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Republic of Kenya

Ministry of Health

PHARMACY AND POISONS BOARD

GUIDELINES FOR SAFE MANAGEMENT OF PHARMACEUTICAL WASTE

JULY 2019

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Prepared by Head, GDP

Sign.....

Date.....9/07/19.....

Director, Inspectorate, Surveillance and Enforcement

Sign.....

Date.....09/07/2019.....

Checked by Head, Quality Management

Sign.....

Date.....09/07/2019.....

Authorized by Chief Executive Officer

Sign.....

Date.....9/7/19.....

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ABBREVIATIONS AND ACRONYMS

CAP ---------- Chapter

E.G ---------- For example

GDP ---------- Good Distribution Practices

INSP ---------- Inspectorate

JKIA ---------- Jomo Kenyatta International Airport

m^3 ---------- Metre Cubed

NEMA ---------- National Environment Management Authority

PPB ---------- Pharmacy and Poisons Board

PVC ---------- Polyvinyl Chloride

Ref ---------- Reference

S/N ---------- Serial Number

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PREFACE

In pursuing their aims of reducing health problems, healthcare services

inevitably create pharmaceutical waste that may itself be hazardous to public health and the environment. Safe methods for managing pharmaceutical waste are therefore essential and should be an integral feature of healthcare services.

Safe management of pharmaceutical waste entails taking all practical steps to ensure that pharmaceutical waste is managed in a manner that protects human health and the environment against the adverse effects which may result from the pharmaceutical waste.

In both the short and the long term, the actions involved in implementing safe pharmaceutical waste management programmes require multisectoral cooperation and interaction at all levels. Establishment of a guideline on safe management of pharmaceutical waste, training of personnel and raising public awareness are essential elements of safe pharmaceutical waste management.

With the publication of these guidelines, the Pharmacy and Poisons Board is establishing a framework for safe management of pharmaceutical waste at all levels of healthcare.

These guidelines are for use by all healthcare providers, pharmaceutical manufacturers, pharmaceutical distributors and staff attached to pharmaceutical waste disposal facilities.

These guidelines are as a result of collective efforts of technical officers from the Pharmacy and Poisons Board with contributions from the National Environment Management Authority, Ministry of Health, County Governments, Pharmaceutical Society of Kenya, Kenya Pharmaceutical Association, Kenya Pharmaceutical Distributors Association, Kenya Association of Pharmaceutical Manufacturers, and operators of NEMA approved pharmaceutical waste disposal sites.

Efforts have been made to include in these guidelines the most recent recommendations on safe management of pharmaceutical waste from the World Health Organization and the National Environment Management Authority.

The Pharmacy and Poisons Board strongly encourages the widespread implementation of these guidelines and is ready to assist users implementing them.

LEGAL FRAMEWORK

The preamble to the Constitution of Kenya states:

> We, the people of Kenya –

RESPECTFUL of the **environment**, which is our heritage, and determined to sustain it for the benefit of future generations

ADOPT, ENACT and give this constitution to ourselves and to our future generations

Article 42 of the Constitution of Kenya provides that every person has the **right to a clean and healthy environment**, which includes the **right to have the environment protected** for the benefit of present and future generations.

Article 69 of the Constitution of Kenya further provides that **the state shall eliminate activities that are likely to endanger the environment**. Every person is duty bound to cooperate with the state in environmental protection.

Section 4 of the Environmental Management and Co-ordination (Waste Management) Regulations provides that any person whose activities generate pharmaceutical waste shall collect, segregate, store, transport and dispose such pharmaceutical waste in the manner provided for in the Regulations.

The 9th schedule in the Environmental Management and Co-ordination (Waste Management) Regulations directs one to the Ministry of Health Guidelines on Safe Disposal of Pharmaceutical Waste for directions on recommended disposal methods for pharmaceutical waste.

DEFINITION OF TERMS

Active pharmaceutical ingredient - Any substance or mixture of substances in a finished pharmaceutical product intended to furnish pharmacological

activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

Antibiotic – antimicrobial medicine

Antineoplastic – inhibiting the development of abnormal tissue growth

Chemical waste – waste containing chemical substances (e.g. laboratory reagents; film developer; disinfectants that are expired or no longer needed; solvents; waste with high content of heavy metals, e.g. batteries; broken thermometers and blood pressure gauges)

Cytotoxic – toxic to the cell

Disposal site – any area of land on which pharmaceutical waste disposal facilities are physically located or final discharge point without the intention of retrieval but does not mean a re-use or re-cycling plant or site

Safe management of pharmaceutical waste – taking all practical steps to ensure that pharmaceutical waste is managed in a manner that protects human health and the environment against the adverse effects which may result from the pharmaceutical waste

Incineration – high temperature (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

Infectious waste – waste suspected to contain pathogens and that poses a risk of disease transmission (e.g. waste contaminated with blood and other body fluids; laboratory cultures and microbiological stocks; waste including excreta and other materials that have been in contact with patients infected with highly infectious diseases in isolation wards)

National Environment Management Authority – principal instrument of the Government of Kenya for the implementation of all policies relating to the environment and established under the Environmental Management and Co-ordination Act Number 8 of 1999

Non-hazardous or general healthcare waste – waste that does not pose any particular biological, chemical, radioactive or physical hazard

Pathological waste – human tissues, organs or fluids; body parts; fetuses; unused blood products

Pharmaceutical waste – waste containing pharmaceuticals e.g. pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals (bottles, boxes)

Pharmaceutical waste generator – 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

Pharmacy and Poisons Board – national medicines regulatory authority of Kenya established under the Pharmacy and Poisons Act CAP 244 Laws of Kenya

Radioactive waste – waste containing radioactive substances (e.g. unused liquids from radiotherapy or laboratory research; contaminated glassware; packages or absorbent paper; urine and excreta from patients treated or tested with unsealed radionuclides; sealed sources)

Segregation – any activity that separates waste materials for processing

Sharps waste – used or unused sharps (e.g. hypodermic, intravenous or other needles; auto-disable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass)

Storage – the temporary placement of pharmaceutical waste in a suitable location or facility where isolation, environmental and health protection and human control are provided in order to ensure that the pharmaceutical waste is subsequently retrieved for disposal

VISION
To be a centre of excellence in regulation of Pharmacy profession, medical products and health technologies.

MISSION
To protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and health technologies.

CORE VALUES
The values and principles that underpin the operations of the Board and provide operational guidelines for service delivery are:

- Commitment to public health
- Professionalism
- Integrity
- Timeliness
- Teamwork

CORE FUNCTIONS

1. To ensure the quality, safety and efficacy of medical products and health technologies
2. Regulation of training and practice of pharmacy
3. Advising the government on any matter relating to the regulation of medical products, health technologies and pharmaceutical services

PURPOSE OF THE GUIDELINES

The safe management of pharmaceutical waste is vital in protection of public health and the environment and must be undertaken by all concerned on a continous basis.

So far, the Pharmacy and Poisons Board has not published a guideline on safe management of pharmaceutical waste.

With these guidelines, the Pharmacy and Poisons Board articulates the most appropriate methods and practices for safe management of pharmaceutical waste.

These guidelines should be used together with other existing laws and guidelines on management of healthcare wastes including but not limited to: the Environmental Management and Co-ordination Act (Number 8 of 1999), the Environmental Management and Co-ordination (Waste Management) Regulations and the Ministry of Health National Guidelines for Safe Management of Health Care Waste.

SCOPE OF THE GUIDELINES

These guidelines shall apply to pharmaceutical waste. Pharmaceutical waste shall be waste containing pharmaceuticals e.g. pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals (bottles, boxes).

These guidelines do not apply to:

1. Sharps waste
2. Infectious waste
3. Pathological waste
4. Radioactive waste
5. Chemical waste
6. Non-hazardous or general healthcare waste

1.1 Introduction

The Kenyan health sector (private and public) receives pharmaceuticals in varying quantities either as donations or through normal procurement activities. Pharmaceuticals are important elements of a country's healthcare system and adequate stocks are required at all times.

In the process of ensuring the availability of pharmaceuticals at all times, some medicines may expire. Humanitarian donations during disasters may introduce large quantities of pharmaceuticals in the supply chain. Pharmaceuticals in normal transaction may also be damaged during transportation, storage and handling, thereby becoming unsafe for use. Other medicines may be rendered obsolete due to introduction of newer replacements or change in treatment guidelines. Irrational drug use, poor stock control practices and poor procurement practices also lead to accumulation of unwanted pharmaceuticals in the healthcare system.

The accumulation of pharmaceutical waste has several consequences and these include:

1. **Administrative**. The constraints of accumulated pharmaceutical waste are high storage demands and unnecessary human effort in managing the stocks.
2. **Economic**. The unwanted inventory constitutes significant capital that would otherwise be used for much needed pharmaceutical supplies.
3. **Health**. The accumulated pharmaceutical waste pose significant health hazard especially if disposed off indiscriminately. Antineoplastic medicines are cytotoxic.
4. **Environmental**. The accumulated pharmaceutical waste pose significant environmental hazard especially if disposed off indiscriminately. Pharmaceuticals disposed off in waterways can lead to toxicity to wildlife. Flue gases from pharmaceutical waste incinerators may have an impact on people living and working close to a pharmaceutical waste incineration site.

1.2 Pharmaceutical waste minimization

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

To minimize pharmaceutical waste, the following practices are recommended:

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

1.3 Responsibility of a pharmaceutical waste generator

Any person whose activities generate pharmaceutical waste shall collect, record, segregate, store, transport and dispose such pharmaceutical waste in the manner provided for in these guidelines.

Without prejudice to the foregoing, any person whose activities generate pharmaceutical waste has an obligation to 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.

1.4 Segregation and packaging of pharmaceutical waste

Pharmaceutical waste shall at the point of generation and at all stages thereafter be segregated from other categories of healthcare waste. Cytotoxic pharmaceuticals such as antineoplastic agents shall be segregated from other pharmaceutical waste. Compressed-container medications (aerosols, inhalers) shall be segregated from other pharmaceutical waste. Efforts should be made to ensure that pharmaceutical wastes are in their original packaging to aid identification and prevent reaction between incompatible molecules.

All pharmaceutical waste shall be securely packaged for storage or transport in **brown** plastic bags or **brown** rigid containers which shall be labeled legibly in English or Kiswahili with the following information.

1. The identity of the pharmaceutical waste. An inventory (list) of the pharmaceutical waste can be applied where the container has assorted pharmaceutical waste
2. The name, physical address and telephone contact of the pharmaceutical waste generator
3. The total weight of the pharmaceutical waste
4. Warning or caution statements which may include any of the following as appropriate:

a. the words "**WARNING**", "**CAUTION**", "**POISON**" or "**DANGER! KEEP AWAY FROM UNAUTHORIZED PERSONS**"
b. a pictogram of a skull and 2 crossbones

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

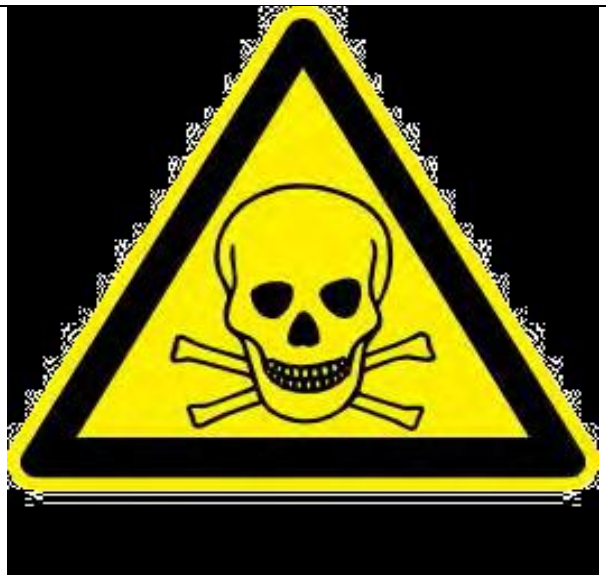
The use of plastic bags (bin liners) in the storage and transport of pharmaceutical waste is on the condition that the plastic bags are legibly and permanently labelled the name of the industry manufacturing the pharmaceutical product and the end-user (here being the NEMA licensed waste handler/transporter).

1.5 Storage of pharmaceutical waste

All pharmaceutical waste shall be stored in designated quarantine stores (marked **PHARMACEUTICAL WASTE STORE**) away from usable pharmaceuticals. These storage areas should be cleaned regularly.

Pharmaceutical waste should be disposed within 1 year from the date of generation.

Storage facilities for pharmaceutical waste should be labeled on the outside with the hazard sign of a skull and 2 crossbones and with the 'No Entry for Unauthorized Persons' signage.



Hazard sign for pharmaceutical waste storage areas

No entry for unauthorized persons in pharmaceutical waste storage areas

1.6 Transportation of pharmaceutical waste

No person shall transport or allow to be transported pharmaceutical waste save in a means of conveyance so as to prevent scattering, escaping, flowing, spillage or leakage of the pharmaceutical waste.

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.

Importation of pharmaceutical waste into the territory of Kenya is not allowable under any circumstances.

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.

Onsite transportation of pharmaceutical waste should be separate from infectious waste.

Drivers engaged in offsite transport of pharmaceutical waste should be medically fit to drive and have appropriate training on risks and the handling of pharmaceutical waste. The training should cover the following topics:

1. Relevant legal regulations
2. Safe handling of pharmaceutical waste
3. Pharmaceutical waste labeling and documentation
4. Emergency and spillage procedures

Vehicles engaged in transport of pharmaceutical waste should be licensed by NEMA, road worthy and fulfill the following design criteria:

1. The vehicle should be labelled "**PHARMACEUTICAL WASTE CARRIER**" and have the name and address of the pharmaceutical waste carrier.
2. A hazard sign for pharmaceutical waste (a skull and 2 crossbones) should be displayed on the vehicle.
3. There should be a suitable system for securing the load during transport.
4. Empty plastic bags, suitable protective clothing, cleaning equipment, tools and disinfectant, together with special kits for dealing with liquid spills, should be carried in the vehicle.

A consignment note should be prepared before offsite transport of pharmaceutical waste. This consignment note should be carried by the driver and should have the following information in case of accidents or official inspection:

1. Pharmaceutical waste source
2. Pharmaceutical waste pick-up date
3. Destination
4. Driver's name
5. Number of containers
6. Total weight of the pharmaceutical waste

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

1.7 Pharmaceutical waste treatment and disposal methods

Before treatment and disposal, pharmaceutical waste should be labeled and sorted using proper personal protective equipment (helmet, heavy duty rubber gloves, fume filter masks and disposable water repellant gowns). Pharmaceutical waste can be sorted according to dosage form (solids, semi-solids, powders, liquids, inhalers or aerosols) or by active pharmaceutical ingredient, depending on treatment options available.

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's 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

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

Note: Cytotoxic drugs should never be landfilled.

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

1. Return to original supplier
2. Chemical degradation in accordance with manufacturers' instructions
3. Incineration at high temperatures. Full destruction of cytotoxic drugs may require incineration temperatures up to 1200 °C and a minimum gas residence time of two seconds in the second chamber. The incinerator should also be equipped with gas-cleaning equipment. Incineration at lower temperatures may release hazardous cytotoxic vapours into the atmosphere. Incineration in single-chamber incinerators or by open-air burning is inappropriate for the disposal of cytotoxic drugs.

1.8 Incineration

Incineration is a high temperature (800 – 1450 °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.

A disadvantage of incineration is the release of combustion by-products into the atmosphere and the generation of residual ash.

Incineration requires no pre-treatment, provided the following waste types are not included or are kept to an absolute minimum:

1. Halogenated materials such as polyvinyl chloride (PVC) plastics (packaging material for pharmaceutical waste needing incineration should not contain PVC material)
2. Sealed ampoules or vials that may implode during the combustion process

3. Pharmaceuticals thermally stable in conditions below 1200 °C (e.g. 5-fluorouracil)

1.9 Encapsulation

Encapsulation involves filling containers with pharmaceutical waste, adding an immobilizing material, and sealing the containers. The process uses either cubic boxes made of high-density polyethylene or metallic drums, which are three quarters filled with pharmaceutical residues. The containers or boxes are then filled up with a medium such as plastic foam, bituminous sand, cement mortar, or clay material. After the medium has dried, the containers are sealed and placed into landfill sites.

The main advantage of encapsulation is its effectiveness in reducing the risk of scavengers gaining access to hazardous pharmaceutical waste.

1.10 Inertization

The process of inertization involves mixing pharmaceutical waste with cement and other substances before disposal to minimize the risk of toxic substances contained in the pharmaceutical waste migrating into surface water or groundwater.

For the inertization of pharmaceutical waste, the packaging should be removed, the pharmaceuticals ground, and a mixture of water, lime and cement added. A homogenous mass is formed, and cubes (e.g of 1 m^3) or pellets are produced onsite. Subsequently, these can be transported to a suitable storage site. Alternatively, the homogenous mixture can be transported in liquid state to a landfill and poured onto the surface of previously landfilled municipal waste, then covered with fresh municipal waste.

The following are typical proportions (by weight) for the mixture:

1. 65% pharmaceutical waste
2. 15% lime
3. 15% cement
4. 5% water

The process is reasonably inexpensive and can be performed using relatively unsophisticated mixing equipment. Other than personel, the main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer and supplies of cement, lime and water.

1.11 Supervision of disposal of pharmaceutical waste

All disposal of pharmaceutical waste (with the exception of returning to donor or manufacturer) shall be done under the supervision of a PPB Inspector and at NEMA approved pharmaceutical waste disposal sites.

Application to the PPB for supervision of pharmaceutical waste disposal shall be in the prescribed form (Annex 1. Application For Disposal of Pharmaceutical Waste).

The applicable fee payable to the PPB for supervision of pharmaceutical waste disposal and issuance of a Certificate of Safe Disposal of Pharmaceutical Waste shall be Ksh.2, 500 and is payable at the time of application for disposal of pharmaceutical waste.

A supervision of disposal form shall be filled and signed by representatives of the Pharmacy and Poisons Board and the pharmaceutical waste disposal facility (Annex 2).

The Certificate of Safe Disposal of Pharmaceutical Waste shall be in the prescribed format (Annex 3. Certificate of Safe Disposal of Pharmaceutical Waste)

2 REFERENCES

Environmental Management and Co-ordination Act. Number 8 of 1999. Government of Kenya

Environmental Management and Co-ordination (Waste Management) Regulations 2006. Legal Notice 121. Government of Kenya

Health Care Waste Management Standard Operating Procedures. First edition. Ministry of Health. Government of Kenya, June 2016

Health Care Waste Management Strategic Plan 2015 – 2020. Ministry of Health. Government of Kenya, April 2015

National Guidelines for Safe Management of Health Care Waste. Ministry of Medical Services and Ministry of Public Health and Sanitation. Government of Kenya, January 2011

Kenya National Guidelines on Safe Disposal of Pharmaceutical Waste. Republic of Kenya. Ministry of Health. March 2001.

Safe management of wastes from health-care activities. Second edition. World Health Organization. 2014.

3 ANNEXES

3.1 Annex 1. Application for disposal of pharmaceutical waste PPB/GDP/INSP/GUD/020

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

APPLICATION FOR DISPOSAL OF PHARMACEUTICAL WASTE

1. NAME OF FACILITY: _____

2. FACILITY 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: _____

3.2 Annex 2. Supervision of disposal of pharmaceutical waste

PPB/GDP/INSP/GUD/020

PHARMACY AND POISONS BOARD
P.O. BOX 27663-00506
NAIROBI

This is to certify that the pharmaceutical waste:

From (company) _____

Application reference number _____

Weighing _____

was safely disposed off

Through the following disposal method _____

On _____

At the following pharmaceutical waste disposal site

_____

Witnesses

S/N	NAME	ORGANIZATION	SIGNATURE
1			
2			
3			

3.3 Annex 3. Certificate of Safe Disposal of Pharmaceutical Waste

PPB/GDP/INSP/GUD/020

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

Through the following disposal method _____

On _____

At the following pharmaceutical waste disposal site

_____

In compliance with the Environmental and Co-ordination (Waste Management) Regulations and the Pharmacy and Poisons Board Guidelines on Safe Management of Pharmaceutical Waste.

Signed:

_____

Registrar,
Pharmacy and Poison Board

END OF DOCUMENT

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