Government of Nepal
Ministry of Health and Population
Department of Durg Administration

Updated draft Guidelines for the Safe Disposal of Unwanted Pharmaceutical

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1. Purpose

The purpose of these guidelines is to ensure the safe disposal of unwanted pharmaceuticals, safeguarding public health and the environment. These aim to raise awareness and establish collaborative disposal procedures among all stakeholders.

2. Scope

These guidelines apply to Pharmaceutical manufacturers, Distributors/whole sellers, Retailers, Importers and any entities involved in the disposal of unwanted pharmaceuticals in Nepal including hospitals & hospital Pharmacies, Clinical trial centers, an local government entities etc.

Pharmaceuticals that should never be used and should always be considered as Unwanted **pharmaceutical** if they are:

- Expired pharmaceuticals
- Unsealed liquid preparation, eye drops, tubes of creams, ointments, etc.
- Cold chain breached pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines)
- Bulk or loose tablets and capsules without proper labelling
- Pharmaceuticals with any signs of damage to the packaging or the product

3. Why be concerned about unwanted pharmaceuticals and their safe disposal

Traces of pharmaceutical by-products are now shown to be found in surface, ground, and drinking waters around the world

Pharmaceuticals, including those for treating human and animal conditions, range from highly toxic (Cytotoxic agents) to those causing milder physiological effects like anti-microbials etc. The concern arises with unwanted pharmaceuticals, as they often do not decompose easily in the environment. This persistence means they can be absorbed by plants, animals, and humans, potentially causing harm.

4. Relevance of the Guidelines

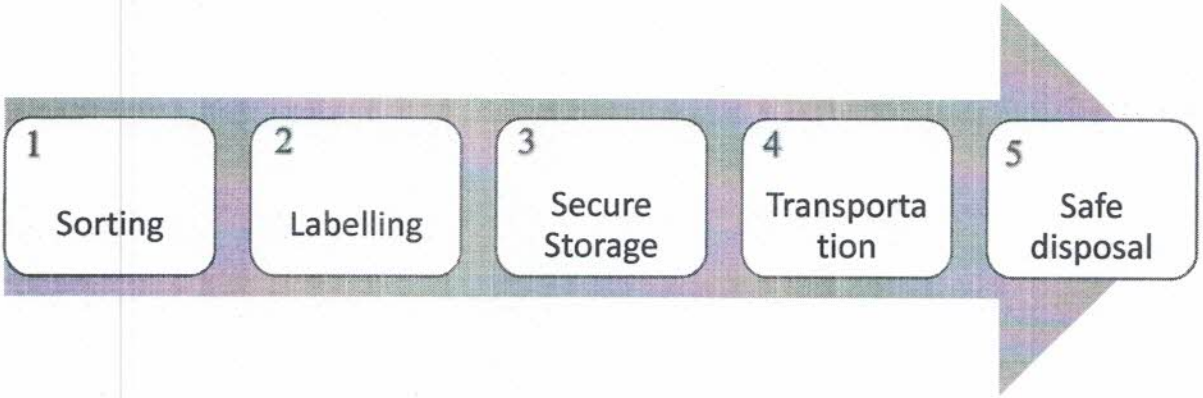
In the context of existing protocols such as the Health Care Waste Management Guidelines 2014, National Health Care Waste Management Standards and Operating Procedures 2020, and National Guidelines on Procedures Related to the Destruction of Expired and Unusable Drugs, Chemicals, and Medicinal Materials 2022, there was still a need for specific guidance. The Department of Drug Administration (DDA) crafted these guidelines to address the unique disposal requirements of various stakeholders within Nepal. These include manufacturers, distributors, retailers, and entities handling regulatory samples or operating within institutions like the DDA or the National Medicines Laboratory (NML). This specialized approach provides comprehensive and pertinent instructions to ensure the safe and effective disposal of unwanted pharmaceuticals from all relevant sources.

5. How to utilize these guidelines

This guideline does not impose new regulatory obligations but serves as a tool offering targeted compliance strategies for the safe disposal of unwanted pharmaceuticals. It promotes best practices and concentrates on the storage, transportation, and safe disposal of various categories of unwanted pharmaceuticals, including bulk hazardous materials, trace chemotherapy waste, non-hazardous items, and recalled or defective products, including SF pharmaceuticals. For safe disposal practices, it is crucial to follow the step-by-step processes outlined in the subsequent sections of this guide.

6. Key Steps to ensure a successful safe disposal of unwanted pharmaceuticals

The safe disposal of unwanted pharmaceuticals involves a series of established steps to prevent environmental contamination and ensure public safety. These steps, which include sorting, labeling, secure storage, transportation, and the final disposal, are designed to manage pharmaceutical waste responsibly and efficiently from start to finish. Each phase plays a critical role in the overall disposal process, requiring adherence to both regulatory guidelines and best practices.



6.1 Sorting

Sorting is the key step to separate the pharmaceuticals into categories that require different disposal methods.

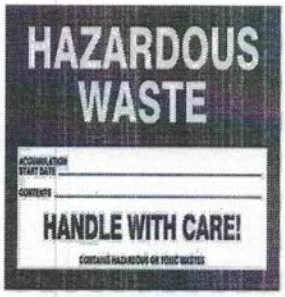
Category that requires Special disposal	Antineoplastics, Controlled Drugs, Anti-infectives, Hormonal products, vaccines, Radio pharmaceuticals etc

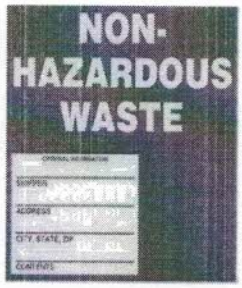
All other pharmaceuticals should be sorted by dosage form

- Solid & Powders: Tablets, capsules, granules, powders for injection
- Semi-solids: Creams, lotions, gels, Suppositories, etc.
- Liquids: Solutions, suspensions, syrups, etc.
- Aerosol & Inhalers: Including propellant-driven sprays and inhalers
- Parenteral dosage form (e g. ampoules & vials etc.)
- Intravenous solutions (with no added medicine), enteral and parenteral feeds. Such as Sodium chloride, sterile water, and glucose Solutions

6.2 Labelling

Accurately Label on unwanted pharmaceuticals and include all relevant information. Some examples of labels are mentioned as:





6.3 Secure Packaging & Storage

Secure packaging and storage are crucial for managing unwanted pharmaceuticals. These should be kept in designated areas with controlled access until decisions regarding disposal or requalification are finalized. This approach is essential for:

- Preventing unauthorized access to ensure that only qualified personnel can handle these substances.
- Minimizing environmental impact by avoiding any inadvertent release of harmful substances.
- Ensuring proper containment to maintain the integrity of pharmaceuticals and prevent leaks or spills.
- Maintaining accurate records for tracking, compliance, and auditing purposes.

Packing Container

- Constructed of material that is compatible with the waste
- Spill, leak, and puncture- proof
- Kept closed except during active addition or removal of waste to/from the container

Emergency Protocols

Develop protocols for spillage, unauthorized access, and equip storage areas with emergency tools like spill kits and fire extinguishers.

6.4 Transportation

Transportation of pharmaceutical waste must be conducted by specialized carriers. It is best practice for this waste to be directly collected by a waste contractor at the point of generation.

6.5 Safe Disposal

Appropriate procedure implementation is very important for safe disposal of unwanted pharmaceuticals to prevent stockpiling, ensuring compliance with regulations, especially for controlled and hazardous products.

Accountability

Manufacturers and/or Importers are accountable for the accepting the unwanted pharmaceuticals from distributors or retailers and safe disposal according to safe environmental practices. Disposal companies are responsible for the integrity of pharmaceuticals collected from various sources until final disposal.

Certification

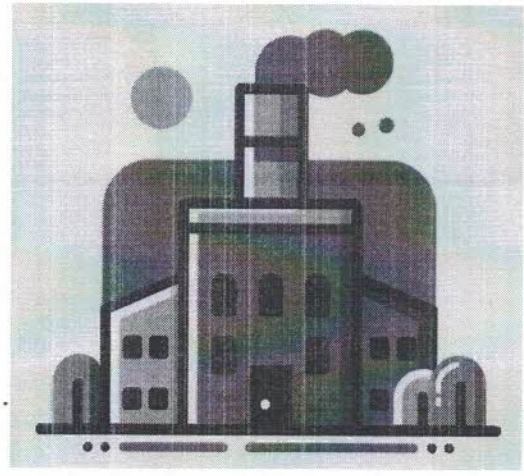
Disposal companies must issue a Certificate of Safe Disposal post-disposal, authenticated by designated observers present during the disposal.

Record-Keeping

Maintain disposal records with corresponding certificates, each uniquely identified, and archive them for at least five years.

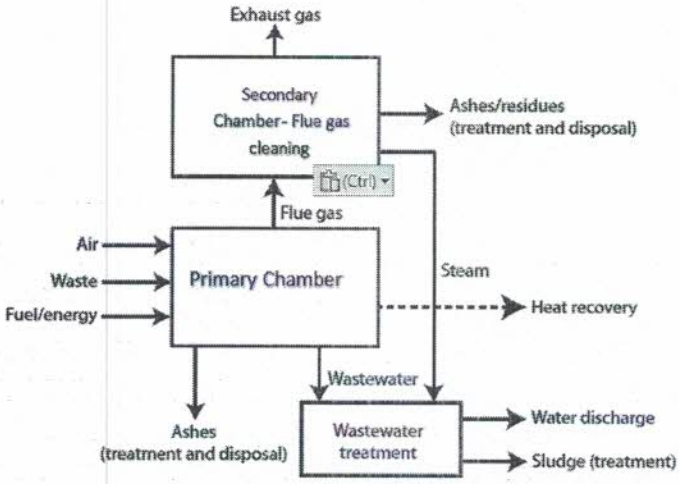
7. Disposal Methods -At a Glance

7.1 Incineration



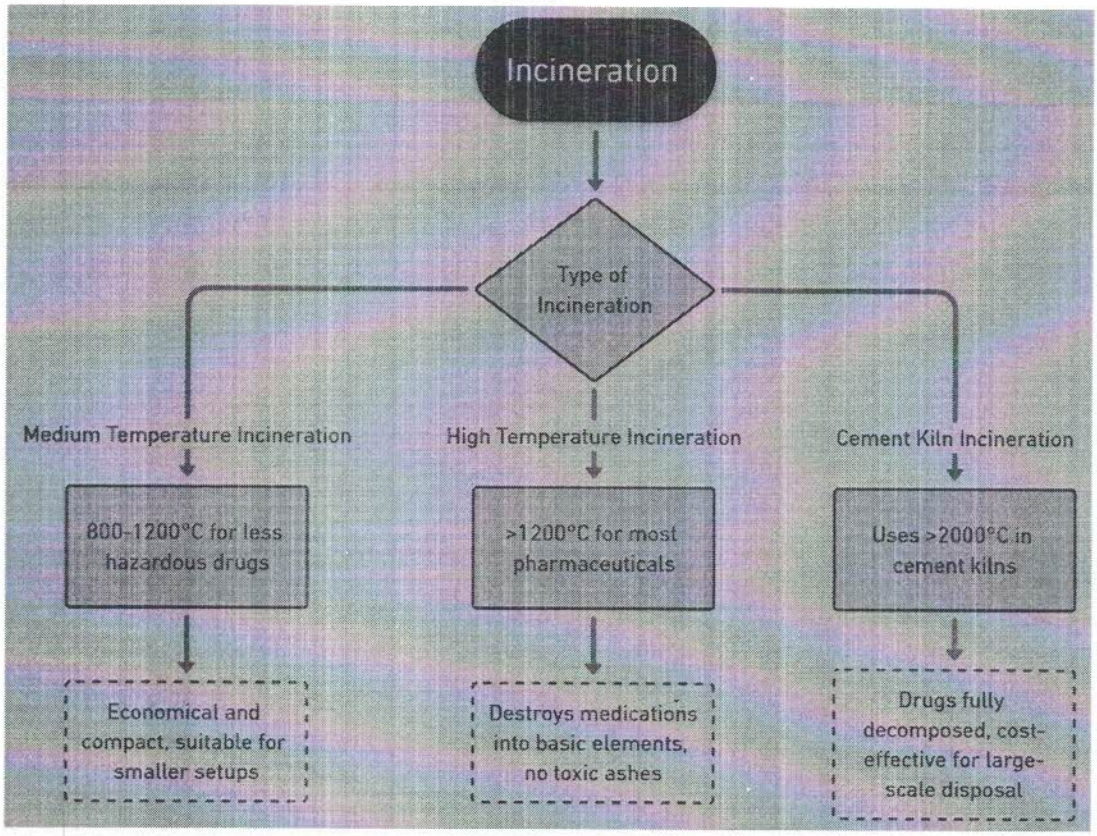
It is the most widely used method for safe disposal of unwanted pharmaceuticals.

Medium Temperature Incineration between 800-1200°C can be suitable for less hazardous drugs. This still ensures the complete breakdown of pharmaceuticals. Medium temperature incinerators provide economical and compact solutions for smaller waste disposal setups. **High Temperature Incineration** has become the preferred solution for most unwanted pharmaceuticals, even for antineoplastic drugs disposal. Incineration using an engineered incinerator at over 1200°C completely destroys medications into their basic atomic elements. No toxic ashes remain, requiring landfilling. Usually, High-temperature incineration in oxygen-rich environments leaves behind no complex pharmaceutical compounds to threaten ecosystems or health. Dual chamber incinerator fitted with flue gas cleaning system should be used for safe disposal practices. Thus, Dual-chamber systems are run by incinerating materials in a primary chamber and then incinerating the gases for a few seconds in a secondary chamber. afterward, emissions from this system are cleaner and safer for the environment.



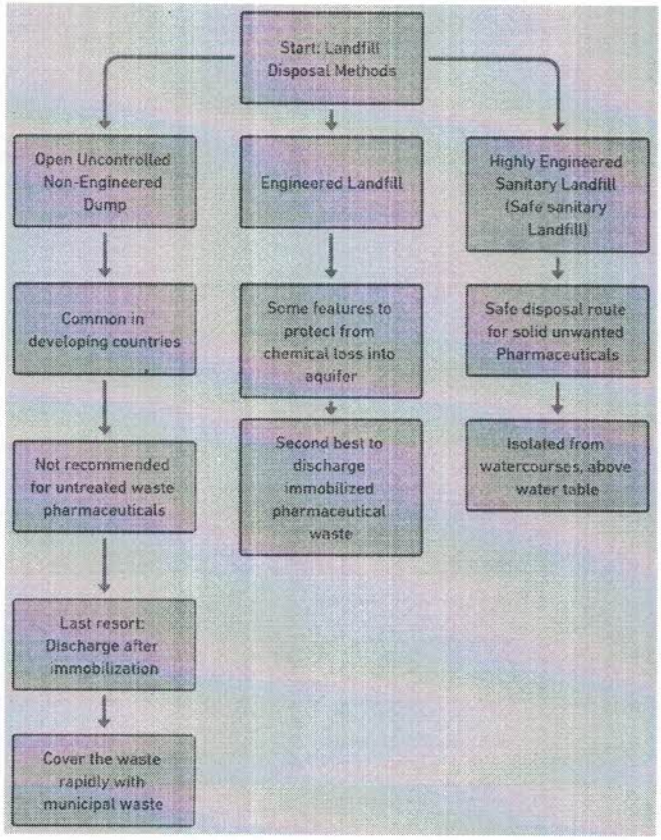
Schematic diagram of dual chamber incinerator

Cement Kiln Incineration represents another high-temperature option that takes advantage of required temperatures over 2000°C in cement manufacturing. By feeding pharmaceutical waste into active cement kilns, drugs get fully decomposed in the process. This approach is cost-effective, particularly for larger-scale controlled drugs disposal **programs**.

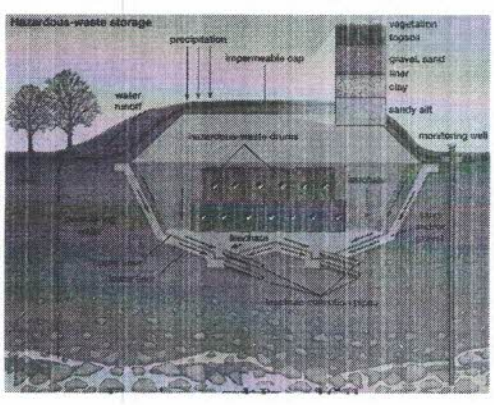


7.2 Landfill

Landfilling means putting waste directly into a dump site without any treatment beforehand. It's the most common way to get rid of solid waste. It's the most ancient and prevalent technique for managing solid waste. There are three main types of landfills:



Open uncontrolled non-engineered dump: These are often found in developing countries and are the simplest form of waste disposal sites. They don't protect the environment because waste is just thrown in without any safety measures. It's especially bad to put untreated unwanted pharmaceuticals here because it can lead to



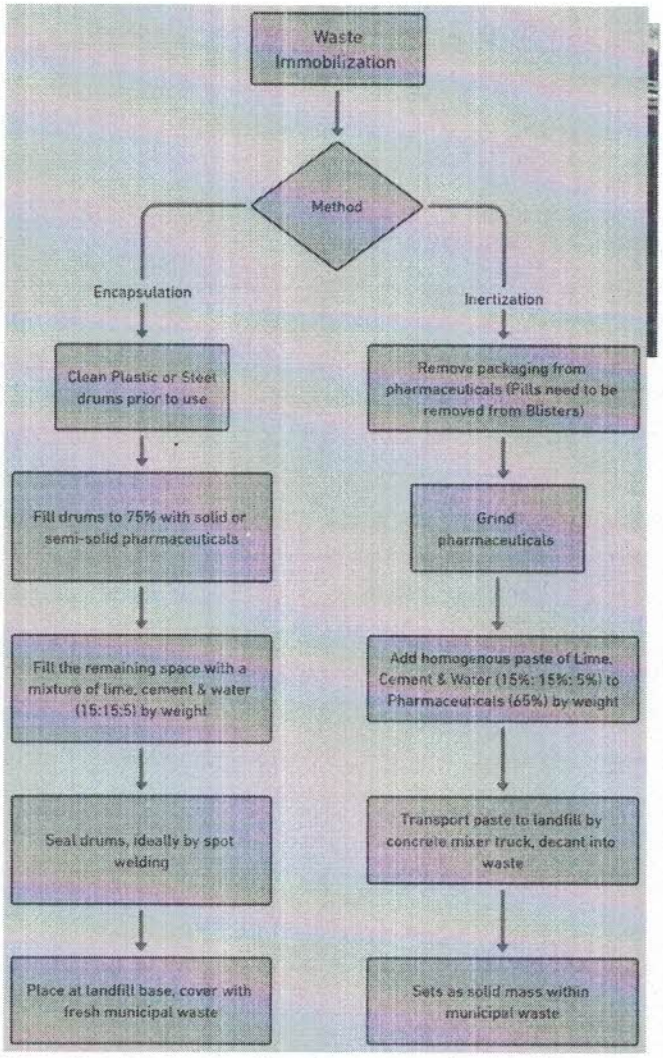
pollution and water contamination. If there's no other option, unwanted pharmaceuticals should at least be covered quickly with other trash to reduce risks.

Engineered landfill These landfills have special designs to prevent chemicals from leaking into the groundwater. While it's still not ideal to put unwanted pharmaceuticals here without treating it first, it's better than in open dumps.

Highly Engineered Sanitary Landfills: These are the safe option for disposing of waste, including unwanted pharmaceuticals. They're designed to protect groundwater and keep the site clean. Every day, the waste is squashed down and covered with soil.

7.3 Waste Immobilization-Encapsulation

Encapsulation is a way of disposal of unwanted pharmaceutical in which the waste is immobilize inside a solid block within a drum, made of either plastic or steel. Before using these drums, they need to be cleaned and checked to ensure they haven't previously held explosive or hazardous materials. In this process, cut and bend back the drum lids beforehand. After filling them to with unwanted pharmaceuticals to 75%, a specific mix of lime, cement, and water in the ratios of 15:15:5 by weight is added until the drum is full. Once filled, close the drum lids tightly, securing them through methods like seam or spot welding to ensure they're sealed. Finally, the sealed drums are placed at the bottom of a landfill, covering them with fresh municipal waste. Encapsulation method for Anti-neoplastic unwanted pharmaceuticals is some what different that is explained in these guidelines under section 6.1.



7.4 Inertization

Inertization is a process similar to encapsulation, but it starts by removing all packaging from the pharmaceuticals, like pills from blister packs. Then, the drugs are ground up and mixed with water, cement, and lime to create a uniform paste. Workers need to wear protective gear due to dust. This paste is then taken to a landfill in a concrete mixer truck and poured into the general waste, where it hardens among the trash. It's a cost-effective method that doesn't require fancy equipment, just a grinder or roller for crushing, a concrete mixer, and basic materials like cement, lime,

and water. The mix typically consists of 65% pharmaceutical waste, 15% lime, 15% cement, and at least 5% water to achieve the right consistency.

7.5 Sewer System

Certain liquid pharmaceuticals, such as syrups and intravenous (IV) fluids, can be diluted with water and disposed of in small amounts through sewer systems over time through fast-flowing watercourses. This method is only suitable for inert, non-toxic drugs, as standard municipal wastewater systems do not fully destroy medications.

7.6 Burning in open containers

Burning pharmaceuticals in open containers is not recommended because it can release harmful pollutants into the air. While it's okay to burn paper and cardboard packaging if recycling isn't an option, polyvinyl chloride (PVC) plastic must not burnt. Despite not being a preferred disposal method, burning is sometimes used for very small amounts of pharmaceutical waste, but this practice is generally advised against due to environmental concerns.

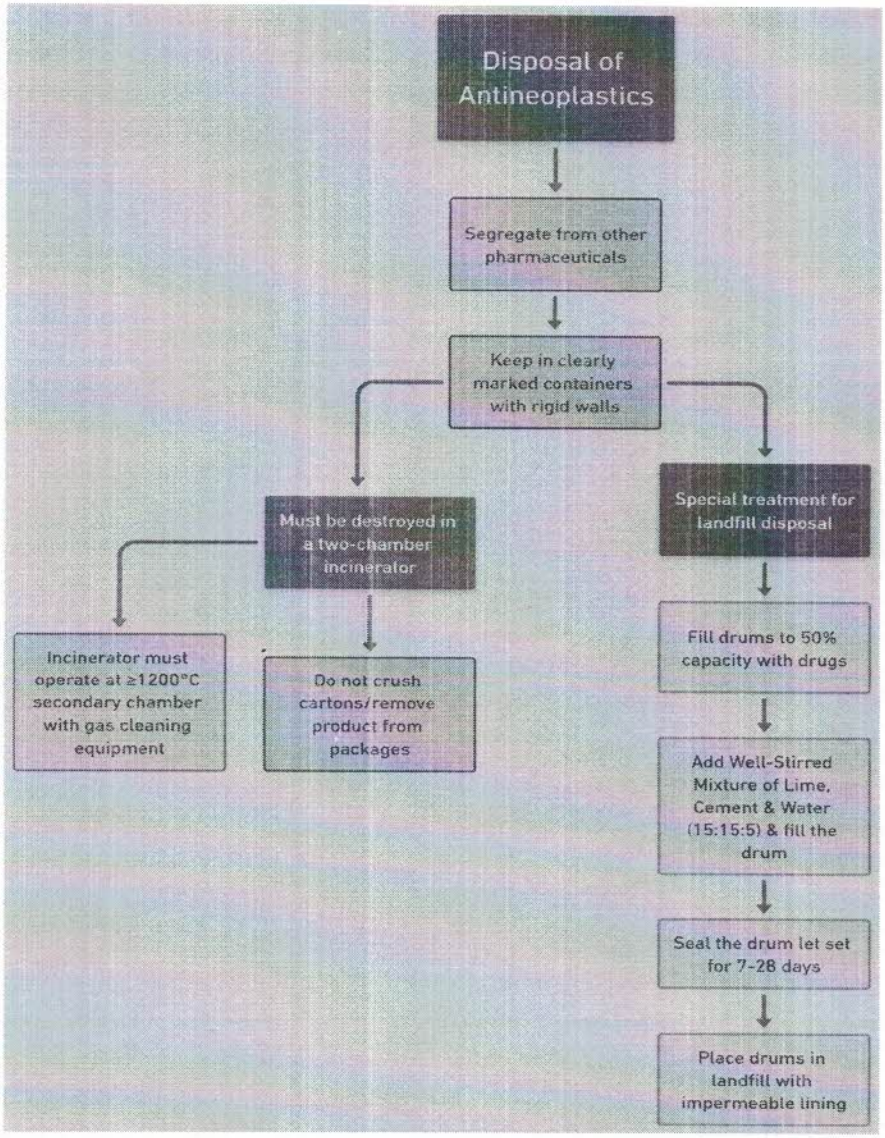
7.7 Chemical decomposition

It is an alternative disposal method for pharmaceuticals when incineration isn't available, requiring adherence to manufacturer-provided guidelines to ensure safety and effectiveness. Chemical decomposition of drugs breaks down pharmaceuticals using other chemicals such as acids, alkalis, oxidising agents, or reducing agents. This method involves breaking down the waste chemically as the manufacturer suggests and then burying it in a landfill. However, it's not the go-to method unless you have access to chemical expertise, since it's complex and time-consuming. Plus, this method always need to have the necessary chemicals on hand. While it might work for getting rid of small amounts of certain drugs, like antineoplastic agents, it's not suitable for large batches. For more than 50 kg of such drugs, the process becomes impractical because it requires repeated application of this method. However, the drawbacks are the generation of chemical effluent requiring further neutralization before final disposal and the inability to treat a wide variety of drug types within the same process.

8. Preferred methods for safe disposal

8.1 Anti-neoplastic Unwanted Pharmaceuticals

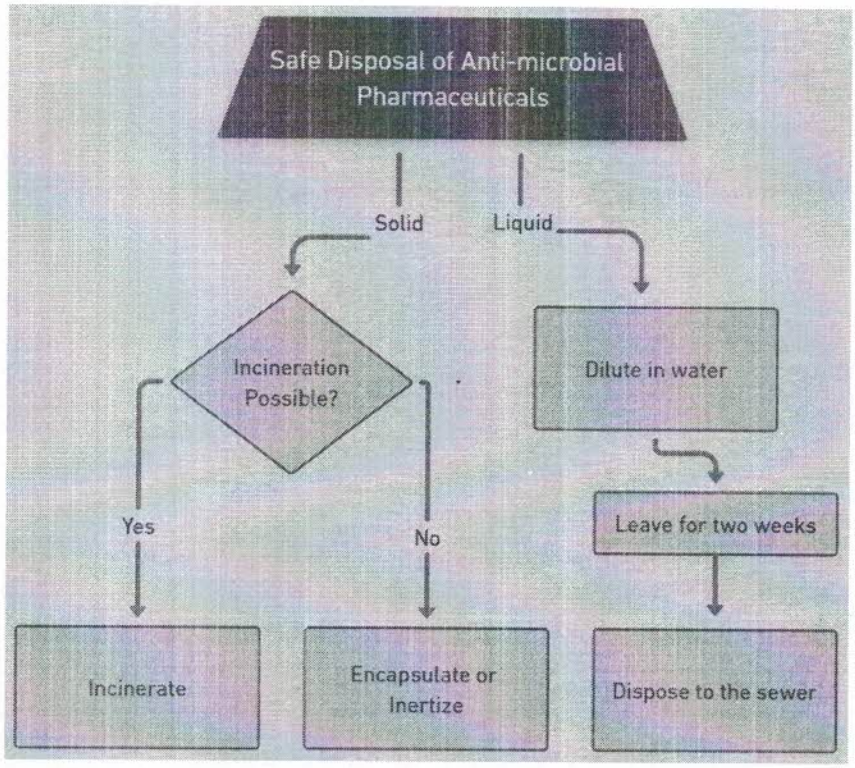
Incineration: These drugs need to be incinerated in a two-chamber incinerator that can reach a high temperature of at least 1200°C in the secondary chamber, equipped with gas cleaning facilities to fully incinerate the antineoplastics and prevent emission of harmful substances.



Landfill (Require special treatment for disposal): Antineoplastic drugs/waste should never be disposed of in landfill without special treatment. The process involves filling drums to 50% capacity with the antineoplastic drugs. Add a well-stirred mixture of lime, cement, and water in the proportions of 15:15:5 (by weight) to the drums until they are full. Additional water may be needed to achieve a satisfactory liquid consistency. Seal the drums through seam or spot welding and allow them to set for 7 to 28 days to form a solid block, securely isolating the waste. Place the sealed drums at the working face of a landfill that has been lined with an impermeable layer, such as clay or a synthetic membrane, to further isolate
the waste from the environment.

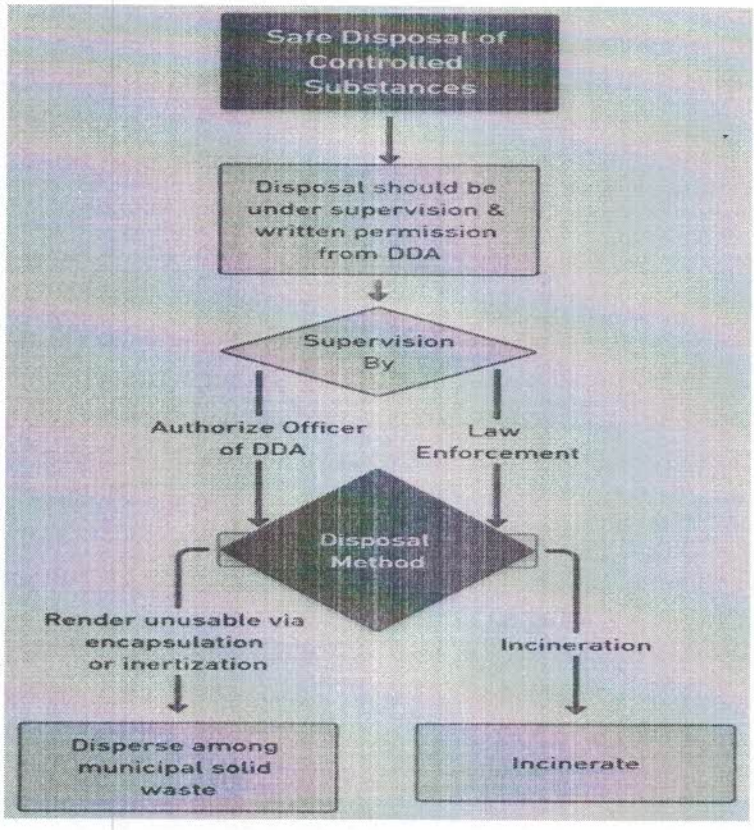
8.2 Safe disposal of Anti-microbials

Anti-microbial drugs require careful disposal to prevent harm to the environment and public health. They should never be thrown away untreated due to their instability and potential development of antimicrobial resistance. The preferred method of disposal is incineration, which safely breaks down their active components. If incineration isn't available, encapsulation or inertization are viable alternatives to stabilize these drugs before disposal. For liquid anti-infective drugs, a dilution in water followed by a two-week waiting period allows for safe disposal into the sewer system, minimizing potential risks.



8.3 Safe disposal of Controlled drugs

Controlled substances, due to their potential for abuse, require permission from DDA followed by witnessed destruction. Controlled drugs must be stored in a well segregated place under lock and key until they are safely disposed of.

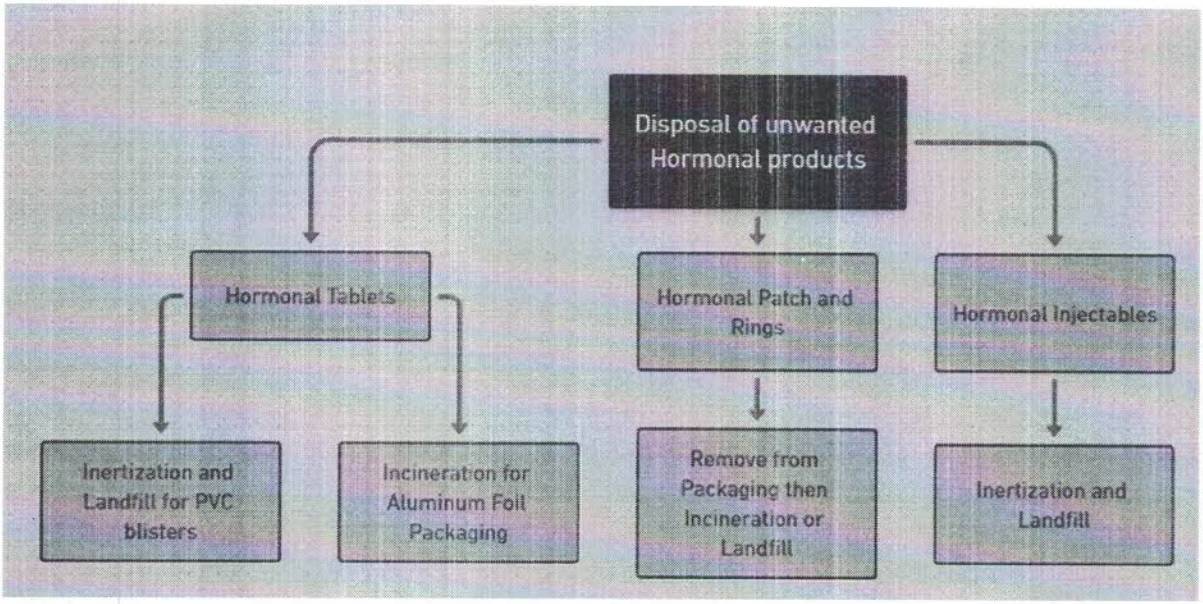


The preferred methods for making these substances unusable include encapsulation or inertisation, after which they can be mixed with municipal solid waste in a landfill. Alternatively, incinerating these substances is also an effective way to safely dispose of them, completely eliminating their potential for misuse. The date of destruction and the quantity destroyed should be recorded against the appropriate entry of the controlled drugs register. The

witness shall sign and date the entry; including a statement to confirm their witness of the disposal of controlled drugs.

8.4 Safe disposal of Unwanted Hormonal products

For hormonal tablets, the disposal method of choice is inertization followed by deposition in a landfill. It is imperative to note that tablets encased in PVC blisters should not be incinerated due to the release of toxic substances. Conversely, those packaged in aluminium foil are suitable for incineration. For hormonal patches and rings, these should be disposed of by removing the packaging and then may be incinerated or landfilled. When it comes to injectables, the standard disposal procedure also involves inertization followed by landfilling. On occasion and as a less favored option, injectables may undergo chemical inactivation for disposal, with careful consideration to avoid worker and environmental hormone exposure.



8.5 Preferred methods for safe disposal of Vaccines

The mass vaccination result in significant amounts of waste, including used vials and sharps, presenting challenges for countries with limited resources and disposal capabilities. This situation requires effective management strategies to ensure both public safety and environmental protection.

Safe Containment: Used vaccination equipment like vials, ampoules, and syringes should be placed in puncture-resistant sharps containers. These containers must be sealed and replaced when two-thirds full and kept away from unauthorized access. Safe disposal involves the sterilization followed by the destruction method:

Sterilization of Vials and Syringes:

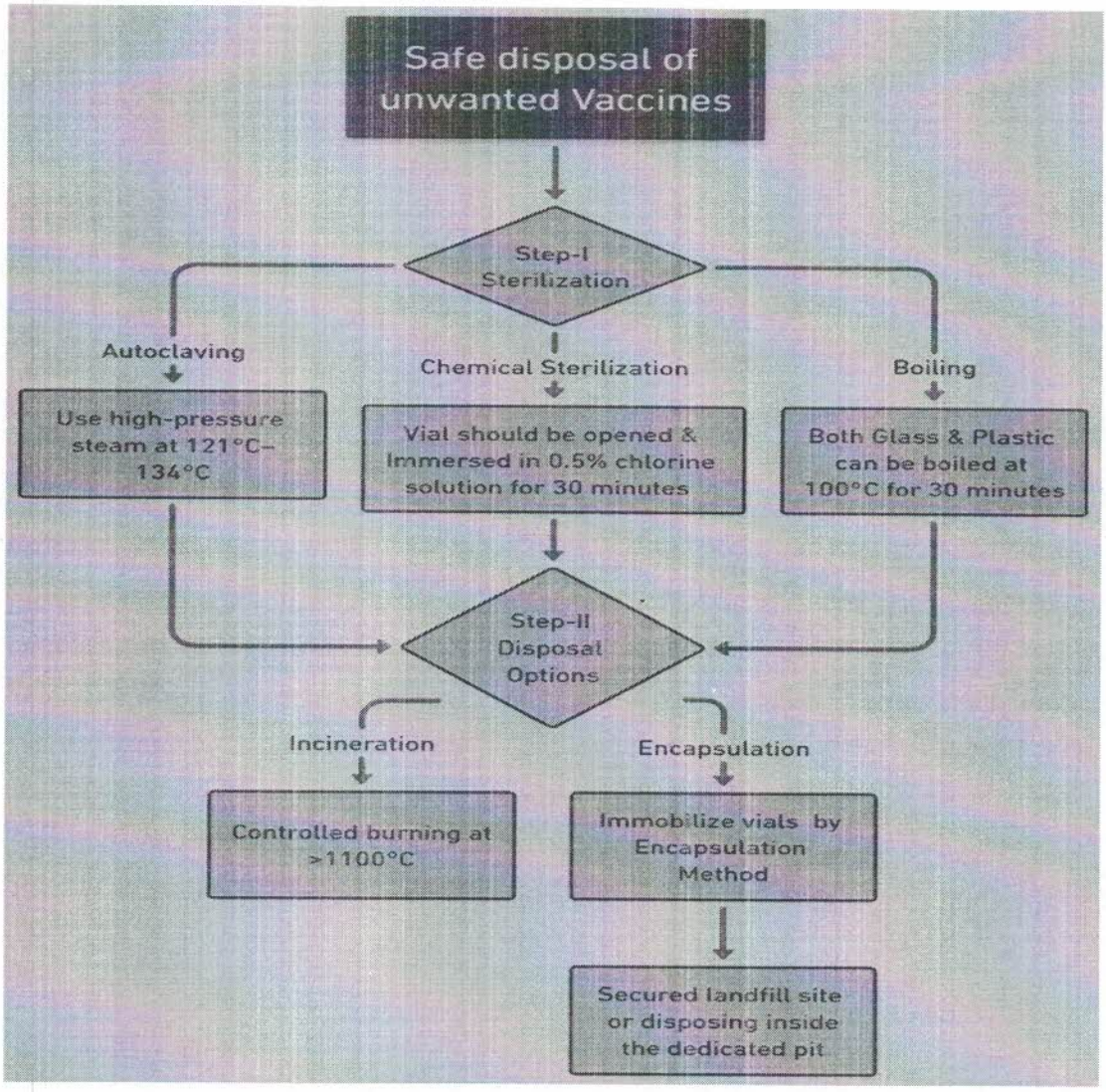
Autoclaving: This involves using high-pressure steam at at temperatures between 121°C (250°F) and 134°C (273°F), under 15–30 psi (1.0–2.0 bar) pressure, between 10 and 60 min, depending upon the material and the type of

Temperature (°C)	Sterilization Time (min) for 1 Cycle
132–134	3–10
121	8–30

organism to be inactivated. It's the most eco-friendly option. Liquid-filled glass vials need to be opened to prevent bursting. After autoclaving, vials should be incinerated.

Chemical Sterilization: Involves immersing vials in a 0.5% chlorine solution (made from mixing water and liquid bleach) for at least 30 minutes. Both the vials and the chlorine solution must then be disposed of.

Boiling: Boiling vials at 100°C for 30 minutes destroys pathogens. This method works for both glass and plastic vials.



Disposal of Vials and Syringes:

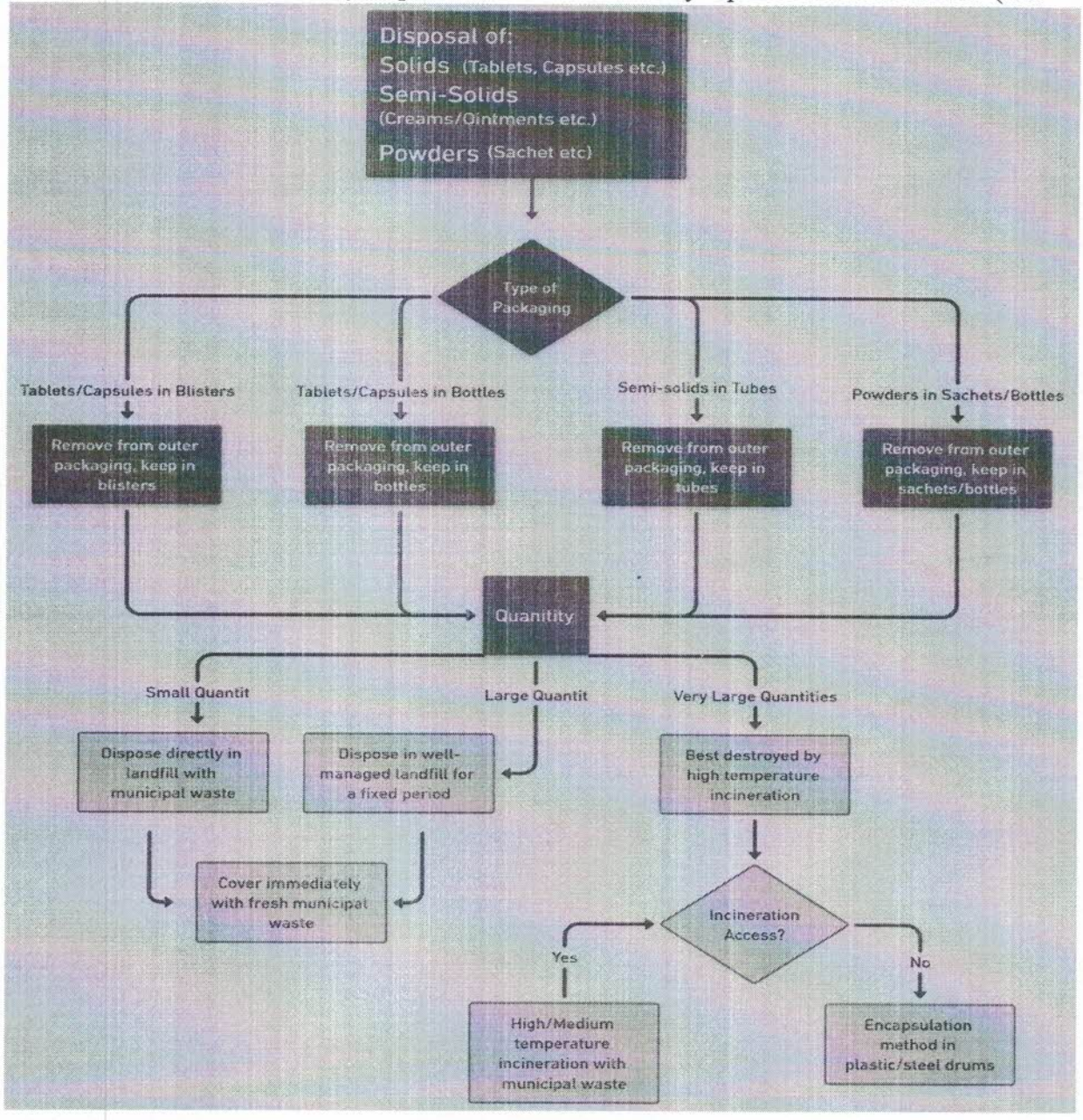
Incineration at temperatures above 1100°C in specialized incinerators ensures complete combustion. Ashes and residues are treated as toxic waste. Vials are immobilized (Encapsulation) using a material like cement in a container, then sealed and buried. This method doesn't inactivate pathogens but prevents the vials from being reused or accessed.

8.6 Safe disposal of Solids, semi-solids and powders (Except Anti-infective drugs, controlled drugs and antineoplastics)

Initial Sorting and Packaging Removal: Solids, semi-solids, and powders unwanted pharmaceuticals must first be taken out of their external packaging while keeping them within their original inner packaging. This step aims to reduce the volume of waste. Medications should then be sorted. Tablets and capsules remain in plastic or foil blisters but should be removed from any external packaging.

- Bottled tablets and capsules are similarly should be removed from outer packaging but kept in their bottles.
- Semi-solids in tubes and powders in sachets or bottles are treated likewise.

Disposal Method Determination: Solids, semi-solids, and powders unwanted pharmaceuticals can be directly disposed of in landfills if they represent a small fraction (not



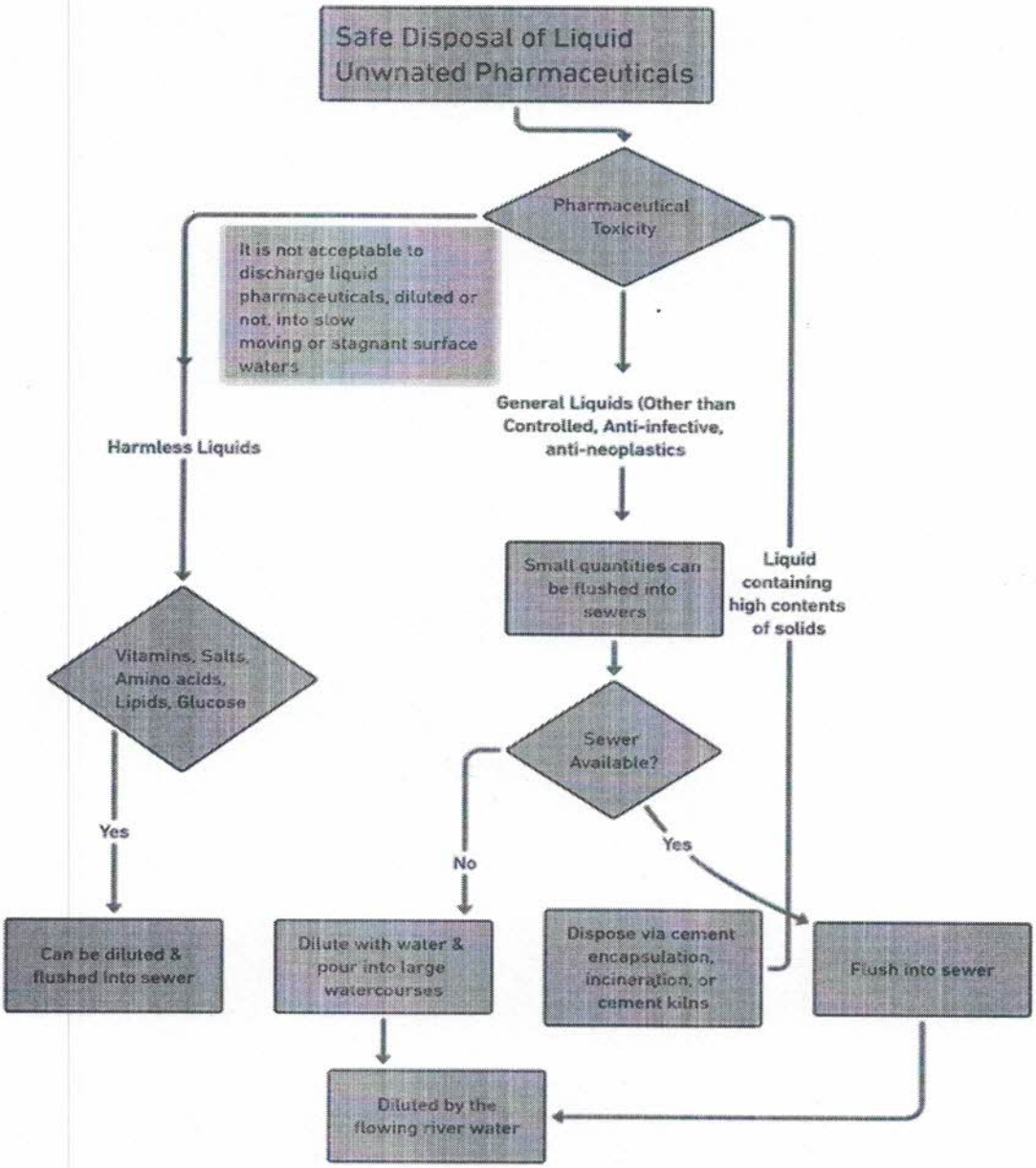
more than 1%) of the daily waste, or up to 5-10% in emergency or large stockpile situations, provided the municipal waste disposal exceeds 50 metric tons daily. These should be placed at the landfill's working face and immediately covered with municipal waste, ensuring security measures against scavenging. For the disposal of substantial amounts of solid and semi-solid pharmaceuticals, destruction via high temperature incineration is the optimal method. Nonetheless, incineration at medium temperatures is also a common practice for these forms of pharmaceuticals, on the condition that they are significantly mixed or "diluted" with a large volume of municipal waste.

8.7 Preferred method for safe disposal of Liquids

Pharmaceuticals with Low or No Toxicity: Liquids that considered to be readily biodegradable organic materials, such as liquid vitamins, can be safely diluted and discharged into sewer systems. This category also includes solutions containing certain salts, amino acids, lipids, or glucose, which can similarly be disposed of in sewers due to their harmless nature. **Other Liquid Pharmaceuticals**: For liquids that do not fall under controlled substances, anti-infective drugs, or antineoplastics, small quantities can be directly flushed into sewer systems. In areas lacking sewer systems or functional sewage treatment facilities, these pharmaceuticals should be significantly diluted with water before being released into large, flowing river water bodies to ensure immediate dispersion and dilution.

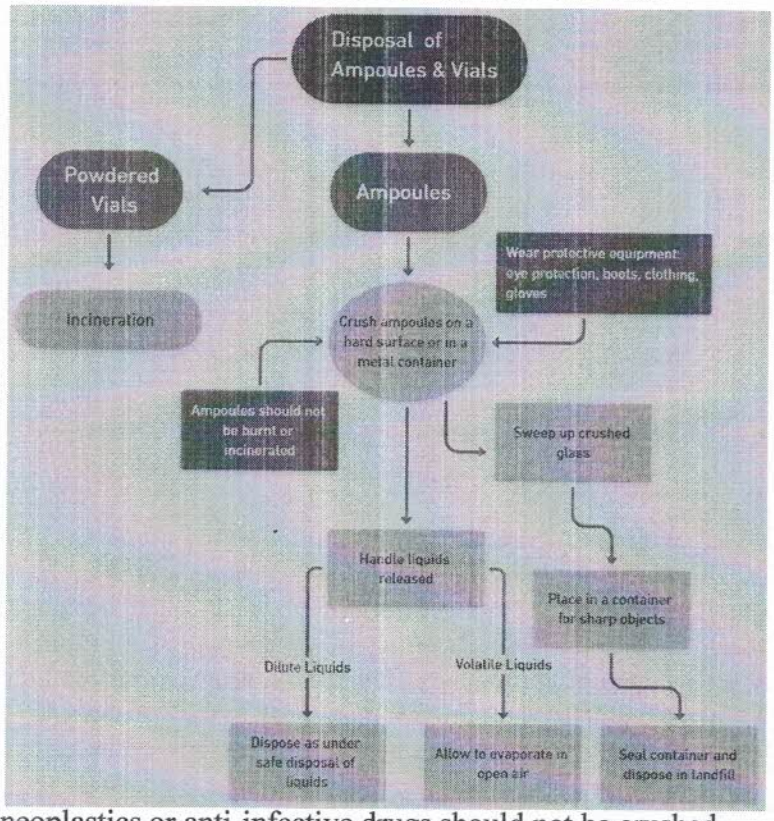
Disposal Methods for Liquid Waste: Liquid pharmaceutical wastes, excluding those unsuitable for sewer disposal, can be treated using cement encapsulation, incinerated at high temperatures, or disposed of in cement kilns. These methods are suitable for managing a broader range of liquid pharmaceuticals, ensuring their safe and effective disposal.

Prohibitions on Disposal: It is imperative to avoid discharging liquid pharmaceuticals, whether diluted or not, into slow-moving or stagnant bodies of water, as this can lead to environmental harm and pose risks to aquatic life and water quality.



8.8 Preferred method for safe disposal of Ampoules & Vials

Disposing of ampoules involves safely crushing them on a hard, impermeable surface or within a metal container using a heavy object. Personnel must wear protective gear, including eye protection and gloves. The resultant broken glass should be collected, placed in a puncture-resistant container, sealed, and then disposed of in a landfill. Any liquid from the ampoules is to be diluted and disposed of according to the guidelines for liquid pharmaceuticals. It's important not to incinerate ampoules as they can explode, causing harm and potential damage to the incineration equipment. Furthermore, high temperatures can cause the glass to melt and block the machinery. For volatile substances in small amounts, allowing them to evaporate outdoors is acceptable. However, ampoules containing antineoplastics or anti-infective drugs should not be crushed or have their contents released into sewers. Instead, these should undergo encapsulation or inertization for safe disposal.



8.9 Preferred method for safe disposal of Aerosol Canister & Inhalers

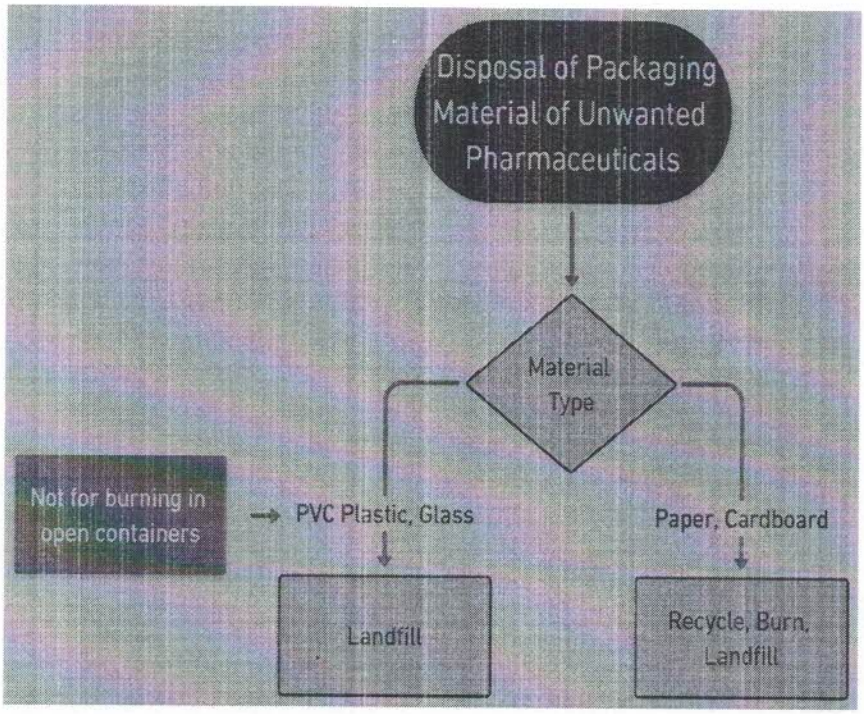
Despite their use, aerosols and inhalers cans can be hazardous. They contain pressurized substances that can explode under certain conditions, posing risks to people and the environment. Therefore, proper disposal is crucial, especially in the workplace where they could ignite or explode, endangering workers and facilities. Empty aerosols can go into regular recycling or can be disposed of by landfill. If not empty, these should be treated as treat as hazardous waste and use special collection or recycling facilities. To mitigate risks associated with aerosol cans: Never heat or puncture them and handle them gently to avoid drops or impacts.

Unwanted Filled aerosols or unused inhalers like expired aerosols and inhalers required to be empty before disposal. Preferable method includes emptying with a puncturing/draining unit attached to a compatible 30 or 55-gallon liquid collection drum. A filter (usually of activated carbon for adsorption) is also attached to the drum fitted with anti-static ground wire to any nearby confirmed ground source. Once

contents have been fully discharged, emptied steel or aluminum aerosol cans can be recycled or should be disposed of in a landfill, dispersed among municipal solid wastes.

8.10 Preferred method for safe disposal of Packing materials

- **Polyvinyl chloride (PVC) Plastic, High Density Poly Ethylene (HDPE), and Glass**: These materials are not to be burned in open containers due to the toxic fumes they can emit. Instead, they should be sent to a landfill. It's important that landfills used for these materials are equipped to handle potentially hazardous waste. Recycling of PVC and HDPE material is crucial for mitigating the environmental impact of PVC wastes, which take decades to decompose in landfills.



- **Paper and Cardboard**: These materials offer more flexibility in disposal options. They can often be recycled, which is the most environmentally friendly option. If recycling is not feasible, these materials can be burnt. When neither recycling nor burning is available or practical, paper and cardboard can also be landfilled.

9. Guidelines for handling and safe disposal of un-wanted Pharmaceuticals at different Levels

9.1 Manufacturers & Importers

Due to their expertise and resources, manufacturers & importers are responsible for safely disposing of unwanted pharmaceuticals, including those returned from the market. This process is crucial for environmental protection and accountability for product life cycles.

Manufacturers & Importers are required to accept the returned or re-called unwanted pharmaceuticals, for storage & safe disposal, from the distributors, retailers, institutions and entities where they had supplied those pharmaceuticals

Domestically manufactured medicines:

- Return the expired, unused, damaged or products returned from the market to the manufacturers. Such returns should be traceable.
- Record of such returns shall be maintained and produce to DDA inspector during surveillance visit.

Imported medicines:

- Return the expired, unused, damaged or products returned from the market to the manufacturers, if possible. Such returns should be traceable.
- If return to the manufacturer is not possible, then the importer or the representative of the manufacturers shall take ownership to destroy products keeping record thereof. Record of such returns shall be maintained and produce to DDA inspector during surveillance.

Responsibilities: Quality Assurance and Store Departments oversee disposal, while Officers and Housekeeping manage pharmaceutical transfers. Managers ensure segregated storage.

Handling Returns: Collect unwanted pharmaceuticals, log returns, quarantine, investigate reasons, and store awaiting destruction.

Sorting & Segregation: Segregate based on dosage, packaging, and properties, label clearly, and wear protective gear.

Storage Protocols: Allocate specific areas, implement robust security, and inspect containers regularly.

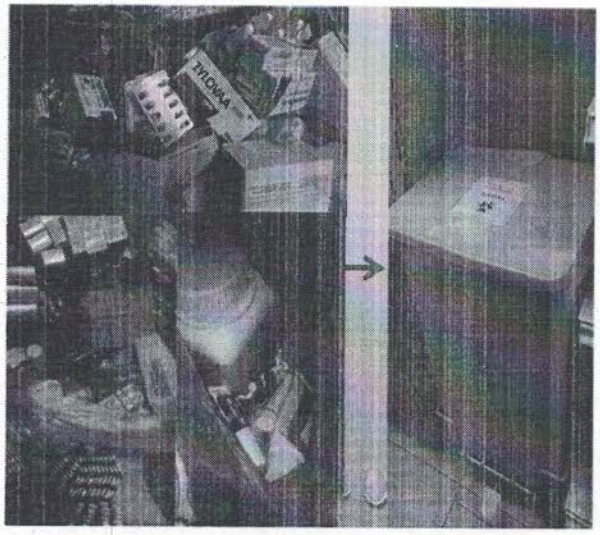
Transporting: Document weights, collaborate with security for loading, issue gate passes, and use GPS-tracked, secure vehicles.

Documentation: Use digital and hard-copy records, assign unique identifiers, and maintain comprehensive transfer records.

Waste Disposal Engagements: Partner with approved waste disposal entities, assess facilities, and comply with environmental regulations.

9.2 Distributors & Retailer

These should recognize unwanted pharmaceuticals generated internally or returned from retailers. Distributors should also accept returned unwanted pharmaceuticals from retailers and arrange return to manufacturer/importer and should follow the following guidelines:



- Upon receipt, verify each returned item from retailers.
- Document product details, including name, quantity, batch number, and reason for return.
- Store returned items in a designated, secure area separate from saleable stock.
- Clearly label these items as "Returned for Disposal".
- Notify the respective manufacturer or importer about the returns, providing detailed inventory lists.
- Discuss and confirm the process for returning these items.
- Package the unwanted pharmaceuticals securely for transportation.
- Ensure packages are labeled correctly, indicating they are for disposal.
- Arrange for safe and secure transport of the items back to the manufacturer or importer.
- Adhere to any specific transport guidelines provided by the manufacturer or importer.

9.3 Guidelines regarding administrative procedure for the safe Disposal of SF, defective, re-called unwanted pharmaceuticals.

Throughout this procedure, both the DDA and the manufacturer or importer have clear responsibilities. The DDA oversees and enforces the recall process, ensuring public safety and compliance, while the manufacturer or importer is responsible for the execution of the recall, including communication, collection, and safe disposal of the recalled pharmaceuticals, following DDA's regulations and guidelines. Safe disposal of the recalled pharmaceuticals should follow following steps for the safe disposal:

Step 1: Notification of Recall

- Regulatory Recall: In the case of a regulatory recall, the DDA will announce the recall on public platforms, such as their official website and media outlets, and will issue instructions to the manufacturer or importer for executing the recall.
- Voluntary Recall: If the recall is initiated voluntarily by the manufacturer or importer, they are required to inform in writing to DDA about the recall according to the established guidelines for recall procedures.

Step 2: Communication and Coordination

- Manufacturer or Importer: Upon receiving recall instructions from the DDA or initiating a voluntary recall, the manufacturer or importer must communicate in writing the recall details to distributors, pharmacies, and healthcare providers, outlining necessary actions to secure and return the recalled product.

Step 3: Collection of Recalled Products

- Distributors & Pharmacies: These entities are responsible for informing consumers and facilitating the return of the recalled product, acting as collection points.

Step 4: Compliance and Reporting

- Manufacturer or Importer: Must ensure compliance with the DDA's recall instructions, track the returned products, and submit a comprehensive report to the DDA on the recall's implementation, including quantities collected and methods of notification.

Step 5: Disposal Approval Process

Manufacturer or Importer: Develops a disposal plan for the collected recalled pharmaceuticals and submits it to the DDA for approval.

- Application for disposal of re-called products shall be made to the Director General by and shall be accompanied by a list of products to be disposed of. For each item the following shall be clearly stated: -
  i. Trade name and/or generic name
  ii. Strength and dosage form where applicable
  iii. Type of packaging material and pack size

iv. Quantity
v. Manufacturer
vi. Expiry dates
vii. Batch or lot number
viii. Market declared value
ix. Reasons for disposing

Step 6: Safe Disposal

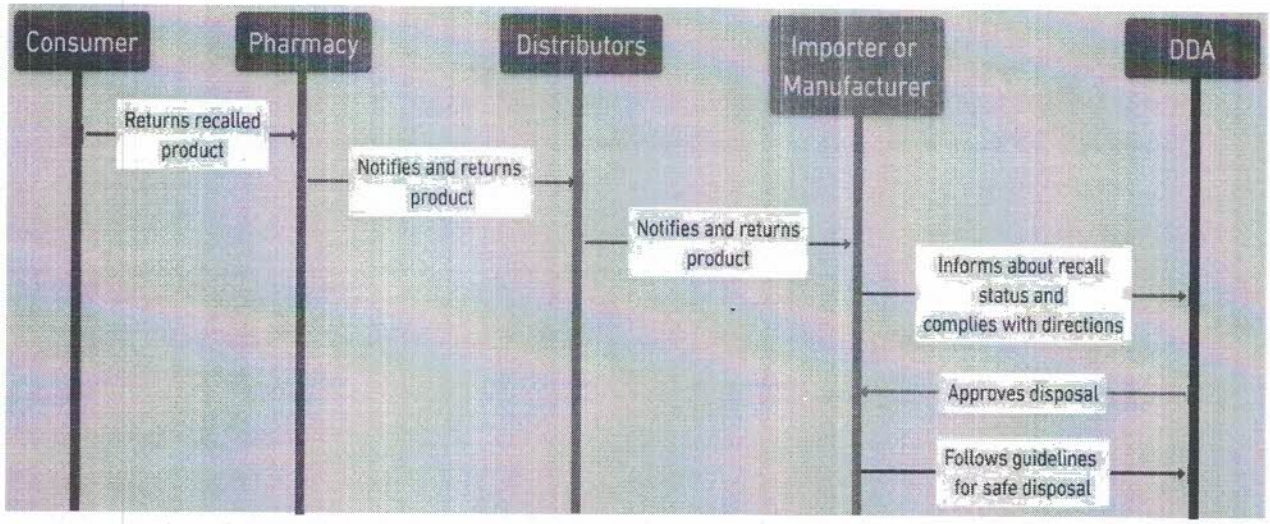
- Manufacturer or Importer: Once the DDA approves the disposal plan, the manufacturer or importer proceeds with the safe disposal of the recalled products in accordance with the approved methods, ensuring adherence to these guidelines.

Step 7: Documentation and Closure

- Manufacturer or Importer: Documents the entire disposal process and provides the DDA with evidence of proper disposal, such as receipts or certificates from disposal companies.

Step 8: Monitoring and Follow-up

- DDA will review the documentation submitted by the manufacturer or importer to verify proper disposal. The DDA may also perform follow-up audits to ensure comprehensive compliance with the recall and disposal procedures.



9.4 Guidelines for the safe Disposal of unwanted pharmaceuticals at Quality Control Laboratories

In the disposal of expired and unused pharmaceutical samples in quality control laboratories, regulatory compliance and administrative control play critical roles. These pharmaceuticals should only be disposed of as per methods detailed in these guidelines. Additionally, it's imperative that these samples be retained for a period mandated by legal requirements before disposal. The retention period allows for any potential audits, investigations, or quality control analyses that might be necessary. Only after this period has elapsed, and with proper authorization, should the disposal proceed. This protocol ensures that all actions are documented and traceable, aligning with compliance standards and reducing the risk of legal implications for the facility.

9.5 Guidelines for the safe Disposal of unwanted pharmaceuticals at Home

Always store medicines safely until disposal and follow the following guidelines:

Return to Pharmacy:

- Collect all unwanted/expired medications.
- Keep them in original containers and obscure personal info.
- Hand them over to pharmacy staff or use a designated drop-off box.