

Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies

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International Pharmaceutical Federation
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Table of contents

1. Introduction.....	3
1.1 Background.....	3
1.2 Prevention of waste from pharmaceutical donations.....	3
Appropriate donations.....	3
Good donations may be wasted.....	4
1.3 The cost of disposal of waste pharmaceuticals.....	4
The cost of waste pharmaceutical high temperature incineration.....	4
Quoted weights of pharmaceutical waste.....	4
1.4 Purpose of the guidelines.....	4
What the guidelines do not cover.....	5
1.5 Who will find the guidelines useful?.....	5
1.6 Administrative aspects of writing-off unwanted pharmaceuticals.....	6
1.7 Steps to be taken.....	6
Decision.....	6
Approval.....	6
Planning.....	7
Forming work teams.....	7
Health and safety of work teams.....	7
Sorting.....	7
Disposal.....	7
Security.....	7
1.8 Consequences of improper disposal or non-disposal.....	8
1.9 Public information.....	8
2. Disposal methods	11
2.1 Return to donor or manufacturer.....	11
Cross-frontier transfer of pharmaceutical waste.....	11
2.2 Landfill.....	11
Open uncontrolled non-engineered dump.....	11
Engineered landfill.....	12
Highly engineered sanitary landfill.....	12
2.3 Waste immobilization: encapsulation.....	12
2.4 Waste immobilization: inertization.....	12
2.5 Sewer.....	13
2.6 Burning in open containers.....	13
2.7 Medium temperature incineration.....	13
Halogen content of pharmaceutical waste.....	14
2.8 High temperature incineration using existing industrial plants.....	14
2.9 Chemical decomposition.....	15

3. Sorting categories.....	17
3.1 The objectives of sorting.....	17
Practical advice on sorting.....	17
3.2 Optimum conditions for sorting.....	17
3.3 Sorting categories.....	18
3.4 Pharmaceuticals and other materials which can still be used.....	18
3.5 Expired or unwanted pharmaceuticals.....	18
3.6 Hazardous or potentially hazardous non-pharmaceutical materials.....	19
3.7 Recyclable material.....	19
4. Recommended disposal methods by sorting category.....	21
4.1 Solids, semi-solids and powders.....	21
Anti-infective drugs, controlled drugs and antineoplastics.....	21
Other drugs.....	21
4.2 Liquids.....	22
Pharmaceuticals with no or low toxicity.....	22
Other liquid pharmaceuticals (except controlled drugs, antineoplastics or anti-infective drugs).....	22
4.3 Ampoules.....	23
4.4 Anti-infective drugs.....	23
4.5 Controlled substances.....	23
4.6 Antineoplastics.....	23
Special treatment for antineoplastics.....	24
Antineoplastic drug disposal.....	24
4.7 Disinfectants.....	24
4.8 Aerosol canisters.....	25
References.....	28
Further reading.....	30
Annex I: Disposal by incineration.....	32

Table of figures

Table 1: Summary of disposal methods in and after emergencies.....	16
Table 2: Summary of pharmaceutical categories and disposal methods in and after emergencies.....	26

1. Introduction

1.1 Background

During conflicts and natural disasters large quantities of pharmaceuticals are often donated as part of humanitarian assistance. Undoubtedly many of the pharmaceuticals save lives and alleviate suffering, but some donations given by well-meaning but uninformed people may cause problems. Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs, be unrecognizable because they are labelled in a foreign language or may have been sent in unwanted quantities. Donated pharmaceuticals with a long shelf-life may be mismanaged, particularly in the confusion during and after armed conflict or a natural disaster. Staff and storage space may be lacking and the pharmaceutical management system in disarray. Such problems also occur when drug donations form part of development assistance. Smaller quantities of pharmaceutical waste may accumulate in the absence of emergency situations, due to inadequacies in stock management and distribution, and to lack of a routine system of disposal. Safe disposal of these unwanted or expired drugs often creates a major problem.

These disposal guidelines are based on a report on the safe disposal of unwanted and unusable drugs in Mostar, which had accumulated during the war in Bosnia and Herzegovina. Quantifying pharmaceutical waste may be difficult. One report states that 50–60% of the 27,800–34,800 metric tons of medical supplies donated to Bosnia and Herzegovina between 1992 and mid-1996 were considered to be inappropriate, and by mid-1996 there were an estimated 17,000 metric tons of unusable drugs stockpiled in warehouses and clinics throughout the country¹. These dramatic figures are contested: something in the region of 1,000 metric tons is considered by some to be more reasonable. A recent figure of 2,000 metric tons of pharmaceutical waste in Croatia is regarded as accurate. Unusable donated drugs hindered the efficient operation of pharmacies in many of the states of the former Yugoslavia and represented a significant disposal problem.

1.2 Prevention of waste from pharmaceutical donations

Appropriate donations

Inappropriate donations may be minimized by donors adhering to the interagency *Guidelines for Drug Donations*². The key principles are that drugs donated shall address the expressed needs of the recipients and that the date of expiration on arrival shall be no less than one year, unless there is clear evidence from the recipients that they have the logistic and managerial capacity to store and distribute shorter-dated drugs efficiently. The blind donation of pharmaceuticals based on unsubstantiated assumptions of recipient needs and logistic capacities is a major factor in the production of pharmaceutical waste.

Good donations may be wasted

Mismanagement of received donations may turn a good donation into pharmaceutical waste.

1.3 The cost of disposal of waste pharmaceuticals

The cost of waste pharmaceutical high temperature incineration

Pharmaceuticals are ideally disposed of by high temperature (i.e. above 1,200°C) incineration. Such incineration facilities, equipped with adequate emission control, are mainly to be found in the industrialized world. Quotations for disposing of the pharmaceutical waste in Croatia and Bosnia and Herzegovina in this way range from US\$2.2/kg to US\$4.1/kg. To incinerate the current stockpile of waste pharmaceuticals in Croatia would therefore cost between US\$4.4 million and US\$8.2 million.

Quoted weights of pharmaceutical waste

The gross weights mentioned previously include packaging. Actual pharmaceutical contents may be half, or less than half, of the gross weight.

1.4 Purpose of the guidelines

These guidelines provide advice on the implementation of safe disposal of unusable pharmaceuticals in emergencies and in countries in transition where official assistance and advice may not be available. They are not meant to supersede local, regional or national laws regarding disposal of drugs, but to provide assistance where there is insufficient guidance or none at all.

A number of methods for safe disposal of pharmaceuticals are described. These are methods which involve minimal risks to public health and the environment, and include those suitable for countries with limited resources and equipment. The adoption of the guidelines by ministries of health, environment and other relevant ministries, and their practical application, will contribute to the safe and economical elimination of stockpiles of unusable 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. Indeed many countries do not possess such a facility. It is for this reason that these guidelines are suggested as practical interim alternatives to assist those charged with the safe disposal of unwanted pharmaceuticals. The current guidelines propose a number of marginally less safe treatments and disposal methods, which are however acceptable from the relative risk point of view, when balanced against the risks related to improper or non-disposal (see Section 1.8).

What the guidelines do not cover

There is no attempt to cover the management of other wastes generated by health institutions, for example, infectious waste, photographic chemicals, solvents, wastes with a high content of heavy metals (e.g. mercury and cadmium), chemical laboratory wastes, or radioactive waste. The management of health care wastes generated in normal conditions (i.e. neither during nor after emergencies) is not included. Specialized advice for these categories of waste is available from WHO^{3, 4, 5}.

The wider subject of normal drug supply and management⁶ is not covered. This includes drug waste minimization and waste separation within the health institution. It is assumed that management procedures and staffing are in place to cover these aspects. In the event of insufficient qualified staff and management capacity to undertake safe disposal then the pharmaceutical waste must be securely stored.

1.5 Who will find the guidelines useful?

These guidelines can be used by all relevant health authorities, competent to authorize the use or disposal of drugs. In many countries drug disposal will also involve environmental and waste management authorities, and experts at ministerial, regional and local level. Depending on the situation in the country, the appropriate authority may be a department responsible for pharmaceutical management within the ministry of health, the drug regulatory authority (if different from the former), a regional or local health authority (pharmaceutical officer) or the ministry of environment, etc. It is the responsibility of the qualified appropriate authority to implement the guidelines in coordination with regional and local health authorities, as well as with the directors of health facilities that face the problems of drug disposal.

A local task force or advisory committee should be established at an early stage to assess, analyse and address the problem of drug disposal, and to monitor activities. Furthermore, it is suggested that such a task force has a maximum of five members and that meetings are held as near to the site of the stockpile as possible. Members may be chosen from:

- the drug regulatory authority or ministry of health;
- the ministry of the environment;
- the audit section of the ministry of health;
- institutional pharmacists;
- a qualified hazardous waste expert may be appointed by the authority to be responsible for pharmaceutical waste disposal. If this is done the person appointed should become a member of the task force. The individual can be an expert in environmental management, a registered water chemist, hydrogeologist or sanitary engineer. The choice of expert depends on the technical problems to be faced

Nongovernmental organizations with pharmaceutical programmes may also have to deal with unusable waste stocks of pharmaceuticals that require disposal. Disposal should be undertaken in conjunction with the relevant authority where such exists.

In non-emergency situations large stockpiles do not usually accumulate, and waste pharmaceuticals are best disposed of on a routine basis, small quantities at a time. This should be organized on a local and institutional level.

1.6 Administrative aspects of writing-off unwanted pharmaceuticals

Few countries have adequate administrative provisions for writing-off pharmaceutical stock. In the public sector drugs are the property of the state, for which strict accounting procedures are necessary. If procedures exist at all, they tend to be complicated and time-consuming, and in practice the disposal of expired stock is difficult. This applies both to drugs that are procured through the normal channels and to donated drugs.

Administrative and regulatory procedures concerning safe disposal of pharmaceuticals, that are in line with national drug and environment legislation, should be adopted and implemented in countries that receive drug donations.

Simplifying procedures in general would probably be the best solution. One approach would be to state that donated drugs are not entered into the government inventory or considered state property unless specifically accepted as such. In this case any drug that is not officially accepted can be destroyed without the need for governmental approval; however, correct disposal procedures must be followed. A further solution would be to establish special, simplified, administrative procedures for writing-off unwanted donations.

1.7 Steps to be taken

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

Decision

The hospital, district or regional pharmacist or organizations with pharmaceutical programmes decide when action needs to be initiated, because of an accumulation of unwanted pharmaceuticals which are unfit for human consumption and for veterinary treatment.

Approval

Approval and sanctioning of disposal of pharmaceuticals must be sought from the appropriate authority. This authority will differ from country to country and may be the department responsible for pharmaceutical management within the ministry of health, the drug regulatory authority, or the regional or local health authority (pharmaceutical officer). In some countries the ministry of the environment should be involved. The guidelines are particularly useful in

emergency situations or for countries in transition where official regulations have not yet been developed. In non-emergency situations when significant quantities of donated pharmaceuticals are disposed of, for whatever reason, it may be necessary and judicious to inform the donor.

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 metre.

Forming work teams

Work should be conducted by teams consisting of supervising pharmacists 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.

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 (for example, inertization, see Section 2.4) and when there is a risk of powders being liberated. Particular care is required when handling antineoplastics.

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 safely used and returned to the pharmaceutical supply system and those that require 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.

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.

Security

Controlled substances (e.g. narcotics and psychotropics) require tight security and control. In some countries, scavenging of material from landfills is a frequent problem, and, disposed drugs may be recovered and sold by the scavengers.

Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from landfills. Immobilization (see Sections 2.3 and 2.4) 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.

1.8 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, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastics 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 some countries scavenging in unprotected insecure landfills is a hazard.
- 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 2.3 on waste encapsulation.

1.9 Public information

The public should be informed about the problem of safe disposal of donated expired pharmaceuticals. Key points to present to the media are:

1. the vast majority of pharmaceuticals are donated with the intention to help; there are only rare occurrences of "dumping" by unscrupulous companies to gain tax relief or off-load unwanted stock;

2. when pharmaceuticals pass their expiry date they do not automatically become hazardous, they simply become less efficacious;
3. most pharmaceuticals are relatively harmless to the environment; they do not present a serious threat to the public or environment unless handled recklessly;
4. the risk from disposal of pharmaceuticals is low provided it is properly handled;
5. pharmaceutical disposal should be undertaken at minimum financial cost and with minimum risk to public health and the environment considering the local circumstances;
6. disposal of pharmaceuticals should be carried out under the supervision of regional and national authorities, who organize it according to strict criteria; it must not be carried out by individuals.

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. Good public relations, including comprehensive dissemination of information, is, therefore, an important element in achieving satisfactory safe disposal.

2. 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. Pharmaceutical sorting categories are described in Section 3 and the recommended disposal methods for each pharmaceutical sorting category in Section 4. Firstly however, the various disposal methods are briefly described here and summarized in Table 1.

2.1 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.

Cross-frontier transfer of pharmaceutical waste

There are currently no international conventions regulating transfer of pharmaceutical products across frontiers. However, expired or spoiled pharmaceuticals are considered as hazardous waste and as such, if transferred across frontiers, become regulated and subject to the Basel Convention on the Transfrontier Shipment of Hazardous Wastes^{7,8,9}. This involves prescribed procedures to obtain permission to cross international borders along the transit route prior to actual transport. These procedures can take several months to complete.

2.2 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. Three types are recognized.

Open uncontrolled non-engineered dump

A 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 wastes 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 watercourses can lead to pollution, with the risk of drinking water contamination in the worst cases.

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.

Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer a relatively safe disposal route for municipal solid wastes, including waste pharmaceuticals¹⁰. 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, and advice is available from WHO¹¹.

2.3 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 4.6).

2.4 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.

2.5 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.

2.6 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. 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.

2.7 Medium temperature incineration

In many countries there are no high temperature, two-chamber incinerators designed to handle more than 1% halogenated compounds. Such incinerators meet strict emission control standards, such as those published by the European Union¹². However, it is likely that only medium temperature furnaces and incinerators will be available. 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.

Halogen content of pharmaceutical waste

Pharmaciens Sans Frontières, working in Bosnia (Mostar), found the halogen content of donated pharmaceuticals for disposal to be very low; well below the maximum permissible values for incinerators/plants licensed for non-halogen wastes in the European Union.

2.8 High temperature incineration using existing industrial plants

Industries which use high temperature technology, such as cement kilns¹³, 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.

Cement kilns are particularly suited for the disposal of expired pharmaceuticals, chemical waste, used oil, tyres, etc. 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.

Cement producers in many countries are keen to use alternative fuels, as their use reduces the fuel bill without adversely affecting the quality of the cement. With appropriate environmental impact control mechanisms in place there will be even less impact on the surrounding area. It is recommended that discussions be held with cement companies and the appropriate environmental agencies to arrange for waste to be disposed of using a cement kiln.

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.

Annex I gives more details of European Community regulations on high temperature incineration of hazardous wastes. 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.

2.9 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.

Table 1: Summary of disposal methods in and after emergencies

Disposal methods	Types of pharmaceutical	Comments
Return to donor or manufacturer, transfrontier transfer for disposal	All bulk waste pharmaceuticals, particularly antineoplastics.	Usually not practical - transfrontier procedures may be time consuming.
High temperature incineration with temperatures greatly in excess of 1200°C	Solids, semisolids, powders, antineoplastics, controlled substances.	Expensive, particularly for purpose-built incinerators. Use of existing industrial plants may be more practical.
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
Immobilization Waste encapsulation	Solids, semi-solids, powders, liquids, antineoplastics, controlled substances.	
Inertization	Solids, semi-solids, powders, antineoplastics, controlled substances.	
Landfill Highly engineered sanitary landfill	Limited quantities of untreated solids, semi-solids and powders. Disposal of waste pharmaceuticals after immobilization preferable. PVC plastics	
Engineered landfill	Waste solids, semi-solids and powders, preferably after immobilization. PVC plastics	
Open uncontrolled non-engineered dump	As last resort untreated solids, semi-solids, powders - must be covered immediately with municipal waste. Immobilization of solids, semi-solids, powders is preferable .	Not for untreated controlled substances.
Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised).	Antineoplastics, and undiluted disinfectants and antiseptics not recommended.
Fast-flowing watercourse	Diluted liquids, syrups, intravenous fluids; small quantities of diluted disinfectants (supervised).	Antineoplastics, and undiluted disinfectants and antiseptics not recommended.
Burning in open containers	As last resort, packaging, paper, cardboard.	Not acceptable for PVC plastics or pharmaceuticals.
Chemical decomposition	Not recommended unless special chemical expertise and materials available.	Not practical for quantities over 50 kg

3. Sorting categories

3.1 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

Sorting involves an initial overall evaluation of the stockpile and subsequent division of pharmaceuticals into those suitable for use and those to be discarded. For those to be discarded a decision is made on the best method of disposal. To be efficient items should only be handled once. Pharmaceuticals suitable for use should remain in their packaging. The pharmaceuticals to be discarded should, when necessary, be separated from their packaging as late in the process as possible.

The sorting process includes:

- identifying each item;
- making a decision on whether it is usable;
- if usable, leaving packaging intact;
- 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.

3.2 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 a pharmacist. They 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.

3.3 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. These 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.

3.4 Pharmaceuticals and other materials which can still be used

A large proportion of the volume of a typical stockpile of waste drugs is not occupied by the pharmaceuticals themselves, but rather by other items, such as medical material and equipment, food, clothing, boxes, pallets, and general rubbish. The first step in dealing with these stockpiles is to remove and dispose of these non-drug, non-chemical items. All such items should be clearly separated from pharmaceuticals and chemicals.

Non-pharmaceutical useful materials

Medical equipment, beds, wheelchairs, dressings, clothing, laboratory glassware, etc. can either be utilized by the institution or by other facilities, recycled, cannibalized for spare parts or disposed to a landfill.

Useful pharmaceuticals

If feasible, pharmaceuticals within their expiry date and considered useful should be separated out and immediately used by the institution or reallocated according to the needs and instructions of the regional health authorities. A list can be prepared giving details of the items available, quantities and expiry dates and circulated to others who can use the materials. **While this separation is logical and appealing, experience indicates that it may not always be an efficient use of time and resources**

Chemicals

Acids, alkalis, reagents, phenol-based chemicals used for cleaning floors, disinfectants, etc. can be put to good use. If large quantities of these items are found a list may be prepared and offered to other potential users, such as hospitals, universities, or school laboratories, etc.

3.5 Expired or unwanted 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)

Special disposal is needed for the following:

- controlled substances; e.g. narcotics, psychotropic substances;
- anti-infective drugs;
- antineoplastics;
- cytotoxic-anti-cancer drugs, toxic drugs;
- antiseptics and disinfectants.

For more information refer to Sections 4.4, 4.5, 4.6 and 4.7.

All other pharmaceuticals should be sorted by dosage form:

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.

3.6 Hazardous or potentially hazardous non-pharmaceutical materials

All non-pharmaceutical, potentially dangerous waste such as chemicals, cleaning solutions, batteries and waste oil must be dealt with on a case-by-case basis by the hazardous waste expert. They must not be handled by the pharmaceutical teams unless expressly directed to do so. This waste requires separate and careful labelling and storage until disposal.

3.7 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.

4. Recommended disposal methods by sorting category

4.1 Solids, semi-solids and powders

Anti-infective drugs, controlled drugs and antineoplastics

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 (refer to Sections 4.4, 4.5 and 4.6). Anti-infective drugs and antineoplastics are encapsulated to delay release to the environment and avoid high concentrations. Controlled drugs should be immobilized under supervision of the pharmacist, the police or a judicial representative, depending on the local regulations.

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. It is further postulated that in emergencies and situations where the stockpile is large (many hundreds of tons), then 5-10% of the total daily municipal waste would be an acceptable daily disposal figure, where disposal of municipal waste is greater than 50 metric tons per day. In this case the landfill should be well managed and the disposal should be for a fixed period of time.

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. Many countries however do not have access to either high or medium temperature incineration plants, and the use of the encapsulation method represents an acceptable, but not always feasible, method of disposal for large quantities of pharmaceuticals.

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 non-drug, 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 tablets 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. If the drug is an antineoplastic, it should be treated according to the procedure for antineoplastics outlined in Section 4.6. Controlled substances should be treated as normal solids, but with supervision according to local regulations. See Sections 4.3 and 4.4 for treatment of anti-infective drugs. Very large quantities of loose tablets should be mixed with other medicines in several different steel drums to avoid very high concentrations of a single drug in any one drum.

4.2 Liquids

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, antineoplastics or anti-infective drugs)

Small quantities of other liquid pharmaceuticals, which are not controlled substances, anti-infective drugs, or antineoplastics, 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 (see Section 2.3), high temperature incineration or in cement kilns (see Section 2.8).

It is not acceptable to discharge liquid pharmaceuticals, diluted or not, into slow moving or stagnant surface waters.

4.3 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.

NB: 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.

4.4 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.

4.5 Controlled substances

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. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

4.6 Antineoplastics

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 walls⁹. 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.

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.

Antineoplastic drug disposal

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

4.7 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 passed, the material can still be used for general disinfection purposes at an appropriate dilution decided by a pharmacist, or disposed of in a chemical waste disposal facility or a cement kiln. Many countries do not have chemical waste disposal facilities, so the materials may have to be shipped out of the country. However this is an expensive and complicated operation and should only be contemplated if there is no viable alternative.

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. The sheets may be obtained from WHO¹⁴.

4.8 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.

Table 2: 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 High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer
Ampoules	Crush ampoules and flush diluted fluid to Sewer	Antineoplastics not to sewer
Anti-infective drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer
Antineoplastics	Return to donor or manufacturer Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)	Not to landfill unless encapsulated Not to sewer. No medium temperature incineration
Controlled drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated.
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	

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Further reading

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Annex I: Disposal by incineration

The European Union Directive on the incineration of hazardous waste (Ref. 12) states that:

"All incineration plants shall be designed, equipped and operated in such a way that the gas resulting from the incineration of the hazardous waste is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions anticipated, to a temperature of at least 850°C, as achieved at or near the inner wall of the combustion chamber, for at least two seconds in the presence of at least 6% oxygen; if hazardous wastes with a content of more than 1% halogenated organic substances, expressed as chlorine, are incinerated, the temperature has to be raised to at least 1100°C."

Article 7 of the same Directive gives emission limit values for the exhaust gases from incineration plants. The values provided are to prevent emissions into the air giving rise to significant air pollution. In addition to temperature and residence time other operating conditions must also be followed to combust pharmaceuticals safely and efficiently (e.g. treatment and handling of ash).

Studies by Pharmaciens Sans Frontières in 1996 in Mostar have shown that the donated pharmaceuticals, in mixed boxes, had a halogen weight content (i.e. the elements chlorine, fluorine, bromine, iodine, and the isotope astatine), of approximately 0.1% of the total weight including associated packaging. This is well below the 1% threshold given in the EU Directive. The very low halogen content reported for the donated pharmaceuticals indicates that the lower temperature of 850°C could be adopted for these types of pharmaceuticals.