

Guidelines
On
Pharmaceutical Waste
Management



(Mauritius)

Pharmaceutical Waste Management

Executive Summary

Pharmaceutical wastes may be classified as hazardous or non-hazardous.

The first step to manage a pharmaceutical waste is to determine whether or not the waste is hazardous.

Pharmaceutical wastes that would be classified as hazardous wastes are defined in the Environment Protection (Standards for hazardous waste) Regulation 2001.

Hazardous Pharmaceutical wastes.

Hazardous pharmaceutical wastes would have to be managed in accordance with the Regulations in force.

Hazardous pharmaceutical wastes may also comprise chemical wastes such as organic solvents, heavy metal wastes.

The recommended method for the disposal of hazardous pharmaceutical wastes is incineration in high temperature incinerators equipped with proper flue gas treatment systems.

In the absence of high temperature incinerators locally, one possibility for the environmentally sound management of these hazardous pharmaceutical wastes would be to dispose of these at the interim storage facility for hazardous wastes at La Chaumiere once the facility is operational.

Non-hazardous pharmaceutical wastes

Non-hazardous pharmaceutical wastes in solid form may be disposed of as normal wastes at land fill, subject to the approval from the Solid Waste Management Division of the Ministry of Environment.

Non-hazardous liquid pharmaceutical wastes may be disposed of in the sewer network subject to the approval of the Wastewater Management Authority.

The procedure for the disposal of pharmaceutical wastes applies to all pharmacies, health institutions/facilities both in the private and public.

A non-exhaustive list of hazardous pharmaceutical wastes, which may be reviewed periodically, is at Annex.

Guidelines on Pharmaceutical Waste Management

Scope

The purpose of this paper is to ensure that the disposal and destruction of medicines and scheduled substances within pharmacies is undertaken safely with due regard to minimizing the risk of such activity causing harm to the environment or harm to health.

The disposal of pharmaceutical wastes must be carried out as per WHO guidelines and in accordance with the existing laws in Mauritius (The Environment Protection (Standards for hazardous waste) Regulation 2001) and, following approval from the Solid Waste Division of the Ministry of Environment as well as the Wastewater Management Authority as the case may be.

The paper focuses primarily on the following aspects of pharmaceutical waste management.

1. Management of hazardous pharmaceutical waste applying best management practices
2. Management of Non hazardous pharmaceutical waste applying best management practices
3. Minimization of pharmaceutical waste

Aim

1. To protect public Health and Safety
2. To provide a safer working environment and
3. To minimize waste generation and environmental impacts of waste disposal
4. To ensure compliance with legislative requirements

Definitions:

For the purpose of this policy, "**Pharmaceutical waste**" means:

- Expired, unused, damaged, recalled and spilled and contaminated pharmaceutical products, medicines, cytotoxic preparations, vaccines and other biologicals.
- Items used in the pharmacy for the handling and manipulation of pharmaceutical products. E.g bottles, ampoules, vials, boxes.

“Disposal” means:

The removal of medicines and scheduled substances destined for destruction without the intention of retrieval, in compliance with existing legislation.

“Destruction” means:

Rendering of medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to health.

Introduction:

Improper disposal of medicines and pharmaceutical products may have a serious impact on the environment and on human health. In general, expired pharmaceuticals do not represent a serious threat to public health or to the environment. Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities or wildlife. Expired drugs may come into the hands of scavengers and children if a landfill is insecure. Pilfering from a stockpile of waste drugs or during sorting may result in expired drugs being diverted to the market for resale and misuse. Most pharmaceuticals beyond their expiry date are deemed to be no longer efficient and a few may develop a different adverse drug reaction profile. There are some categories of expired drugs or defective disposal practices that carry public health risk.

The main health risks are as follows:

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leachate entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, large quantities of

disinfectants should not be discharged into a sewerage system or watercourse but can be introduced if well diluted.

- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air.
- Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public. Scavenging in unprotected and insecure landfills must be considered as a hazard.

Pharmaceutical waste is considered to be dangerous if it contains any of the followings:

1. Chemotherapeutic agents
2. Drugs meeting OSHA criteria
3. Drugs with lethal Dose 50 (LD50 in 50 % of test animals) less than or equal to 50 mg/kg body weight
4. Endocrine disruptors
5. Immunosuppressants
6. Vitamins and mineral preparations with potential toxicity due to chromium, selenium or cadmium
7. Injectables and other sterile preparations containing thiomersal

Controlled substances (e.g. narcotics and psychotropics) require tight security and control. Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from stores. Immobilization is the best method of preventing pilfering from a store.

- In the absence of suitable disposal sites and qualified personnel to supervise disposal, unwanted pharmaceuticals present no risk provided they are securely stored in dry conditions. If stored in their original packing there is a risk of diversion and to avoid this they are best stored in drums with the pharmaceuticals immobilized.

Legislative requirements.

For medicines falling under scheduled substances, the responsible pharmacist of the facility or institution where the scheduled substances (Dangerous Drugs Schedule II and III) are kept, should first obtain approval for destruction from the Registrar of the Pharmacy Board.

The scheduled substances should only be destroyed in the presence of a pharmacy Inspector or any person duly authorized by the pharmacy Board.

Such person or pharmacist as the case may be, shall issue a certificate confirming the destruction of the medicine and must contain the following particulars:

- The generic and the brand name of the drugs that have been disposed of.
- The quantity of drugs
- The Batch Number and the expiry dates
- Reason(s) for disposal
- Method and date of disposal

The Dangerous Drug Register is amended accordingly to account for the medicines that have been disposed of.

Pharmaceutical waste:

Sound management of pharmaceutical products facilitates waste minimization and is of prime importance to better waste management in general. Pharmaceutical products before being therapeutic agents are first of all chemicals. These chemicals despite being in small quantities can be hazardous to human health , animal life, aqualife and the environment. They may cause intoxication either by acute or chronic exposure and injuries ,including burns. Intoxication can result from absorption of a chemical or a pharmaceutical substance through the skin or mucous membrane or from inhalation or from ingestion.

Many cytotoxic drugs are extremely irritating and have harmful effects after direct contact with the eyes and skin. They may also cause dizziness, nausea, headache or abnormalities. Special care in handling genotoxic waste is therefore essential ; any discharge of such waste into the environment could have disastrous ecological consequences.

Categorization of pharmaceutical waste:

Pharmaceutical waste can be broadly classified as Hazardous and Non- Hazardous.

- **Hazardous pharmaceutical waste:**

By definition **Hazardous waste** is **waste** that poses substantial or potential threats to public health or the environment. A waste is considered as hazardous if it possesses at least one of the following unique and measurable properties or characteristics:

1. Ignitability
2. Corrosivity
3. Reactivity
4. Toxicity

Ignitability: Liquid preparations (taxol injection) containing at least 24 % alcohol are products that are likely to cause ignition. Other products that fall under this category are (i) substances that readily supply oxygen ($KMNO_4$, and H_2O_2), (ii) flammable aerosols and (iii) collodion based preparations.

Corrosivity: Any waste which has a PH of less than or equal to 2 or greater than or equal to 12.5 exhibits the characteristics of corrosivity (glacial acetic acid and sodium hydroxide)

Reactivity wastes: are wastes that are unstable under normal conditions. They can cause explosions, toxic fumes, gases or vapours when heated , compressed or mixed with water. E.g Nitroglycerine

Toxic wastes are waste that affect living organisms by exhibiting characteristics of lethality. These wastes include products such as chemotherapeutic agents, antibiotics, selenium in anti dandruff shampoos, lindane, chloroform , m-cresol in

injections, phenyl mercuric acetate in eye preparations, Mercurochrome, warfarin, phenol, epinephrine, resorcinol and nicotine amongst others .

Insulin and vaccines are categorized as infectious wastes.

Annex 1 is a list of hazardous pharmaceutical waste which is not exhaustive and which may be periodically revised or as and when required..

- **Non-Hazardous wastes:**

All pharmaceutical wastes that are not hazardous are categorized as Non – hazardous pharmaceutical wastes. They are considered as solid waste and disposed of in landfills.

Disposal methods:

1. Incineration

Incineration is the best way to dispose of pharmaceutical products. The wastes should be mixed with other combustible materials such as packaging materials to ensure optimum combustible conditions. Hazardous pharmaceutical waste can be disposed of by this method provided that the resulting toxic gases are not allowed to escape in the open air. This can be achieved by using industrial incinerators with the following specifications:

Type of incinerator: rotary kiln incinerators

Chambers: two

Minimum temperature : at least 1100 degree Celsius.

However pressurized containers should not be incinerated as it may explode during incineration and cause damage to the equipment.

Also, wastes with high heavy metal content (e.g lead, cadmium, mercury) should not be incinerated as it will cause emission of metallic compounds into the atmosphere.

Cytotoxic waste which is highly hazardous and which normally should not be landfilled unless encapsulated, may be incinerated at high temperatures (above 1200 degree Celsius) so as to completely destroy them. Incineration at lower temperatures may result in the release of hazardous cytotoxic vapours in the air.

2. Landfill disposal

Small quantities of pharmaceutical wastes produced on a daily basis may be land filled provided they are dispersed in large quantities of general waste. Non hazardous solid wastes are generally disposed of by this methods. Cytotoxic and narcotics should however be never land filled even in small quantities.

Landfilling of large quantities of pharmaceutical wastes is not recommended unless the waste is encapsulated which minimizes the risk of ground water contamination. Large amounts of pharmaceutical waste should not be disposed of with genral wastes nor should they diluted and discharged into sewer except for mild solutions such as vitamin preparations.

3. Encapsulation

This method is used to immobilize waste prior to disposal into landfill. It generally applies to large quantities of pharmaceutical wastes.

Method: The waste is removed from its secondary packages but not from its primary packages (strips or bottles). It is then filled in plastic or steel drum to 75 % of its capacity. The remaining space is filled with either plastic foam, sand , cement or clay. The drum is closed with a lid and is either buried or disposed in a landfill .

Hazardous waste such as antineoplastics and anti-infectives are normally encapsulated before they are land filled. Encapsulation may also apply to semi solids.

4. Discharge to a sewer

Moderate quantities of relatively mild liquid or semi solid pharmaceuticals, such as solutions containing vitamins, cough syrups,intravenous solutions , eye drops (but not antibiotics or cytotoxic drugs) may be diluted in a large flow of water and discharged into sewers. It is inappropriate to dispose of pharmaceutical wastes in slow moving or stagnant water. Fast flowing water sources should be used to flush the diluted liquid pharmaceuticals.

Segregation of pharmaceutical wastes

Hazardous waste: Pharmaceutical wastes categorized as hazardous are segregated and collected **in purple plastic bags** and labeled as Hazardous pharmaceutical waste where the name of place where the waste has been generated.

Pharmaceutical wastes generated in hospital/clinic wards should be returned to the pharmacy store for disposal with a duly filled waste generation record.

Vaccines and biologicals should be discarded as infectious wastes.

Non –Hazardous waste: Pharmaceuticals not listed in the hazardous list should be considered as non hazardous and should be further segregated into liquids and solid/semi solid.

The non hazardous pharmaceutical wastes should be discarded into **green plastic bags** and should be labeled as Non Hazardous pharmaceutical waste (Solid or liquid) and the name of place where it is generated..

The used ampoules containing non-hazardous pharmaceutical wastes should be crushed on a hard impermeable surface and disposed of as sharps.

Storage of pharmaceutical wastes:

All pharmaceutical wastes generated at a particular facility or institution must be stored in dry places prior to disposal. All waste-bag seals should be in place and intact until they are transported to disposal sites.

The Office of the Director Pharmaceutical Services may be contacted for any clarification or further information in this respect. (tel. 2011334, 2013608).

Hazardous Pharmaceutical waste List.

1. All antineoplastics
2. All antibiotics
3. All immunosuppressants
4. All endocrine disruptors
5. Adrenaline
6. Physostigmine
7. Nitroglycerine
8. Warfarin
9. Disulfiram
10. Phenol
11. Lindane
12. Chloral hydrate
13. Chloroform
14. Ethyl Ether
15. Formaldehyde
16. Selenium
17. Pharmaceuticals containing heavy metals (Barium, mercury, cadmium, thiomersal)
18. Resorcinol
19. Products containing nicotine
20. Mercurochrome
21. Hydrogen peroxide
22. Potassium permanagate
23. Alcohol based products

Note: the above list is not comprehensive and exhaustive. The list is subject to revision as and when required.

