-dated medicines efficiently. The blind donation of pharmaceuticals based on unsubstantiated assumptions of recipient needs and logistic capacities is a major factor in the production of pharmaceutical wastes.
- b. The commercial importers, wholesalers, and retailers shall ensure that medicines and health products with different expiration dates are sold, distributed, or used in accordance with the principle of First-Expired First-Out. Medicines that are not frequently used should not be imported in large quantities. Importers should avoid selling large quantities of medicines and health products with short expiration dates (three months to expiration) to their customers except justified that the medicine(s) shall be consumed before expiration.

## 4.0. PROCEDURES FOR HANDLING AND DISPOSAL OF UNFIT MEDICINES AND HEALTH PRODUCTS

#### 4.1. Unfit medicines and health products

Medicines and health products shall be considered unfit when they are:

- 4.1.1 Expired
- 4.1.2 Improperly sealed

- 4.1.3 Damaged, unexpired but improperly stored
- 4.1.4 Improperly labeled
- 4.1.5 Falsified and substandard
- 4.1.6 Prohibited
- 4.1.7 Unauthorized

#### 4.2 Handling of unfit medicines and health products at facility level

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

- 4.2.1 Maintain a register book (Annex I) for unfit medicines and health products.
- 4.2.2 Keep them into different categories by dosage form such as: -a) Solids, semi-solids, powders, capsules, powders for injection, tablets, granules, creams, gels, suppositories etc.
- b) Liquids: Solutions, suspension, syrups, mixtures, lotions, aerosol, inhalers etc.
- 4.2.3 Keep separately medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicines or health products.
- 4.2.4 Keep in containers according to their dosage forms to facilitate verification exercise, sorting and selection of disposal method.
- 4.2.5 Demarcate an area for keeping containers of unfit medicines and health products which shall be labeled conspicuously with words "Expired medicines/health products Not for Sale" or "Unfit medicines/health products Not for sale".
- 4.2.6 Maintain safe custody of unfit pharmaceutical products in registered premises until they are disposed of to avoid pilferage.

- 4.2.7 The request for disposal of unfit medicines and health products shall be made by county or hospital pharmacist, owners, person-in-charge of facility, dispensers, and inspectors (including inspectors at ports of entry) to avoid accumulation of such unfit products.
- 4.2.8 Application for disposal of unfit medicines from Government institutions shall be accompanied by an approval from entity's Pharmacist, with approval of the Head of the Institution declaring that the products have been written off and that they are subject to disposal as required by the pharmaceutical waste's disposal as indicated herein.

## 5.0. Procedures for application to dispose of unfit medicines and health products

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

- 5.1. Request in writing to the Managing Director of LMHRA by using application form (Annex II) which is available at LMHRA offices or LMHRA's website: www.lmhra.gov.lr
- 5.2 A request shall be accompanied by a list of products to be disposed of and should state clearly trade name, generic name and strength (where applicable), dosage form, pack size, quantity, manufacturer, batch number and market value of product.
- 5.3 Once the request has been received by LMHRA, the Managing Director shall send the application to the Head of Inspectorate. The head of Inspectorate shall give the communication to the focal person on Wastes Management who shall acknowledge and inform the applicant through a letter that will be approved by the Head of Inspectorate that the Wastes Management Team conducts verification

of the product quantity. In case of counties where there are no LMHRA offices, the applicant shall be informed to contact the County Pharmacist for same.

5.4 LMHRA Head Offices shall send the focal person on Wastes Management to inspect the pharmaceutical wastes to verify and authenticate the information submitted.

#### 6. 0. SORTING AND VERIFICATION EXERCISE

6.1 During verification exercise, Pharmacists who are LMHRA inspectors shall supervise sorting exercise of unfit medicines and health products before determination of disposal method. Some of the examples of category of products and their recommended disposal methods are highlighted on the table below:

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

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

#### **6.2.1.** Identification of the product.

- 6.2.2. Separate medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicinal or cosmetic products.
- 6.2.3 Sort according to Disposal/Destruction Method (Annex IV)
- 6.3 Staff involved in sorting exercise shall be provided with protective gears such as gloves, boots, overalls and dust masks and shall be briefed on the sorting exercise, health and safety risks associated with handling the materials.
- 6.4 Sorted medicines and health products shall be carefully packed into steel drums or cardboard boxes or jute bags and information to be indicated outside the container shall include; dosage form(s) and proposed mode of disposal/destruction. The materials should be kept in a dry secure and preferably separate room to avoid being confused with in–date medicines or health products until disposal is carried out.
- 6.5 After verification the applicant shall be informed by either the Office of the Managing Director or the Inspectorate Department through the focal person on Pharmaceutical Wastes Management by means of a letter indicating the proposed mode of disposal/destruction and shall be directed to arrange with the Inspectorate to submit a bill request to Accounts where an invoice is issued for payment of cost of the disposal/destruction at the LMHRA disposal site approved by EPA. In cases where LMHRA does not have and approved disposal site, the

LMHRA shall arrange with the respective local authority e.g. County Health Officer/Pharmacist to determine disposal site and date of destruction.

## 7.0. The cost of disposal/destruction shall be borne by the owner of the product.

- 7.1. Pharmaceutical wastes disposal cost shall vary with the manner in which the wastes are accumulated; that is, Medicines and health products that are imported in good quality and are in circulation and subsequently gets expire or damage and are taken off shelves by owner, kept and reported; this category of wastes shall be charged US\$3.00/Kg.
- 7.2. Medicines and health products that are imported and immediately found to be falsified, damaged, substandard, unregistered, or prohibited, this category of wastes shall be charged US\$3.00/Kg.
- 7.3. Medicines and health products that are imported in good quality and are in circulation and subsequently got expired or damaged but were intentionally kept on shelves and being willfully sold to the Liberian Public shall be un-shelved, quarantined and charged US\$5.00/Kg.

#### 8.0. DESTRUCTION OF UNFIT MEDICINES AND HEALTH PRODUCTS

Disposal/destruction of unfit medicines and health products shall involve the following procedures:

8.1 The focal person on Pharmaceutical Wastes Management at LMHRA shall coordinate the entire exercise. Other LMHRA Inspectors, and the County Pharmacist of the county in which the destruction is taking place shall supervise various aspects of the disposal exercise. While the County Health Officer, Environmental Protection Agency Officer, shall serve as observers during the transport of consignment from the owner's premises or temporary storage site to

the disposal site as well as during the entire destruction exercise as deemed necessary.

- 8.2 Unfit medicines and health products shall be transported in a closed motor vehicle or if in opened vehicle, must be properly covered to avoid pilferage.
- 8.3 Supervisors and other workers shall wear protective gears such as overalls, gloves, masks, helmets and boots during the disposal/destruction exercise.
- 8.4 Upon completion of the exercise, a Drug Disposal Form (Annex V) shall be duly filled in and signed by the supervisors and owner/owner's representative.
- 8.5. Drug Disposal Form shall be sent to LMHRA offices.
- 8.6 Once LMHRA offices have received the form, a certificate of destruction of unfit medicines and health products (Annex VI) shall be prepared and sent to the consignee.
- 8.7 Particular care shall be taken while handling anticancer drugs, narcotic drugs and Penicillin to avoid associated hazards.

#### 9. ANNEXES

Annex I
Format of Register Book of unfit Medicines/and health products

S/N	Name of prod	uct	Strength	Dosage	Quantity	Batch	Cost Value
			(where	form		Number	
			applicable)				
	Trade Name	Generic Name					

Signed:	Date
Manager/Proprietor/Designate	

#### 10. Annex II

#### **Model of Application Form for Disposal of unfit Products**

Form I	No				• •	•
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To: Managing Director

Liberia Medicines and Health Products Regulatory Authority (LMHRA)

Adjacent Concern Worldwide Office

VP Road, Old Road, Sinkor

Monrovia, Liberia

Name of Premise	(Contact number)
Undertaking the business of (spec	cify)hereby apply
for disposal of unfit (Medicines o	r Medical supplies) Premise license Number
Issued on	
Location of Business	
Name of person in-charge of the b	business
	Reason for disposal
Attached herewith is the list of pr	oducts to be disposed off.
Declaration:	
I certify that the information prov	rided in the application form is true and correct.
Date of application	Signature of Applicant
Stamp	
For official use only:	
Received by:	Signature Date
Stamp	
11. Annex III	
Model of Verification Form	1
Form No	
Liberia Medicines and Health Pro	oducts Regulatory Authority (LMHRA)
P.O. Box 1994	
2 <sup>nd</sup> & 3 <sup>rd</sup> Floors, Sekou Tour	e Avenue
Mamba Point	
Monrovia, Liberia	
Name of applicant	Contact number
undertaking the business of (specify)	)
Location of Business	
Weight (in Kg)	Value (in US\$/LD\$)

Does the actual product(s) tally with the list of product(s) submitted to LMHRA?
YES/NO
Other observation
(s)
Suggested mode of destruction
Name of ApplicantSignature
Date of verification
1. Name of LMHRA Inspector
2. Name of LMHRA Inspector

#### **Disposal Methods**

#### 12.1. Landfill

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

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

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

Three types of landfill methods are recognized as outlined below:

#### 12.2. Landfill for untreated unfit medicines and Health products

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

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

The disposal exercise should be done amid tightly security supervised by technical personnel.

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

#### 12.3. Engineered landfill

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

#### 12.4.. Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer relative safe disposal route for unfit medicines and cosmetic products. An appropriate landfill consists of an evacuated pit isolated from water courses and which is above water table. Once unfit medicine and cosmetic products are thrown into the pit, they are compacted and covered with soil to maintain sanitary environment.

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

## 12.5.. Landfill for treated unfit medicines and health products waste immobilization

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

#### 12.5.1. Encapsulation

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

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

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

Steel drum lids should then be bent back and sealed by seam or spot welding. The sealed drum lids should be placed at the base of a landfill site and covered with fresh municipal solid waste. The method is applicable to solids waste, semi-solids, powders, and liquids.

#### 12.6. Inertization

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

The main tools required for the operation are a grinder or road roller to crush the medicines/health products, lime and water.

Medicines or cosmetics waste, lime, cement and water are mixed in the following ratios by weight 65%, 15%, 15% and 5% respectively. Water can be added more than the required amount when need arises to have satisfactory liquid consistency.

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

#### 12.7. **Sewer**

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

#### 12.8. Medium temperature incineration

This method involves the use of medium temperature incinerators. Unwanted solid pharmaceuticals may be destroyed by using a two-chamber incinerator that operates at the minimum temperature of 8500 degrees Celsius, with a combustion retention time of at least two seconds in the second chamber. It is recommended that prior to destruction; pharmaceutical waste should be diluted with large quantities of municipal waste (approximately 1:1000).

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

#### 12.9. **High temperature incineration**

This involves the use of high temperature incinerator, which operates at a temperature well in excess of 8500 degrees Celsius. Cement kilns can reach temperatures of 14500 degrees centigrade – 20000 degrees Celsius that is suitable for total destruction of organic waste component. These have long combustion retention times and disperse exhaust gases via tall chimneys, often to high altitudes thus reducing the risk of environmental effect.

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

#### 12.10. Burning in open containers

Paper and cardboard packaging materials, if they are not to be recycled, may be burnt. Polyvinyl Chloride (PVC) plastic however must not be burnt. Unfit medicines and cosmetics should not be destroyed by burning at low temperatures in open containers, as toxic pollutants may be released into the air. It is strongly recommended that only very small quantities of unfit medicines and health products be disposed of in this way.

#### 12.11. Return to donor or manufacturer

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

13. Annex V

**Model of Disposal Form** 

The destruction exercise was conducted at (location, site)	ve supervised theon (s) (state clearly):
Disposal of unfit product (as per attached list) belonging to  Mr/Mrs./Mss./Dr/Pharm address	on (s) (state clearly):
The destruction exercise was conducted at (location, site)	(s) (state clearly):
this date	(s) (state clearly):
Names, title and signatures of LMHRA Inspector(s), other supervisor(s) adisposal exercise: -  Name  No. NAME  Title/Position  Signature	(s) (state clearly):
1	
2	Kg
3	Kg
The total weight of the products destroyed is	Kg
Name and signature of owner/in charge/representative of the organization:  (Name)	Kg
Name and signature of owner/in charge/representative of the organization:  (Name)	
(Name)	
Names, title and signatures of LMHRA Inspector(s), other supervisor(s) a disposal exercise: -  Name  No. NAME  Title/Position  Signature	
Name)	
Names, title and signatures of LMHRA Inspector(s), other supervisor(s) a disposal exercise: -  Name  No. NAME  Title/Position  Signature	
disposal exercise: - Name  No. NAME Title/Position Signature  1	
disposal exercise: - Name  No. NAME  Title/Position  Signature	
disposal exercise: - Name  No. NAME Title/Position Signature  1	
Name  No. NAME  Title/Position  Signature	nd witness of the
No.NAMETitle/PositionSignature1	
1	
	Date
2	
3	
4	
5	
6	

## THE LIBERIA MEDICINES AND HEALTH PRODUCTS REGULATORY AUTHORITY ACT OF 2010

#### CERTIFICATE OF DISPOSAL

I, being the person in-charge with the administration of the law relating to the control of
Pharmaceutical Products to which the Liberia Medicines and Health Products Regulatory
Authority Act of 2010 apply, hereby certify the destruction of expired, improperly sealed,
damaged, unexpired but improperly stored, improperly labeled, counterfeit, substandard and
adulterated, prohibited, and unauthorized pharmaceutical products belonging to
of (Address)
took place on
The said consignment was destroyed by
at under the witness and supervision of LMHRA
Inspectors, Environmental Officer, Health Officer and Police officer as specified in the
attached disposal form with S. No
wastes disposed is Kg and its value is
US/LD\$
Name Signature Date:
MANAGING DIRECTOR

#### WITH TOTAL DIRECTOR

15. Annex VII

#### **REPUBLIC OF LIBERIA**

#### LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY

2<sup>nd</sup> and 3<sup>rd</sup> Floors, Sekou Toure Avenue Mamba Point Monrovia, Liberia

### Standard Operating Procedures (SOP) for Pharmaceutical and other hazardous medical Wastes Management in Liberia

- 1. **PURPOSE:** To provide a SOP establishing uniform policies, procedures and responsibilities for the receipt, labeling, management, storage, and disposal of pharmaceutical wastes, and to establish the requirements for environmental compliance.
- 2. **SCOPE:** This SOP applies to the management of pharmaceutical and other hazardous medical wastes within the healthcare delivery system.

#### 3. GENERAL

a. Pharmaceutical and other hazardous medicinal wastes and health products are those that can no longer be used for its intended purpose, because they have been contaminated, damaged or have gone beyond their shelf-life. They could be chemicals or other substances that are potentially dangerous to human health and safety or the environment when improperly treated, stored, transported, disposed of, or otherwise mismanaged. This SOP outlines how wastes management units within the LMHRA will care for both pharmaceutical and other hazardous medicinal wastes from receipt to disposal (otherwise identified as cradle to grave).

#### 4. RESPONSIBLITIES.

#### a. Pharmaceutical Wastes Management Unit

- a. Has overall responsibility for the safe removal, handling, and disposal of all pharmaceutical and other hazardous medicinal wastes as well as environmental compliance management program
- b. Ensure full awareness regarding the timely appropriate collection, storage, labeling, transporting, and disposal of these wastes.
- c. Ensure all pharmaceutical and other hazardous medical wastes generators comply with their respective regulatory requirements.
- d. Identify and develop wastes protectorate accumulation points within all pharmaceutical and health entities. Ensure that all entities have access to Wastes Management Guidelines and SOP.

#### b. Entity's Supply Technicians (pharmacist, dispenser, etc.) should:

- a. Track products throughout the supply process cycle from receipt to disposal.
- b. Minimize wastes generation whenever possible or feasible through rational requisition and appropriate information dissemination.
- c. Conduct quarterly inspections of all targeted entities, through appropriate coordination.

#### **Procedures for the Application for Pharmaceutical Wastes Disposal**

- 1. Write a letter to the Managing Director informing the Authority that there are accumulations of unfit pharmaceutical products in your entities.
- 2. Attach a list of the unfit products, which should include: trade name, generic name strength, dosage form, pack size, quantity, manufacturer, batch number, and market value of each.
- 3. The Managing Director shall acknowledge the letter and send same to the head of inspectorate who will also acknowledge the application and send the communication to the Manager on Wastes Management.
- 4. Upon receipt of the communication by the Manager for pharmaceutical waste management, s/he shall formerly inform the applicant on the date and time of verification and quantification with approval from the Head of Inspectorate.
- 5. The Manager shall go with a team to the premise of the applicant on the date and time scheduled to verify and authenticate the information provided in order to quantify and appropriately charge the cost for the disposal exercise with regards to the type and nature of the unfit products. The cost will be approved by the Head of Inspectorate and formally communicated to the applicant.
- 6. Before the date of the commencement of the disposal exercise, the applicant shall be instructed to do preliminary separation where infusions, injectable, and syrups will be separately placed at one location and tablets, capsules, and dry suspensions separately placed at another location, while health products are also placed at separate location inside the same storage facility.
- 7. Based on the agreement reached, the applicant shall obtain an invoice from LMHRA Accounts and be requested to deposit the cost of the disposal into the LMHRA's Accounts and the deposit slip be given to the Manager who will report same to the Accounts section of the Authority and obtained the official receipt and deliver it to the applicant.
- 8. If there is space in the Authority's Wastes Management temporary storage facility that can accommodate the volume of wastes that is available in the premise of the applicant, the wastes should be collected and transferred to said temporary storage site; but if the volume is wastes is large, it shall remain quarantine in the premise of the applicant and date of disposal shall be scheduled within 10 working days.
- 9. In case of any delay on the part of the Authority due to any unforeseen reason(s), the applicant shall be appropriately notified through written communication signed by the Manager and approved by the Head of Inspectorate.

#### **Procedures for pharmaceutical wastes Disposal**

- 1. Before the disposal exercise commencement, there shall be a disposal plan formulated by the Manager in relation to the volume of pharmaceutical wastes and presented to the head of Inspectorate.
- 2. The Head of Inspectorate shall review, modify, and finalize the plan with the Management of LMHRA for its approval for implementation.
- 3. The Manager shall go to the disposal site to meet with the local authorities on the ground and shall recruit locally base casual laborers.
- 4. All required materials for the disposal exercise shall be obtained at least one day ahead of the exercise.
- 5. During the disposal exercise, the collection and transfer shall be supervised by LMHRA's pharmacists from storage sites to disposal site.
- 6. The entire wastes disposal team shall be given all needed outfits on the day of the disposal which shall include: safety boots, goggles, gloves, helmets, nose masks, and joint suits.
- 7. The Authority's hired casual laborers shall be used to load the unfit products on available vehicles and offload same at the disposal site.
- 8. After offloading, there shall be complete professional separation of unfit products into various pharmaceutical dosage forms under the direct supervision of professional pharmacists.
- 9. If there is no temporary storage facility for the sorted wastes, there shall be immediate disposal of the separated wastes according to all the various available acceptable professional disposal methods. The crushing, for which there is currently no facility at along the disposal site will, for now be done at the Monrovia City Corporation at its Weine Town's disposal Site in Paynesville.
- 10. During every stage of the disposal exercise, there shall be pictorial evidence by the display of action photos of activities.
- 11. All issued outfits shall be returned by all members of the wastes management team to the supervisors for onward reporting to the Manager.
- 12. A comprehensive report shall be written by the Manager in collaboration with the General Supervisor/Head of inspectorate and be submitted to the project officer within five working days after the completion of the disposal exercise.
- 13. The project officer along with the Head of Inspectorate shall review and finalize the report and subsequently submit same to the Management of LMHRA within three working days for onward submission to relevant stakeholders.

#### **Procedures for Wastes Management Team during Disposal Exercise**

There shall be no banding contract signed with any causal worker. The maintenance of the work to the end depends on one's effective working habit.

- 1. With the exception of the drivers, no assignment shall be permanent; that is, any worker can be rotated to any location of the work by the Coordinator in consultation with the Head of Inspectorate.
- 2. Every assigned supervisor shall give summary report of every day's activities during the next day early morning hours meeting, and such shall include:
  - a. Observations
  - b. Challenges

- c. Recommendations
- 3. Every supervisor shall be responsible for all outfits issued to workers assigned under him/her and fully account for same.
- 4. All workers shall strongly be advised to work with great care and be in their available outfits as there shall be no medical insurance provided for staff hired for the disposal exercise.
- 5. There shall be clear photos of all activities produced by assigned supervisors depicting the undertaking of these activities.
- 6. Payment of compensation to casual workers shall be made on the last day of work; even in the case of dropped out.
- 7. Every supervisor must ensure the safety of both personnel and equipment/materials assigned to him/her.
- 8. Supervisors assigned shall report all items issued to their supervisees after the completion of the disposal exercise to the Manager.
- 9. Full adherence to this SOP is the due obligation for all participants.

Pharm. Keturah C. Smith Managing Director, LMHRA