LEGAL NOTICE NO. 99

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

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

ARRANGMENT OF RULES

Rule

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

IN EXERCISE of the powers conferred by section 44 (1) (n) 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 may be cited as the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022.

Interpretation.

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

"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 including materials, equipment and residue that are contaminated by cytotoxic drugs;

"falsified medical products" means 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 of 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; and

"substandard medical products" means products that are authorised but fail to meet their quality standards or specifications.

Application of the Rules.

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

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

(b) items contaminated by or containing pharmaceutical waste including bottles and boxes;

(c) applicable medical devices;

(d) substandard and falsified medical products;

(e) obsolete investigational medicinal products; and

(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; or

(f) non-hazardous or general healthcare waste.

Pharmaceutical waste minimization.

4. For the purposes of these Rules, a waste generator shall be encouraged to employ pharmaceutical waste minimization through the adoption of the following practices—

(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 pharmaceuticals (less than a third of shelf life remaining) from a supplier except when the consumption rate of the pharmaceuticals is high;

(c) ordering pharmaceuticals from suppliers who accept the return of short-dated pharmaceutical supplies;

(d) implementing a First Expiry First Out stock control system;

(e) dispensing of all the medicines in a given container; and

(f) replacing pre-packaged unit dose liquids with patient-specific oral doses.

Management of pharmaceutical waste.

5. (1) A person shall not collect, record, segregate, store, transport or dispose any pharmaceutical waste except in the manner provided in these Rules.

(2) A person who contravenes the provisions of sub-rule (1) commits an offence and shall be liable, on conviction, to the penalty prescribed by section 51 of the Act.

Responsibility of waste generator.

6. (1) A waste generator shall collect, record, segregate, store, transport and dispose of 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 including—

(a) incorporating environmental considerations in the design and disposal of pharmaceutical waste; and

(b) improvement of the production process through—

(i) the elimination of use of toxic raw materials;

(ii) the minimising of the emission of toxic waste; and

(iii) the conservation of raw materials and energy.

Segregation of pharmaceutical waste.

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

(2) The segregation of waste under sub-rule (1) shall be as follows—

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

(b) compressed-container medications (including aerosols and 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 sub-rule (1) shall include the following—

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

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

(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; and

(c) a label prepared in accordance with these Rules.

Labeling of pharmaceutical waste.

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

(2) The label envisaged under sub-rule (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—

(a) date;

(b) product trade name;

(c) active pharmaceutical ingredient;

(d) dosage form;

(e) unit of issue;

(f) quantity; and

(g) justification.

Handling and collection of pharmaceutical waste.

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

(2) Any plastic bag or bin liner used in the storage or transportation 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 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) Pharmaceutical waste shall be stored in designated quarantine stores marked with the words "PHARMACEUTICAL WASTE AREA" which shall be away from other usable pharmaceuticals.

(2) A storage facility used for the storage of 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 that shall be kept by the waste generator.

Transportation of pharmaceutical waste.

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

(2) A person shall not transport pharmaceutical waste destined for another country through any part of the territory of Kenya without a valid Prior Informed Consent for such transportation issued by the National Environment Management Authority.

(3) On-site transportation of pharmaceutical waste should be separated from infectious waste.

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

(5) A vehicle used in the transportation of pharmaceutical waste shall be licensed by the National Environment Management Authority and meet the following criteria—

(a) be road worthy;

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

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

(d) bear a hazard sign for pharmaceutical waste (skull and two crossbones);

(e) have a suitable system for securing the load during transport;

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

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

(6) During off-site transportation of pharmaceutical waste, the driver shall carry a consignment 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) the total weight of the pharmaceutical waste; and

(g) any other relevant information.

(7) On the delivery of a consignment of pharmaceutical waste, 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) A person shall not import pharmaceutical waste into the territory of Kenya.

(2) A person who contravenes sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

Export of pharmaceutical waste.

15. (1) A person shall not export pharmaceutical waste without a valid permit issued by the 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 sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

Pharmaceutical waste treatment and disposal methods.

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

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

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

Supervision of disposal of pharmaceutical waste.

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

(2) The application for the disposal of pharmaceutical waste 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 by the Board within thirty days after the receipt of the application for the disposal of pharmaceutical waste.

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 (r. 16(3))

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 to 1200 °C

SECOND SCHEDULE (r. 17(2), (3))

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 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 (Kshs)*
Application for the disposal of pharmaceutical waste	2500

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 100

THE PHARMACY AND POISONS ACT

(*Cap.* 244)

IN EXERCISE of the powers conferred by section 44(1)(d) of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, after consultation with the Pharmacy and Poisons Board, makes the following rules—

THE PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES) RULES, 2022

PART I—PRELIMINARIES

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

Interpretation.

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

Cap. 244.

"Act" means the Pharmacy and Poisons Act;

"blood product" means a medicinal product based on a blood constituent which is prepared industrially and includes albumin, immunoglobulin and a coagulating factor;

"cosmetics" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes;

"good manufacturing practice certificate" means a document issued by a competent regulatory authority that certifies compliance to good manufacturing practice;

"immunogenic substance" means an unformulated active substance which may be—

(a) subsequently formulated with excipients to produce a medicinal product;

(b) whole bacterial cells, viruses, or parasites whether live or killed, split bacterial cells, viruses, or parasites, crude or purified antigens isolated from killed or living cells;