PHARMACY, MEDICINES & POISONS BOARD

GUIDELINES FOR DESTRUCTION OF MEDICINES AND HEALTH PRODUCTS

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1.0 INTRODUCTION

The Pharmacy, Medicines and Poisons Board (PMPB) was established through an Act of Parliament(PMP Act number 15 of 1988).The subsequent establishment of a Secretariat in Lilongwe in 1991, marked the implementation of the provisions of the Act. The Board is empowered through the Act to ensure that safe, quality and efficacious medicines and medical supplies are used by the general public.

To ensure implementation of this, a number of activities are required to be put in place such as a system for proper disposal of medicinal products and medical supplies. These guidelines were developed in order to give direction to stakeholders on how to dispose off medicines. It gives direction on handling of unwanted medicines and procedures for application for medicine disposal and the actual exercise for destruction.

In developing this guide, PMPB anticipates that stakeholders will utilise them in order to prevent accumulation of expired medicines in storage areas which can act as a source of illegal medicine handling.

For some time now, disposal of medicinal products was not done in a professional way as a result of lack of guiding tools. This has resulted into accumulation of unwanted medicines in both Government and Private institutions, a practice which may prove hazardous to health. Hazards associated with expired medicines may result from improper disposal procedures and handling activities by everyone in the medicine distribution system.
Improper disposal of medicines may result in the following:

1. Improper disposal procedures may allow some unwanted medicines to be marketed in the illegal markets
2. Risk of thefts and their reuse
3. May cause serious health effects, if used
4. Contamination of drinking water
5. Killing of bacteria necessary for sewage treatment non-biodegradable antibiotics, antineoplastic and disinfectants.
6. Result in release of toxic atmospheric pollutants from burning medicines at low pressure or in an open container.

In order to protect the public from above, all public and private institutions and stakeholders are required to adhere to procedures in these guidelines.

2.0 PROCEDURES FOR HANDLING AND DISPOSAL OF UNWANTED MEDICINES AND HEALTH PRODUCTS

Unwanted Medicines shall include:

1. Expired
2. Improperly sealed
3. Damaged

4. Improperly labelled
5. Counterfeit
6. Substandard
7. Adulterated
8. Prohibited
9. Obsolete

2.1 Steps taken

Steps needed to be taken before disposing of unwanted medicines and health products as follows:

2.1.1 Decision:

The pharmacist-In-charge or a person responsible of the institution in consultation with management shall decide when action needs to be taken to dispose of unsafe medicines and health products accumulated in their stores

2.1.2 Approval:

Approval for disposal should be sought from PMPB.
Fill health product disposal log form PMPB/INS/FORM 06
Send filled form together with proof of payment to PMPB
In case of Government institutions, another approval from relevant ministry is required.

2.1.3 Planning:

Planning in terms of funding, human resources, expertise, professional time, space, equipment, material and available disposal options is required. This is essential before practical steps are taken to start disposal. To obtain a rough estimate of the volume of materials to be sorted, it is recommended that measurements are made using a tape measure and conversion from volume of material to weight is made using a density figure of 0.2 metric tons/cubic metre.

2.2 Handling of unwanted Medicines and Health products

1. These should be stored and segregated away from usable stock and labelled in red eg "Rejected drugs"
2. Safe custody of these medicines should be maintained.
3. Register indicating name of the product, Name of manufacturer, Batch number, date of rejection, reasons for rejection and should be maintained and readily available for scrutiny
4. The products should be kept in different categories by dosage form eg

    i. **Solids**: semisolids, powders, capsules, powder for injection, granules, creams, gels, suppositories
    ii. **Liquids**: solutions, suspension, syrup, mixtures, linctus, aerosols
    iii. **Non**-medicinal products
5. Antineoplastics and controlled substances should be kept separately

6. Keep in containers according to their dosage forms so as to facilitate verification exercise, sorting and selection of disposal method
7. Establish an estimate of the cost of products
8. An application for disposal of unwanted medicines shall be made to the Registrar listing the number and quantity of products and a rough estimate of cost. This should be submitted together with an application fee.
9. On receipt of the application, PMPB will communicate the date to carry out destruction
10. For Government institutions, **two (2)** requests should be made: One to the relevant Ministry informing them that they would like to carry out disposal exercise under supervision of PMPB. The request should list the products, quantity and an approximate total cost.
    Another application for disposal shall be made to the PMPB listing the number of quantity of products and a rough estimate of cost. This should be submitted together with an application fee.

3.0 PROCEDURE FOR APPLICATION TO DISPOSE OFF UNSAFE MEDICINES AND HEALTH PRODUCTS

A person who intends to carry out the disposal of products shall follow the following procedure:

1. Request in writing to the Registrar of the PMPB by using application form(Appendix 1)
2. The request shall be accompanied with a list of products to be disposed off and quantity stating trade name, generic name and strength(where applicable) dosage form, pack size, quantity, manufacturer, batch number, and market value of the product.
3. Once the request has been received, PMPB shall acknowledge and inform the applicant in writing and arrange a date for disposal after payment of drug destruction fee within 14 days.
4. The applicant is expected to communicate the date for destruction to City/Town Assembly, the Police, and other relevant authorities.
5. When the date for destruction is agreed, PMPB shall send inspectors to the premises to verify and authenticate the information submitted and carry out the activity in a team which is called **Board Of Survey** (this is composed of: Drug inspector, Police officer ,City/Town Assembly Officer, other officer from relevant authority).
6. Before the actual drug destruction, the Board Of Survey will authenticate the information which was submitted with supervision of the Drug Inspector in an exercise which is called "**sorting and verification exercise**"

4.0 SORTING AND VERIFICATION EXERCISE

During verification, the Drug Inspector shall supervise sorting exercise of the unwanted products before determination of disposal method.
Some of the categories of products and their recommended disposal methods are stated below:

Serial No	Category	Disposal method
1	Solid, semi-solid, powder	Landfill, incineration and waste immobilization
2	Liquids	Sewer, high temperature incineration and treated waste
3	Antineoplastics	Treated waste and land fill, high temperature incineration and return to manufacture
4	Controlled drugs	Treated waste and land fill, high temperature incineration
5	Aerosols/inhalers	Landfill without waste inertization
6	Disinfectants	Sewer or fast flowing water course
7	PVC plastics, glass(ampoules, vials, bottles)	Landfill and recycle
8	Paper cardboard	Burn, recycle, landfill

Sorting should be done in an open or in a well ventilated area/building as close as possible to stock pile in an orderly manner.
After completion of verification exercise, a verification form shall be filled and signed by all members of the Board of Survey. Verification exercise shall involve the following stages:

1. Product identification
2. Separate products which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicinal products.
3. Sorting according to method of destruction
4. Staff involved in sorting exercise shall be provided with protective gears by PMPB such as gloves, boots, overalls and dust masks and shall be briefed on the sorting exercise, health and safety risks associated with handling the materials.
5. Sorted medicinal products shall be carefully packed in cardboard boxes or jute bags and information to be indicated outside the container shall include: dosage form(s) and proposed mode of destruction.
6. Materials should be kept in a dry, secure and preferably separate room to avoid mix-up with usable medicines.
7. The total cost of drug destruction is borne by the owner.

5.0 DESTRUCTION OF UNWANTED MEDICINES AND HEALTH PRODUCTS

1. A Drug inspector, City/town Health Officer and Police officer shall supervise the transportation of products from the owners premises to the disposal site.
2. The destruction exercise shall be supervised by A Drug inspector, City/town health Officer and Police Officer.
3. The unwanted products shall be transported in a closed motor vehicle to avoid pilferage.
4. Supervisors shall wear protective gear such as overalls, gloves, masks, caps and boots during the exercise.
5. Upon completion, a drug disposal form should be dully filled and signed by Supervisors and owners representatives.
6. Copies of drug disposal form shall be sent to owner, City/Town Assembly and PMPB

7. A certificate of drug destruction shall be issued by the PMPB.

Note: During destruction, particular care should be taken with medicines such as antineoplastics, narcotics and penicillin's to avoid associated hazards.

6.0 DISPOSAL METHODS

6.1 Land fill

This involves placing the unwanted medicine and health products directly into a land disposable site without prior treatment. The method is used for disposing of solid waste. Small quantities of unwanted medicines and heath products produced on a daily basis may be land filled provided that they are dispersed in large quantities of general waste. Cytotoxic, narcotic medicines and cosmetic medicines containing heavy metals such as mercury should not be land filled even in small quantities.

6.2 Land fill for untreated products

This method is applicable to small quantities of products. It involves placing untreated waste medicine into uncontrolled, non-engineered, open dump. The products should be covered immediately with large quantity of other type of waste or soil/sand to prevent scavenging by unscrupulous people. Discharging of untreated expired medicines into such a site is not recommended except as a last resort. They should preferably be discharged after immobilization by encapsulation or inertization. It should be noted that discharging in open uncontrolled dump with insufficient isolation from the aquifer or other water courses can lead to pollution with the risk of contamination of drinking water. The exercise should be done with tight security by police and supervised by technical personnel. The method is applicable to solids, semisolids, powders, pharmaceutical waste dosage forms, cosmetics.

6.3 Engineered landfill

The method has some features to protect from loss of chemicals into the aquiver. Direct deposit of products is second best to discharging immobilized products into such a landfill.

6.4 Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer relative safe disposal route for products. An appropriate landfill consists of an evacuated pit isolated from water courses and which is above water table. Once products are thrown into the pit, they are compacted and covered with soil to maintain sanitary environment. Limited quantities of untreated products in the form of solids, semi-solids and powders are disposed of using this method.

6.5 Landfill for treated ~~expired medicines~~ unsafe medicines and products(waste immobilization)

Immobilization of can be done in the following ways:

6.5.1 Encapsulation

In this process, unwanted products are immobilized in a solid block within a plastic or steel drum. The drum should be cleaned before using it and should not have contained explosives or hazardous materials.

The exercise starts by filling the drum to 75% of its capacity with solid and semi-solid products. The remaining space is filled by pouring in a medium such as cement or cement-lime mixture, plastic foam or bituminous sand. For ease and speed of filling, the drum lid should be cut open and bent back. Once the drum is filled to 75% capacity, the mixture of lime, cement and water in proportion of 15:15:5(by weight) is added and the drum is filled to capacity. Steel drum lid should be bent back and sealed by seam or spot welding. The sealed drum lids should be placed at the base of a landfill site and covered with fresh municipal solid waste. The method is applicable to solid waste, semisolids, powders and liquids.

6.5.2 Inertization

This method involves removing packaging materials (inner and outer container).The products are ground and a mixture of water, cement and lime added to form a homogenous paste. The paste is transported in liquid state by concrete mixer truck to a landfill site and decanted into a normal municipal waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The main tools required for the operation are a grinder or road roller(to crush the medicines) .Concrete mixer, cement and water are mixed in the following ratios by weight:65%,15%,5% respectively. Water can be added more than the required amount when need arise in order to have satisfactory liquid consistency.

This method is applied to solids, semisolid, powders, antineoplastics, controlled drugs and cosmetics containing heavy metals e. g mercury.

6.5.3 Sewer

This is a method used whereby unwanted medicinal and cosmetic products in liquid form e.g. syrups, lotions and intravenous fluids are diluted with water and flushed into a proper functioning sewage system in small quantities over a period of time without causing serious public health or environmental effect. Fast flowing watercourses may likewise be used to flush small quantities of well diluted liquid medicines, cosmetics or antiseptics.

6.5.4 Medium temperature incineration

This involves the use of medium temperature incinerators. Expired solid pharmaceuticals may be destructed by using a 2-chamber incinerator that operates at a minimum

temperature of 850^{o}cwith a combustion retention time of at least 2 seconds in the second chamber. It is recommended that pharmaceutical waste should be diluted with large quantity of municipal waste (approx:1:1000) prior to destruction. Medium temperature furnaces may be used in absence of medium temperature incinerator. This type of incinerator is not suitable for incineration of halogenated compounds as they need a higher temperature incinerator. This method may be used for solids, semi-solids, powders and controlled medicines.

6.5.5 High temperature incineration

This involves the use of high temperature incinerator, operating at a temperature in excess of 850^{o}c .These are sophisticated incinerators and are expensive. Alternatively cement kilns serve the same purpose. Cement kilns can reach temperatures of 1450-2000^{o}c that is suitable for total destruction of organic waste compounds. These have long combustion retention times and disperse exhaust gases via tall chimneys thus reducing the risk of environmental effect. It may be necessary to remove packaging materials prior to incineration to avoid clogging and blockage of incinerator kiln.

6.5.6 Burning in open containers

Paper and cardboard packaging materials may be burnt if they are not going to be recycled. Polyvinyl chloride (PVC) plastic however must not be burnt. Products should not be destroyed by burning at low temperatures in open containers as toxic pollutants may be released into the air. It is strongly recommended that only very small quantities of products are disposed off in this way.

6.5.7 Return to donor or manufacturer

The possibility of returning products for safe disposal by the manufacturer should be explored particularly for medicines which present problems eg antineoplastics and heavy metals. It may also be reasonable to return them to donor for disposal in the case of donations.

7.0 REFERENCES

1. WHO Guidelines for safe disposal of unwanted pharmaceuticals in Emergencies
2. WHO guidelines for drug donations,1996. WHO/DAP96.2
3. Management Sciences for Health/WHO/DAP, Managing drug supply, 2nd edition, Harford (CT) 1997