GUIDELINES FOR STORAGE AND DESTRUCTION OF RETURNED THERAPEUTIC GOODS

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1. HISTORY

This is the first edition of these guidelines.

2. APPLICATION - Guidelines for Industry

This document is applicable to pharmaceutical manufacturers and importers for assurance of secure stock returns to eliminate pilferage and liquidation of the returned stocks. These aspects include, storage, distribution, transportation, documentation and record-keeping practices.

3. PURPOSE

These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the distribution (Including both dispatch and return) of pharmaceutical products from and to the premises of the manufacturer. This includes all parties involved in trade and distribution of medicines, pharmaceutical manufacturers, including the manufacturers of finished products and pharmaceutical wholesalers as well as other parties such as distributors, logistics providers, transport companies and forwarding agents and their employees. The objective of these guidelines is to assist and provide information to pharmaceutical manufacturers and importers for assurance of secure stock returns to eliminate pilferage and liquidation of the returned stocks.

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4. INTRODUCTION

Distribution (Including both dispatch and return of Pharmaceutical products) is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage and distribution of such products. The objective of these guidelines is to assist and provide information to pharmaceutical manufacturers and importers for assurance of secure stock returns to eliminate pilferage and liquidation of the returned stocks. These aspects include, storage, distribution, transportation, documentation and record-keeping practices. These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the distribution of pharmaceutical products to and from the premises of the manufacturer of the product.

5. LEGAL BACKGROUND

Drug Regulatory Authority of Pakistan (DRAP) is performing post marketing surveillance under 4(c) of DRAP Act, 2012 and is responsible for evaluation, coordination and monitoring of safety, efficacy and quality of drugs, drugs recall and withdrawals through Division of Quality assurance and Laboratory Testing. Under section 7 (t) of the DRAP Act, 2012, the Authority develops, adopts, issues and enforce the standards and guidelines to ensure safety, efficacy and quality of therapeutic goods.

GLOSSARY

Acronyms

BMR	Batch Manufacturing Record
BPR	Batch Processing Record
DRAP	Drug Regulatory Authority of Pakistan
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
MSDS	Material Safety Data Sheet
NRA	National Regulatory Authority
RRA	Reference Regulatory Authority
WHO	World Health Organization

Definitions

Batch (or Lot)	means a defined quantity of starting material, packaging material, or finish product processed in a single process or series of processes so that it could be expected to be homogeneous in the case of continuous manufacture the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity, and to complete certain stages of manufacture it may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to from a final homogeneous batch;
Batch No. (or Lot number)	means a distinctive combination of numbers and or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, and that permit the production history of the batch to be traced and revived.
Batch Records / Batch Manufacturing Record (BMR)/ Batch Processing Record (BPR)	batch records mean all documents associated with the manufacture of a batch of bulk product or finished product showing a history of each batch of product and of all circumstances pertinent to the quality of the final product.
Board	means the concerned Board or any competent forum legally authorized under DRAP Act, 2012, The Drugs Act, 1976 and the rules framed thereunder.
Defective Product	Attributes of therapeutic goods which may affect the quality, safety and/or efficacy of the product.
Drug	means drug as defined in Schedule-I of the DRAP Act, 2012.
Investigation product (IP) / Investigational Medicinal product (IMP)	means investigational therapeutic goods including pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled or formulated or packaged in a way different from the approved form or when used for an unapproved indication or when used to gain further information about an approved use
Licensee	means manufacturer, importer, distributor, registration holder or enlistment holder of therapeutic goods
Manufacture	manufacture means all operations of production, quality control, release, storage and the related controls.
Manufacturer	means a company that carries out at least one step of manufacture.

Marketing Authorization	means a document issued by the DRAP under the DRAP Act, 2012, as a certificate of registration / enlistment of a therapeutic good.
Mock Recall	A mock recall demonstrates the ability to recall feed in the event of an actual recall. This ensures that employees are familiar with the process so that necessary feed can be recalled quickly and accurately
Pharmaceutical Product	means any drug intended for human use or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form.
Quality Control Laboratory (QCL)	means any laboratory notified for the test/analysis of therapeutic goods
Recall	means the removal of specific batch/batches of a therapeutic good/product from the market for reasons relating to the quality, safety or efficacy and/or if they are not in line with the particulars provided in registration / enlistment application of the product
Returned products / Therapeutic goods	This includes all the products/therapeutic goods returned to the manufacturer due to recall (statutory/voluntary), due to field complaint or return/recall of an Investigational product to its sponsor
Reference Regulatory Authority	means a regulatory authority as notified by any competent forum, board or committee of DRAP for the purpose of reliance.
Substandard and Falsified (SF) Products	Substandard drug means a drug as defined in Section 3 (zz) of the Drugs Act, 1976. Whereas Falsified products include Spurious, Adulterated, Misbranded and Counterfeit drugs (as defined in Section 3 (zb), 3 (a), 3 (s) and 3 (f) of the Drugs Act 1976 respectively).
Therapeutic Goods	includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority under Section 2(xxxvi) of the DRAP Act, 2012. (Therapeutic goods may hereinafter refer as the product.)

6. GENERAL PRINCIPLES FOR STORAGE OF RETURNED THERAPEUTIC GOODS

The principles of GDP (Good distribution practices) should be considered for the distribution of pharmaceutical products, in a country, as a means of establishing minimum standards.

The principles of GDP are applicable both to pharmaceutical and IMP products moving forward in the distribution chain from the manufacturer to the end user and to products which are moving backwards in the chain, for example, as a result of the return or recall thereof. For detailed procedure for destruction of IPs/IMPs is provided in "Guidelines for Conduct of Clinical Research in Pakistan".

Collaboration may be required between all parties including DRAP, customs agencies, law enforcement agencies, manufacturers, distributors and entities responsible for the supply of pharmaceutical products to patients to ensure the quality and safety of pharmaceutical products and to minimize the risk of breaches in the supply chain of returned stocks.

7. ORGANIZATION AND MANAGEMENT

There should be an adequate organizational structure for each entity defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated.

Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions.

A designated person should be appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained for the storage of returned goods.

8. PERSONNEL

All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on written standard operating procedures (SOPs). Personnel should receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training program. In addition, training of the personnel

should include the topic of product security and aspects of product identification. A record of all training, which includes details of subjects covered and participants trained, should be kept.

Personnel dealing with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion) should be given specific training.

Personnel involved in the distribution of pharmaceutical products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, infectious or sensitizing, should be provided with protective garments as necessary.

9. QUALITY SYSTEM

The quality system should include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality. The totality of these actions is described as the quality system.

Market Authorization Holders should from time to time conduct mock recall activities at least once a year to check the effectiveness of recall system in place. The focus of these activities should be on return/receiving and traceability of therapeutic goods. The quality system should be able to identify the risks/flaws identified in these activities. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

10.TRACEABILITY OF PHARMACEUTICAL PRODUCTS

Procedures should be present to foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. This is a shared responsibility among the parties involved. There should be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall and secure storage of returned products.

Measures should be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels from the

manufacturer/importer to the entity responsible for selling or supplying the product to the patient or his or her agent(s). Records including expiry dates and batch numbers should be part of a secure distribution documentation enabling traceability.

11.PREMISES, WAREHOUSING AND STORAGE

Principles of Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process.

12.STORAGE AREAS

Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

Storage areas should be of sufficient capacity to allow the orderly storage of returned products.

Receiving areas should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.

To prohibit the unintentional or unauthorized use of returned stocks, separate storage areas should be assigned for the temporary storage until a decision as to their future has been made.

Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination. Validated systems and SOPs are to be provided in order to achieve this purpose.

Broken or damaged items should be withdrawn from intact stock and stored separately in a designated area designed with in the returned goods storage area.

13.STORAGE CONDITIONS AND STOCK CONTROL

Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at intervals defined in SOP.

Any deviation from approved SOP or stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mix-ups, incorrect issues

and receipts, thefts and/or misappropriations of pharmaceutical products. Documentation relating to the investigation should be kept for a predetermined period.

14.VEHICLES AND EQUIPMENTS

Vehicles and equipment used to distribute, store or handle pharmaceutical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind.

The design and use of vehicles and equipment must aim to minimize the risk of returned stock's damage and pilferage. Dedicated vehicles and equipment should be used, where possible, when handling pharmaceutical products. If non-dedicated vehicles and equipment are used, procedures (SOPs) should be in place to ensure that the quality/integrity of the pharmaceutical product will not be compromised.

Where third-party carriers are used, manufacturers and distributors should develop written agreements with carriers to ensure that appropriate measures are taken to safeguard returned pharmaceutical products.

Mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products as well as those suspected of being counterfeits. Such goods should be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

Measures and procedures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

15.DISPATCH AND RECEIPT

Records for the dispatch of pharmaceutical products should be prepared and include at least the following information:

- Date of dispatch;

- Complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
- Complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, distributor, hospital/clinic etc.);
- A description of the products including, e.g. name, dosage form and strength;
- Quantity of the products, i.e. number of containers and quantity per container;
- Applicable transport and storage conditions;
- A unique number to allow identification of the delivery order; and
- Assigned batch number and expiry date.

Incoming shipments (returned/recalled stocks) should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and that labelling appears intact.

16.TRANSPORTATION AND PRODUCTS IN TRANSIT

Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Moreover, Product shipments should be secured and include the appropriate documentation to facilitate identification and verification of compliance with regulatory requirements.

Pharmaceutical products should be stored and transported in accordance with procedures such that:

- The identity of the product is not lost.
- Adequate precautions are taken against spillage, breakage, misappropriation and theft.

Physical segregation should be provided for the storage and distribution during transit of returned pharmaceutical products and suspected counterfeits. The products should be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

Packaging materials and shipment containers should be of suitable design to prevent damage of pharmaceutical products during transport. Seal control programs should be in place and managed properly.

17.DOCUMENTATION

Written instructions and records which document all activities relating to the transportation of returned stocks, including all applicable receipts and invoices should be available.

Distributors should keep records of all pharmaceutical products received. Records should contain at least the following information:

- Date;
- Name of the pharmaceutical product;
- Quantity received, or supplied; and
- Name and address of the supplier.

The title, nature and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.

All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

The nature, content and retention of documentation relating to the distribution of pharmaceutical products and any investigations conducted and action taken, should comply with national legislative requirements.

The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

Mechanisms should exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to DRAP.

Permanent records, written or electronic, should exist for each returned products indicating recommended storage conditions, any precautions to be observed. Pharmacopoeial requirements and current national regulations concerning labels and containers should be respected at all times.

Where the records are generated and kept in electronic form, back-ups should be maintained to prevent any accidental data loss.

18. RETURNED PRODUCTS ASSESSMENT

The necessary assessment and decision regarding the disposition of returned products must be made by person authorized by the management of the firm. The nature of the product returned to the distributor or manufacturer, any special storage conditions required, its condition and history and the time elapsed since it was issued, should all be considered in this assessment.

Destruction of pharmaceutical products should be carried out keeping in view the requirements provided by Pakistan Environment Protection Agency and with due consideration to protection of the environment. Furthermore, for destruction of raw materials, concerned MSDS may also be referred. Moreover, records of all returned and/or destroyed pharmaceutical products should be kept for a predetermined period.

19. CONTRACT ACTIVITIES

Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.

The contract should define the responsibilities of each party including observance of the principles of GDP and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of counterfeit medicines into the distribution chain, such as by suitable training programs.

Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function.

20. PROCESS OF DISPOSAL OF RECALLED PHARMACEUTICAL PRODUCT

The process of safe and environment friendly process of disposal of defective/recalled pharmaceutical products consists minimally of following steps:

20.1. Decision & Approval

20.1.1. In case of a statutory recall:

The relevant Board will decide the fate of the recalled stocks i.e. either the remedial action to be complied by the firm or the destruction of the stocks.

20.1.2. In case of a voluntary recall:

The licensee/manufacturer will inform the QA&LT Division of DRAP. QA&LT division will monitor the recall of the defective batches of the product and will forward the matter to the relevant Board for deciding the fate of the recalled stocks. The relevant Board will then decide the fate of the recalled stocks i.e. either the remedial action to be complied by the firm or the destruction of the stocks considering the **Guidelines for Recall of Defective Therapeutic Goods.**

21. PLANNING

It is the responsibility of licensee to make arrangements for the necessary expertise, human resources, professional time, space, equipment, material and available disposal options and coordination with the relevant field office of DRAP.

22. HEALTH AND SAFETY OF WORK TEAMS

All workers should wear appropriate protective equipment including overalls and boots at all times whereas gloves, masks and caps when required. 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. Special care is required when handling anticancer, steroidal, hormonal and high allergy risk products.

23. 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 according to the method of disposal and the nature of product.

23.1. 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 designated areas prior to their disposal. The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets). The following are the subcategories for sorting of pharmaceutical products:

23.1.1. Expired or defective pharmaceuticals

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

- all expired pharmaceuticals;
- 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)

23.1.2. Sorted by active ingredient (Special disposal needed)

These may include;

- Controlled substances; e.g. narcotics, psychotropic substances;
- Anti-infective drugs;
- Cytotoxic/antineoplastics;
- Antiseptics and disinfectants.

23.1.3. Sorted by dosage form

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

23.1.4. Recyclable materials

- 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 program exists for the reuse of such materials, they can be separated from the pharmaceuticals prior to their disposal in the landfill.

24. 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 disposal methods.

25. SECURITY

Controlled substances (e.g. narcotics and psychotropics) require strict security and control (add requirements from Ministry of narcotic control). Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from landfills. Immobilization (see Sections 7.2 and 7.3) 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.

26.DISPOSAL METHODS / STRATEGIES

26.1. Landfill

26.1.1. Open uncontrolled non-engineered dump

Non-engineered dump is probably the most common land disposal method in developing countries. Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used. Discarding of untreated waste pharmaceuticals into such a site is not recommended except as a last resort. They should preferably be discharged after immobilization by encapsulation or inertization. As a last resort, where it is not possible to immobilize the waste

pharmaceuticals, then the untreated waste products must be covered rapidly with large quantities of municipal waste to prevent scavenging. It should be noted that discarding in open, uncontrolled dumps with insufficient isolation from the aquifer or other water courses can lead to pollution, with the risk of drinking water contamination in the worst cases.

26.1.2. 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.

26.1.3. Highly Engineered sanitary landfill

Properly constructed and operated landfill sites offer a relatively safe disposal route for 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. Upgrading an uncontrolled waste disposal site to a reasonable standard should be considered.

26.2. 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. 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. 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 as provided later in this guidance document.

26.3. 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 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.

26.4. 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.

27.BURNING/INCINERATION

27.1. Incineration 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.

27.2. Medium temperature incineration

In absence or unavailability of high temperature, two-chamber incinerators, medium temperature furnaces and incinerators can be used. 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.

27.3. 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. Many countries do not possess and cannot justify economically, expensive and sophisticated chemical waste disposal facilities, so the use of an industrial plant provides a viable and cheap alternative.

Pharmaceuticals should be introduced into the furnace as a reasonably small proportion of the total fuel feed. It is suggested that as a sensible "rule of thumb" no more than 5% of the fuel fed into the furnace at any one time is pharmaceutical material. Cement kilns typically produce 1,500 to 8,000 metric tons of cement per day and therefore quite large quantities of pharmaceutical material can be disposed of in a short period. It may be necessary to remove packaging and/or to grind the pharmaceuticals to avoid clogging and blockage of the fuel feed mechanisms.

28. 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.

29. RECOMMENDED DISPOSAL METHODS

Following are the recommended disposal methods for the destruction of returned therapeutic goods:

S.No.	Category	Sub-category	Recommended method
01	Solids, Semi-solids & powders	Anti-infective drugs, controlled drugs and anti-neoplastic drugs	• If there is no adequate incineration unavailable then encapsulation or inertization is recommended before discharge to a landfill.
		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. • 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.
02	Liquids	Pharmaceuticals with no or low toxicity	• Readily biodegradable organic pharmaceuticals and other harmless solutions (different concentrations of certain salts, amino acids, lipids or glucose) may be diluted and flushed into a sewer.
		Other liquid pharmaceuticals (except controlled drugs, anti-neoplastics or anti-infectives)	• Small quantities of other liquid pharmaceuticals, can be flushed into sewers. • If there are no sewers available 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.

03	Ampoules	N/A	• 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. • Volatile liquids in small quantities can be allowed to evaporate in the open air. • Ampoules of antineoplastics or anti-infective drugs must not be crushed and the liquid discharged to sewers. They should be treated using the encapsulation or inertization disposal methods described above.
04	Anti-infective drugs	N/A	• Preferably 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.
05	Controlled substances	N/A	• Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. • These products should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.
06	Anti-neoplastics	N/A	• 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. • Encapsulation or inertization. • Discharged in a sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.
07	Disinfectants	N/A	• 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. • disposed of in a chemical waste disposal facility or a cement kiln.
08	Aerosol containers	N/A	• Provided they do not contain poisonous substances, they should be disposed of in a landfill, dispersed among municipal solid wastes.

30. REFERENCES

In developing these guidelines, guidance documents referred are;

i. The DRAP Act, 2012.

ii. WHO good distribution practices for pharmaceutical products (WHO technical report series, No. 957, 2010)

iii. Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies (WHO/EDM/PAR/99.2)