	GUIDELINES FOR THE HANDLING AND SAFE DISPOSAL OF UNWHOLEOME PHARMACEUTICAL PRODUCTS IN SIERRA LEONE	
REV No: 002	Doc No. PBSL/GL/012	Version #: 03
Issue date: 16 March, 2023	**Effective date: 20 March, 2023**	Approved by Registrar

Pharmacy Board of Sierra Leone
PMB 322
Central Medical Stores Compound
New England Ville
Freetown

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Acknowledgements

In general, expired, deteriorated or unwanted pharmaceuticals pose a serious threat to public health or to the environment. Their improper disposal may be hazardous and may lead to contamination of water supplies or local sources used by nearby communities or wildlife. They may come into the hands of scavengers and children if a landfill is insecure. Pilfering from a stockpile of these drugs or during sorting may result being diverted to the market for resale and misuse.

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

The Pharmacy Board, therefore, acknowledges efforts put in the development of these guidelines, especially by the Pharmacy Board Management for constructive comments and inputs during deliberation and approval of the guidelines.

The Pharmacy Board also appreciates the information obtained from the guidelines of other national medicines regulatory authorities (NMRAs) such as the NAFDAC and FDA (Ghana) Guidelines for the safe disposal of unwholesome products for adoption by the Pharmacy Board of Sierra Leone.

Executive Summary

These guidelines have been developed to provide guidance to all stakeholders handling drugs, vaccines, medical devices, cosmetics and chemical substances (hereafter referred to as products) to ensure safe disposal of unwholesome products and prevent their re-entry into the supply chain. These guidelines are hereby made for information, guidance and strict compliance by all concerned.

1.0 INTRODUCTION

Unwholesome products may accumulate due to deficiencies in stock management and distribution, and to lack of a routine system of disposal. The lack of safe disposal of these products often creates a major problem. They must therefore be destroyed in such a manner that does not allow recovery.

Medicines and other regulated products shall be considered as unwholesome when they are expired, deteriorated, damaged, counterfeit, substandard, unauthorized or banned.

2.0 OBJECTIVE:

a) To provide guidance to applicants on the procedure for submitting applications to the Pharmacy Board for pharmaceutical product destruction.
b) To enlighten applicants on the processes involved for the handling and safe of unwholesome pharmaceutical products.

3.0 SCOPE:

The Guidelines shall apply to all unwholesome or unwanted pharmaceutical products including allopathic medicines, controlled drugs, donated drugs, medical devices, chemical substances, cosmetic products and nutritional agents.

These Guidelines are for the general public and in particular, companies that intend to dispose of unwholesome medicines and other regulated products

In pursuance of Section 32, these Guidelines are hereby made to provide for the proper handling and disposal of unwholesome products so as to protect human health and the environment from potential hazards.

4.0 REQUIREMENTS

4.1 CATEGORIES OF APPLICANTS

The applicant eligible for applying to the Pharmacy Board for the sale disposal of unwholesome pharmaceutical products shall be any one of the following:

a) Registered Import and wholesale pharmaceutical companies licensed by the Pharmacy Board.
b) Governmental and Quasi- Governmental agencies that deal with medical products (e.g., NMSA, all Health programs, etc.).
c) Non- Governmental Organizations (NGOs) that run health programs and facilities approved by the Ministry of Health.
d) Pharmaceutical Manufacturers
e) Clinical trial sponsors and Principal investigators
f) Recipients of donations
g) Proprietors of pharmaceutical business
h) Pharmacy professionals in charge of pharmaceutical business and hospitals (private and public)
i) District or Hospital Pharmacist
j) Pharmacists working for NGOs running public health programs
k) Members of the general public

4.2 GENERAL REQUIREMENTS

4.2.1 No person shall dispose of any unwholesome product without permission and supervision from the Board. Approval of application and safe disposal of any unwholesome product shall be sought from the Board.

4.2.2 The applicant shall pay the prescribed fee for the destruction exercise to be done by the Board. The applicant shall be responsible for conveyance of the unwholesome products to the site of destruction.

4.2.3 In order to properly manage unwholesome products at a store, Warehouse or facility, the applicant shall adhere to the following requirements:

a) Maintain an inventory book for unwholesome medicines and other regulated products.
b) Sort the unwholesome products into different categories by dosage form as shown below:
   i. Solids, Semi-solids and Powders: capsules, powders for injection, tablets, granules, creams, gels, suppositories etc.
   ii. Liquids: solutions, suspension, syrups, mixtures, lotions, aerosol, inhalers etc.
   iii. Keep separately unwholesome products, especially those that fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicines or materials.

4.2.4 Store in containers according to their dosage forms to facilitate verification exercise, sorting and selection of disposal method.

4.2.5 Demarcate an area for storing unwholesome products which shall be labeled conspicuously with words such as 'Expired Products', 'Not for Sale' or labeled in red ink to avoid their unintended use. Maintain safe custody of unwholesome or other regulated products in the warehouse/store until they are disposed of to avoid pilferage.

4.3 SPECIFIC REQUIREMENTS

4.3.1 Any one of the applicants mentioned in 4.1 above may decide when action needs to be initiated, because of an accumulation of unwholesome product which are unfit for human consumption and for veterinary treatment.

4.3.2 The applicant intending to destroy specific quantities of unwholesome pharmaceuticals shall submit a written application or request, preferably with a letter head to the office of the Registrar of the Pharmacy Board of Sierra Leone using the under-mentioned address:

C/o Central Medical Stores compound
New England Ville
Freetown
Sierra Leone

4.3.3 The following information should be available in the application letter:

i. The name, dosage form, strength and expiry date of each product.
ii. The batch number, quantity and market value of each product.
iii. The total commercial value of the unwholesome products
iv. Country of Origin
v. The reason (s) for the destruction
vi. Whether disposal will be done directly by the Board or under the supervision of the Board provided the applicant has an incinerator).
vii. The name(s) of the Pharmacist(s) or Representative(s) of the applicant(s) who will witness the destruction as required by the procedure.

4.3.4 The letter shall be stamped and signed by a person authorized by the Board or a registered Pharmacist working for the applicant before submission to the Board.

4.3.5 If the application is complete, Pharmacy Board replies to the applicant(s) by acknowledging receipt of the letter of application(s). If not, the application will be rejected stating reasons for the rejection.

4.3.6 Consumers are also encouraged to move unwholesome products to the nearest retail outlets, and these products shall be moved onto the Pharmacy Board office or these products shall be taken to the Pharmacy Board office by the consumers.

4.4 SORTING AND VERIFICATION EXERCISE

4.4.1 The premises will be visited by Pharmacy Board inspector(s) to verify and authenticate the information submitted. If after verification, the submitted list is varied by addition of other products, the applicant shall be made to pay an additional fee as required.

4.4.2 The Pharmacy Board inspector(s) will supervise sorting exercise of unwholesome products before determination of disposal method. The inspectors will quantify and weigh the unwholesome products to be disposed of.

4.5 PAYMENT OF DISPOSAL FEE

After quantification and weighing and determining the method of disposal, the Pharmacy Board of Sierra Leone communicates in writing to the applicant stating the cost for the safe disposal of the unwholesome products. The payment by the applicant is non-refundable, and payment should be made before the disposal exercise is done by the Board.

In the event where the applicant has an incinerator or similar facility for the destruction or safe disposal of its unwanted products, the Board will supervise the exercise. No disposal fee will be required to be paid by the Applicant. Instead, the applicant will only be required to facilitate the transportation of the Pharmacy Board personnel(s) to and from the destruction site and provide incentive for the number of days the destruction will be carried out.

4.6 SCHEDULING OF DESTRUCTION EXERCISE

Upon payment to the Board, a date is scheduled for the destruction exercise. The applicant will be informed about the date of the disposal exercise.

For supervision by the Board, a date agreeable by both parties is scheduled for the destruction exercise.

4.7 DESTRUCTION EXERCISE

The Board shall conduct the destruction exercise on the scheduled date in the presence of key stakeholders, including Pharmacy Board inspectors, security officers, applicants or their representatives as well as representatives from EPA and MOH.

4.8 ISSUANCE OF DESTRUCTION CERTIFICATE

Upon completion of the destruction exercise, the Board will issue a certificate of destruction to the applicant. For the destruction exercise supervised by the Board, no certificate of destruction is issued to the applicant.

5.0 GLOSSARY:

5.1 DEFINITION OF TERMS:

For the purpose of these guidelines, the following terms shall be defined as follows:

Act
Means the Pharmacy and Drugs Act, 2001

Applicant
Means any person or institution or company that applies formally to get market authorization for one or more pharmaceutical products.

Authorized Representative / Local Responsible Person or Agent
A person residing in the country or cooperate body registered in the country who has received a legal mandate from the applicant to act on his behalf with regards to matters pertaining to registration, importation, clearance and/or destruction of pharmaceutical products in the country.

Board
Means the Pharmacy Board of Sierra Leone, or its acronym "PBSL" established under section 2 (two) of the Pharmacy and Drugs Act, 2001

Certificate
Means a certificate issued by the Board.

Consignment
Means a quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Container

Means any material employed in the packaging of a pharmaceutical product. It could be a bottle, jar, box, sachet, strip, blister or other receptacle which contains the finished pharmaceutical product.

Controlled drug
Means any narcotic drug, psychotropic substance or precursor as described under Part VI of the Pharmacy and Drugs Act, 2001.

Damaged pharmaceutical product
Means a product that has undergone physical, chemical or mechanical damage to such an extent that it can no longer be useful for human use.

Destruction
Means the safe disposal of any unwholesome products beyond retrieval.

Deteriorated pharmaceutical product
Means a product that has undergone physical and/or chemical degradation due to poor storage practices, and it has lost its quality, potency and/or efficacy, rendering unfit for human consumption

Donation
Means an act of presenting pharmaceutical products free of cost to recipients in emergency situations or as a part of development aid in none-emergency situations.

Donor
Means a governmental or nongovernmental organization or individual who voluntarily donates pharmaceutical products as a donation.

Expiry date
Means the date given on the individual container (usually on the label) of a drug product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

Expired pharmaceutical product
Means a pharmaceutical product that has exceeded its shelf life or expiry date

In Vitro Diagnostic Medical Device
A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provid information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

Importer
Means a person or institution licensed and/or authorized to import pharmaceutical product(s) into the country.

Label
Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any pharmaceutical product when it is being supplied.

Manufacturer
Means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceutical products

Medical Device
Any instrument, apparatus, laboratory equipment and reagents, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article which is intended by manufacturer to be used, alone or in combination for human beings or other animals for one more of the specific purpose(s) of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury;
b) Investigation, replacement, modification or support or the anatomy or of a physiological process;
c) Supporting or sustaining life;
d) Control of conception;
e) Disinfection of medical devices;

f) Providing information for medical or diagnostic purposes by means of in-vitro examination or specimens derived from the human body or other animal; and does not achieve its

primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Pharmaceutical product
Any product presented in its finished dosage form, intended for use as a medicine or as a remedy for the purpose of medical, dental or veterinary treatment. It includes locally-manufactured or imported drug (allopathic, herbal, nutritional supplements, biological & vaccines, veterinary), medical devices, cosmetics, chemical substances, household chemicals or investigational product

Recipient
Means a governmental, non-governmental or private health Institution that voluntarily receive pharmaceutical products as a donation.

Unwholesome products
Means any product that does not meet regulatory requirement or when consumed or used can be injurious to health of the consumer. They include expired, deteriorated, damaged, substandard and falsified products, unauthorized or banned products.

5.2 ABBREVIATIONS

EPA	Environmental Protection Agency
FCC	Freetown City Council
MOHS	Ministry of Health and Sanitation
NGO	Non-Governmental Organization
NMSA	National Medical Supplies Agency
PBSL	Pharmacy Board of Sierra Leone

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