THE PHARMACY AND POISONS ACT
(*Cap 244*)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (PHARMACEUTICAL WASTE MANAGEMENT) RULES, 2022

Citation.

1. These Rules maybe cited as the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

"Act" means Pharmacy and poisons Act;

"Board" means Pharmacy and Poisons Board

"cleaner production measures" means preventive measures applied to processes, products and services to minimise waste production and limit environmental pollution;

"cytotoxic pharmaceutical waste" means waste associated with cytotoxic drugs which contain chemicals that are toxic to the cells. This includes materials, equipment, and residue that are contaminated by cytotoxic drugs

"falsified medical products" products that deliberately or fraudulently misrepresent their identity, source, composition or both

"incineration" means the use of temperatures (in excess of 800 °C) dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a significant reduction of waste volume and weight

"segregation" means the separation waste materials for processing;

"waste generator" means any person whose activities or activities under his or her direction produces pharmaceutical waste or if that person is not known, the person who is in possession or control of that pharmaceutical waste;

"waste management" means any activities either administrative or operational used in handling, packaging, treatment, condition, storage and disposal of waste;

"substandard medical products" products that are authorized but fail to meet their quality standards or specifications

Application

3. (1) These Rules shall apply to the management of pharmaceutical waste which shall include—

(a) waste containing pharmaceuticals that are expired, damaged or no longer needed;

(b) items contaminated by or containing pharmaceutical waste such as bottles, boxes

(c) applicable medical devices;

(d) substandard and falsified medical products;

(e) obsolete investigational medicinal products

(f) cytotoxic pharmaceutical waste

(2) These Rules shall not apply to —

(a) sharps waste

(b) Infectious waste

(c) Pathological waste

(d) Radioactive waste

(e) Chemical waste

(f) Non-hazardous or general healthcare waste

Pharmaceutical waste minimization

4. (1) Pharmaceutical waste minimization is always preferable to generating pharmaceutical waste and then managing its subsequent disposal.

(2) To minimize pharmaceutical waste, the following practices are recommended:

(a) Checking of the expiry date of all pharmaceuticals at the time of delivery to ensure they have acceptable shelf life
(b) Refusal to accept short-dated (less than a third of shelf life remaining) pharmaceuticals from a supplier except when consumption rate is high
(c) Ordering pharmaceuticals from suppliers who accept the return of short dated stock
(d) Implementing a First Expiry First Out stock control system
(e) Dispensing of all the medicines in a given container
(f) Replacing prepackaged unit dose liquids with patient-specific oral doses

Pharmaceutical waste management.

5. (1) No person shall collect, record, segregate, store, transport or dispose any pharmaceutical waste except in the manner provided in these Rules

(2) Any person who contravenes paragraph (1) commits an offence and shall be liable, on conviction, to a fine not exceeding five hundred thousand shilling, or to imprisonment for a term not exceeding one year, or to both.

Responsibility of waste generator.

6. (1) A waste generator shall collect, record, segregate, store, transport and dispose that pharmaceutical waste in the manner provided for in these Rules.

(2) A waste generator shall adopt cleaner production measures in the management of pharmaceutical waste, which measures may include—

(a) incorporating environmental consideration in the design and disposal of a product;

(b) improvement of production process through□

(i) elimination of use of toxic raw materials;

(ii) minimising the emission of toxic waste;

(iii) conservation of raw materials and energy.

Segregation of pharmaceutical waste

7 (1) A waste generator shall segregate any pharmaceutical waste from other forms of medical waste at the point of generation and at all stages thereafter.

(2) The segregation of waste under paragraph (1) shall be as follows□

(a) cytotoxic pharmaceutical waste shall be segregated from other forms of pharmaceutical waste;

(b) compressed-container medications (aerosols, inhalers) shall be segregated from other forms of pharmaceutical waste;

Packaging of pharmaceutical waste.

8. (1) A waste generator shall take reasonable steps to ensure that pharmaceutical waste is in a package that is easily identifiable, including being in its original primary packaging, to aid in identification and preventing reaction between incompatible molecules.

(2) The measures envisaged under paragraph (1) include the following□

(a) in as far as practicable, ensuring pharmaceutical wastes are in their original primary packaging;

(b) securely packaging any pharmaceutical waste in a suitable bags, container or any other appropriate package;

(c) appropriately labelling any package containing pharmaceutical waste

(3) Where a package contains different types of pharmaceutical waste, a waste generator shall include an inventory of all the pharmaceutical waste contained in the package indicating the following□.

(a) a description of each pharmaceutical waste and the quantity contained therein;

(b) the total weight of the pharmaceutical waste;

(c) labelled in accordance with these Rules.

Labeling of pharmaceutical waste.

9 (1) Every waste generator shall ensure that every container or package for storing such waste is labelled in easily legible characters, written in both English and Kiswahili.

(2) The label envisaged under paragraph (1) shall contain the following information—

(a) a description of the pharmaceutical waste;

(b) the name, physical address and telephone contact of the waste generator;

(c) any of the following warning or caution statements, as may be appropriate□

(i) the words “WARNING” or “CAUTION”;
(ii) the word “POISON”;
(iii) the words “DANGER; KEEP AWAY FROM UNAUTHORIZED PERSONS”; or
(iv) a pictogram of a skull and crossbones;

(3) Where a package contains different types of pharmaceutical waste, it shall be packed in the manner specified under rule 8.

Recording of pharmaceutical waste

10. A waste generator shall maintain records of pharmaceutical waste with updated information on the following: date, product trade name, active pharmaceutical ingredient, dosage form, unit of issue, quantity and justification.

Handling and collection of pharmaceutical waste.

11 (1) Waste collection and storage bags for pharmaceutical waste needing incineration should not be made of chlorinated plastics.

(2) Any plastic bag or bin liners used in the storage or transport of pharmaceutical waste shall be legibly and permanently labelled with the name of the waste generator and the end-user.

(3) A waste generator shall ensure that such pharmaceutical waste is transferred to a person who is licensed to dispose such pharmaceutical waste in an approved pharmaceutical waste disposal facility.

Storage of pharmaceutical waste.

12 (1) All pharmaceutical waste shall be stored in designated quarantine stores marked with the words “PHARMACEUTICAL WASTE AREA” away from usable pharmaceuticals.

(2) Any storage facility used for pharmaceutical waste shall□

(a) be labeled on the outside with the hazard sign of a skull and two crossbones;

(b) have a sign with the words “NO ENTRY FOR UNAUTHORIZED PERSONS”.

(c) be properly secured and locked and;

(d) have a register of persons entering and exiting the facility is to be kept by the waste generator

Transportation of pharmaceutical waste

13. (1) Any person transporting any pharmaceutical waste shall use a means of conveyance so as to prevent scattering, escaping, flowing, spillage or leakage of the pharmaceutical waste.

(2) No person shall transit pharmaceutical waste destined for another country through the territory of Kenya without a valid Prior Informed Consent for such movement issued by the National Environment Management Authority.

(3) Onsite transportation of pharmaceutical waste should be separated from infectious waste.

(4) A driver engaged in offsite transportation of pharmaceutical waste shall be medically fit to drive and have appropriate training on risks and the handling of pharmaceutical waste.

(5) Any vehicle engaged in transport of pharmaceutical waste shall be licensed by National Environment Management Authority and meet the following criteria□

(a) be road worthy

(a) labelled with the words "PHARMACEUTICAL WASTE CARRIER";

(b) bear the name and address of the pharmaceutical waste carrier;

(c) bear a hazard sign for pharmaceutical waste (skull and 2 crossbones);

(d) have a suitable system for securing the load during transport.

(e) have empty plastic bags, suitable protective clothing, cleaning equipment, tools and disinfectant, and special kits for dealing with liquid spills.

(f) be designed so as to prevent spillage, leakage or scattering of such pharmaceutical waste.

(6) During offsite transportation of pharmaceutical waste, a consignment note shall be carried by the driver indicating

(a) the source of the pharmaceutical waste;

(b) the date of pick-up of the pharmaceutical waste;

(c) the details of the driver;

(d) the destination of the pharmaceutical waste;

(e) the number of containers being transported;

(f) Total weight of the pharmaceutical waste;

(g) any other relevant information.

(7) On completion of a journey, the consignee shall confirm receipt of the pharmaceutical waste and the driver shall return the consignment note to the waste generator.

Importation of pharmaceutical waste

14. (1) No person shall import pharmaceutical waste into the territory of Kenya.

(2) A person who contravenes paragraph (1) commits an offence and shall be liable, on conviction to a fine of not exceeding one million shillings, or to imprisonment for a term not exceeding two years or to both.

Export of pharmaceutical waste

15 (1) No person shall export pharmaceutical waste without a valid permit issued by National Environment Management Authority and a valid Prior Informed Consent document issued by the designated national authority of the receiving country.

(2) A person who contravenes paragraph (1) commits an offence and shall be liable, on conviction to a fine of not exceeding one million shillings, or to imprisonment for a term not exceeding two years or to both.

Pharmaceutical waste treatment and disposal methods.

16 (1) Before treatment and disposal, pharmaceutical waste shall be sorted according to dosage form or by active pharmaceutical ingredient, depending on treatment options available.

(2) Pharmaceutical waste shall be disposed within one year from the date of generation.

(3) Pharmaceutical waste shall be disposed based on dosage in the manner set out in the First Schedule.

Supervision of disposal of pharmaceutical waste

17. (1) Any disposal of pharmaceutical waste shall be done under the supervision of Board and at pharmaceutical waste disposal site approved by the National Environmental Management Authority.

(2) An application for pharmaceutical waste disposal shall be made to the Board in the form set out in the Second Schedule and accompanied by the fee set out in the Second Schedule.

(3) The Certificate of Safe Disposal of Pharmaceutical Waste shall be in the form set out in the Second Schedule and shall be issued within thirty days of the receipt of a complete application.

Disposal under section 46

18. Where goods are to disposed under section 46 of the Act, the goods shall be destroyed or disposed of in the manner set out in these Rules and in an environmentally sound manner.

FIRST SCHEDULE

MANNER OF DISPOSAL

A. Disposal of small quantities of pharmaceutical waste

The following are the options for disposal of small quantities of pharmaceutical waste□

1. Return of expired pharmaceuticals to the donor or manufacturer where possible
2. Encapsulation and burial in a sanitary landfill
3. Inertization with subsequent□
    (a) Production of cubes or pellets which are then transported to a suitable storage site
    (b) Pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste
4. Chemical decomposition in accordance with the manufacturer' recommendations if expertise and materials are available
5. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection
6. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

B. Disposal of large quantities of waste

The following are the options for disposal of large quantities of pharmaceutical waste:

1. Encapsulation and burial in a sanitary landfill
2. Inertization with subsequent:
    (a) Production of cubes or pellets which are then transported to a suitable storage site
    (b) Pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste
3. Incineration in kilns that operate at high temperatures (in excess of 800 °C).
4. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection
5. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

C. Disposal of Cytotoxic drugs

The following are the recommended disposal methods for pharmaceutical waste comprised of cytotoxic drugs such as antineoplastic agents

1. Cytotoxic drugs should never be landfilled.

2. Return to original supplier

3. Chemical degradation in accordance with manufacturer's instructions

4. Incineration at high temperature. Full destruction of cytotoxic drugs may require incineration temperatures up to1200 °C

SECOND SCHEDULE

PART A: FORMS

APPLICATION FOR DISPOSAL OF PHARMACEUTICAL WASTE

PHARMACY AND POISONS BOARD.
P.O. BOX 27663 – 00506,
NAIROBI.

1. Name of applicant: _____

2. Applicant address:

   Physical: _____

   Postal: _____ Telephone: _____

   Email: _____

3. Description of pharmaceutical products to be disposed

S/N	Product trade name	Active Pharmaceutical Ingredient (s)	Dosage form	Unit of issue	Quantity	Proposed method of disposal

For public health facilities attach the Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) – FO 58

4. Justification for disposal of pharmaceutical waste

   _____

5. Proposed disposal site

   Name: _____

   Location: _____

6. Applicant details

Name: _____

Designation: _____

Signature: _____

Date: _____

CERTIFICATE OF SAFE DISPOSAL OF MEDICAL DEVICE AND PHARMACEUTICAL WASTE

PHARMACY AND POISONS BOARD

P.O. BOX 27663-00506

NAIROBI

Certificate of Safe Disposal of Pharmaceutical Waste

This is to certify that the pharmaceutical waste:

From (company) _____ Application

reference number _____ Weighing _____

was safely disposed off

on _____

Through the following disposal method _____

and at the following pharmaceutical waste disposal site _____

In compliance with the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022 and the Pharmacy and Poisons Board Guidelines on Safe Management of Pharmaceutical Waste.

Signed:

_____

Chief Executive Officer,
Pharmacy and Poison Board, Kenya.

PART B: FEES

Particulars	**Amount (Ksh)**
An application for disposal of pharmaceutical waste	2,500

Made on the ……..……..., 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.