World Health Organization

Guidelines for the safe disposal of expired drugs

People involved in drug supply management are familiar with the problem of drugs reaching expiry dates before the stocks are used. Expired drug stocks present problems with serious implications.

Expired drugs imply financial losses because they should no longer be distributed and must be discarded.

Expired drugs must be disposed off safely, without harming people and the environment. Pharmaceutical products may lose their potency in the degradation process. Physical changes may also lead to reduced absorption, rendering the products less effective. The manufacturer of a pharmaceutical product can only be held responsible for any harmful effects of the product within its shelf life and only if the product was transported and stored under the conditions recommended by the manufacturer.

It is recommended

NOT

to use expired drugs at all

It is important to have a good drug management system:

- Estimation of drugs based on health service utilization data and standard treatment regimens,
- A well functioning stock inventory control system,
- Practicing ó*First Expiry First Out*ô (FEFO) and ó*First In First Out*ô (FIFO) for drugs stocked,
- Coordination with health institutions, and
- Negotiation with suppliers for the possible return of drugs that are about to expire.

Due to constraints in funding for disposal of waste pharmaceuticals, cost-effective management and methods are needed.

The following are the recommended guidelines for the safe disposal of expired drugs:

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 antineoplastics. 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.

2. Landfill

To 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. The following types are recognized:

a. Open uncontrolled non-engineered dump

Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used. They should preferably be discharged after immobilization by encapsulation or inertization.

b. Engineered landfill

An appropriate landfill consists of an evacuated pit isolated from watercourses and above the water table. Each dayÕs solid waste is compacted and covered with soil to maintain sanitary conditions. The term ósafe sanitary landfillôrefers to such a site that is adequately situated, constructed and managed.

3. Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. 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. 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. 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. The drugs 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.

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 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.

5. 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 war damaged.

6. 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.

7. 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. It is recommended that the pharmaceutical waste be diluted with large quantities of municipal waste (approximately 1:1000).

8. 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.

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. Incinerators conforming to these regulations may be used for the disposal of halogenated compounds, X-ray contrast media and povidone iodine; lower temperature incinerators should not be used.

9. Chemical decomposition

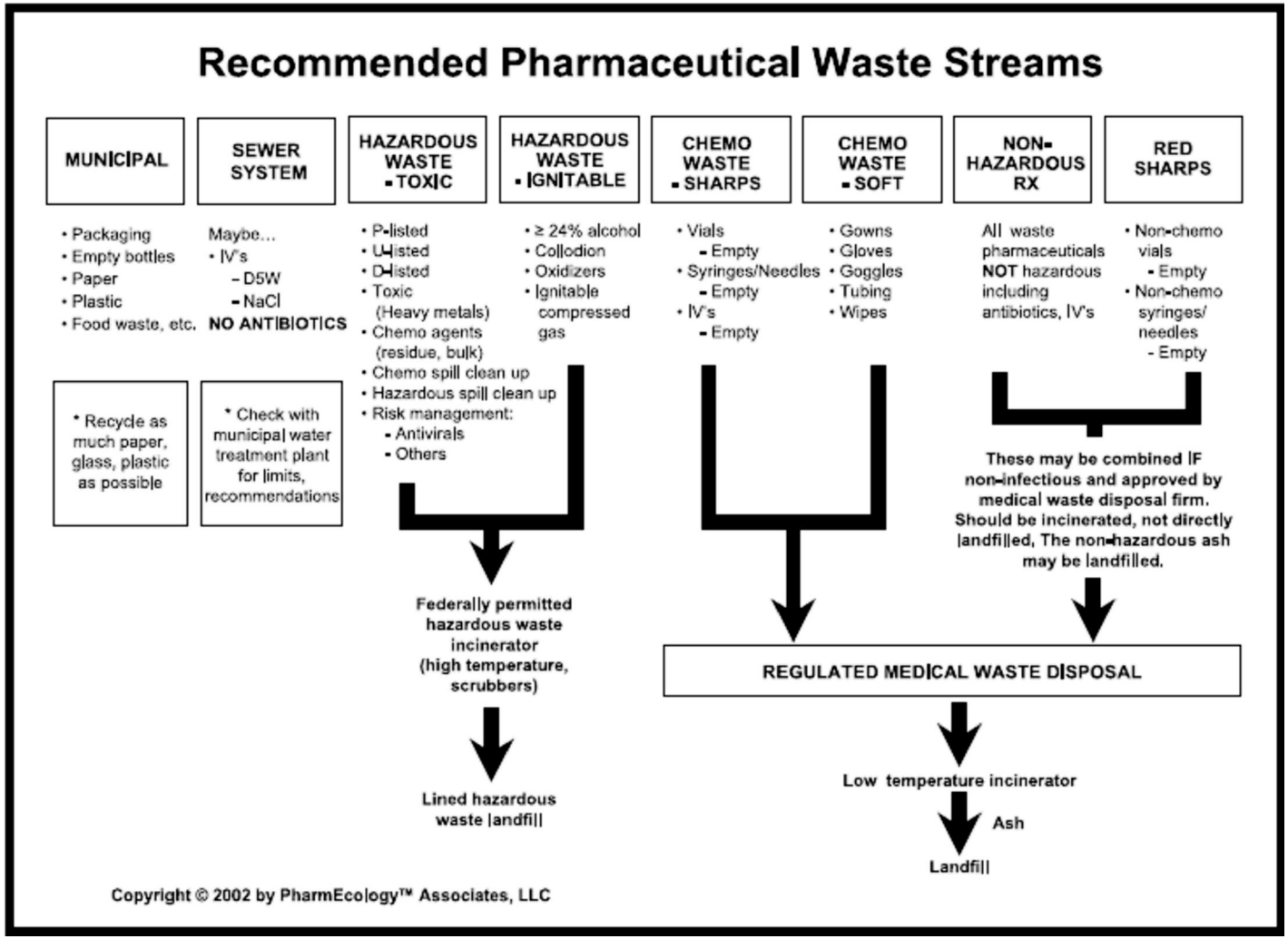
If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill. This method is not recommended unless chemical expertise is readily available. Chemical inactivation is tedious and time consuming, 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 antineoplastics, chemical decomposition is not practical, as even small consignments need to be treated through repeated application of this method.

Summary of disposal methods in and after emergencies

Disposal methods	Types of pharmaceutical	Comments
1. **Return to donor or manufacturer** (Transfrontier transfer for disposal)	All bulk waste pharmaceuticals, particularly antineoplastics	Usually not practical ï transfrontier procedures may be time consuming.
2. **Landfill** a. Highly engineered sanitary landfill.	Limited quantities of untreated solids, semi-solids and powders. PVC plastics.	Disposal of waste pharmaceuticals preferable after immobilization
b. Engineered landfill	Waste solids, semi-solids and powders, preferably after immobilization. PVC plastics.	Immobilization of solids, semi-solids, powders is preferable.
c. Open uncontrolled non engineered dump	Untreated solids, semisolids, powders	As last resort. Not for untreated controlled substances. Must be covered immediately with municipal waste.
3. **Waste Immobilization:** encapsulation	Solids, semi-solids, powders, liquids, antineoplastics, controlled substances	
4. **Waste Immobilization:** inertization	Solids, semi-solids, powders, antineoplastics, controlled substances.	
5. **Sewer** (Fast-flowing watercourse)	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised).	Not recommended for antineoplastics, and undiluted disinfectants and antiseptics.
6. **Burning in open containers**	Packaging, paper, cardboard.	As last resort. Not acceptable for PVC plastics or pharmaceuticals.
7. **Medium temperature incineration** with two-chamber incinerator with minimum temperature of 850°C. Cement kiln incineration in the absence of high temperature incinerators	Solids, semi-solids, powders, controlled substances.	Antineoplastics best incinerated at high temperature.
8. **High temperature incineration** with temperatures greatly in excess of 1200°C	Solids, semisolids, powders, antineoplastics, controlled substances	Expensive.
9. **Chemical decomposition**		Not recommended unless special chemical expertise and materials available. Not practical for quantities over 50 kg.

Summary of pharmaceutical categories and disposal methods in and after emergencies

Category	Disposal methods	Comments
Solids	Landfill	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill
Semi-solids	Waste encapsulation	
Powders	Waste inertization	
	Medium and high temperature incineration (Cement kiln incinerator)	
Liquids	Sewer	Antineoplastics not to sewer
	high temperature incineration(Cement kiln incinerator)	
Ampoules	Crush ampoules and flush diluted fluid to sewer	Antineoplastics not to sewer
Anti-ineffective drugs	Waste encapsulation	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer
	Waste inertization	
	Medium and high temperature incineration (Cement kiln incinerator)	
Antineoplastics	Return to donor or manufacturer	Not to landfill unless encapsulated
	Waste encapsulation	Not to sewer
	Waste inertization	No medium temperature incineration
	Medium and high temperature incineration (Cement kiln incinerator)	
Controlled drugs	Waste encapsulation	Not to landfill unless encapsulated
	Waste inertization	
	Medium and high temperature incineration (Cement kiln incinerator)	
Aerosol canisters	Landfill, Waste encapsulation	Not to be burnt, may explode
Disinfectants	Use To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 litres per day under supervision)	No undiluted disinfectants to sewers or water courses Maximum 50 litres per day diluted to sewer or fast-flowing watercourse No disinfectants at all to slow moving or stagnant watercourses
PVC plastic, glass	Landfill	Not for burning in open containers
Paper, cardboard	Recycle, burn, landfill	


Recommended Pharmaceutical Waste Streams
MUNICIPAL
SEWER SYSTEM
HAZARDOUS WASTE - TOXIC
HAZARDOUS WASTE - IGNITABLE
CHEMO WASTE - SHARPS
CHEMO WASTE - SOFT
NON-HAZARDOUS RX
RED SHARPS
• Packaging
• Empty bottles
• Paper
• Plastic
• Food waste, etc.
Maybe...
• IV's
– D5W
– NaCl
NO ANTIBIOTICS
• P-listed
• U-listed
• D-listed
• Toxic (Heavy metals)
• Chemo agents (residue, bulk)
• Chemo spill clean up
• Hazardous spill clean up
• Risk management:
- Antivirals
- Others
• ≥ 24% alcohol
• Collodion
• Oxidizers
• Ignitable compressed gas
• Vials
- Empty
• Syringes/Needles
- Empty
• IV's
- Empty
• Gowns
• Gloves
• Goggles
• Tubing
• Wipes
All waste pharmaceuticals NOT hazardous including antibiotics, IV's
• Non-chemo vials
- Empty
• Non-chemo syringes/ needles
- Empty
* Recycle as much paper, glass, plastic as possible
* Check with municipal water treatment plant for limits, recommendations
These may be combined IF non-infectious and approved by medical waste disposal firm. Should be incinerated, not directly landfilled, The non-hazardous ash may be landfilled.
Federally permitted hazardous waste incinerator (high temperature, scrubbers)
Lined hazardous waste landfill
REGULATED MEDICAL WASTE DISPOSAL
Low temperature incinerator
Ash
Landfill
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