GUIDELINE FOR SAFE DISPOSAL OF EXPIRED AND UNWANTED PHARMACEUTICALS

NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

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1. Introduction

Medicines can take many years to degrade and persist for a long time in the environment. Many medicines are now detectable at low levels in the environment.

Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by communities and wildlife.

To prevent unnecessary environmental contamination, medicines should **not** be treated as general waste. They are not suitable for landfill and should not be poured down the sink, flushed down the toilet or otherwise permitted to enter the water table.

The National Medicines Regulatory Authority Act No. 05 of 2015 empowers the National Medicines Regulatory Authority (NMRA) to recall and dispose of medicine, medical devices, borderline products or investigational medicinal products. Disposal of pharmaceuticals should be carried out under the supervision of an Authorized Officer appointed. And also prior approval should be obtained from the authority before disposing of items.

Information on pharmaceutical disposal must be carefully handled as it may be politicized and sensationalized. If the public and media are not kept judiciously informed of the efforts to dispose of expired pharmaceuticals safely, the disposal work may be severely hampered by misinformation propagated by uninformed journalists and politicians.

A number of methods for safe disposal of unusable and unwanted pharmaceuticals are described. They are methods which involve minimal risks to public health and environment.

2. Purpose

This guideline provides advice on the implementation of safe disposal of unusable unwanted pharmaceuticals. (Section 7.4 -List of unwanted pharmaceuticals)

The best environmental option for pharmaceutical destruction is purpose-built high temperature incineration with adequate flue gas cleaning. However, this is not the only method that can be used to achieve adequate disposal.

Though this high tech facility is available in Sri Lanka , other marginally less safe treatments and disposal methods are also considered.

NMRA holds the sole responsibility in disposing pharmaceuticals in the country with support of central and provincial health authorities. Other relevant government agencies are also consulted whenever necessary. E.g: Central Environmental Authority.

3. REQUIREMENTS

3.1 Prior approval should be obtained from the NMRA who intends to dispose unusable and unwanted (including recalled and Substandard and falsified (SF) products) pharmaceuticals.

3.2 Every manufacturer, importer, wholesaler, retailer, Donor, Government or private hospital, specialized campaign who handle pharmaceuticals, must maintain a register of unusable and unwanted pharmaceuticals as described in the annexure 1.

3.3 The stock of unusable and unwanted pharmaceuticals which is to be disposed, shall be separately stored in a demarcated location under strict supervision.

3.4 A formal request to the Chief Executive Officer of the NMRA shall be forwarded, who intends to dispose unusable and unwanted pharmaceuticals. as described in the annexure 11 and the list of products in both hard and soft copy (excel format) with the following details: a) Product description b) Quantities c) Unit cost d) Total commercial values and e) Reason (s) for which the products are declared unwholesome. f) Batch (applicable to recalled SF products)

3.5 The authority upon receipt of such request shall acknowledge and refer the matter to the Head, Inspectorate & Enforcement Division to verify and authenticate the information (Annexure 111) submitted in relation to the consignment to be disposed.

3.6 Whenever necessary, more details of certain items shall be asked by the authority.

3.8 By considering the composition, nature of the items, quantity and reason for destruction, the authority shall inform the most appropriate method of disposing, to the applicant.

3.9 The applicant shall arrange the disposal accordingly, under the supervision of an authorized officer of the NMRA.

4. Steps to be taken

A series of steps need to be taken when disposing of unwanted pharmaceuticals, and these are briefly summarized below.

4.1 Decision

The Medical Supplies Division, Hospitals, Provincial Health Authorities Importers, health campaign and private sector institutions (whole sale pharmacies and drug stores) decide when action needs to be initiated, because of an accumulation of unwanted pharmaceuticals which are unfit for human consumption and for veterinary treatment.

4.2 Approval

The National Medicines Regulatory Authority (NMRA) is responsible for approval and sanctioning of disposal of pharmaceuticals.

4.3 Planning

Planning, in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal options will be required. This is essential before practical steps can be 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 meter.

4.4 Forming work teams

Work should be conducted by teams consisting of authorized officers and general medical workers, who are preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel. The size of each team, and the ratio of experts to workers, will be determined by the volume and composition of the stockpiles, and working conditions at the sites.

4.5 Health and safety of work teams

All workers should wear appropriate protective equipment including overalls and boots at all times, and gloves, masks and caps when appropriate. Masks should be worn when tablets or capsules are being crushed as part of the disposal technique and when there is a risk of powders being liberated. Particular care is required when handling antineoplastic.

4.6 Sorting

The objective of sorting is to separate the pharmaceuticals into separate categories for which different disposal methods are required. The separation should be made into those that can be required, disposal by different methods. For example, controlled drugs (e.g. narcotics), antineoplastic drugs and antibiotics all require special methods of disposal. Substantial investment in human resources may be required for identifying and separating pharmaceuticals.

4.7 Disposal

Disposal options vary considerably between situations, and the ideal solution may not be feasible. The aim of these guidelines is to propose the simplest, safest and most practical alternatives.

4.8 Security

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 landfills. Immobilization (see Sections 5.3 and 5.4) is the best method of preventing pilfering from a store or landfill. If, as a last resort, pharmaceuticals must be discarded direct to a landfill then they must be covered immediately with a large quantity of municipal waste.

5 Consequences of improper disposal or non-disposal

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 past their expiry date become less efficacious and a few may develop a different adverse drug reaction profile.

There are some categories of expired drugs or defective disposal practices that carry a public health risk. The main health risks are summarized below:

• 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, antineoplastic and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastic 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. Ideally this should be avoided.

• Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public.

• 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, as described in Section 6.3-waste encapsulation.

6 Disposal methods

Constraints in funding for disposal of waste pharmaceuticals necessitate cost-effective management and methods. The main way to achieve this is to sort the material to minimize the need for expensive or complicated disposal methods.

6.1 Return to donor or manufacturer

Wherever practical the possibility of returning unusable drugs for safe disposal by the manufacturer should be explored; particularly drugs which present disposal problems, such as antineoplastic. For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date it may be possible to return them to the donor for disposal.

6.2 Landfill

Landfill means to place waste directly into a land disposal site without prior treatment or preparation. Landfill is the oldest and the most widely practiced method of disposing of solid waste. Three types are recognized.

6.2.1 Engineered landfill

Such a landfill has some features to protect from loss of chemicals into the aquifer. Direct deposit of pharmaceuticals is second best to discharging immobilized pharmaceutical waste into such a landfill.

6.2.2 Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer a relatively safe disposal route for municipal solid wastes, including waste pharmaceuticals. The top priority is protection of the aquifer. An appropriate landfill consists of an evacuated pit isolated from watercourses and above the water table. Each day's solid waste is compacted and covered with soil to maintain sanitary conditions. The term "safe sanitary landfill" refers to such a site that is adequately situated, constructed and managed.

6.3 Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials

previously. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and 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 lids should be cut open and bent back. Care should be taken to avoid cuts to hands when placing pharmaceuticals in the drums. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets which can then be put on a pallet transporter.
Encapsulation of antineoplastic drugs requires a slightly different technique (see Section 7.6).

6.4 Waste immobilization: inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.
The approximate ratios by weight used are as follows:
• Pharmaceutical waste: 65% • lime: 15% • cement: 15% • water: 5% or more to form a proper liquid consistency.

a. Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydrogeologist or sanitary engineer may be required in situations where sewers are in disrepair or have been damaged.

b. Burning in open containers

Pharmaceuticals should not be destroyed by burning at low temperature in open containers, as toxic pollutants may be released into the air. Paper and cardboard packaging, if they are not to be recycled, may be burnt. Polyvinyl chloride (PVC) plastic however must not be burnt. While burning pharmaceutical waste is not advocated as a method of disposal, it is recognized that it is not infrequently used. It is strongly recommended that only very small quantities of waste pharmaceuticals be disposed of in this way.

6.6.1 Medium temperature incineration

In emergency situations the responsible authorities may consider it acceptable to treat expired solid form pharmaceuticals using a two-chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber. Many older municipal solid waste incinerators are medium temperature incinerators and the use of these facilities is encouraged as an interim measure, rather than less safe options, such as inadequate discharge to a landfill. In this case, it is recommended that the pharmaceutical waste is diluted with large quantities of municipal waste (approximately 1:1000). Such incinerators are not designed to incinerate halogenated compounds safely. The very low halogen content in most pharmaceuticals is likely to result in negligible halogen content in the combustion gases.

6.6.2 Novel high temperature incineration

Industries which use high temperature technology, such as cement kilns, coal fired thermal power stations or foundries usually have furnaces that operate at temperatures well in excess of 850°C, have long combustion retention times and disperse exhaust gases via tall chimneys, often to high altitudes.
Several features of cement kilns make them suitable for pharmaceutical disposal. During burning the cement raw materials reach temperatures of 1450°C while the combustion gases reach temperatures up to 2000°C. The gas residence time at these high temperatures is several seconds. In these conditions all organic waste components are effectively disintegrated. Some potentially dangerous or toxic combustion products become adsorbed into the cement clinker product or are removed in the heat exchange equipment.

6.7 Chemical decomposition

If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill. This method is not recommended unless chemical expertise is readily available. Chemical inactivation is tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times. For disposal of a small quantity of antineoplastic drugs this method may be practical. However for large quantities, for example, more than 50 kg of antineoplastic, chemical decomposition is not practical, as even small consignments need to be treated through repeated application of this method.

7. Sorting

7.1 The objectives of sorting

The objective of sorting is to separate the pharmaceuticals into categories that require different disposal methods. The appropriate safe disposal method recommended will depend principally on the pharmaceutical dosage form of the drugs. Segregated temporary storage areas or receptacles must be provided for each sorted category.

Practical advice on sorting
The sorting process includes:
• identifying each item;
• If not usable, making a judgement on the optimal method of disposal and sorting accordingly;
• leaving packages and boxes intact until reaching their location, prior to definitive disposal or transport to an institution for use.

7.2 Optimum conditions for sorting

Sorting should be done in the open or in a well ventilated and, if necessary, heated covered structure designated by the local authority. Sorting should be done as close as possible to the stockpile in an orderly way, with all sorted material clearly labelled and separated at all times. Staff supplied with protective equipment (gloves, boots, overalls, dust masks, etc.), should work under the direct supervision of an authorized officer, and should receive training on the sorting criteria, and health and safety risks associated with handling the materials.
Once sorted, the pharmaceuticals should be carefully packed into steel drums or into containers such as sturdy cardboard boxes, with the contents clearly indicated on the outside of the containers. The materials should be kept in a dry secure and preferably separate room to avoid being confused with in-date pharmaceuticals, until disposal is carried out.

7.3 Sorting categories

The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as controlled substances (e.g. narcotics), antineoplastic (cytotoxic-anti-cancer) drugs and any other hazardous non-pharmaceutical products that may have been mixed among the pharmaceuticals. This must all be stored in separate, secure designated areas prior to their separate, safe disposal.
The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets). The following sorting categories and subcategories are suggested.

7.4 Expired or unwanted pharmaceuticals

Pharmaceuticals that should never be used and should always be considered as pharmaceutical waste are:

- all expired pharmaceuticals;
- all recalled and SF products
- all unsealed syrups or eye drops (expired or unexpired);
- all cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines);
- all bulk or loose tablets and capsules. If unexpired these should only be used when the container is still sealed, properly labelled or still within the original unbroken blister packs;
- all unsealed tubes of creams, ointments, etc. (expired or unexpired).

7.5 Sorted by active ingredient (special disposal needed)

- controlled substances; e.g. narcotics, psychotropic substances;
- anti-infective drugs;
- Cytotoxic/antineoplastics;
- antiseptics and disinfectants.

7.6 Sorted by dosage form (all other pharmaceuticals):

- solids, semi-solids and powders -tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories, etc.;
- liquids - solutions, suspensions, syrups, etc.;
- ampoules;
- aerosol canisters including propellant-driven sprays and inhalers.

7.7 Recyclable material

Waste paper, cloth, packing materials, clothes, gauze and wooden items, such as pallets, can be recycled, burned or disposed of as normal waste to a landfill.

Plastic, metal and glass items can be reused (glassware can be given to laboratories, mechanical items given to scrap dealers), recycled (if facilities are available) or disposed of in a landfill. Depending on the type of material and its proposed reuse, appropriate treatment, such as cleaning or disinfection, may be needed. Other general rubbish can be disposed of in a landfill. If a recycling programme exists for the reuse of such materials, they can be separated from the pharmaceuticals prior to their disposal in the landfill.

8. Recommended disposal methods by sorting category.

8.1 Solids, semi-solids and powders

8.1.1 Anti-infective drugs, controlled drugs and antineoplastic

If it is not possible to return these to the manufacturer or adequate incineration is unavailable, then encapsulation or inertization is recommended before discharge to a landfill.

Anti-infective drugs and antineoplastic are encapsulated to delay release to the environment and avoid high concentrations. Controlled drugs should be immobilized under supervision of the authorized officer, the police or a judicial representative, depending on the relevant regulations.

8.1.2 Other drugs

Small quantities of solid and semi-solid pharmaceuticals, typically not more than 1% of the total daily waste, can be disposed of directly in a landfill with large volumes of municipal solid waste, if no other suitable method is available. The figure of 1% is based on expert opinion rather than scientific evidence.

The pharmaceutical solid waste should be disposed of at the base of the working face of the landfill and covered immediately by fresh municipal waste. Security measures to prevent scavenging should be in place. Pharmaceuticals classed as readily biodegradable organic material in the solid or semi-solid form, e.g. vitamins, can also be disposed of in a landfill.

Large quantities of solid and semi-solid pharmaceuticals are best destroyed by high temperature incineration as previously described. Medium temperature incineration is however widely practiced for solid form pharmaceuticals, provided that the pharmaceuticals are “diluted” in large quantities of municipal waste. Whenever there is no access to either high or medium temperature incineration plants, the use of the encapsulation method represents an acceptable, but not always feasible, method of disposal for large quantities of pharmaceuticals.

8.1.3 Procedure

Solids, semi-solids and powders should be removed from their outer packaging but remain in their inner packaging and placed in clean plastic or steel drums, for treatment according to the encapsulation method. Removing outer packaging dramatically reduces the volume for disposal for methods such as encapsulation. Small quantities of pharmaceuticals still within their packaging may be discharged into a landfill as described above. They should be immediately covered with municipal waste. Outer packaging should be disposed of as nondrug, non-chemical materials by recycling or burning.

The separation of materials should be as follows:
• tablets and capsules in plastic/foil blisters should be removed from all outer packaging but not from blisters;
• tablets and capsules in bottles should be removed from outer packaging but not bottles;
• tablets and effervescent in tubes should be removed from outer packaging but not from tubes;
• powders in sachets or bottles should be removed from outer packaging but not from sachets or bottles.
Any large quantities of a single type of drug should be checked by the supervising pharmacist to ensure that the drug is not an anti-infective drug, antineoplastic or controlled substance.

8.2 Liquids

8.2.1 Pharmaceuticals with no or low toxicity

Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers.
Other liquid pharmaceuticals (except controlled drugs, antineoplastic or anti-infective drugs)
Small quantities of other liquid pharmaceuticals, which are not controlled substances, anti-infective drugs, or antineoplastic, can be flushed into sewers. If there are no sewers or there is no functioning sewage treatment plant, liquid pharmaceuticals can be first diluted with large volumes of water and poured into large watercourses, providing they are immediately dispersed and diluted by the flowing river water.
Liquid pharmaceutical waste may be disposed of using the cement encapsulation procedure, high temperature incineration or in cement kilns.
It is not acceptable to discharge liquid pharmaceuticals, diluted or not, into slow moving or stagnant surface waters.

8.3 Ampoules

These can be crushed on a hard impermeable surface (e.g. concrete) or in a metal drum or bucket using a stout block of wood or a hammer. Workers doing this should wear protective equipment, such as eye protection, boots, clothing and gloves. The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill. The liquids released from the ampoules should be diluted and disposed of as described above.
Ampoules should not be burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator. Melted glass will also clog up the grate of a furnace or incinerator if the operating temperature is above the melting point of glass.
Volatile liquids in small quantities can be allowed to evaporate in the open air.

8.4 Anti-infective drugs

Anti-infective drugs should not be discarded in an untreated form. Generally they are unstable and are best incinerated, and if that is not possible encapsulated or inertized. Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.

8.5 Controlled substances

Control substances should be destroyed under the supervision of an Authorized officer stipulated in the NMRA Act. Such substances must not be allowed into the public domain as they may be abused. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

8.6Antineoplastics

Antineoplastic drugs, previously called cytotoxics or anti-cancer drugs, have the ability to kill or stop growth of living cells. They are used in the chemotherapy of cancer which is usually performed in specialized treatment centres. It is extremely unlikely that they would form part of an aid donation in emergencies. However, if unwanted and discharged into the environment they can have very serious effects, such as interfering with reproductive processes in various life forms. Their disposal must therefore be handled with care.

Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. They should ideally be safely packaged and returned to the supplier for disposal.

If this option is not possible they must be destroyed in a two-chamber incinerator which operates at a high temperature of at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment. An after-burner (i.e. the secondary chamber) is important for the destruction of cytotoxic waste, as it is possible that antineoplastic solutions could become aerosolized following the initial combustion in the primary chamber. As a result, without a higher temperature secondary chamber, degraded antineoplastic material may be emitted

from the chimney. The secondary combustion chamber consequently ensures that such antineoplastic substances are fully incinerated.

Antineoplastic drugs/waste should never be disposed of in a landfill other than after encapsulation or inertization. Work teams handling these drugs must avoid crushing cartons or removing the product from its packages. They may only be discharged in a sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.

8.6.1 Special treatment for antineoplastics

For antineoplastics drums should be filled to 50% capacity with drugs, after which a well stirred mixture of lime, cement and water in the proportions of 15:15:5 (by weight), should be added and the drums filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. The drums should then be sealed by seam or spot welding and left to set for 7 to 28 days. This will form a firm, immobile, solid block in which the wastes are relatively securely isolated. The drums are then placed at the working face of a landfill which has been lined with an impermeable layer of clay or membrane.

8.6.2 Antineoplastic drug disposal

Methods of disposal:	1. return to supplier; 2. high temperature incineration; 3. waste encapsulation
Methods of disposal of antineoplastics not to be used:	4.low and medium temperature incineration; 5. disposal to sewers and water courses; 6. directly to landfill.

8.7 Disinfectants.

In general disinfectants do not have an expiry date. They can be stored and gradually used over time so there is no real need to dispose of them. Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly large quantities should not be put into watercourses since the disinfectants will damage aquatic life. Small quantities of diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits. The guideline control proposed is 50 litres total per day, with the disposal spread over the whole working day.

If possible, disinfectants should be used, for example for toilet cleaning in hospitals. Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an expiry date. If this date has past, the material can still be used for general disinfection purposes at an appropriate dilution decided by an authorized officer, or disposed of in a chemical waste disposal facility or a cement kiln.

The World Health Organization publishes chemical safety sheets for common disinfectants and pesticides. The sheets provide data on the chemical composition of the substance and indicate suitable methods of disposal.

8.8 Aerosol canisters

Disposable aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator. Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.

9. References.

Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies: Interagency Guidelines © World Health Organization 1999 ,WHO/EDM/PAR/99.2

10. Related Documents and forms

- Annexure 1 –Details of the items to be disposed (A register)
- Annexure 11- Application for disposal
- Annexure 111- Verification form

11. APPROVAL AND REVIEW DETAILS

	NAME	SIGNATURE
Prepared by	Mrs. Deepika Bulathsinhal Mr.Amith Perera	
Reviewed By	Mrs. Amara Pinnawala	
Recommended By	Mr.Ajith Priyadarshana	
Approved by	Dr.Kamal Jayasinghe	

Annexure- 1- Register of unusable and unwanted pharmaceuticals

S/N	Product category (Eg- Antibiotics,steroids,anti diabetic ets..)	Name of the product		Strength	Dosage form	Batch Number	Pack Size	Reason for disposal	Value (Rs.)	Quantity
		Generic Name	Trade Name							

Annexure 11- Application Form for Disposal of unusable and unwanted pharmaceuticals

To: Chief Executive Officer
National Medicines Regulatory Authority
120, Norris canal Road
Colombo 10

I / We ... ... of *(company/institution postal address)* …………………………………………………………………………………………… hereby apply for disposal of unusable and unwanted pharmaceuticals, stored at No……………………………………………..

Details of items as annexure 1 are attached.

Retail/Wholesale License Number- ……………………… issued on- ……………………......................

Name & contact details of the in-charge of disposal- …………………………………………………………

Declaration: I certify that the information provided in the application form is true and correct.

Signature - ....
Name of Applicant-………………………..
Designation-………………………………..
Date-... ... ...
Rubber Stamp

For official use only:

Received by: .... Signature...

Rubber Stamp

Annexure 111 - Verification Form

National Medicines Regulatory Authority
120, Norris Canal Road
Colombo 10

Name of applicant. ... ... of (postal address)... ... ... …… undertaking the business of (specify)……....
Location of Business…….....
Does the actual product(s) tally with the list of product(s) submitted to NMRA? Yes/No
Other observation (s).....
Suggested mode of destruction.....

Date of verification.....
1. Name of Drug Inspector.....Signature.....
2. Name of Drug Inspector.....Signature.....