Safe management of pharmaceutical waste from health care facilities global best practices

World Health Organization

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Summary of key themes illustrated by case studies

#	Country/region	Key themes
1	Nepal	Guidance, awareness, training: guideline
2	Colombia	Guidance, awareness, training: resolution – extended producer responsibility (EPR)
3	Canada	Guidance, awareness, training: take-back programme
4	Indonesia	Guidance, awareness, training: campaign
5	Australia	Guidance, awareness, training: advocacy
6	Worldwide	Prevention and minimization: sustainable procurement
7	Netherlands	Prevention and minimization: sharing marketplace
8	Australia	Prevention and minimization: recycling – carbon footprint
9	Oman	Prevention and minimization: recycling
10	Guinea	Collection and storage: cleanup Transport: transboundary
11	Haiti	Collection and storage: cleanup
12	Serbia	Collection and storage: cleanup Transport: transboundary
13	Benin	Guidance, awareness, training: training Collection and storage: cleanup Treatment and disposal: inertization
14	Yemen	Transport: reverse logistics
15	European Union (EU)	Treatment and disposal: coprocessing
16	Nepal	Treatment and disposal: inertization

Acronyms and abbreviations

ADHD	attention-deficit/hyperactivity disorder
ANMF	Australian Nursing and Midwifery Federation
API	active pharmaceutical ingredient
BPOM	Indonesian Food and Drug Authority
DGIS	Directorate-General for International Cooperation of the Netherlands
DTG	dolutegravir-based regimen
EFV	efavirenz-based regimen
EPPP	environmentally persistent pharmaceutical pollutant
EPR	extended producer responsibility
EU	European Union
GHSC-TA	Global Health Supply Chain – Technical Assistance
HFC	hydrofluorocarbon
HPSA	Health Products Stewardship Association
INCB	International Narcotics Control Board
LMICs	low- and middle-income countries
NIOSH	National Institute for Occupational Safety and Health of the United States
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-p-dioxin
PCDF	polychlorinated dibenzofuran
PPE	personal protective equipment
PVC	polyvinyl chloride
SBDMA	Supreme Board of Drugs and Medical Appliances
TEQ	toxic equivalence
UN	United Nations
UNEP	United Nations Environment Programme
UNODC	United Nations Office on Drugs and Crime
USP	United States Pharmacopeia
WHO	World Health Organization

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Glossary of terms

Term	Definition
Active pharmaceutical ingredient (API)	A chemical substance contained in a pharmaceutical and is responsible for the pharmaceutical's therapeutic effect.
Analgesics	Substances used to relieve pain. Analgesics are also called pain relievers or painkillers.
Anti-infective drugs	Substances to prevent or treat infections.
Antiseptics	Substances that inhibit the growth and development of harmful microorganisms on the skin.
Antibiotics	Substances that destroy or weaken certain microorganisms, especially bacteria, and are commonly used to treat bacterial infections.
Antifungals	Substances that inhibit the growth of fungi and are used to treat fungal infections.
Antivirals	Substances that inhibit the growth of viruses and are used to treat virus infections.
Antineoplastics	Substances that inhibit or prevent the development and spread of neoplasms and are used to treat cancer.
Controlled substances	Controlled medicines are those identified by the International Narcotics Control Board (INCB) and the United Nations Office on Drugs and Crime (UNODC) as products at risk of illicit distribution and that pose a threat to populations when consumed outside of legitimately prescribed and indicated use.
Coprocessing	The use of suitable waste materials (such as pharmaceutical waste resulting from manufacturing processes) for energy and/or resource recovery, thereby reducing the use of conventional fuels and/or raw materials through substitution (e.g. cement kilns).
Disposal	Any operation on waste which may or may not lead to the recovery of materials or energy. Waste disposal may be done in more than one stage including interim operations and final disposal operations. Disposal operations are listed in Annex IV of the Basel Convention (see Chapter 3.1).
Encapsulation	Encapsulation is a disposal operation based on solidification, a clean-up method that prevents hazardous waste from coming into contact with potential leaching agents by entrapping the waste in a monolithic mass of high structural integrity.
Environmentally persistent pharmaceutical pollutants (EPPPs)	Environmentally persistent pharmaceutical pollutants are pharmaceuticals designed to degrade slowly or not at all and that therefore pose a particular risk when they enter and persist in the environment.

Term	Definition
Emergency	A situation that impacts the lives and well-being of many people or a significant percentage of a population and generates a requirement for substantial multisectoral assistance. Emergencies may be acute episodes, such as those arising from extreme weather events (e.g. hurricanes/typhoons, flooding), earthquakes and disease outbreaks (e.g. Ebola, cholera), or have a slow onset, such as drought and situations arising from war, conflict and mass migration. Multiple emergencies can occur concurrently. The World Health Organization defines three grades for emergencies, signifying the level of operational response by the Organization: Grade 1 (limited response), Grade 2 (moderate response) and Grade 3 (major/maximum response).
Essential medicines	Essential medicines are those that satisfy the priority health care needs of a population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.
Extended producer responsibility (EPR)	A policy approach that holds the original producers responsible for the entire lifecycle of their products, especially for takeback, recycling and final disposal.
Hazard	An intrinsic potentially harmful property or the ability (of any substance) to cause harm. Harm is an injury or damage to the health of people and/or to the environment.
Hormones	Substances used to increase diminished hormone levels in the body.
Immobilization	The prevention of free movement of the contaminants from waste or byproducts into the environment. Immobilization options include encapsulation and inertization of pharmaceutical waste.
Immunological agents	Substances used to stimulate immunity to a particular infectious disease or pathogen (e.g. vaccines).
Incineration	Destruction of waste by combustion, typically in facilities designed to achieve high-temperature oxidation of hazardous wastes, often converting them into less harmful residues such as ash, gases and heat.
Inertization	A variant of encapsulation that involves removing packaging materials, paper, cardboard and plastic from pharmaceutical waste before immobilizing the waste by entrapping it in a monolithic mass of high structural integrity.
Landfill	A method of waste disposal. This document distinguishes between different landfill safety levels: 1. engineered landfills (safest method): An engineered landfill is a disposal operation that combines natural protection with engineered systems to ensure long-term confinement and control of hazardous and other waste. Engineered landfills should be designed in accordance with the type of waste that will be disposed of there, based on the risk that type of waste presents and the site where the facility will be operating. They are not accessible to unauthorized persons. 2. controlled landfills: Controlled landfills have fewer safety measures than engineered landfills. Environmental protection is limited. Access to the site is restricted. 3. uncontrolled landfills or dumpsites: Uncontrolled landfills or dumpsites are waste disposal areas that are not engineered or controlled and where solid waste is dumped in an unplanned manner without consideration for environmental and health standards. Openly accessible to the public and the informal sector (scavengers).

Term	Definition
Narcotics	Analgesic substances that have the potential to induce sleepiness, dull the senses, relieve pain and induce euphoria. Common narcotics include opioids, such as morphine and codeine, and synthetic opioids, such as oxycodone, hydrocodone and fentanyl.
Nonhazardous waste	Waste that does not pose any specific biological, chemical, radioactive or physical hazard.
Pharmaceutical	Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. This document focuses on pharmaceuticals for humans.
Psychotropics	Substances that are used to treat the symptoms of mental disorders, reduce disability and prevent relapses. Antipsychotics, antidepressants, mood stabilizers and antiepileptic medications comprise the main categories of psychotropic medications.
Reverse logistics	The process of planning, implementing and controlling the efficient, cost-effective flow of raw materials, in-process inventory, finished goods and related information from the point of consumption to the point of origin for the purpose of value recapture or proper disposal.
Scavenging/informal waste handling	The informal handling of solid waste at landfills/dumpsites and the removal of usable material.
Treatment	Any method, technique or process for altering the biological, chemical or physical characteristics of waste to reduce the hazards it presents and facilitate, or reduce the costs of, disposal. The basic treatment objectives include volume reduction, disinfection, neutralization and other changes of composition to reduce hazards.

1 Executive summary

This document provides a summary of existing, relevant recommendations for the safe management of pharmaceutical waste and uses case studies to illustrate best practices for managing pharmaceutical waste. It focuses on pharmaceutical waste generated in health care settings, including secondary and tertiary hospitals, primary care centres, dental clinics and laboratories. The scope covers pharmaceutical waste produced during routine operations as well as in outbreaks and emergencies. This category of waste includes unused medications, unsealed pharmaceutical products, loose or bulk tablets and capsules, and pharmaceuticals damaged in cold chain storage.

Improper management of pharmaceutical waste endangers both human health and the environment. Low-temperature burning of pharmaceutical waste releases harmful chemicals that pollute the air, putting waste workers and local communities at particular risk, while poorly managed landfills and dumpsites can lead to scavenging, the reselling of expired medications, and the generation of leachates, which contaminate soil and water. Active pharmaceutical ingredients (APIs), such as antibiotics, can contribute to the development of antimicrobial resistance. Most wastewater treatment plants are unable to fully remove or inactivate APIs, resulting in their persistence in treated water and the subsequent contamination of surface waters. Additionally, pharmaceuticals can accumulate in the sludge produced during wastewater treatment.

Every country is strongly encouraged to have and enforce their own national pharmaceutical waste management policy and relevant guidelines as part of their health care waste guidelines or other relevant health guidelines. The pharmaceutical policies and guidelines should incorporate relevant aspects of global policies and treaties, to which most countries are signatories (Chapter 3).

Priority should be given to waste prevention and minimization (Chapter 4). Prevention and minimization strategies should be integrated into a country's legal framework and emergency preparedness and response plans. When revising the legal framework, it is important to address the impact of proper stock management, as well as procurement and donation policies, on waste generation. Pharmaceutical management processes can be optimized through rational use of medications, sustainable procurement practices that account for environmental impacts, and the establishment or use of national marketplaces and redistribution platforms for unused, near-expiry medications. Additionally, recycling and reuse options should be explored. Preventing and minimizing pharmaceutical waste is both economically and environmentally beneficial, as it reduces waste volume, lowers waste management costs and lessens the potential environmental harm caused by unsafe disposal.

While the management of pharmaceutical waste varies depending on the type of health facility and services provided, standard procedures include classification and segregation, interim storage, and regular collection for treatment and disposal in accordance with international conventions as well as national regulations. Appropriate management and administration practices include the definition of clear responsibilities, engagement of knowledgeable and trained staff, routine inventory, tracking and documentation, and defined and executed communication schemes (Chapter 5). Pharmaceutical waste is classified as:

- **nonhazardous pharmaceutical waste**, which is not classified as hazardous but still needs to be disposed of properly to prevent misuse or environmental damage;
- **hazardous pharmaceutical waste**, which poses a risk to health and the environment due to harmful ingredients and interactions or hazardous characteristics, e.g. poisonous (acute), ecotoxic, toxic (delayed or chronic), carcinogen, flammable, corrosive, reactive or explosive; and
- **hazardous controlled substances**, which need to be specifically managed to prevent the di-version and nonmedical use of those substances as well as the illicit use of drugs.

Though treatment and disposal options vary, human and environmental health risks should be minimized in all situations. The types of treatment options, listed from optimal to those that should be avoided, are summarized in Table 1 and further elaborated in Chapter 6.

Table 1 Summary of treatment options

Treatment options	Technologies/methods	Notes
Optimal	• High-temperature incineration with flue gas cleaning; • coprocessing in a high-temperature process (cement kiln); and • immobilization in engineered landfill.	• High-temperature processes must be compliant with the processes and air pollution controls outlined in the Stockholm Convention (see Chapter 3.1).
Interim	• High-temperature incineration with no or limited flue gas treatment; • medium-temperature dual-chamber incineration with auxiliary burners; • burial in engineered landfill; and • immobilization in controlled landfill.	• The incinerators must include burners and fans to ensure complete combustion.
Temporary	• Temporary storage.	• Safe storage should be temporary while optimal or interim options are being planned and budgeted.
Immediate short-term response in emergency situations	• Encapsulation in uncontrolled landfill.	• This should be temporary while optimal or interim options or storage are being planned and budgeted.
Not recommended/ to be avoided	• Low-/medium-temperature incineration without auxiliary burners; and • burial in uncontrolled or controlled landfill.	• Incinerators that are low or medium temperature and do not have auxiliary burners release harmful pollutants, pose risks to humans and the environment, and are not recommended. • Burial is only recommended as an interim option in an engineered landfill where controls ensure waste doesn't leach into the environment.

Source: prepared by the authors of this document.

Waste minimization and prevention should be accompanied by systems to support ongoing operation and maintenance, including regular budgets, trained personnel and monitoring. It is especially crucial for interim and immediate options to be coupled with plans and investments to transition to safer and more sustainable options over time.

Finally, the recommended treatment and disposal methods are explained based on waste categories (Chapter 7). Nonhazardous pharmaceutical waste (e.g. general waste) should be either recycled (as appropriate) or sent to controlled and managed engineered landfills. All hazardous pharmaceutical waste like antineoplastics, anti-infective products and controlled pharmaceutical products, should be treated and disposed of via optimal options.

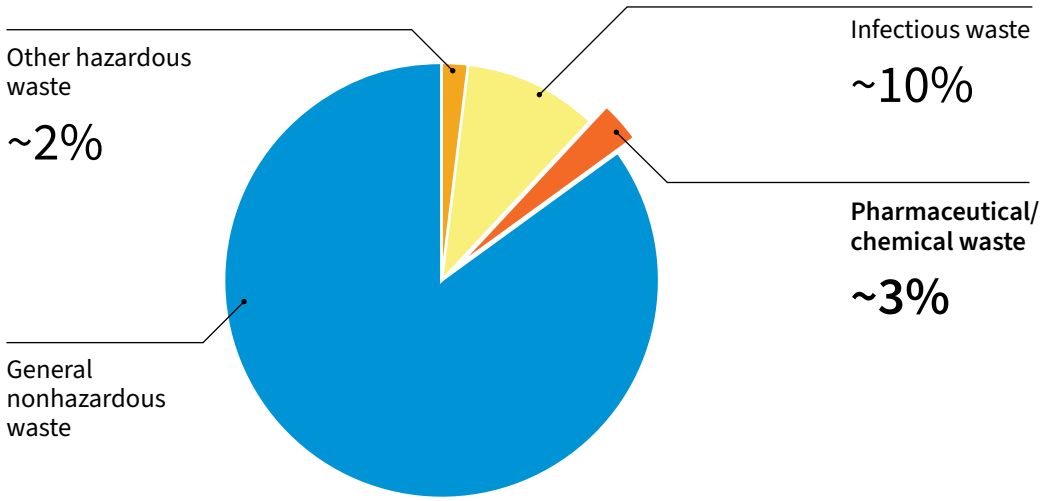
Annex 1 provides a classification system that can be used to categorize and prioritize pharmaceuticals (nonhazardous, hazardous and controlled), Annex 2 contains a waste registration template, Annex 3 describes a standard operating procedure, Annex 4 lists the specifications for a hazardous waste incinerator in accordance with the Stockholm Convention, and Annex 5 provides links to useful tools and guidance.

2 Introduction

2.1 Sources and risks of pharmaceutical waste

Pharmaceutical waste is one type of health care waste that is generated at various sources including pharmaceutical production and research sites, health care facilities, veterinary clinics, animal farms, pharmacies and households. This document focuses on waste generated by the acquisition, distribution and use of pharmaceutical products in health care facilities. It does not cover biological waste, infectious waste or waste from other types of medical procedures, such as sharps waste. Fig. 1 illustrates different types of waste typically generated in health care facilities *(1)*.

Fig. 1 Typical waste composition in health care facilities



Source: adapted from the WHO document *Safe management of wastes from health-care activities (1)*.

Unsafe management of pharmaceuticals is a growing concern and trends indicate that 3% to 50% of household medication ends up in the solid waste cycle *(2)*. In low- and middle-income countries (LMICs) this percentage is likely to be higher due to reasons including resource limitations and a lack of infrastructure. Other risks that are more prevalent in LMICs include noncompliant use of antibiotics and other medicines, donations of medicines out of alignment with best practices, and a lack of inventory management systems.

Pharmaceutical waste may contain biologically active or toxic residues, including active pharmaceutical ingredients (APIs), their metabolites or transformation products *(3, 4)*. Different classes of APIs have been detected in the environment, including antibiotics, anticonvulsants, hormones, anti-inflammatory agents, analgesics and antihypertensives. Residues of pharmaceuticals in the environment have been measured in 89 United Nations (UN) Member States. For example, 414 active substances or their transformation products were reported in Germany, 749 in the European Union (EU) and 992 worldwide *(5)*.

2.1.1 The risks of unsafe disposal of pharmaceuticals and the spread of antimicrobial resistance

This section highlights the broader context and risks associated with pharmaceutical waste.

Unsafe pharmaceutical waste management is among the factors accelerating the emergence of resistant genes and pathogens that affect humans, animals and the environment *(6)*. Pharmaceuticals designed to be slowly degradable or even nondegradable present a special risk when they enter and persist in the environment. These are known as environmentally persistent pharmaceutical pollutants (EPPPs)[1] *(7)* and are found in some antibiotics. Improper disposal of antimicrobial EPPPs contributes to the continued emergence of antimicrobial resistance through various channels, such as contamination of soil and water bodies, direct exposure to other microorganisms or facilitation of horizontal gene transfer. Antimicrobial resistance compromises the effective prevention and treatment of an expanding variety of infections caused by bacteria, parasites, viruses and fungi where standard treatments, such as antibiotics, become ineffective. According to recent estimates, in 2019, 1.27 million deaths were directly attributed to drug-resistant infections globally and 4.95 million deaths were associated with bacterial antimicrobial resistance *(8)*.

2.1.2 The consequences of inappropriate donations of pharmaceutical products

Inappropriate medicine donations may unintentionally contribute to the accumulation of unwanted and unused pharmaceuticals in a country. To avoid such harms and to support best practices regarding medicine donations, the World Health Organization (WHO) has collaborated with other organizations to issue guidance on appropriate medicine donations *(9)*. Recommendations include ensuring donations are based on expressed need and relevant to the disease pattern in the recipient country and that quantities and planning are jointly agreed on by donor and recipient countries. Furthermore, donations should be approved for use in donor and recipient countries and obtained from a quality-assured source, and the cost of all aspects of handling the medicines, including disposal and reverse logistics, should be paid for by the donor agency.

A systematic review of drug donations from 1998 to 2008 found that only 56% of donations were appropriate given the characteristics of the event and recipient need and only 12.5% of drugs requested by recipient countries were received *(10)*. In emergencies, demand estimates are often less accurate due to changing situations and can stress facility operations with the storage of excess and expired pharmaceuticals. Standardized kits, such as the Interagency Emergency Health Kits, provide clear information on estimation methods that facilitate the informed selection of kits in emergencies and help avoid waste if properly used.

A recent review of actual policies and practices provided encouraging results, including that most of the least developed countries had clear policies on medicine donations. However, the review noted that many donors do not have publicly available policies, and information management, medication presentation, the influence of the pharmaceutical industry, and donation sustainability could all be improved *(11)*.

1 EPPPs can be found in antibiotics, hormones, anti-inflammatory drugs, antidepressants, beta blockers, antiepileptic drugs and X-ray contrast media.

2.1.3 Low-temperature or inadequate burning

In settings where appropriate incineration systems are unavailable, pharmaceutical waste is often burned in low-temperature incinerators or open pits. This practice releases toxic pollutants that harm both human health and the environment, especially since pharmaceuticals are often incinerated together with their plastic packaging at low temperatures. For example, blister packs, a common form of pharmaceutical packaging, are made using polyvinyl chloride (PVC) plastic, which has chlorine as a main constituent *(12)*. Burning or incinerating chlorine-containing waste releases dioxins and furans into the environment, which have been associated with cancers, reproductive and developmental disorders, immune system suppression, and hormonal disruptions in both humans and animals. Only incinerators operating at between 850 and 1100 °C with gas-cleaning equipment can comply with the international emission standards for dioxins and furans.

2.1.4 Inadequate and poorly managed landfills and dumpsites

Pharmaceuticals are often disposed of within municipal solid waste systems, either when waste is not properly segregated in health care facilities or when it is disposed of by households. When landfills are not properly engineered or managed, a number of adverse health effects may occur. For example, informal waste handlers may gather expired pharmaceutical waste to resell and be exposed to needlestick injuries, blood, pathogens and chemicals in the waste products. In addition, landfill leachate, a complex and hazardous liquid, can contain antimicrobials and toxic organic pollutants that can promote the development of antimicrobial-resistant bacteria and genes and have ecological effects on the environment and public health.

2.1.5 Unsafe management of wastewater and sludge

Many pharmaceutical products, such as ibuprofen and ketoprofen, decompose during the wastewater treatment process. However, others, such as carbamazepine or sulfamethoxazole, do not decompose easily, including when they are disposed of in wastewater treatment processes where they then flow out with the treated sewage *(13)*. Most wastewater treatment plants are unable to fully remove or inactivate APIs, resulting in their persistence in treated water, the subsequent contamination of surface waters, and the presence of APIs in the sludge generated during wastewater treatment. When this sludge is used as fertilizer in agriculture, the residual pharmaceutical waste can contaminate soil, crops and groundwater. Considering the persistent nature of some pharmaceutical products, the exposure to humans, animals and the environment, and the cost of treating the problem, it is important to prevent and minimize the presence of pharmaceuticals in waste/wastewater at the point of generation. Though it falls outside the scope of this document, safely managing wastewater and solid waste generated from the manufacture of antibiotics is a critical element of the overall safe management of pharmaceutical waste (see Box 1).

Box 1 Guidance on wastewater and solid waste management for manufacturing antibiotics

The emergence and spread of antimicrobial resistance caused by antibiotic pollution could undermine the effectiveness of antibiotics globally, including the medicines produced at the manufacturing sites responsible for the pollution. WHO guidance on this topic includes best practices for risk management, including internal and external audits and public transparency. The guidance recommends progressive implementation and stepwise improvement where required, recognizing the need to protect and strengthen the global supply and to ensure appropriate, affordable and equitable access to quality-assured antibiotics.

Source: WHO *(14)*.

2.1.6 Insufficient enforcement of legislation

Several key international treaties and guidelines inform how countries manage pharmaceutical waste. However, awareness and enforcement of these global treaties and conventions may be limited or nonexistent in many countries. The legislation will be discussed in more detail in Chapter 3 of this document.

2.1.7 Summary of risks

Table 2 provides a summary of unsafe practices, risks and mitigation measures concerning the disposal of pharmaceuticals. A number of viable, cost-effective mitigation measures that offer a "no-regrets" investment exist. The following sections will discuss what can be done in health care facilities specifically.

Table 2 Unsafe practices, risks, and mitigation measures for the safe disposal of pharmaceutical waste

Unsafe practice	Risks	Mitigation measures
Overconsumption and over procurement of antibiotics	• Development of antimicrobial resistance in humans; • spread of antimicrobial resistance in environment through human waste and unsafe disposal of excess antibiotics; and • additional pharmaceutical waste.	• Follow guidance on "access", "watch" and "reserve" antibiotics in the *WHO AWaRe (Access, Watch, Reserve) antibiotic book (15)*. • Implement avoidance and minimization strategies (e.g. adequate procurement, improved inventory management, improved prescription practices).
Noncompliant medicine donations	• Additional pharmaceutical waste.	• Follow WHO or national guidelines for medicine donations.

Unsafe practice	Risks	Mitigation measures
Disposal in unsecure landfills or dumpsites	• Exposure of animals and humans to harmful substances; • contamination of water bodies and soil; and • diversion to illicit or informal markets.	• Locate landfills to minimize leachate entering aquifers and surface water. • Secure and manage landfills to prevent illegal entry.
Burning of pharmaceuticals at low temperatures or in open containers	• Release of toxic pollutants into air, water and soil.	• Install and manage high-temperature incinerators with flue gas scrubbers to remove toxins. • Transport pharmaceutical waste from small facilities to larger ones. • Employ reverse logistics to send pharmaceutical waste back to the warehouse.
Disposal of hazardous pharmaceuticals (e.g. antibiotics and antineoplastics) in sewerage system	• Killing of "good" microorganisms that facilitate biotreatment of sewage; and • further contamination of water bodies and environment, and contribution to persistence.	• Set up systems for patients to bring expired/unused medicines back to the pharmacy where they can be disposed of via appropriate systems.

Source: WHO *(1, 15, 16)*; WHO, Food and Agriculture Organization of the United Nations and World Organisation for Animal Health (*17*).

2.2 Purpose

This document summarizes existing guidance on the safe management of pharmaceutical waste and uses case studies to illustrate best practices for implementing the guidance. It focuses on pharmaceutical waste generated in health care facilities, including secondary and tertiary hospitals, primary health care facilities, dental clinics and laboratories. The scope covers pharmaceutical waste generated during development/peace-time activities and in outbreaks and emergencies. Pharmaceutical waste generated by households and manufacturing facilities and veterinary pharmaceuticals used for aquaculture, companion animals and livestock are beyond the scope of this document.

The document focuses on pharmaceutical waste in solid, fluid or gaseous form. Table 3 outlines the types of pharmaceutical waste that are included as well as those that are not.

Table 3 Types of pharmaceutical waste and whether they are included in this document

Waste type	Details	Examples	Included in document
Excess and expired pharmaceuticals	Pharmaceuticals that have expired, are unwanted or are surplus to requirements, e.g. residual product from open packages that exceed prescribed amounts and cannot be redistributed.	Expired or excess antineoplastics, anti-infective substances, controlled substances, antidepressants, hormone suppressants, vaccines (noninfective vaccines: COVID-19, Ebola, diphtheria, tetanus, Hib, hepatitis B, human papillomavirus (HPV), H1N1/ H5N1 influenza, rabies, oral cholera vaccine, hepatitis A etc.), sleep disorder agents, syrups, eye drops, tubes of creams, ointments etc.	Yes
Pharmaceutical products that are damaged or have been tampered with	Damaged products, including primary packages that are open or show other signs that the product has been tampered with, especially where there is a risk of the product being falsified.		Yes
Unidentified or expired bulk products	Product details are missing or the bulk product has expired.		Yes
Cold-chain-damaged pharmaceuticals	The cold chain of the pharmaceuticals during storage or transport was interrupted and the pharmaceuticals cannot be used anymore.	Insulin, polypeptide hormones, noninfective vaccines, etc.	Yes
Radiopharmaceuticals	This is radioactive waste and requires specific procedures. Specialized guidance is available from WHO *(1)*.	Gallium-67 citrate, Indium-111 chloride, Iodine-125 human serum albumin, Technetium-99m bicisate etc.	No
Certain types of vaccines	Vaccines that are considered potentially infectious. Managed and disposed of as infectious waste.	Measles-mumps-rubella (MMR combined vaccine), rotavirus, smallpox, chickenpox, yellow fever, shingles, varicella-zoster, oral poliovirus vaccine (OPV), live-attenuated Japanese encephalitis vaccine and live-attenuated influenza vaccines.	No

Source: WHO *(1, 18)*.

As stated, radiopharmaceuticals and live vaccines have been excluded because their primary hazardous characteristics – radioactivity in radiopharmaceuticals and potential infectiousness in live vaccines – fall outside the scope of this document.

This document describes several methods for safe disposal of pharmaceuticals that apply the best available techniques and best environmental practices in accordance with the Basel and Stockholm Conventions *(19, 20, 21, 22)* (see Chapter 3.1) and involve a risk-based approach. The best available techniques described include those suitable for countries with limited resources and equipment or during emergencies for settings with limited disposal capacities.

During regular health service delivery, the amount of pharmaceutical waste generated is small. On average, only 3% of the waste generated in a health facility is pharmaceutical and chemical waste *(23)*. In resource-limited settings, the generation rates can be lower due to limited drug availability and use. Large amounts of pharmaceutical waste often accumulate during emergencies or when regular standard pharmaceutical waste processes are not enforced, leading to waste buildup over the years. In such cases, additional measures are required to detail information about kinds and amounts of waste (if not already available) and to find solutions for the treatment and disposal of large quantities of hazardous and nonhazardous waste. These processes are typically supported or organized by the relevant authorities, as this is usually a national or regional issue that needs to be addressed.

Often, pharmaceutical waste storage is also used to store other types of health care waste and non-hazardous general waste. Examples include expired dressings and expired, unused personal protective equipment (PPE), medical equipment, wheelchairs and laboratory glassware. All potentially hazardous nonpharmaceutical waste such as chemicals, cleaning solutions, insecticide-treated bed nets, heavy-metal-containing devices like batteries, thermometers, sphygmomanometers and fluorescent bulbs must be dealt with on a case-by-case basis by the hazardous waste expert. This waste requires separate and safe waste management *(1)*.

2.3 Existing guidance and basis for document

This document synthesizes a number of recommendations and best practices from the existing guidance documents. The main document used is the WHO guidance on safe management of health care waste *(1)*. It also draws on the WHO *Overview of technologies for the treatment of infectious and sharp waste from health care facilities (24)* and the WASH FIT implementation tool *(25)* as well as the inter-agency *Guidelines for medicine donations (9)* and the user guidance of the Sustainable Procurement Index for Health *(26)*. The existing guidance on which this document draws is illustrated in Fig. 2.

Fig. 2 Existing guidance on which this document draws

Source: WHO *(1, 9, 24, 25)*; United Nations Development Programme, Health Care Without Harm, Arup, Swedish International Development Cooperation Agency *(26)*.

A summary of relevant tools and guidance related to pharmaceutical waste management can be found in Annex 5.

2.4 Target audience

This document is for health authorities and health facility staff trained to use pharmaceuticals and manage pharmaceutical waste. It is also intended for environment, waste and police authorities managing waste transport, treatment and final disposal. Appropriate authorities include those responsible for pharmaceutical waste management within the ministry of health, the national regulatory authority, the food and drug authority, a regional or local health authority (pharmaceutical officer) or the ministry of environment.

3 Legislation

3.1 Global legislation

As countries review their national policies on the management of pharmaceutical waste, it will be helpful to review global treaties, conventions and guidelines that influence and, in many cases, dictate, this process. Most countries are signatories to these treaties. The relevant major global conventions and regulations are listed in Table 4.

Table 4 Major global policies, resolutions and guidelines related to pharmaceutical waste

Title	Content
Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal *(19, 20)*	This treaty's overarching objective is to protect human and environmental health against the adverse effects of hazardous waste. It aims to do so by reducing the movement of hazardous waste between countries, especially to less developed countries. Many pharmaceutical wastes are classified as hazardous under this Convention.
Stockholm Convention on Persistent Organic Pollutants *(21, 22)*	This global treaty is intended to protect human health and the environment from persistent organic pollutants by restricting and ultimately eliminating their production, use, trade and release. Persistent organic pollutants are highly dangerous, long-lasting chemicals, some of which can be found in pharmaceutical waste or in its treatment.
International Labour Organization Chemicals Convention *(27)*	The International Labour Organization Chemicals Convention is a treaty that aims to protect workers from the harmful effects of chemicals in the workplace. It includes chemical classification, chemical labelling, safety data sheets, risk assessment, worker information, emergency response and regular inspections. The convention also applies to any new substances developed after its adoption.
United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances *(28)*	It provides additional legal mechanisms for enforcing the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971. Additionally, the United Nations Economic and Social Council and its subsidiary body, the Commission on Narcotic Drugs, have issued several resolutions expanding the scope and reiterating the provisions of this convention.
United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations *(29)*	The Model Regulations cover the classification of dangerous goods and their listing, the use, construction, testing and approval of packaging, and consignment procedures (marking, labelling, placarding and documentation). They aim to ensure a high level of safety by preventing accidents involving persons and property and avoiding damage to the environment during transport, while also providing a uniform regulatory framework that can be applied worldwide to any mode of national or international transport.

Title	Content
Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa *(30)*	This is an agreement between African countries that bans importing hazardous waste into Africa. It was created by 12 Member States of the Organization of African Unity at Bamako, Mali, in January 1991. They were concerned that The Basel Convention did not completely prevent wealthier countries from sending their hazardous and radioactive waste to Africa. The Bamako Convention is similar to the Basel Convention but is stricter in prohibiting the transport of any hazardous or radioactive waste into Africa.

Source: see citations in table.

3.2 Legislative framework

Every country is strongly encouraged to have their own national pharmaceutical waste management policy and relevant guidelines as part of their broader health care waste guidelines or other relevant health guidelines. The pharmaceutical policies and guidelines should incorporate relevant portions of the previously mentioned global policies and treaties, to which most countries are already signatories.

To develop or refine national policies and guidelines on pharmaceutical waste management, in addition to incorporating aspects of relevant global policies, it is helpful to 1) review legislation from countries with comprehensive policies and guidelines to determine which are applicable; 2) consider using the WHO One Health approach ("an integrated, unifying approach that aims to sustainably balance and optimize the health of humans, animals, plants and ecosystems" *(6)*); and 3) incorporate the five guiding principles of health care waste management as referenced in the WHO document *Safe management of wastes from health-care activities (1)*.

1. When establishing or reviewing legislation on pharmaceutical waste, it is important to consider the following key policy requirements:
   - Waste reduction: reduce, reuse, reprocessed, renewable, recyclable – these priorities guide pharmaceutical waste management.
   - Identify/classify types of pharmaceutical waste: determine which pharmaceuticals are hazardous and nonhazardous, and which are controlled substances.
   - Controlled substances: ensure controlled substances are immediately secured and handed over to the appropriate authorities.
   - Staff training: ensure staff are properly trained in handling hazardous pharmaceutical waste.
   - PPE: ensure all health workers are protected by appropriate PPE when handling pharmaceutical waste.
   - Proper containers: use appropriate containers for storing and transporting hazardous pharmaceutical waste. These should be sound, colour coded, compatible with the waste and leakproof. Special rules apply to ignitable or reactive waste. Keep containers closed and ensure that they are labelled as hazardous pharmaceutical waste.
   - Storage: pharmaceutical waste awaiting disposal must be stored in such a manner that access by unauthorized persons is prohibited.
   - Pretransport requirements: follow packaging, labelling, marking and placarding rules for offsite disposal.

- Tracking: track the waste to reduce the risk of unused and used hazardous waste pharmaceuticals being diverted onto the black market.
- Land disposal restrictions: meet the land disposal restrictions.
- Shipping: ship hazardous waste to disposal facilities using a manifest; keep manifests for three years.
- Spill cleanup: immediately contain and clean up any spills.
- Accumulation time limit: identify a time limit for accumulation of hazardous pharmaceutical waste before it is sent for treatment or to a reverse distributor, and be able to prove the accumulation start date.
- Return of unused drugs: whenever possible, send unused hazardous drugs to reverse distributors for credit from the manufacturer.
- Enforcement: enforce severe penalties for not following these regulations; penalties apply not only to the waste transportation company but also to the waste generator.

Compliance requires facilities to invest in proper waste segregation systems, disposal methods, and staff training. It can be costly, yet without this investment there can be significant fines and legal repercussions. Noncompliance can result in improper waste management practices that could have very real environmental and health impacts.

2. The One Health approach includes multiple authorities and sectors at various levels in the development or revision of policies, regulations, strategies and guidelines. Roles and responsibilities must be identified and clearly defined in the legal framework.
3. As outlined in the WHO document *Safe management of wastes from health-care activities (1)*, five guiding principles are widely recognized as the basis for effective and controlled management of pharmaceutical waste. These principles have been used in many countries when developing their policies, legislation and guidance and are described in Table 5.

Table 5 Five guiding principles for effective and controlled management of wastes

Principles	Definition
The "polluter pays" principle	"producers of waste are legally and financially responsible for the safe and environmentally sound disposal of the waste they produce. This principle also attempts to assign liability to the party that causes damage" *(1)*.
The "precautionary" principle	"is a persuasive principle governing health and safety protection" *(1)* and is defined under the Rio Declaration on Environment and Development as Principle 15: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" *(31)*.
The "duty of care" principle	"stipulates that any person handling or managing hazardous substances or wastes or related equipment is ethically responsible for using the utmost care in that task. This principle is best achieved when all parties involved in the production, storage, transport, treatment and final disposal of hazardous wastes (including health-care waste) are appropriately registered or licensed to produce, receive and handle named categories of waste" *(1)*.

Principles	Definition
The "proximity" principle	"recommends that treatment and disposal of hazardous waste take place at the closest possible location to its source to minimize the risks involved in its transport. Similarly, every community should be encouraged to recycle or dispose of the waste it produces, inside its own territorial limits, unless it is unsafe to do so" *(1)*.
The "prior informed consent" principle	"requires that affected communities and other stakeholders be apprised of the hazards and risks, and that their consent be obtained. In the context of health-care waste, the principle could apply to the transport of waste and the siting and operation of waste-treatment and disposal facilities" *(1)*.

Source: WHO *(1)*, United Nations *(31)*.

The development and contents of the guidelines in Nepal are summarized in Case Study 1.

Case Study 1
Nepal:
National guideline for pharmaceutical waste management

The Government of Nepal issued the *National guideline for pharmaceutical waste management* in 2018. It covers the hazards, the international and national legal framework, the current situation in Nepal, and the design of a national pharmaceutical waste system for minimization, segregation, storage, transport, treatment and disposal. In particular, the guideline outlines the training and promotion activities and responsibilities. An authorized Pharmaceutical Waste Management Committee should be formulated at the central level, then at the provincial, district and local levels. The Terms of Reference are outlined in the annex and include conducting audits and reports as well ensuring the implementation of waste avoidance and minimization programmes and training programmes as well as preparing overall pharmaceutical waste strategies.

Source: Government of Nepal, Ministry of Health and Population, Department of Drug Administration *(32)*.

3.2.1 Extended producer responsibility

One strategy that countries can consider enacting for management of pharmaceutical waste is extended producer responsibility (EPR), which aims to decrease the negative impacts of pharmaceuticals on the environment and to create incentives for the pharmaceutical industry to design their products to be as green as possible. EPR is a policy approach that holds producers responsible for the entire lifecycle of their products, especially for takeback, recycling and final disposal. Manufacturers of pharmaceutical products are responsible for managing and disposing of their products' waste throughout its lifecycle, including after it has been used by consumers. All the estimated environmental costs associated with a product throughout the product lifecycle are added to the market price of that product *(33)*. To achieve

maximum success, EPR programmes require funding and the enactment of national policies that enforce the programmes and engage pharmacies in collecting pharmaceutical waste. An alternative approach is to have voluntary programmes conducted as a public service. This may include running take-back programmes several times a year or asking pharmacies or law enforcement facilities to install permanent drop boxes. However, without legislation and funding, these programmes are generally limited. Case Study 2 describes how EPR is regulated in Colombia.

Case Study 2
Colombia:
Extended producer responsibility


REPÚBLICA DE COLOMBIA

MINISTERIO DE AMBIENTE, VIVIENDA Y DESARROLLO TERRITORIAL

RESOLUCIÓN NÚMERO
(0371)
26 de Febrero de 2009

"Por la cual se establecen los elementos que deben ser considerados en los Planes de Gestión de Devolución de Productos Posconsumo de Fármacos o Medicamentos Vencidos".

EL MINISTRO DE AMBIENTE, VIVIENDA Y DESARROLLO TERRITORIAL

In 2009, the Ministry of Environment and Sustainable Development of Colombia introduced a resolution as part of the national policy for regulating waste management from hazardous products: Resolution 371 on Establishing the elements to be considered in the Management Plans for the Return of Pharmaceutical Products and Expired Medicines *(34)*. The Resolution "places the responsibilities and costs of implementation on the manufacturers and importers of pharmaceuticals and medications in line with the 'polluter pays' principle. By 2018, a total of 680 manufacturers and importers were participating in the policy, equivalent to 95 percent of the market share. Moreover, a total of 2593 take-back points had been established to collect medicines, covering 70 percent of the population, and more than 930 tons of medicines had already been properly disposed of" *(35)*.

Source: Colombian Ministry of Environment, Housing and Territorial Development *(34)*, World Future Council *(35)*.

Case Study 3 highlights how Canada has improved administrative procedures to implement a take-back programme.

Case Study 3
Canada: medication return programme

In Canada, the Health Products Stewardship Association (HPSA) has implemented a nationwide medication return programme to combat pharmaceutical waste. Through simplified administration and collaborations with pharmacies and health care facilities, the initiative has established collection points for unused medications and sharps in Ontario, British Columbia, Manitoba, New Brunswick and Prince Edward Island. HPSA is 100% funded by registered producers of consumer health products. Public education campaigns highlight the environmental and health risks of improper disposal, encouraging individuals to utilize designated drop-off locations. By providing a convenient and responsible disposal solution, HPSA has supported the collection of a total of 5 120 105 kg of medications between 1997 and 2023 (average ~197 kg per year). The programme involves 6389 collection locations such as pharmacies and 152 member producers in its mission to act as a bridge between health care and the environment.

Source: HPSA *(36)*.

4 Waste prevention and minimization

Preventing the generation of pharmaceutical waste should be the top priority. National legislation and countries' emergency preparedness and response plans may include prevention principles to ensure adoption throughout the supply chain. Some prevention measures at operational levels include:

- employing robust forecasting approaches and monitoring forecasts for medicines and other pharmaceuticals;
- including environmental criteria in procurement processes to allow prioritization of versions of a given medicine that reduces environmental harm, e.g. due to having less plastic in the packaging;
- following the WHO injection safety principles *(37)* to avoid overuse of injectable medicines, thereby reducing syringe and sharps waste;
- implementing systems to redistribute excess amounts of medicines across facilities within a geographic region of a country – provided that the packaging and chain of custody have been verified – to ensure that the medicines are used before they expire;
- reinforcing good inventory management principles to avoid undue expiry, e.g. first-in-first-out principle;
- separating hazardous and nonhazardous pharmaceutical waste and limiting the use of more expensive or complicated treatment methods to what is necessary; and
- where safe and allowed, separating medicines and recycling pharmaceutical packaging to reduce the bulk.

Procurement criteria can favour products certified as having been manufactured in accordance with good manufacturing practices and should include waste management as part of overall planning. As pharmaceutical research and development advance towards products that minimize environmental impact, procurement criteria should favour these products where clinically appropriate. Case Study 4 and Case Study 5, from Indonesia and Australia respectively, illustrate how countries can promote and advocate the safe management of pharmaceutical waste.

Case Study 4
Indonesia:
“Let’s Dispose of Medication Waste Properly” campaign

In 2019, the Indonesian Food and Drug Authority (Badan Pengawas Obat dan Makanan – BPOM) initiated the campaign “Let’s Dispose of Medication Waste Properly” (translation from Indonesian). This initiative encouraged people to properly dispose of expired, damaged or unused medications to prevent any misuse. Promotion tools included videos, banner, flyers, gimmicks (pens, glasses, notebooks etc.) and social media ( ). Unused or expired pharmaceuticals were collected in 1000 pharmacies from 15 cities. In one month, 383 364 pieces of pharmaceutical waste were collected, which had an economic value of US$ 41 007. The waste was collected and treated using mobile incinerators by contracted companies, which were paid by BPOM. However, this initiative was stopped in 2021 because the mobile incinerators were not authorized by the Ministry of Environment and Forestry. To date (2024), this issue has still not been solved and discussions on how to meet environmental standards and continue to safely treat and dispose of pharmaceutical waste are ongoing.

Graphic: banner design used during the campaign.
Source: information provided by BPOM *(38)*.

Case Study 5
Australia: advocacy of pharmaceutical waste management

An audit by the Australian Nursing and Midwifery Federation (ANMF) in Victoria revealed that the 2009 operational guideline on clinical waste, which includes pharmaceutical waste, was not being enforced and the educational materials created were not being utilized. Pharmaceutical waste bins were rarely provided and instead the waste was most commonly being put into sharps bins, the contents of which were crushed (hammermilled) and chlorinated. This meant pharmaceuticals disposed of by health care services were frequently entering waterways. It took significant and unrelenting organizational and political advocacy to get this problem listened to and addressed.

ANMF brought stakeholders together in a public webinar and representative departments of the regulator – the Environment Protection Authority Victoria – met to discuss the problematic situation of pharmaceutical waste. Based on the information provided and the ensuing discussion, in 2024, the regulator issued correspondence to health service providers in Victoria, reminding them of the law and their obligations. Hospitals were notified about inspection campaigns that would result in compliance advice or remedial notices in the event of breaches. Hospitals were assessed on:

- the adequacy of pharmaceutical waste bins and systems in place for lawful disposal;
- training records to determine whether appropriate training for medical waste disposal had been conducted; and
- waste records to determine whether systems and processes were enabling lawful disposal of medical waste – including pharmaceutical waste.

Source: unpublished case study by the ANMF *(39)* and the Climate and Health Alliance *(40)*.

4.1 Process optimization

4.1.1 Rational use

Pharmaceutical waste can be prevented or minimized through rational medicine use, for example, in accordance with WHO or national treatment guidelines. Ensuring access to quality-assured medicines can limit consumption of certain medicines, such as oxytocin, where it has been documented that prescribers will use higher or repeated doses if faced with a poorly performing product. Another example is avoiding the overprescription of injectable medicines, which have been documented as being the subject of inappropriate financial incentives, but which increase sharps waste. Where warranted and helpful, manufacturers can play a role by extending expiry dates and adjusting package sizes to reduce the risk of accumulation of unused or expired drugs *(41)*. Extending expiry dates involves additional studies to determine whether a given product or existing inventories have stability and efficacy beyond the stated shelf life. These are decisions that require both the manufacturer and the regulator to review data and make appropriate decisions. Examples of improved stock management are outlined in Box 2.

Box 2 Examples of improved stock management

- Using contract modalities that accommodate staggered deliveries of product with sufficient shelf life in relation to local consumption patterns;
- considering pooled procurement or other collective purchasing for products that have a large minimum order quantity to mitigate the problem of quantities that cannot be consumed prior to expiry;
- following good inventory management practices to reduce avoidable expiration, e.g. the first-in-first-out principle; and
- establishing and using guidance on what constitutes an acceptable residual shelf life to avoid deliveries of short-dated products that cannot be used prior to expiry.

Source: WHO *(42)*.

4.1.2 Procurement

Minimizing pharmaceutical waste is crucial during the procurement stage, emphasizing the importance of good forecasting and good inventory management practices. Other criteria should include establishing minimum shelf-life guidance that can be applied to individual products. The environmental impact and the generation of waste can be minimized by considering environmental criteria in procurement processes where possible, as outlined in Box 3.

Box 3 UN sustainable procurement indicators

Environment

- Sustainable resource use
- Prevention of pollution and waste
- Climate change mitigation and adaptation
- Protection of the environment and biodiversity

Social

- Inclusion of people with disabilities
- Human rights and labour issues
- Gender issues
- Social health and well-being

Economic

- Whole lifecycle costs
- Local communities and small and medium-sized enterprises
- Understanding supply chains

UN definition: "Procurement is called sustainable when it integrates requirements, specifications and criteria that are compatible and in favour of the protection of the environment, of social progress and in support of economic development, namely by seeking resource efficiency, improving the quality of products and services and ultimately optimizing costs" *(43)*.

Source: UN Global Marketplace *(43)*. Graphic adapted from *The sustainable procurement (SP) indicators* page of the UN Global Marketplace *(44)*.

In procurement terms, environmental criteria are criteria used to compare two or more versions of the same product to determine which will have the lowest environmental impact. It is not intended to replace the principles of medicine selection, where a medicine should be selected and used for its indicated purpose. Procurement authorities may consider requesting environmental impact information in procurement tenders. This level of technical information may not be routinely available and it may be necessary to phase in such requirements. The following information about the manufacturing process of pharmaceuticals should be considered during the procurement process *(26)*:

- greenhouse gas emissions from production and shipping of product
- resource depletion (water, energy and material consumption)
- chemical/toxic impact on human health and the environment
- human rights, labour rights and gender equality.

In Sweden, Stockholm County Council provides a database of commercially independent drug information such as the environmental impact of pharmaceuticals *(45)*. This helps health care providers to select the least harmful options for prescription, procurement or donation policies. Where oral and intravenous administration are both available, the oral route avoids the generation of additional hazardous sharps waste.

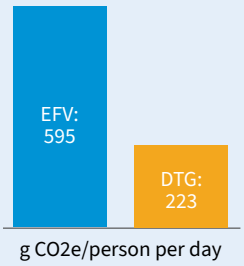
Case Study 6 shows how implementing green manufacturing and procurement practices can reduce both emissions and costs.

Case Study 6
Worldwide: green manufacturing and procurement practice – reduction of carbon emissions and costs

A Unitaid study evaluated the impact on worldwide emissions along the lifecycle of the products when shifting from an efavirenz-based regimen (EFV) to a dolutegravir-based regimen (DTG) for HIV treatment. "DTG enables faster viral suppression, has fewer side effects, and is significantly more affordable". "The analysis revealed that EFV is significantly more emissive than DTG by a factor of 2.6", which is mainly due to the higher concentration of APIs.

According to the study, "the shift in treatment turns out to have made a drastic difference". Considering the high number of HIV patients ("from 14.4 million people in 2016 to 27.2 million in 2027 on first-line treatments"), it is estimated that "the transition from EFV to DTG resulted in a decrease of annual emissions from HIV treatment by 3.4 million tons of CO_2e by 2027, with a cumulative difference of 26 million tons over the decade 2017–2027. This is equivalent to having removed the full CO_2e emissions of the city of Geneva over the same 10-year period".

"It is estimated that the introduction of DTG will have saved 1.1 million additional lives by 2027 and that the use of DTG will generate financial savings of US$8 billion by 2028 for HIV programs in LMICs, relative to what would have been achieved with EFV".



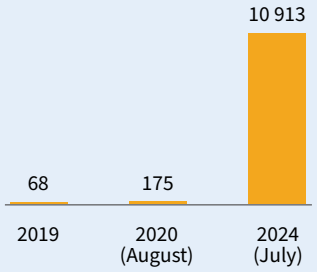
Source: Unitaid *(46)*.

4.1.3 Marketplace and redistribution

Options to use enhanced logistics information management systems, such as "control towers" or "visibility and analytics networks" facilitate redistribution of excess product to other facilities to reduce unnecessary expiration. Examples are national marketplaces and redistribution platforms for unused close-to-expiry-date medicine (e.g. six months prior to the expiry date; see Case Study 7). This option provides better matching of supply and demand and can contribute to waste prevention and economic savings.

Case Study 7
Netherlands: pharmaceutical sharing marketplace – PharmaSwap

PharmaSwap is a sharing marketplace in the Netherlands for pharmacists that creates transparency regarding the supply and demand for expensive medicines approaching their expiry date. It is governed by the law of the Netherlands. The pharmaceuticals can be offered via the PharmaSwap platform, the price is agreed and a logistics partner picks the pharmaceuticals up the next day. The platform provider receives a fee from the user, which includes the transport (e.g. the fee for a sales price of €0 to €250 is €25). In July 2024, 1128 pharmacists in the Netherlands voluntarily enrolled in the scheme. Since 2019, the destruction of 11 156 packages was avoided; instead, they were reissued to patients and represent a total value of €1 607 064.



No. of saved medication packages

Source: PharmaSwap *(47)*.

4.1.4 Recycling and reuse

The amount and impact of pharmaceutical waste can be minimized by recycling and reusing packaging materials. In countries where a recycling industry is available, packaging materials such as cardboard boxes, information leaflets, packing foil and plastic can be recycled. Cold chain packaging should prioritize reuseable containers over nonrecyclable materials such as Styrofoam wherever possible. If Styrofoam cannot be avoided, for example, in large cold chain pallets, options to use materials that can be repurposed should be considered. For example, insulation that is blown in to large pallets can be replaced with insulation sheets, which can be repurposed as building insulation, for example. Depending on the type of material and its proposed reuse, appropriate treatment, such as cleaning or disinfection, may be needed. The following case studies from Australia (Case Study 8) and Oman (Case Study 9) highlight how recycling activities can be implemented at the facility level and the national level.

Case Study 8
Australia: environmental and cost benefits of rigorous pharmaceutical waste segregation – making use of recycling

A pharmacist from St Vincent's Hospital Melbourne, Australia, conducted a waste study on a 64 L pharmaceutical waste bin collection point in a hospital pharmacy that serviced a palliative care ward. In Australian hospitals, pharmaceutical waste is collected by waste contractors, transported offsite and treated via high-temperature incineration as per local environmental requirements. Prestudy, the bin attracted 64 L pharmaceutical waste per month. Over a six-month period in 2024, this waste was rigorously segregated and recyclable material (packaging, information leaflets, glass and plastic bottles, blister strips) was removed and diverted to appropriate recycling streams. This process resulted in an 80% volume reduction, 50% weight reduction and 70% cost savings due to reduced bin collection, which amounts to yearly savings of US$ 268 from only one collection point in the pharmacy. Benefits for the environment are estimated to be a greenhouse gas emissions reduction of 100 kg CO_2e, along with a reduction in persistent environmental pollutants (dioxins and furans) and heavy metals as byproducts of the incineration process.

The barriers encountered were: 1) the time required for rigorous waste segregation, 2) a lack of information from manufacturers about the material composition of their products, 3) a lack of information from waste contractors about their processes, and 4) a lack of take-back initiatives offered by manufacturers for difficult-to-recycle products, such as blister strips and multicomponent plastics. For such initiatives to be successful, hospital management must provide support in order to promote and prioritize waste segregation and recycling and advocate take-back programmes.

Source: Climate and Health Alliance *(40)*.

Case Study 9
Oman: recycling pharmaceutical packaging at a national level

According to Royal Decree 46/2009 of Oman, expired, damaged and rejected pharmaceutical products are fully managed by the Oman Environmental Services Holding Company (be'ah) before being treated using an incinerator. be'ah implements best practices in waste management and sustainability initiatives. This process is executed in collaboration with Oman's Ministry of Health and with the involvement of pharmacies and hospitals. Additionally, it encompasses household take-back programmes. Meanwhile, plastics, cardboard, brochures and other nonhazardous materials within the pharmaceutical products are separated by the generators and recycled through approved recyclers, which have been certified and listed by be'ah. The recycling companies are monitored regularly and pay for the recyclables, which are then processed and resold. By the end of Q1/2024, 60% of pharmaceutical manufacturers and distributor companies had established formal agreements with be'ah. These agreements are now recognized as an integral component of government policies applicable to all pharmaceutical companies.

Source: Safe management of pharmaceutical waste (Sultanate of Oman, unpublished data, no date) provided by be'ah *(48)*.

4.2 Appropriate donations

The revision of the legal framework should consider the impact of proper stock management as well as procurement and donation rules on the generation of waste. Donation guidelines should be made available, whether a country relies on the inter-agency donation guidelines *(9)*, national guidelines or other sound principles of donation. Donations of pharmaceutical products must be based on a quantification of need for medicines that is used in accordance with treatment guidelines. This should be done in collaboration with local stakeholders in the recipient country. Product distribution, inventory management and final disposal of any unused or expired products should be included and budgeted in any donation plan. Any imported products must also be approved in advance by the national medicine regulatory authority prior to shipment. It is in the best interest of donors and distributing partners to have a thoughtful conversation about the options, criteria and costs regarding pharmaceutical waste disposal before an offer is made *(49)*.

Unsolicited or unwanted pharmaceutical donations should never be delivered to a country. Sending donations that have not been completely approved in advance can lead to confiscation at ports of entry, which becomes a waste management burden without any benefit to the recipient country. The inter-agency *Guidelines for medicine donations (9)* outline four key principles:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed and documented need and unsolicited drug donations are to be discouraged.
2. A donation should be given according to the recipient's documented needs and conform to the governmental policies and administrative arrangements of the recipient country.

3. There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There should be no double standards in terms of quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

Furthermore, all donated pharmaceuticals should align with international standards and support mechanisms throughout all stages of the donation processes (see Box 4).

Box 4 Inter-agency *Guidelines for medicine donations*

Pharmaceutical or medicine donations may take various forms, ranging from long-term donations of a single medicine for defined disease conditions to emergency donations of large varieties of medicines for general health care delivery. The guidelines are intended to provide guidance on achieving the best donation practice by both donors and recipients, and to serve as a basis for preparing national or institutional donation guidelines. They are meant to be reviewed, adapted and implemented by governments and organizations dealing with medicine donations.

Source: WHO *(9)*.

Recipient countries should have defined procedures for valuing donations, entering them in their budget records, and rejecting or disposing of inappropriate donations, and these procedures need to be shared with the donors. Administrative pharmaceutical procedures tend to be complicated and time-consuming and the disposal of expired stock is difficult in practice. Simplifying procedures is recommended. One approach would be to state that donated drugs are not included in government inventories or considered state property unless specifically accepted as such. During emergencies, emergency kits for different emergencies and settings can be used to reduce inappropriate medicine donation and save the time and resources of the recipient countries when it comes to sorting donated medicines.

4.3 Additional considerations regarding emergency preparedness and response

Emergencies can increase the types and the quantities of pharmaceutical products needed and procured by the affected country. Forecasting is typically less accurate in emergency situations due to rapidly changing conditions and this may lead to the generation of additional pharmaceutical waste. The amounts of waste generated may increase further due to a breakdown in the supply chain system and poorly managed medicine donations *(50)*. In severe situations, such as the COVID-19 pandemic, waste volumes increased drastically due to the necessary use of PPE. In developing pandemic and emergency preparedness plans, countries should include pharmaceutical waste management as well as general health-care-related waste plans. Plans should consider a comprehensive assessment of:

- local and regional manufacturers, importers and suppliers of pharmaceuticals;
- the location, number and size of warehouses, waste storage facilities and landfills;
- the number and capacities of trucks as well as operational and planned pharmaceutical waste treatment equipment;

- flow(s) between waste storage facilities, landfills and waste management treatment plants;
- human resource capacities and communication patterns; and
- destruction timelines.

In addition to accepted components of emergency preparedness plans such as the concept of operations for the response and responsibilities, the management of health care waste, including pharmaceutical waste, should be clearly included *(51)*. A communication strategy should be incorporated to establish clear communication protocols among stakeholders and to raise awareness within the community and among emergency personnel and health care workers. A national whole-of-government plan can be a synthesis of ministry-specific plans, which provide details on the required resources, capacities and capabilities that each ministry will employ in its response. For waste management, this is particularly important because countries will often need to rely on interim or transitional methods for health care waste management until such a time as processes are implemented that minimize human and environmental health risks and adhere to international regulations *(1)*. The plan for pharmaceutical waste management may include a prioritization plan for pharmaceutical waste treatment and disposal based on the risk posed by the different kinds of pharmaceuticals.

4.4 Cost considerations

Cost-effective management and methods of treating and disposing of pharmaceutical waste are important in sustainable planning. For example, the segregation of hazardous waste, which is more expensive, reduces overall costs. The United States Environmental Protection Agency has estimated that only about 5% of all pharmaceutical waste is hazardous *(52)*. However, this could vary from country to country. The costs of the storage, transport, treatment and disposal of such waste should be considered during the planning phase. Where safe waste treatment and disposal facilities are not available, these systems must be established and operated, repaired and maintained, all of which will require funds. Recyclable waste can be monetized if there is a market to purchase and use plastics, paper metals and other products.

In accordance with the inter-agency *Guidelines for medicine donations (9)* the costs of international and local transport, warehousing, port clearance, storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency, unless specifically agreed with the recipient in advance. An example of costs incurred by inappropriate donations in Indonesia is outlined in Box 5.

Box 5 Example from Indonesia: costs of pharmaceutical waste from post-tsunami donations

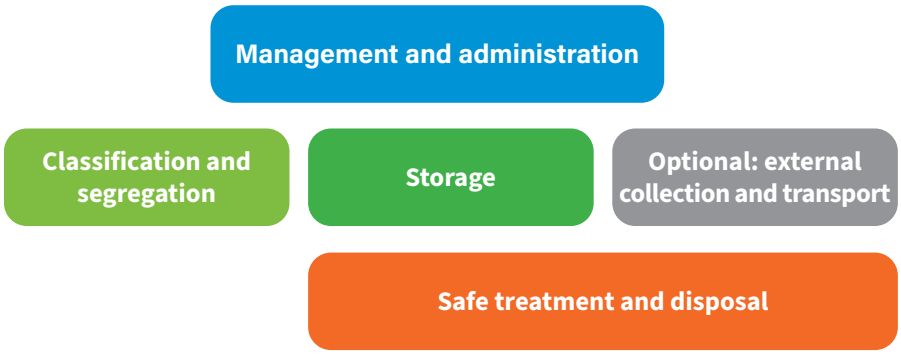
Twenty-five per cent of the medications donated to the city of Banda Aceh in Indonesia after a large tsunami hit in 2004 had an inadequate expiry date (already expired, too short or no expiry date) and 70% were labelled in foreign languages. Considering the drugs that had already expired, were due to expire in six months or had no expiration date, 600 t of waste had to be destroyed at a total cost of €2 400 000 (approximately US$ 3 000 000), equivalent to €4 per kg of pharmaceutical waste. This could have been avoided if international best practices for pharmaceutical donations had been put in place.

Source: Pharmaciens Sans Frontières *(53)*.

5 Pharmaceutical waste management components

The management of pharmaceutical waste varies depending on the type of medical facility and services provided as well as the available waste treatment and disposal options. Standard procedures for managing the generated pharmaceutical waste include classification and segregation, interim storage and regular collection for treatment and disposal in accordance with national regulations. An overview of the different components for managing pharmaceutical waste are outlined in Fig. 3.

Fig. 3 Pharmaceutical waste management components



Source: created for this document using information from the WHO document *Safe management of wastes from health-care activities (1)*.

All components should be in line with the national and facility-based policies, regulations and guidance.

5.1 Management and administration

National guidance and legislation govern the importation, regulatory affairs and prescription of all medicines, regardless of whether they are purchased privately, donated or procured via public sector systems. In the case of public-sector procurement of pharmaceuticals, procurement, inventory management and other administrative procedures apply.

Pharmaceutical product disposal is managed similarly for all medicines, and special provisions and monitoring practices apply to controlled medicines. The national authority may be the ministry of environment, ministry of health or another agency depending on the structure of the national system. The appropriate authority's approval and sanctioning of the pharmaceutical disposal must be sought.

As part of good inventory management, all pharmaceuticals should be recorded as dispensed or distributed, lost to damage, expired or lost to shrinkage (suspected mismanagement).

Generally, pharmaceutical products written off as waste are recorded. It is common in good checks and balances for records of the final disposition of pharmaceutical products to be signed and countersigned by parties from separate divisions. This involves identifying, categorizing, quantifying and documenting all pharmaceutical waste generated. Each pharmaceutical waste product should be recorded in the register book or be part of the pharmacy's barcode-based inventory system in accordance with national regulations. An example of a template is given in Annex 2, which includes the general description (brand name, strength and dosage), manufacturer/supplier, unit type and size, quantity, batch number, expiry date, reason for disposal, physical form (solid, fluid, semisolid) and hazardous characteristics.

5.1.1 Controlled substances

Controlled substances (e.g. narcotics, psychotropics and antipsychotics) require tight security and control following strict rules and processes in line with national regulations. In some countries, illicit reselling or reuse by staff and informal and unauthorized waste collection (scavenging) of material from hospital waste disposal areas or landfills is a frequent problem, and drugs that have been disposed of may be recovered and sold by the informal sector *(18)*. Controlled medicines are those identified by the International Narcotics Control Board (INCB) and the United Nations Office on Drugs and Crime (UNODC) as products at risk of illicit distribution and that pose a threat to populations when consumed outside of legitimately prescribed and indicated use. The UNODC obliges Member States to take action to avoid illegal distribution. The INCB requires submission of substantiated forecasts for annual use of controlled medicines, including any adjustments made for waste, damage, expiry or other loss. Per the UNODC, countries should have specific processes for ensuring that controlled medicines are inertized, immobilized and/or disposed of in a manner that ensures that they cannot be illicitly distributed. The legal requirements for disposal of controlled medicines will depend on national legislation and may include incineration and a process supervised by authorized agents such as law enforcement staff. Box 6 describes the illicit scavenging and recycling of medical waste in Bangladesh.

Box 6 Example from Bangladesh: an illicit economy – scavenging and recycling of medical waste

Data were collected in Dhaka, Bangladesh, using a variety of techniques based on formal representative sampling for fixed populations (such as recycling operatives) and adaptive sampling for roaming populations (such as scavengers). Hazardous items (including expired medicines, used syringes, knives, blades and saline bags) were scavenged, repackaged and resold to the community. Some employees from health care facilities were also observed selling hazardous items directly to scavengers, and both employees and scavengers were observed supplying contaminated items to an informal plastics recycling industry. This trade was made possible by the absence of segregation, secure storage and proper disposal of medical waste. Corruption, a lack of accountability and individual responsibility were also found to be contributors. In most cases, the individuals involved with these activities did not understand the associated risks.

Source: MA Patwary, WT O'Hare and MH Sarker *(54)*.

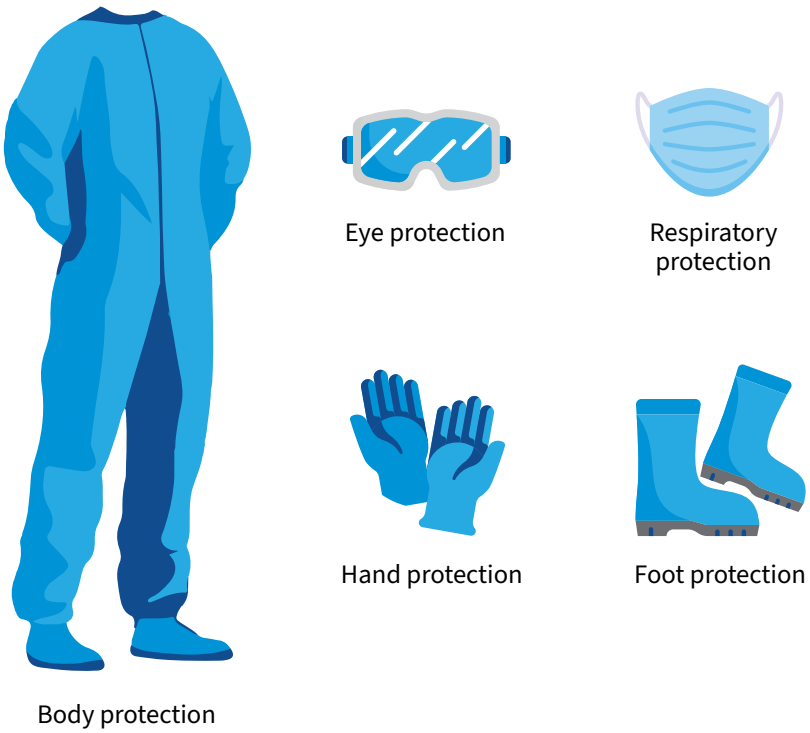
5.1.2 Responsibilities

Relevant authorities should be involved from the beginning. It may be useful to establish a task force or advisory committee with clear mandates to assess, analyse and address the problem of pharmaceutical disposal and to monitor activities. Due to the specific nature of the drugs, the police should secure the process. This committee would be responsible for ensuring the safe and legal disposal of the controlled substances and monitoring and documenting the disposal process to prevent diversion or misuse. The choice of members depends on the technical problems faced. People from the relevant authorities as well as chief pharmacists, medical waste experts, environmentalists, licensed chemists, hydrogeologists or sanitary engineers may serve as members. Such committees will need to plan for funding, human resources, professional time, space, equipment, transportation and materials, and the available disposal options will need to be considered. The planning horizon should be based either on the annual budget planning or ad-hoc planning for accumulated waste, e.g. after or in emergencies.

5.2 Pharmaceutical waste management steps

Pharmaceutical waste management is divided into the following steps: classification and segregation, waste storage, external collection and transport to central treatment and disposal facilities (if applicable), and waste treatment and disposal. Workers should always wear appropriate PPE to mitigate workplace hazards in line with the results of a risk-based assessment. Types of PPE include body protection such as aprons or overalls, foot protection such as shoes or boots, hand protection such as gloves, respiratory protection such as masks, eye protection such as goggles (see Fig. 4).

Fig. 4 Examples of PPE for waste workers



The PPE required must be identified from case to case depending on the following factors *(55)*:

- characteristics of the pharmaceutical ingredients (hazardous characteristics)
- volumes and concentrations
- presence of additional hazards (for example, extreme temperatures or chemical hazards)
- type of work being carried out
- other PPE being worn
- individual needs of the worker
- availability of national regulations and organizational requirements.

Staff must be trained in and monitored for the correct use of PPE.

5.2.1 Classification and segregation

The objective of segregation is to identify and separate pharmaceuticals into categories for which different treatment and disposal methods are required. They should be separated into those that can be returned to the pharmaceutical supply system and those that require treatment/disposal via different methods. The appropriate safe treatment and disposal method recommended will depend principally on the hazardousness of the ingredients and in some cases on the pharmaceutical dosage form of the drugs. For example, controlled drugs (e.g. narcotics) require notification of and handing over to the appropriate national authorities. Antineoplastic drugs and antibiotics all require special methods of disposal. Substantial investment in human resources may be required for identifying and separating pharmaceuticals. The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as:

- **nonhazardous pharmaceutical waste**, which is not classified as hazardous but still needs to be disposed of properly to prevent misuse or environmental damage;
- **hazardous pharmaceutical waste**, which poses a risk to health and the environment due to harmful ingredients and interactions or hazardous characteristics, e.g. poisonous (acute), ecotoxic, toxic (delayed or chronic), carcinogen, flammable, corrosive, reactive, explosive *(19 Annex III)*; and
- **controlled substances**, which need to be specifically managed according to national guidelines,[2] in some cases by the police, to prevent them being diverted for illicit distribution or used for illicit or nonmedical purposes.

Table 6 presents examples of the suggested pharmaceutical categories based on the APIs.

[2] Controlled substances are also classified as such under the UN Single Convention on Narcotic Drugs of 1961 (https://www.unodc.org/pdf/convention_1961_en.pdf) and its updates (https://www.incb.org/incb/en/narcotic-drugs/index.html).

Table 6 Suggested pharmaceutical categories and examples

Nonhazardous pharmaceutical waste	Hazardous pharmaceutical waste	Controlled substances waste
Nonhazardous electrolytes, glucose, herbals, minerals, salts, vitamins	Anaesthetics, analgesics, antiaddiction agents, antibacterials, anticonvulsants, antidementia agents, antidepressants, antiemetics, antifungals, antigout agents, antimigraine agents, antimyasthenic agents, antimycobacterial agents, antineoplastics, antiparasitic, antiparkinson agents, antispasticity agents, antivirals, bipolar agents, blood glucose regulators, blood products, cardiovascular agents, central nervous system agents, dental and oral agents, dermatological agents, fetotoxic and teratogen vitamins, gastrointestinal agents, genetic/enzyme/protein disorder agents, genitourinary agents, hormonal agents, hormone suppressants, immunological agents, inflammatory bowel disease agents, metabolic bone disease agents, respiratory tract agents, skeletal muscle relaxants, sleep disorder agents, ophthalmic agents, otic agents, vaccines containing mercury (thimerosal) or cresol-based preservatives	Anabolic steroids, codeine (when combined with certain other substances), cough preparations with less than 200 mg codeine per 100 mL or per 100 g, ketamine (when used for medical purposes), loperamide (antidiarrheal medication, when in combination with other substances), methamphetamine, narcotics (e.g. fentanyl, morphine, oxycodone, tramadol), psychotropic substances (e.g. alprazolam, diazepam, lorazepam)

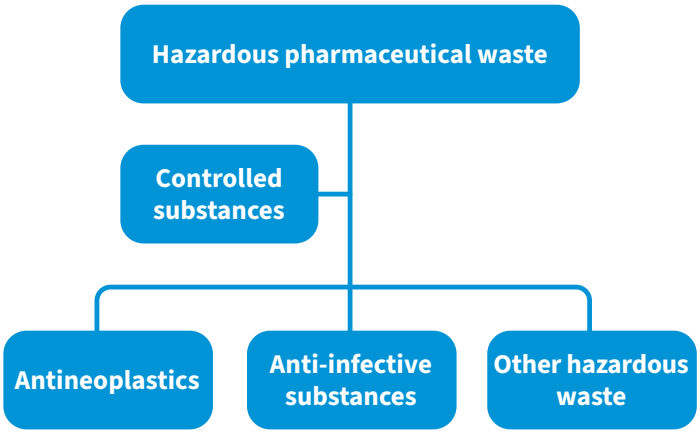
Source: adapted from the *USP therapeutic categories model guidelines* page on the website of the United States Food and Drug Administration *(56)*.

Note: "The dose makes the poison" – nonhazardous pharmaceuticals can become hazardous when consumed or disposed of into the environment in too high concentrations. Some vitamins can be potentially fetotoxic, or even teratogenic, at high doses. A list of potentially fetotoxic vitamins can be found in Chapter 3 of Annex 1.

A comprehensive list of pharmaceutical products and waste classifications can be found in Chapter 1 of Annex 1. Further information on pharmaceutical products can be taken from the WHO *Model list of essential medicines (57)*, which is updated every two years.[3] Fig. 5 shows the sorting scheme for hazardous pharmaceutical waste.

3 In addition, the National Institute for Occupational Safety and Health United States (NIOSH) has published the NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016 (https://www.cdc.gov/niosh/healthcare/hazardous-drugs/index.html).

Fig. 5 Sorting of hazardous pharmaceutical waste



Source: created for this document using information from the WHO document *Safe management of wastes from health-care activities (1)*.

Sorting can also depend on the dosage form:

- solids, semisolids, and powders: tablets, capsules, suppositories, granules, powders for injection, creams, ointments, lotions, gels;
- fluids: solutions, suspensions, ampoules, vials, intravenous solutions, syrups; and
- gaseous forms: aerosols such as sprays and inhalers.

The different treatment and disposal options for the different categories can be found in Chapter 7.

The pharmacist or agency responsible for accounting for pharmaceutical waste is also responsible for ensuring segregation of the waste into specific, defined categories. The segregation method used must be maintained up to the final disposal stage. Pharmaceuticals without labels or that cannot otherwise be identified should be considered hazardous.

Segregation of large amounts of pharmaceutical waste after emergencies or accumulation of larger quantities: work should be conducted by teams of competent members of the health workforce, including pharmacists, pharmacy technicians or other experienced pharmaceutical warehouse personnel. The size of each team and the ratio of experts will depend on the volume and composition of the accumulated waste and working conditions at the sites. To protect the workers, PPE such as overalls, boots, gloves and masks should be worn according to the results of a risk-based assessment carried out in the specific situation, as outlined earlier in this document.

Sorting should be done in the open or in a well-ventilated covered structure designated by the local authority. It should be carried out as close as possible to the storage facility and in an orderly way, with all sorted material clearly labelled and separated. Staff supplied with PPE should work under the direct supervision of a pharmacist and should receive training on the sorting criteria and the health and safety risks associated with handling the materials.

5.2.2 Waste storage

After the generated pharmaceutical waste has been sorted and documented, it must be safely stored until it is moved to final treatment and disposal. National regulations for the storage of pharmaceutical waste should be in place to guide this process, including by determining the amount and nature of waste that can be stored in any facility as well as the length of time it can be stored there. An appointed pharmacist or equivalent is also responsible for monitoring the storage of the waste.

In the case of small amounts of waste, they should be stored in a designated and secured area of the storage facility in clearly labelled boxes or containers for short-term storage. In the case of larger amounts, an enclosed room or container should be used. After sorting, if necessary, pharmaceuticals should be carefully packed into steel drums or other 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, secured and separate area to avoid being confused with valid pharmaceuticals.

The storage areas should be sized according to the quantities of waste generated and the frequency of collection. Storage of pharmaceutical waste must be secured and separate from all other areas of a facility, including the main pharmacy stores, patient areas, administrative offices and food preparation areas. The storage area should only be accessible to authorized persons and should be properly labelled according to the type of waste (as defined in the national regulation). The storage area should have adequate lighting and should be kept tidy. Boxes or other containers should still be stored according to good distribution practices, e.g. on shelves, not stacked more than six high, not on the ground etc.

If multiple types of waste are stored in the same area, they should be separated by category, e.g. hazardous (controlled/antineoplastic/anti-infective and other hazardous waste) and nonhazardous compartments. Hazardous liquid waste should also be stored on shelves, which should be equipped with collection trays to catch any liquid from leakages. Controlled drugs may need to be stored in a locker for security reasons. All storage areas should be labelled accordingly.

In anticipation of sudden increases in pharmaceutical waste volumes during emergencies, it is recommended to plan and install additional storage capacity as part of emergency preparedness and response planning. Specific precautions should be considered in case pharmaceutical waste is piled up for longer times without proper documentation and management of the storage facility. In the event of high volumes of pharmaceutical waste, a rough calculation of the waste volume to be sorted is recommended as the basis of a costing and management plan. Waste should be measured, either by calculating the volume of the primary packaging or, in the case of waste that has been stored in bins or other containers, the volumes should be measured and given a density figure of 0.2 t/m^3 *(18)*. An estimation of the amount of waste helps with the detailed planning of sorting equipment and human resources as well as the space and storage needed. An exemplary calculation is outlined in Box 7.

Box 7 Exemplary calculation of pharmaceutical waste volume and weight

- Waste volume: measure and multiply together the length, width and height of the stored waste. The pharmaceutical waste stockpile is 4 m long x 2 m wide x 2 m high = 16 m^3 of pharmaceutical waste.
- Waste weight: multiply volume by waste density (assumption 0.2 t/m^3), e.g. 16 m^3 x 0.2 t/m^3 = 3.2 t.

Source: WHO *(18)*.

If the safety conditions of the pharmaceutical waste are unknown, the site should be treated as a potentially contaminated site. The assessment of the storage site includes the identification of waste types and amounts of waste but also looking for potential explosion and fire hazards, various mechanical/physical risks, obstacles, levels, and potential biological hazards caused by moulds and fungi. Spillages and leaks from the waste must be remediated appropriately once the waste has been removed from the storage location. Box 8 provides an action plan that can be followed when large amounts of pharmaceutical waste have accumulated.

Box 8 Action plan for managing large amounts of accumulated pharmaceutical waste

A specific action plan for dealing with large amounts of pharmaceutical waste after emergencies or long-term accumulation of waste should be developed. The plan should incorporate all necessary aspects and all activities that need to be performed:

- responsible persons
- site description
- waste information
- general approach to assess the site
- hazard identification
- site-specific organization, procedures and schedules for cleaning
- safety equipment
- tools and equipment
- labelling
- types of waste packaging receptacles, use of special vehicles
- information about destination and transport of collected waste (hazardous and nonhazardous).

Source: written by this document's authors and contributors with reference to the WHO document *Safe management of wastes from health-care activities (1)*.

Case Study 10, Case Study 11, Case Study 12 and Case Study 13 describe the cleanup of large quantities of piled-up pharmaceutical waste from Guinea, Haiti, Serbia and Benin.

Case Study 10
Guinea: cleanup of pharmaceuticals after Ebola outbreak

"An excess of donations from the 2014 Ebola outbreak contributed to an existing buildup of unusable health commodities across Guinea, taking up larger and larger volumes of space in warehouses and storerooms and impeding smooth operation of the public health supply chain. Guinea's lack of incinerators appropriate for the disposal of pharmaceuticals and other medical waste meant that most waste could not be disposed of locally".

"Prepared with safety training, process maps, collection procedures, protective equipment, and vehicles, 92 health workers and 42 handlers conducted a physical inventory of waste at more than 500 medical stores, hospitals, clinics, and other health facilities. They then collected and routed the waste to storage sites in each region for consolidation and transport to a central site in Conakry, the nation's capital. Waste collected for disposal included expired or otherwise unusable products like antimalarial medicines; contraceptives used in reproductive health programmes; various commodities for support of maternal, newborn, and child health; and personal protective gear used during the Ebola outbreak".

"All told, nearly 150 tons of medical and pharmaceutical waste … was collected, sorted, weighed, and repackaged in appropriate packaging and containers". In 2017, an international company provided a quote for collecting, transporting and treating/disposing of the waste via high-temperature incineration in France in line with the requirements of the Basel Convention. The quote included:

Service	Description	Cost
Labour cost	Based on two persons at the customer site for 30 days (including travel, accommodation etc.)	US$ 98 000
Equipment	40 ft container, UN packaging materials	US$ 480/t
Transport	Sea shipping	US$ 7300/container
Disposal	Pharmaceutical waste	US$ 600/t
Documentation	Preparation and submission of Transfrontier Waste Shipment Notification under the Basel Convention and European legislation	US$ 4300
Financial guarantee	In accordance with the EU regulation	US$ 2600
Insurance	For all tasks completed	US$ 2000

For collection, transport and disposal in accordance with the Basel Convention, the cost was estimated at about US$ 2600 per tonne of pharmaceutical waste.

Source: Global Health Supply Chain Program *(58)*.

Case Study 11
Haiti:
cleanup of pharmaceutical waste after earthquake

Following the earthquake in Haiti in January 2010, the humanitarian organization Pharmacie et Aide Humanitaire in collaboration with the Haitian Ministry of Health, the Pan American Health Organization and the Program on Essential Medicines and Supplies initiated the project to collect, sort and store the pharmaceutical waste of hospitals in Haiti in 2013. The project was financed by USAID. Eighty health institutions were included and within nine months, 63 322.89 kg, 190.74 m^3 and 33 572 585 units of pharmaceuticals were collected and stored. A team comprising an international pharmacist, a national pharmacist and a driver was set up to conduct a detailed inventory and to separate the waste into 1) controlled substances, 2) antineoplastics, and 3) other waste. After sorting, the waste was packed in new cardboard boxes, labelled and stored in secure sea containers provided for this purpose. The inventories and storage locations were provided to the local and national health authorities.

Source: Pharmacie et Aide Humanitaire and USAID Supply Chain Management System (*Final narrative report: collection, sorting and storage of Pharmaceutical Waste of Hospitals in Haïti*, unpublished data, 2014).

Case Study 12
Serbia:
cleanup of accumulated pharmaceutical waste after conflict situation

In 2012, the Government of Serbia decided to safely collect and dispose of pharmaceutical waste that had accumulated in the country from various donations that occurred during the conflict from 1992 to 2000. With the assistance of the EU Delegation to Serbia, a service tender was launched to support the Serbian Ministry of Health and the Veterinary Directorate of the Serbian Ministry of Agriculture, Forestry and Water Management in removing accumulated pharmaceutical waste from health care facilities and veterinary institutes and in ensuring the safe collection, transport, treatment and disposal of pharmaceutical waste. Pharmaceutical waste was collected from approximately 340 locations where waste had been stored. It was transported to 12 storage areas/export hubs where the waste was secured, identified and labelled according to the Basel Convention. For the transport on public roads, the solid pharmaceutical waste was packed into big bags, and the liquid pharmaceutical, chemical and cytostatic waste was packed into separate approved transport containers. Once the import, transit and export permits had been approved in line with the Basel Convention procedures, around 300 t (approximately 25 truckloads) of pharmaceutical waste was exported to Vienna, Austria, where the waste was incinerated in a hazardous waste incinerator. Overall, the objectives were completed in less than 15 months.

Source: V. Jovanović, J. Manojlović, D. Jovanović, B. Matic and N. Đonović *(59)*.

Case Study 13
Benin: cleanup of counterfeit pharmaceuticals

"In 2017, by request of the Beninese government, USAID's Global Health Supply Chain – Technical Assistance (GHSC-TA) Francophone Task Order conducted a rapid assessment study which evaluated the storage conditions of the seized commodities and the capacity of the available local service providers to dispose of pharmaceutical waste. The project developed an action plan to manage and dispose of accumulated counterfeit pharmaceutical products, selected a local service provider and trained forty staff as well as two staff of the Beninese Ministry of Health in safe pharmaceutical waste management. In December 2017, the local service provider, under GHSC-TA supervision, successfully destroyed 118 tons of counterfeit pharmaceuticals by inertization" and disposal on a government-approved landfill site.

"It demonstrates a shift in how Benin … deals with pharmaceutical waste, moving from expensive exporting to more technologically advanced countries to building capacity in-country. … In addition, the project assisted the Ministry of Health of Benin to revise guidelines for waste management organization for future endeavors".

Source: USAID Global Health Supply Chain Program *(60)*.

5.2.3 External collection and transport

Nonhazardous pharmaceutical waste can be collected, transported and disposed of with the general nonhazardous waste generated in health care facilities as long as the waste is disposed of safely and is protected from scavenging. If this cannot be ensured, nonhazardous waste should be managed like hazardous pharmaceutical waste.

It is recommended that hazardous pharmaceutical waste be treated and disposed of in external central safe facilities. This requires the waste to be segregated, labelled and documented, then collected and transported to a designated waste treatment and disposal facility. The collection and transport of pharmaceutical waste should be done in appropriate containers that are labelled as hazardous waste and prevent leakage and contamination in accordance with the hazardous nature of the pharmaceutical. The containers must comply with regulatory requirements.

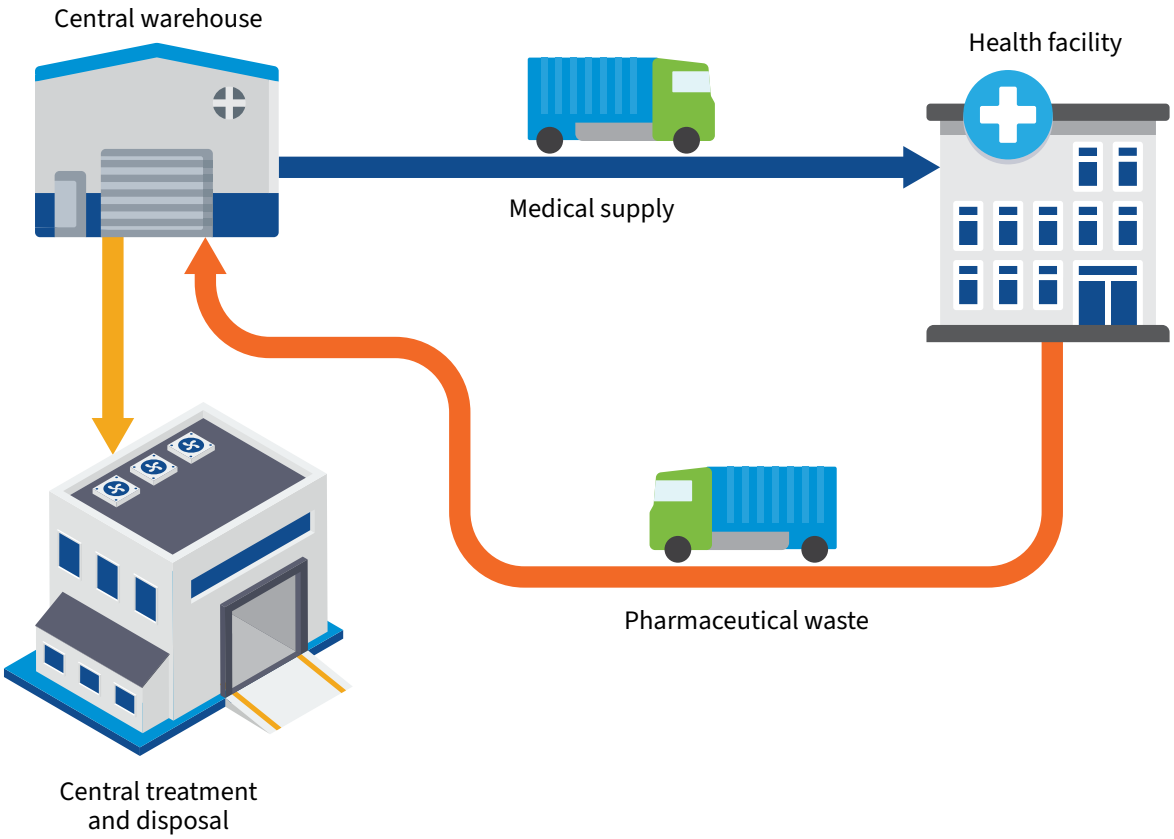
5.2.3.1 Reverse logistics

Reverse logistics is defined as the process of planning, implementing, and controlling the efficient, cost-effective flow of inventory from the point of consumption to the point of origin for the purpose of recapturing value or proper disposal *(61)*. From a logistics perspective, a key issue is the cost-effectiveness and efficiency of getting expired pharmaceutical products from the health facility to somewhere they can be processed or disposed of. In the case of pharmaceutical waste in an LMIC setting, existing vehicles from the medical supply chain or a private-sector waste management company would be used to collect the hazardous pharmaceutical waste and return it to a central storage location/warehouse from which it would be collected for safe centralized treatment and disposal.

A government may consider financing this option in cases where a small amount of hazardous pharmaceutical waste is produced and the health facility is accessible. This is most feasible in urban areas where road transport is good and there are high-temperature incinerators for treatment nearby. This process requires careful planning, documentation, and secure transport of expired hazardous pharmaceuticals in clearly identified hazardous-waste containers. There are some examples in LMIC settings of segregating infectious medical waste and transporting it back to a central facility in dedicated trailers that are attached to government vehicles conducting routine outreach visits.

This ensures that the waste is managed in a controlled, environmentally responsible and compliant manner. Fig. 6 illustrates the reverse logistics scheme and Case Study 14 provides an example from Yemen.

Fig. 6 Reverse logistics scheme



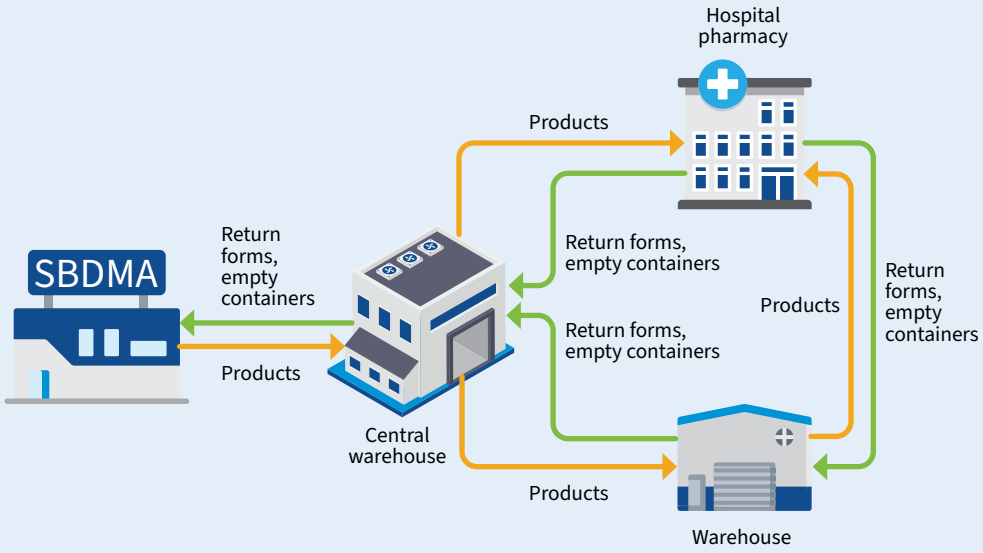
Source: created for this document based on *Returning empty ampoules* (unpublished data, 2019) by the International Committee of the Red Cross *(62)*.

Case Study 14
Yemen: reverse logistics

As part of Yemen national regulation to monitor the consumption of pharmaceuticals and reduce the misuse of such products, a system has been implemented to return pharmaceutical waste to the Supreme Board of Drugs and Medical Appliances (SBDMA). In 2019, with the support of the International Committee of the Red Cross, routine processes and tools were developed to ensure the traceability of the products, quantities and batch numbers that were shipped to each beneficiary. The tools included:

- **a pharmaceutical waste logbook**, the main tool providing all the information for each product (batch number, import permit, dates, related documents, quantities dispatched or received, plus the pharmaceuticals received and returned); and
- **a pharmaceutical waste management presentation** that explains the steps and how to manage all the tools.

Implementing the routine and the tools increased knowledge of the national regulation and raised awareness of the misuse of such products.



Source: Returning empty ampoules (unpublished data, 2019) by the International Committee of the Red Cross *(62)*.

5.2.3.2 Transport of hazardous pharmaceutical waste on public roads

The transport of hazardous pharmaceutical waste must be in line with the relevant national legislation for the transport of dangerous goods on public roads. Where there are no such regulations, the responsible authorities should refer to the latest edition of the United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations *(29)*. For the purpose of transport regulations, hazardous pharmaceutical waste may be classified in Division 6.1 “toxic substances” and assigned to

UN 1851 (waste medicine, liquid, toxic) or UN 3249 (waste medicine, solid, toxic) or classified in Class 3 as "flammable liquids" and assigned to UN 3248 (waste medicine, liquid, flammable, toxic), based on the hazardous properties of the pharmaceutical waste. However, these three entries are generic and will not be appropriate for all medicines; in most cases, safety data sheets should show the appropriate transport classification. Where each package contains less than 5 kg of pharmaceuticals, it is possible to use the "limited quantities" provision, which is less onerous in terms of vehicle requirements, driver training and documentation. The specific transport requirements should be provided by licensed transport companies.

5.2.3.3 Transboundary transport of hazardous pharmaceutical waste

There are currently no international conventions regulating the transfer of pharmaceutical products across frontiers. However, hazardous pharmaceutical waste, if transferred across frontiers, becomes regulated and subject to the Basel Convention *(19, 20)*, as well as the Bamako Convention in the case of Africa *(30)* (see Chapter 3.1). As a result, it is necessary to follow prescribed procedures to obtain permission to cross international borders along the transit route before transport to the final destination in eligible countries. These procedures can take several months to complete. The Basel Convention sets out a detailed "prior informed consent" procedure with strict requirements for transboundary movements of hazardous wastes and other wastes – including hazardous pharmaceutical waste (category Y3 "waste pharmaceuticals, drugs and medicines" are considered hazardous waste when they contain either inorganic or organic constituents: "wastes from the use of pharmaceutical products") *(63)*. This procedure forms the heart of the Basel Convention control system and is based on four key stages:

1. notification
2. consent and issuance of movement document
3. transboundary movement
4. confirmation of disposal.

5.2.4 Treatment and disposal

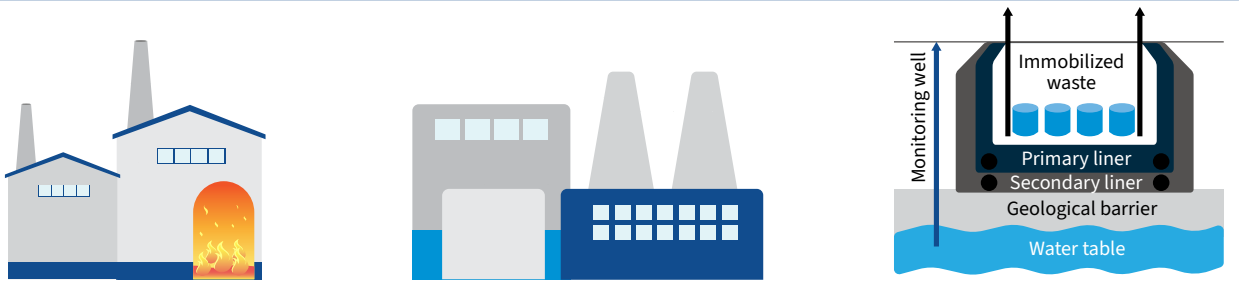
Disposal options vary considerably between situations, and the ideal solution may not be feasible as not all countries have adequate treatment and disposal facilities available and some may have to resort to interim options or an immediate response in emergency situations. Nonhazardous pharmaceutical waste can be treated and disposed of in the same way as other nonhazardous waste as long as the treatment and disposal infrastructure is well protected to prevent illicit reselling or reuse. If this cannot be ensured, nonhazardous pharmaceutical waste should be handled in the same way as hazardous waste. If new waste treatment equipment needs to be purchased, the treatment system should be chosen to suit the specific context and the following should be taken into consideration during the selection process *(24)*:

- relevant national and international regulations and requirements
- environmental and occupational safety factors
- waste characteristics and quantity
- technology capabilities and requirements
- cost considerations
- operation and maintenance requirements.

The site where the new equipment will be installed must be prepared in accordance with the manufacturer's requirements (housing, electricity, water connection etc.). The *Application of the sustainability assessment of technologies methodology: guidance manual* provides a detailed and comprehensive tool for selecting suitable solutions *(64)*. In the following, the various treatment and disposal methods are divided into four categories:

1. optimal options (see Fig. 7):
   - high-temperature incineration with flue gas cleaning that complies with the Stockholm Convention (see Chapter 3.1);
   - coprocessing in a high-temperature process (cement kiln); and
   - waste immobilization followed by disposal in an engineered landfill;

Fig. 7 Optimal treatment and disposal options



High-temperature incineration with flue gas treatment

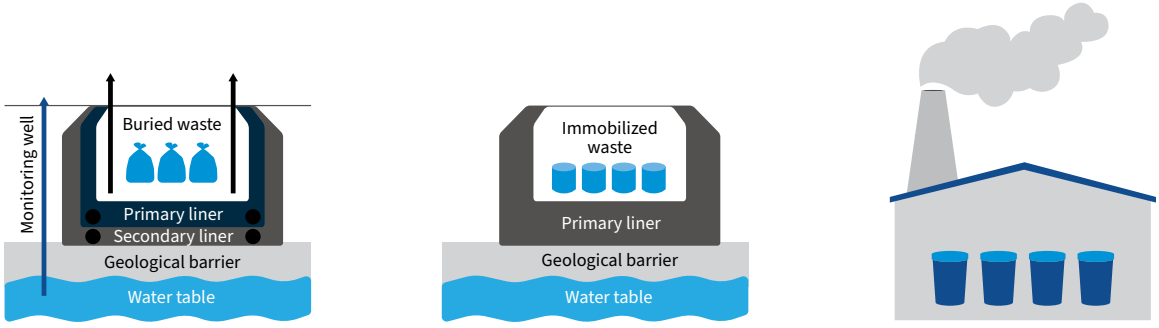
Coprocessing: cement kiln

Engineered landfilling/controlled landfilling after waste immobilization

Source: stock images and graphics prepared by the authors of this document with reference to the WHO document *Safe management of wastes from health-care activities (1)*.

2. interim options (see Fig. 8):
   - safe burial in engineered landfill;
   - waste immobilization followed by disposal in controlled landfill; and
   - high-temperature incineration or dual-chamber medium-temperature incineration with auxiliary burners with limited or no flue gas treatment;

Fig. 8 Interim treatment and disposal options



Safe burial in engineered landfill

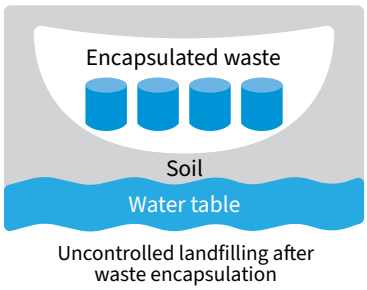
Controlled landfilling after waste immobilization

High-temperature incineration or dual-chamber incineration with auxiliary burners with limited or no flue gas treatment

Source: stock images and graphics prepared by the authors of this document with reference to the WHO document *Safe management of wastes from health-care activities (1)*.

3. immediate short-term response in emergency situations (see Fig. 9; please note that if optimal or interim options are not available at the time, the temporary storage of waste should be considered before resorting to an immediate short-term response):
   - encapsulation in uncontrolled landfill

Fig. 9 Immediate treatment and disposal responses in emergency situations



Source: prepared by the authors of this document with reference to the WHO document *Safe management of wastes from health-care activities (1)*.

4. not recommended – to be avoided:
   - low-/medium-temperature incineration without auxiliary burners
   - burial in uncontrolled or controlled (non-engineered) landfill.

Details on the different treatment and disposal options are outlined in Chapter 6.

In addition to the proven and well-known treatment and disposal options, a range of new and emerging technologies are potentially applicable to the treatment of pharmaceutical waste. These include chemical detoxification, biodigestion, hydrothermal carbonization and magnetic pyrolysis. The use of these technologies needs further research and licensing.

Certain technologies cannot be used for the treatment of pharmaceuticals, as outlined in Box 9.

Box 9 Technologies not applicable to the treatment of pharmaceutical waste

Low-heat thermal-based treatment technologies such as autoclaving, microwaving or frictional heat treatment are **not** suitable for the treatment of pharmaceutical waste. These technologies decontaminate infectious and sharps waste by destroying infectious pathogens such as vegetative bacteria, bacterial spores and viruses via steam-based processes.

Source: WHO *(1)*.

Staff involved in the treatment and disposal of pharmaceutical waste must be properly trained and must always be equipped with proper PPE including gloves, boots and overalls as well as respirators, masks and goggles, or face shields.

5.3 Decision tree

Fig. 10 provides an overview of the decisions regarding the selection of treatment and disposal options for generated pharmaceutical waste. The primary focus should be on preventing or minimizing the generation of waste as outlined in Chapter 4 (process optimization, efficient donation procedures etc.).

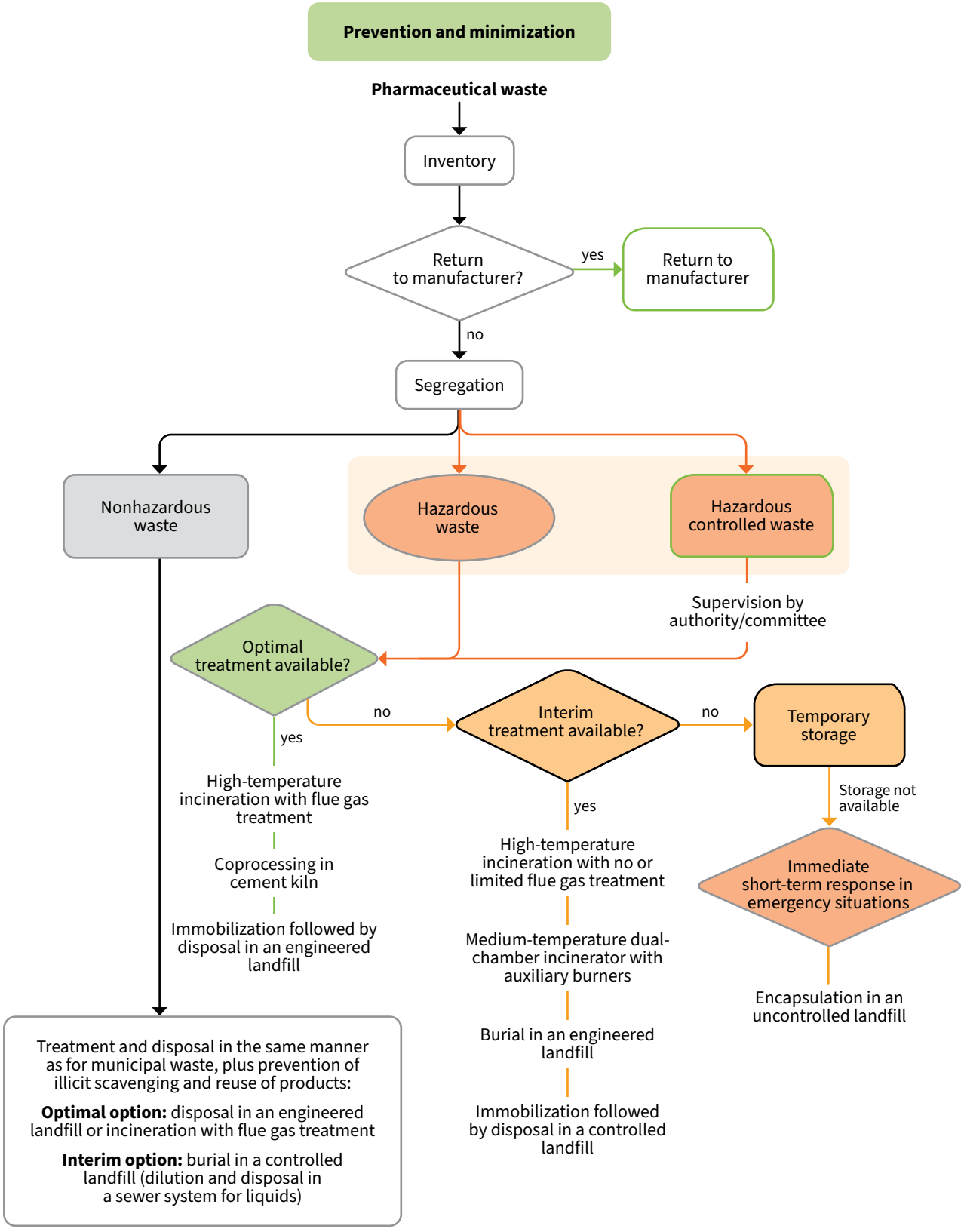
In good inventory management practices, the types and quantities of pharmaceutical waste are imperative for planning and decision-making regarding appropriate treatment and disposal options. The ideal option is to return the pharmaceutical waste to the supplier or manufacturer based on an EPR or take-back programme, if available. Based on the contract, the supplier/manufacturer or contractor may collect the waste for safe centralized treatment and disposal. If an EPR or take-back programme is not in place, the waste must be segregated into the nonhazardous waste and other hazardous waste as outlined in Chapter 5.2.1. Hazardous controlled waste is secured and collected by the police or another appropriate national drug control authority (Chapter 5.1).

The different categories of waste should be handled as follows:

- Nonhazardous waste can be treated and disposed of like municipal waste – illicit scavenging and reuse of products must be prevented by disposing of the waste in an engineered or controlled landfill. Cardboard packaging and leaflets can be recycled. The incineration of large amounts of nonhazardous liquids such as Ringer's solution or saline solutions should be avoided as the combustion temperatures will be reduced and additional fuel needed.
- Hazardous controlled waste such as narcotics must be reported immediately to the relevant authorities/ committee for supervised treatment and disposal.
- Hazardous waste should be treated and disposed of via the recommended optimal options. If the waste is transported across borders for safe treatment and disposal, this should be done in accordance with the requirements of the Basel Convention, and the Bamako Convention for the African region.
- When the optimal treatment and disposal options are not available, interim treatment and disposal options can be considered. If these are also not available, consideration should be given to temporary safe and secure storage of the waste until the optimal or interim treatment and disposal options become accessible.
- When optimal and interim treatment and disposal options are not available and the waste cannot be stored safely, immediate response options may be considered while also planning and budgeting for optimal or interim options.

The interim treatment and disposal options, immediate response options and temporary safe storage must always be accompanied by plans for and investments in incremental improvements including prevention, minimization, and use of best available technologies and best environmental practices (optimal options).

Fig. 10 Decision tree: pharmaceutical waste management



Source: created for this document using information from the WHO document *Safe management of wastes from health-care activities (1)*.

6 Treatment and disposal options

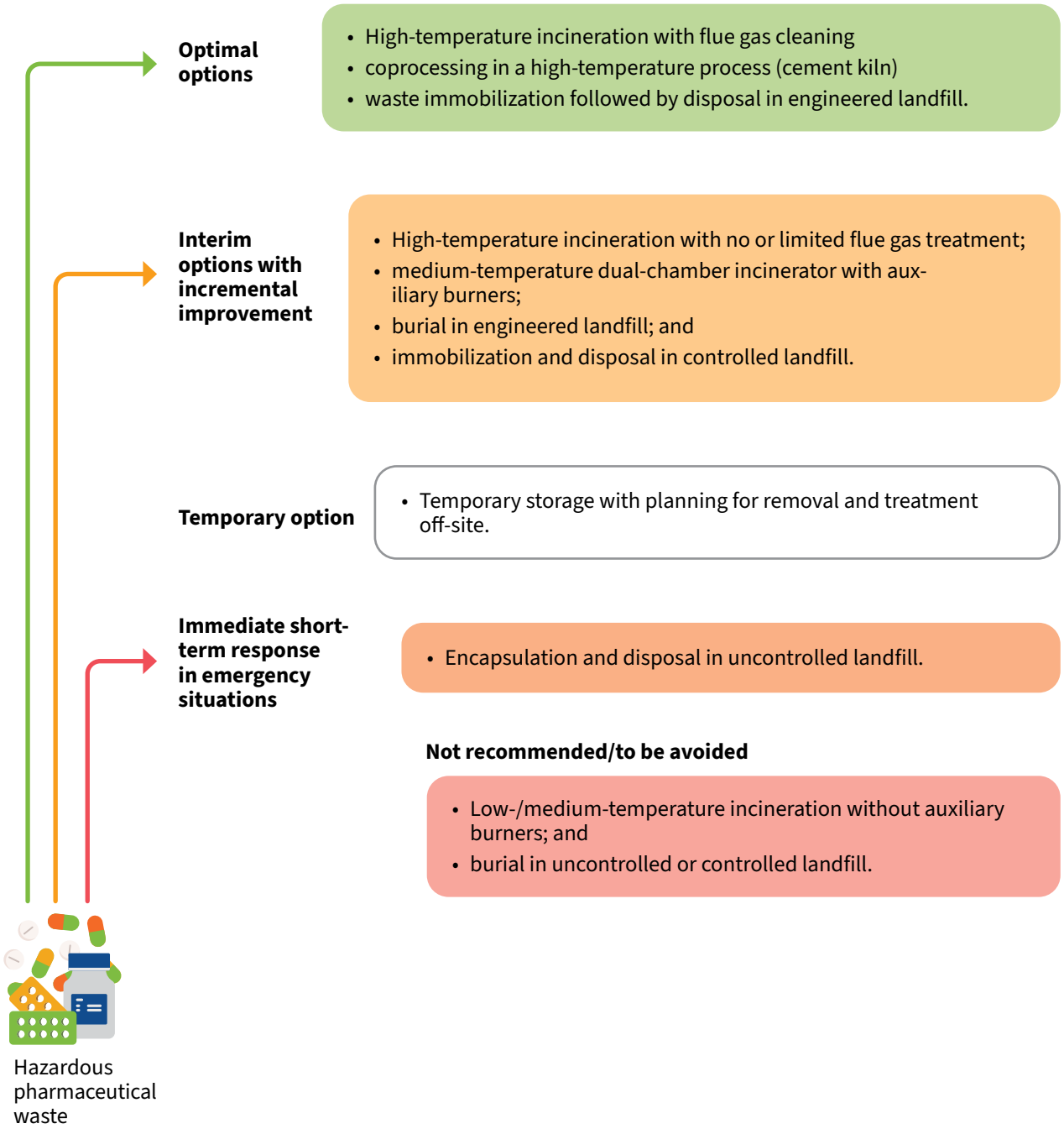
Appropriate treatment and disposal options should be selected based on an evaluation of the potential hazards posed by the waste to human health and the environment and on the best available technique for disposing of the relevant type of waste. It is of the utmost importance that nonhazardous waste be handled separately from hazardous waste, as the treatment and disposal options for nonhazardous waste are less strict and less expensive. If nonhazardous and hazardous waste are mixed, all waste must be treated and disposed of as hazardous waste, adding considerably to the volume and cost of waste treatment.

As outlined in Chapter 5.2.4, the treatment and disposal options are grouped as follows (see Fig. 11):

- optimal options
- interim options with incremental improvement
- temporary storage
- immediate short-term response in emergency situations.

Low-/medium-temperature incineration without auxiliary burners, burial in an uncontrolled or controlled landfill without prior treatment or immobilization, and dilution of hazardous pharmaceuticals are not recommended and should be avoided as they pose a high risk to humans and the environment.

Fig. 11 Treatment and disposal ladder for hazardous pharmaceutical waste



Source: created for this document using information from the WHO document *Safe management of wastes from health-care activities (1)* and the Health Care Without Harm document *Non-incineration medical waste treatment technologies (65)*.

The Basel Convention has developed multiple technical guidelines on the environmentally sound management of various waste streams and on disposal operations that are relevant to medical and health care wastes. The most specific of these guidelines, dated 2002, are the *Technical guidelines on the environmentally sound management of biomedical and healthcare wastes (Y1; Y3) (66)* and still contain relevant information about the management of these specific waste streams. Other guidelines are cited later in this document, where appropriate, and are relevant for coprocessing, specially engineered landfill, and incineration.

6.1 Optimal options

6.1.1 High-temperature incineration with flue gas treatment

To protect the environment from the adverse effects of burning waste, e.g. the release of persistent organic pollutants, the best available techniques compliant with the Stockholm Convention should be used *(22)*. Applying the best available techniques with a suitable combination of primary and secondary measures results in dioxin and furan air emissions no higher than 0.1 ng I-TEQ/Nm (at 11% oxygen),[4] and less than 0.1 ng I-TEQ/L for wastewater discharged from the facility *(22)*. Primary measures for high-heat thermal incinerators include: two burning chambers, the first of which should reach 850 °C and the second of which should reach 1100 °C with a minimum residence time of 2 s for waste with >1% of halogenated substances; auxiliary burners; sufficient oxygen content; and high turbulence of exhaust gases. Additional flue gas treatment systems are needed as secondary measures to prevent the emission of hazardous gases generated from hazardous waste. Such incinerators should meet strict emission control standards, such as those published by the EU *(67)*. Furthermore, to enable combustion control, temperature, oxygen, carbon monoxide and dust must be monitored from a central console via an online system. The fly ash and bottom ash left over from hazardous waste incineration is considered hazardous waste and must be disposed of as such, as outlined in Box 10.

Box 10 Disposal of ash residues from the incineration or burning of hazardous waste

The fly and bottom ash residues from burning hazardous waste can be contaminated with dioxins, leachable organic compounds, and heavy metals and must be treated as hazardous waste. The ash should be disposed of in sites designed for hazardous wastes, e.g. designated cells at engineered landfills, encapsulated and placed in specialized monofil sites, or disposed of in the ground in concrete lined ash pits.

Source: WHO *(24)*.

The requirements for incinerators used for hazardous waste based on the Basel and Stockholm Conventions can be found in Annex 4. They may be adapted to the specific waste burned and should be revised by an incinerator expert/manufacturer. When incinerating pharmaceutical waste in any incinerator, the following should be taken into consideration *(68)*:

- the quantity and category of waste to be disposed of;
- its chemical and physical nature;
- other possible disposal options;
- the total rate of feed of waste into the incinerator in question;
- the blending to ensure optimal combustion;
- the design and operating conditions of the facility;

[4] Toxic equivalences (TEQs) report the toxicity-weighted masses of mixtures of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs).

- measures to be taken to prevent or mitigate air emissions and the spread of pollutants into the environment;
- an assessment of the impact of the specific waste on effluent gas quality;
- problems associated with the management of residues from incineration, e.g. ash; and
- capability for monitoring as required (e.g. effluents).

6.1.2 Coprocessing of pharmaceutical waste in cement kilns

Industries that use high-temperature technology, such as cement kilns, coal-fired thermal power stations or foundries usually have furnaces that operate at temperatures above 850 °C, have long combustion retention times and disperse exhaust gases via tall chimneys, often to high altitudes. Many countries do not possess and, economically, cannot justify expensive and sophisticated chemical waste disposal facilities, so the use of an industrial plant with high-temperature technology provides a viable and cheap alternative. Using waste as fuel for such industrial plants is called coprocessing or co-incineration. Substituting waste material for fuel is a common procedure worldwide, including in the EU, as outlined in Case Study 15.

Case Study 15
EU:
coprocessing of waste in cement plants

"The EU cement industry supports the promotion of industrial symbiosis and the recognition of energy recovery as a waste management solution for nonrecyclable waste. The use of waste materials in the cement industry with a simultaneous energy recovery and material recycling, referred to as co-processing, contributes towards achieving the objectives of the circular economy. The EU cement industry already substitutes 43% of its fossil fuels with alternative fuels derived from waste and biomass in supplying the thermal energy to the cement clinker making process".

Source: EU *(69)*.

Cement kilns are particularly suited for the disposal of pharmaceutical waste, as long as the necessary safety and control mechanisms are in place. During the burning of 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. The essential process characteristics for the use of hazardous and other wastes, fed to the kiln via appropriate feed points, can be taken from the Basel Convention *Technical guidelines on the environmentally sound co-processing of hazardous wastes in cement kilns (70)*. For more information, see Box 11.

Box 11 Practical considerations in coprocessing of pharmaceutical waste at cement plants

- An inventory of the pharmaceutical waste (name, characteristics, hazardous/nonhazardous, solid, liquid, gaseous) is important for the operation of the cement plant as it can be used in planning to ensure adequate combustion of the waste and to devise occupational safety measures in case of blockages or accidents.
- To prevent occupational risks, it is recommended that pharmaceutical waste be fed directly into the kiln (e.g. via a ramp feeding system). Depending on the technical specifications of the cement plant and the physical properties and chemical characteristics of the waste, mechanical or physicochemical processes (preprocessing) may be necessary to transform the waste into a resource that meets the requirements and acceptance criteria of the cement plant. Occupational safety measures based on the risk assessment are of the utmost importance (e.g. dust removal during shredding).
- Waste must be fed into the kiln system only at feeding points that are appropriate based on the waste characteristics.
- Feeding of waste must be avoided during kiln startup and shutdown.
- The technical conditions of the plant that influence emissions, product quality and capacity must be carefully controlled and monitored.
- Capacity-building and training is essential at all levels.

Source: Deutsche Gesellschaft für Internationale Zusammenarbeit, Holcim Technology Ltd, University of Applied Sciences and Arts Northwestern Switzerland, School of Life Sciences Institute for Ecopreneurship *(71)*.

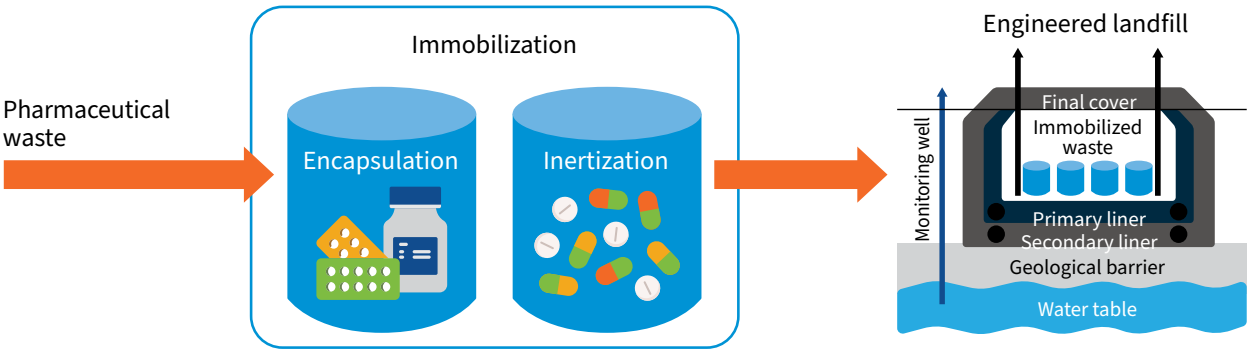
Cement producers in many countries are keen to use alternative fuels to reduce their fuel bill without adversely affecting the quality of the cement. With appropriate control mechanisms in place (such as emission monitoring and abatement technologies), pharmaceutical waste can be incinerated at cement factories and the environmental impact on nearby areas is minimized. The use of pharmaceutical waste as fuel needs to be permitted by the relevant authorities, and safe and secured storage must be guaranteed. Employees at the coprocessing facility must receive appropriate training tailored to their specific job functions and responsibilities. This training must be completed before they are allowed to participate in hazardous waste operations that may expose them to hazardous substances or pose safety and health risks. Training activities should be adequately monitored and documented in terms of curriculum, duration, and participant understanding and applied skills *(70)*.

Pharmaceuticals should be introduced into the furnace as a reasonably small proportion of the total fuel feed. It is suggested that as a rule of thumb, no more than 5% of the material fed into the furnace at any one time should be pharmaceutical material *(18)*. Cement kilns typically produce 1500 t to 8000 t of cement per day and therefore reasonably large quantities of pharmaceutical material can be incinerated in a short period. Inclusion of waste in PVC packaging should be avoided wherever possible if the cement kilns lack adequate air pollution control devices to prevent the dioxins and furans that are produced in the combustion of PVC being emitted in flue gases.

6.1.3 Waste immobilization followed by disposal in an engineered landfill

As engineered hazardous waste landfills are rarely available in LMICs, the immobilization of hazardous pharmaceutical waste followed by disposal in an engineered landfill for nonhazardous waste is an optimal option. Immobilization is the conversion of waste into the structure of a matrix (typically cement) via encapsulation or inertization. It reduces the potential for migration or dispersion of hazardous materials during operational and disposal stages of the waste lifecycle. The immobilized pharmaceutical material can be disposed of in an engineered landfill for nonhazardous waste, as the hazardous components of the waste cannot leak into the environment. A standard operating procedure for the treatment or processing of large bulk amounts of pharmaceutical waste using an automatic cement-based immobilization system has been published by USAID under its Supply Chain Management System *(72)*. In Fig. 12, the immobilization process is shown.

Fig. 12 Immobilization of pharmaceutical waste followed by landfilling



Source: created for this document using information from the WHO document *Safe management of wastes from health-care activities (1)*.

Examples of materials and tools needed are shown in Table 7.

Table 7 Materials and tools for immobilization of pharmaceutical waste

PPE	Materials	Tools
• Overalls/apron • gloves • mask • goggles • closed shoes.	• Cement/lime, sand, water; • metal or plastic vessel: drums or pails with lids; and • label: "Immobilized pharmaceutical waste – don't open".	• Stirring rod or cement hand mixer, or cement mixer.

Source: WHO *(1)*.

6.1.3.1 Immobilization via encapsulation

One possibility for immobilizing pharmaceutical waste is encapsulation. Encapsulation immobilizes the pharmaceuticals in a solid block within a polyethylene or metallic drum without removing the packaging. After encapsulation, the waste can be buried in an engineered landfill. The benefit of encapsulation is its relatively low cost. A vessel such as a drum is filled with pharmaceutical waste, and inert fillers such as plastic foam, bituminous sand, lime, cement mortar or clay is used to eliminate the risk of humans and the environment coming into contact with pharmaceutical residues before their final disposal in landfill *(73)*. Depending on the volume of pharmaceutical waste and the available resources, the waste and inert fillers can be mixed manually using a shovel, or using a manual or automatic concrete mixer. The vessels to be filled should be cleaned before use and should not have previously contained explosive or hazardous materials. They are then filled to 75% capacity with solid and semi-solid pharmaceuticals. Care should be taken to avoid hands getting cut when placing pharmaceuticals in the drums. The people carrying out the task should wear proper PPE appropriate for the kind of hazard, including gloves, mask, goggles, closed shoes, and overalls or an apron. Once the vessels are filled to 75% capacity, the remaining space is filled by pouring in a medium such as cement, plastic foam, bituminous sand, or a mixture of lime, cement and water in the proportions 15:15:5 (by weight; a larger quantity of water may be required to attain a satisfactory liquid consistency). Optionally, a layer of this medium can also be inserted before the pharmaceuticals. Once the vessels are full, their lids should then be sealed, ideally by seam or spot welding. The size of the vessel depends on the options for moving it once filled, as it can become heavy. Vessel/drum sizes of between 30 L and 200 L are often used. For images of the encapsulation process, see Fig. 13.

Fig. 13 Photo documentation: encapsulation of pharmaceutical waste (Cepheid cartridges)

Loading of waste into the vessel | Mixing of cement and pharmaceutical waste | Encapsulation result

Source: Edward Krisiunas, International Solid Waste Association.

Please note:

- For large amounts of pharmaceutical waste, fully automated stationary and mobile encapsulation devices with different capacities (~5 m^2 to ~16 m^2) are available.
- The encapsulating process for antineoplastics is slightly different due to their high level of toxicity and is outlined in Chapter 7.2.1.

6.1.3.2 Immobilization via inertization

Inertization is a variant of encapsulation and involves removing packaging materials, paper, cardboard and plastic from pharmaceuticals, e.g. pills must be removed from their blister packs. Removing the packaging reduces the volume of waste by approximately 50%. However, this procedure is time consuming and requires additional human resources. The safety of the waste management staff involved in this activity must be managed to avoid any exposure. It is recommended not to mix different pharmaceuticals during inertization to prevent unknown chemical reactions. Highly toxic waste such as antineoplastics and explosive materials such as aerosol containers should not undergo inertization due to the high risk of exposure for humans and the environment. If liquid pharmaceuticals require inertization, it is advisable to run tests first to determine the appropriate ratio of liquid to lime and cement to ensure complete solidification and prevent the pharmaceuticals from leaching out.

Solid pharmaceuticals are ground and a mix of water, cement and lime added to form a homogenous paste. A crushing machine may be employed to grind the raw waste into smaller particle sizes. The materials can be mixed manually or using a concrete mixer. Workers must be protected by protective clothing, and masks are required as there may be a dust hazard.

The paste is either poured into drums or transported in liquid form to an engineered landfill, where it is decanted into the regular municipal waste stream. It is then placed at the bottom of the landfill and covered with fresh municipal solid waste. The process is relatively inexpensive and can be carried out using 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 percentages by weight used are shown in Table 8.

Table 8 Inertization: materials and approximate percentages by weight

Materials	Weight (%)
Pharmaceutical waste	65
Lime	15
Cement	15
Water	5 or more to form a proper liquid consistency

Source: WHO *(18)*.

The ratio of pharmaceutical waste, lime, cement and water must be determined based on the kind of waste to be inertized. Fig. 14 shows inertized pharmaceutical waste.

Fig. 14 Example of inertized pharmaceutical waste

Source: Edward Krisiunas, International Solid Waste Association.

After inertization, the waste can be transported and buried in an engineered landfill. Case Study 16 describes how inertization was used in Nepal to dispose of an antiviral drug.

Case Study 16
Nepal: inertization of antiviral capsules

Thirty-six boxes of the antiviral drug molnupiravir expired at the Nepal Health Research Council in January 2024. The national NGO Health Environment and Climate Action Foundation disposed of the waste in an environmentally friendly way on behalf of the Nepal Health Research Council. The waste was weighed, documented and then separated manually into hazardous (molnupiravir capsules) and nonhazardous waste. The waste handlers wore proper PPE and were well trained. The recyclable nonhazardous waste was sent for recycling and the hazardous waste was inertized for disposal in the municipal landfill. The immobilization process included dissolving the capsules in hot water and inertization in cement in a plastic container with lid.

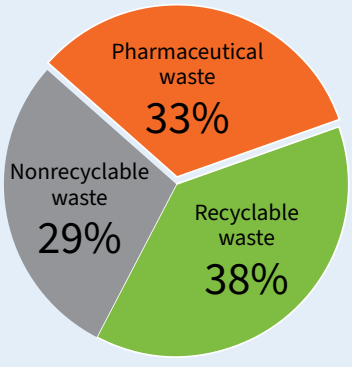
Weighing of waste

Manual separation

Dissolving of capsules

Inertization

All the expired pharmaceutical waste was managed, amounting to 1132 kg. Of this total, 33% was encapsulated (molnupiravir capsules) as hazardous pharmaceutical waste, 38% was recycled (paper) and 29% was nonhazardous but not recyclable (plastic blisters), so was disposed of via the municipal disposal scheme. In summary, 67% of the waste disposed of was nonhazardous.

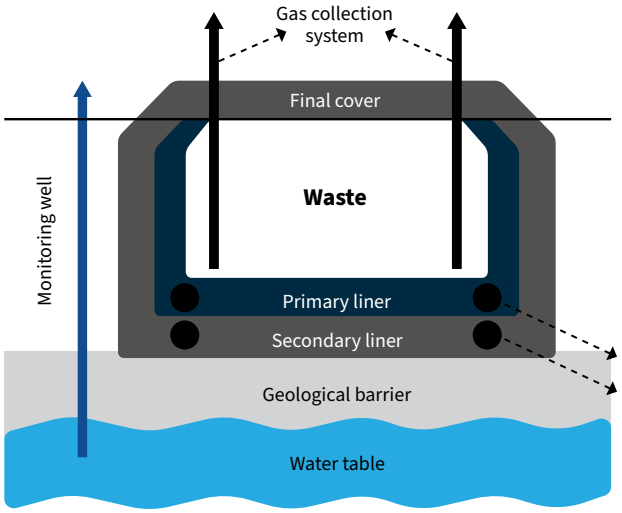


Source: Health Environment and Climate Action Foundation (*Final report – safe management of pharmaceutical waste (molnupiravir capsule – 200 mg) stock at Nepal Health Research Council (NHRC)*, unpublished data, 2024).

6.1.3.3 Disposal of immobilized waste in engineered landfills

The optimal landfill option for the disposal of immobilized hazardous pharmaceutical waste is the properly engineered landfill for nonhazardous waste. These sites also offer a safe disposal route for municipal solid wastes, including nonhazardous pharmaceutical waste *(74)*. The term "engineered landfill" refers to a landfill site that is adequately situated, constructed and managed. Engineered landfills isolate the waste from the environment. The top priority is protecting the aquifer. An appropriate engineered landfill consists of an evacuated pit that is isolated from watercourses and above the water table. An engineered landfill includes gas vents or a gas collection system. Landfill gas consists mainly of methane and carbon dioxide (up to between 90% and 98%) and various other gases and is produced by the decomposition of the organic material in the landfills. Each day's solid waste is compacted and covered with soil to maintain sanitary conditions. The site should be fenced and guarded to prevent unauthorized access. See Fig. 15 for a diagram of an engineered landfill.

Fig. 15 Schematic design of an engineered landfill



Source: adapted from the *Technical guidelines on the environmentally sound disposal of hazardous wastes and other wastes in specially engineered landfill (D5)* issued by the United Nations Environment Programme *(75)*.

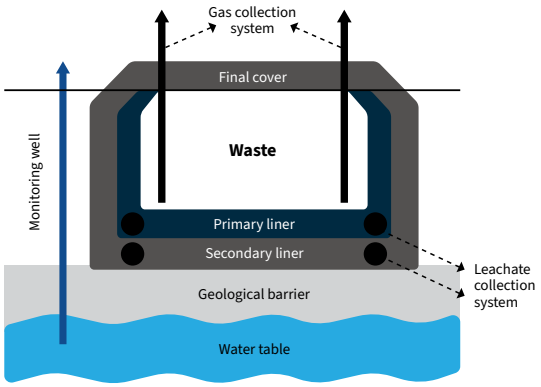
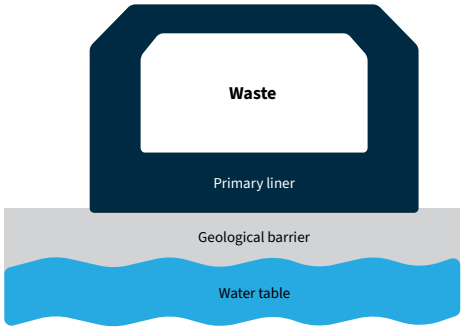
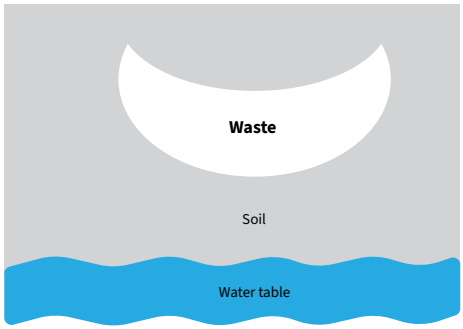
6.2 Interim options with incremental improvement

6.2.1 Landfill disposal

There are multiple landfill designs, each with their own separate processes and characteristics. Each design provides a different degree of safety. There are three possible landfill types. The safest and recommended type is the engineered landfill (as outlined in Chapter 5.2.4), followed by the controlled landfill with fewer safety features, and as an immediate response the uncontrolled landfill with no or very limited safety options (dumpsite). The disposal of pharmaceutical waste in controlled, non-engineered landfills is an interim option, if the waste is immobilized by encapsulation or inertization beforehand. Disposing of pharmaceutical waste in uncontrolled landfills or at dumpsites poses the risk of environmental contamination as well as the illegal reselling of products by informal waste handlers

(scavengers). Incremental improvements towards engineered landfills are of the utmost importance to ensure that waste is disposed of safely. Fig. 16 provides an overview of the different landfill types.

Fig. 16 Overview of landfill types: engineered, controlled and uncontrolled

Type of landfill	Diagram	Description
Engineered landfill (optimal)		Complete isolation of waste from the environment. Comprehensive safety measures are in place to protect the aquifer, the soil and the air (soil liner and barrier system, leachate and gas collection system) and there is monitoring for groundwater contamination. No public access.
Controlled landfill		Partial isolation of waste from the environment. One or more of the safety measures outlined for complete isolation are lacking (e.g. no leachate and gas collection, no monitoring of groundwater, or limited barrier system to prevent leachate). Limited public access.
Uncontrolled landfill (dumpsite)		No isolation of waste from the environment. Waste is in direct contact with the environment, so waste must be immobilized before disposal. Safety measures are lacking. Open access to the public.

Source: prepared by the authors of this document.

The *Technical guidelines on the environmentally sound disposal of hazardous wastes and other wastes in specially engineered landfill (D5)* adopted as part of the Basel Convention provide further details and information on safe landfills for hazardous waste – including hazardous pharmaceutical waste *(75)*.

6.2.1.1 Safe burial in an engineered landfill

In most LMICs, engineered landfills are often not available. An interim option is the use of a controlled landfill, which does not fulfil all criteria of an engineered landfill as outlined in Fig. 16 but has some

features to prevent the loss of chemicals into the aquifer. Before pharmaceutical waste is buried in a controlled landfill, it must be immobilized to ensure that pharmaceutical substances cannot enter the environment and it cannot be taken by the informal sector (scavengers).

6.2.2 High- and medium-temperature incineration with auxiliary burners

In many countries, incineration is only available without the use of auxiliary burners and without (or with limited) flue gas treatment. Some countries have medium-temperature incinerators for the treatment of municipal waste. In low-resource settings, responsible authorities may consider it acceptable to treat pharmaceutical solid waste using a high-temperature incinerator that has auxiliary burners, operates at the minimum temperature of 850 °C in the first chamber and 1100 °C in the second chamber, has a combustion retention time of at least 2 s in the second chamber, and has no or limited flue gas treatment. Many municipal solid waste incinerators are dual-chamber medium-temperature incinerators (≥ 850 °C) that are equipped with auxiliary burners. The use of these facilities may be considered an interim measure. When using municipal incinerators of this kind, it is recommended that pharmaceutical waste be diluted with large quantities of municipal waste. It is suggested that no more than 5% of the material fed into the furnace at any one time should be pharmaceutical material *(18)*.

6.3 Temporary storage

In emergency situations, the amount of pharmaceutical waste can increase drastically. In cases where there are insufficient or no treatment and disposal options available, the priority should be to store pharmaceutical waste in a safe, locked area while plans are made and implemented for safer treatment and disposal solutions. General storage requirements are outlined in Chapter 5.2.2. If stored, the waste must be registered and sorted properly, and the location of the storage facilities, such as buildings, rooms or designated areas in the health care facility, must be indicated clearly as well as documented by the internal administration or pharmacy.

6.4 Immediate response in emergency situations

An uncontrolled, non-engineered landfill or dumpsite is probably the most common land disposal method in LMICs. Untreated waste discharged into an uncontrolled open dumpsite does not protect the local environment and should be avoided. As an immediate response in emergency situations, the waste can be disposed of in an uncontrolled landfill (dumpsite) **only** after immobilization by encapsulation. It must be considered that the encapsulation of waste also poses a risk as informal waste handlers might still remove the pharmaceuticals from the cement block and resell them. The locations of these sites should always be recorded to facilitate the safe disposal of the waste in the future. If pharmaceutical waste is encapsulated and disposed of in an uncontrolled landfill without barriers to protect the water source and air, it is recommended that the location of the burial site be documented to enable the waste to be excavated later for safer disposal. Upgrading an uncontrolled waste disposal site to a reasonable standard should be considered, and advice is available from WHO *(76)*.

6.5 To be avoided, not recommended

The following options, such as low- or medium-temperature incineration without auxiliary burners (small-scale incineration) or burial in an uncontrolled or controlled landfill without prior immobilization, are not recommended and should be avoided. These methods present health and environmental risks and

should only be considered in extreme, limited cases as a last resort. Priority should be given to the interim storage of pharmaceutical waste, allowing time to plan for environmentally safe and sustainable treatment and disposal options in the future.

6.5.1 Low- and medium-temperature incineration without auxiliary burners

In emergency situations where optimal or interim options for the treatment and disposal of hazardous pharmaceutical waste are not available and storage facilities are insufficient or not available, low- or medium-temperature incineration without auxiliary burners, e.g. using small-scale incinerators (single- or dual-chamber, drum and brick incinerators) or burning in a protected pit, may be considered – although these methods are not recommended and should be avoided. Pharmaceuticals should be mixed with municipal waste so that it makes up a reasonably small proportion of the total fuel feed, reducing the potential hazard concentrations. It is suggested that no more than 5% of the fuel fed into the furnace at any one time should be pharmaceutical material *(18)*. Halogenated waste, including PVC blister packs, should be removed from the waste beforehand to prevent the generation of dioxins and furans. The ash from burning hazardous waste is considered hazardous and must be disposed of in a concrete-lined ash pit. A burning pit should be located in an isolated area, away from housing, fenced, and covered with a layer of soil after usage (at least 30 cm). The burned waste should be recorded and the location noted.

6.5.2 Burial in a non-engineered landfill without prior immobilization

As the very last resort and only in rural areas, if it is not possible to immobilize pharmaceutical waste, untreated waste can be disposed of in non-engineered landfills by covering it rapidly with large quantities of municipal waste to prevent scavenging. Ideally, this waste should be unpacked to make it unrecognizable and measures should be implemented to prevent scavenging (e.g. compacting of waste, fencing and labelling of the area). The waste area should be sited away from water sources and other water bodies as well as human settlements. The location of the buried waste should be documented.

7 Treatment and disposal methods by sorting category

Table 9 provides a summary of optimal (O) and interim (I) options for the treatment and disposal of nonhazardous and hazardous pharmaceutical waste in the event that the waste cannot be returned to the supplier/manufacturer.

Table 9 Summary of optimal and interim treatment and disposal methods for the different pharmaceutical categories

Category	Physical form	Treatment/disposal methods	O=Optimal option I=Interim option	Comments
Nonhazardous	Solid	Engineered landfill or treatment using a municipal medium-temperature incinerator (≥ 850 °C).	O	Aerosol cans must be emptied before treatment/disposal.
		Burial in a non-engineered landfill.	I	Aerosol cans must be emptied before treatment/disposal. Scavenging must be prevented/ pharmaceuticals must be unpacked before disposal.
	Liquid	Together with nonhazardous solid waste.	O/I	The same as is outlined for the nonhazardous solids.
		Sewerage system.	I	Dilution if no sewer or functioning sewage plant is available.
	Ampoules/ vials	Together with nonhazardous solid waste.	O/I	The same as is outlined for the nonhazardous solids.
		Emptying and crushing followed by burial in a pit or landfill.	I	Liquids can be disposed of with sewage. Glass must be packed in a drum or container before disposal.

Category	Physical form	Treatment/disposal methods	O=Optimal option I=Interim option	Comments
Hazardous antineoplastics	All forms	High-temperature incinerator (≥ 1200 °C) with flue gas treatment.	O	Ash must be disposed of safely.
		Coprocessing in cement plants.	O	Plants must have adequate safety standards and emergency plans (highly toxic material).
		Encapsulation followed by disposal in an engineered landfill.	O	Not suitable for aerosols. Scavenging must be prevented. Use a designated area.
		Chemical decomposition and disposal with sewage.	O	Treatment must be carried out by trained and knowledgeable experts.
Hazardous anti-infective drugs	All forms	High-temperature incinerator (≥ 1100 °C) with flue gas treatment or coprocessing in cement kilns.	O	Aerosols: the incinerator must be constructed/licensed for the treatment of gaseous waste. Ash must be disposed of safely.
		Immobilization followed by disposal in an engineered landfill.	O	Not suitable for aerosols. Scavenging must be prevented. Use a designated area.
Other hazardous waste	Solid, liquid	High-temperature incinerator (≥ 1100 °C) with flue gas treatment or coprocessing in cement plant.	O	Ash must be disposed of safely.
		Immobilization followed by disposal in an engineered landfill.	O	Scavenging must be prevented. Use a designated area.
		High-temperature incineration with no or limited flue gas treatment (≥ 1100 °C).	I	No liquids, unless the incinerator is designed for that purpose. Ash must be disposed of safely.
		Medium-temperature dual-chamber incineration (≥ 850 °C) with auxiliar burners.	I	No liquids, unless the incinerator is designed for that purpose. Ash must be disposed of safely.
		Burial in an engineered landfill.	I	Use a designated area.
		Waste immobilization followed by disposal in a controlled landfill.	I	Scavenging must be prevented. Use a designated area.

Category	Physical form	Treatment/disposal methods	O=Optimal option I=Interim option	Comments
	Ampoules/ vials	High-temperature incinerator (≥ 1100 °C) with flue gas treatment or coprocessing.	O	Ash must be disposed of safely.
		Encapsulation followed by disposal in an engineered landfill.	O	Scavenging must be prevented. Use a designated area.
	Aerosols/ inhalers	High-temperature incinerator (≥ 1100 °C) with flue gas treatment.	O	The incinerator must be constructed/licensed for the treatment of gaseous waste. Ash must be disposed of safely.
Controlled pharmaceutical products	Same options as outlined for "other hazardous waste" – treatment and disposal are the responsibility of the relevant authorities.		O/I	Treatment and disposal must be performed under the supervision of the relevant authority, an appointed committee, a designated pharmacist (for small amounts), the police or a judicial representative, depending on the local regulations.

Source: adapted from the WHO documents *Safe management of wastes from health-care activities (1)* and *Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies (18)*.

7.1 Nonhazardous waste

Nonhazardous pharmaceutical waste does not pose a risk to the environment, but the illicit scavenging, misuse and selling of waste as new products must be prevented. If nonhazardous and hazardous waste is mixed, all waste must be considered hazardous and must be treated/disposed of as such.

Nonhazardous pharmaceutical waste can be disposed of in a municipal landfill that is protected from scavenging. Municipal waste incineration (medium-temperature incineration – with flue gas treatment if possible) is another option for the treatment of nonhazardous pharmaceutical waste. As an interim option, when other options are not available, it can be buried in a non-engineered landfill, covered with municipal waste and compacted. Scavenging and illicit selling must be prevented.

In addition to the options already outlined, liquid nonhazardous pharmaceuticals that can be classed as readily biodegradable organic material, e.g. nonhazardous liquid vitamins, may be diluted and flushed into a sewer. Harmless solutions of different concentrations of certain nonhazardous salts, amino acids, lipids or glucose may also be disposed of in sewers as an interim option. If there is no sewer or no functioning sewage treatment plant, liquid nonhazardous pharmaceuticals can first be diluted with large volumes of water and then poured into large watercourses, providing that they are immediately dispersed and diluted by the flowing river water.

Specific procedures for nonhazardous aerosols and ampoules/vials are outlined in Chapter 7.3.1.

7.2 Hazardous pharmaceutical waste

The options identified as optimal are recommended for the treatment and disposal of hazardous pharmaceutical waste. If these are unavailable, interim options and secure storage of this waste should be considered before moving to an immediate response in emergency situations. Liquid hazardous pharmaceutical waste must not be discharged into sewers.

7.2.1 Antineoplastics

Antineoplastic drugs, previously called cytotoxics or anticancer drugs, can kill or stop growth of living cells. They are used in cancer chemotherapy, which is usually performed in specialized treatment centres. If unwanted and discharged into the environment they can have serious effects, such as interference in the reproductive processes of various life forms. Their disposal must therefore be handled with care. If the optimal treatment and disposal options are unavailable, the waste should be stored until an adequate solution has been identified.

The treatment and disposal options for antineoplastic waste are:

- high-temperature dual-chamber incineration with flue gas treatment
- coprocessing in cement plants
- waste encapsulation followed by disposal in an engineered landfill
- chemical decomposition followed by disposal in a sewerage system.

Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with solid walls. They should ideally be safely packaged and returned to the supplier for disposal. If this option is not possible, they must be destroyed in a dual-chamber incinerator that operates at a high temperature of at least 1200 °C in the secondary chamber and is fitted with a flue gas cleaning device. The afterburner (i.e. the secondary chamber) is important for the destruction of antineoplastic waste, as it is possible that the waste 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 antineoplastic substances are fully incinerated. A flue gas treatment system is mandatory and it must be ensured that the ash is disposed of as hazardous waste. Another option for safely destroying this waste is the use of coprocessing plants. It must be clarified in advance whether a cement factory has the approval and capacity to handle this specific waste. As antineoplastics are highly toxic, specific safety measures and emergency plans should be in place.

Antineoplastic waste should only ever be disposed of in a landfill except after encapsulation. Work teams handling these drugs must avoid crushing cartons or removing the product from its packages. The encapsulation process for antineoplastics differs slightly from encapsulation of other pharmaceuticals. 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. A larger quantity of water may sometimes be required in order 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. The contents will form a firm, immobile, solid block in which the waste is relatively securely isolated. Next, the drums are placed at the bottom of a landfill that has been lined with an impermeable layer of clay or membrane, then they are covered with municipal solid waste.

Chemical degradation methods that convert antineoplastic compounds into nontoxic/nongenotoxic compounds can be used for dealing with drug residues and for cleaning contaminated urinals, spillages and protective clothing *(77, 78)*. These methods are not used widely and require special trained and knowledgeable personnel such as a chemist or pharmacist. After chemical decomposition, the substances can be discharged into sewage following national and local regulations. Some methods are outlined in Annex 3 of the WHO guideline *Safe management of wastes from health-care activities (1)*.

7.2.2 Anti-infective products

Unsafe disposal of anti-infectives is a cause for concern because of their potential contribution to the spread of antimicrobial resistance and other effects on aquatic biota. Anti-infective drugs should not be discarded in an untreated form. If it is not possible to return these drugs to the manufacturer and adequate high-temperature incineration is unavailable, the recommended approach is encapsulation or inertization followed by burial in an engineered landfill. If the optimal treatment and disposal options are unavailable, the waste should be stored until an adequate solution has been identified.

The methods for disposing of anti-infective waste are:

- high-temperature dual-chamber incineration and flue gas treatment
- coprocessing in cement plants
- waste immobilization (encapsulation or inertization) followed by disposal in an engineered landfill.

7.2.3 Other hazardous waste

Hazardous pharmaceutical waste should ideally be treated before disposal. If optimal or interim options are not available, the waste should be stored until plans for safer treatment and disposal solutions have been made and implemented.

As outlined in Chapter 6, the **optimal options** are:

- high-temperature incineration with flue gas treatment
- coprocessing in a high-temperature process (cement kiln)
- immobilization followed by disposal in an engineered landfill.

If the optimal treatment and disposal methods are not available, the **interim options** are:

- high-temperature incineration (≥ 1100 °C) with auxiliary burners and limited or no-flue gas treatment
- medium-temperature dual-chamber incineration (≥ 850 °C) – preferably with flue gas treatment
- burial in an engineered landfill
- waste immobilization followed by disposal in a controlled landfill.

High-temperature incineration with temperatures reaching 1100 °C (850 °C in the first chamber and 1100 °C in the second chamber) with no or limited flue gas treatment can be used as an interim option. Dual-chamber medium-temperature incineration is widely practised for solid pharmaceuticals, provided that the pharmaceuticals are “diluted” in large quantities of municipal waste. Another interim option is the burial of hazardous pharmaceutical waste in an engineered landfill without prior treatment. As engineered landfills are rarely available, controlled landfills can also be used after the hazardous

pharmaceutical waste has been immobilized to ensure that the pharmaceutical substances cannot leak into the waste, soil and watercourses. It must be guaranteed that there is no access for informal waste handlers (scavengers).

An **immediate short-term response** in emergency situations is:

- encapsulation in an uncontrolled landfill.

The burial of encapsulated hazardous pharmaceutical waste in uncontrolled landfills should be done in a designated area, and the location of the burial should be documented clearly. The burial of inertized pharmaceutical waste in an uncontrolled landfill is not recommended.

7.2.4 Controlled pharmaceutical products

Controlled substances must not be allowed into the public domain as they may be abused. The treatment and disposal options are the same as those outlined for "other hazardous waste" (Chapter 7.2.3). Box 12 details the supervision required.

Box 12 Supervised treatment and disposal of controlled drugs

Controlled drugs should be treated and disposed of under the supervision of the relevant authority, an appointed committee, a designated pharmacist (for small amounts), the police or a judicial representative, depending on the local regulations.

Source: WHO *(79)*.

Hazardous controlled drugs from health care facilities or controlled drugs confiscated by the police or at customs (pharmacy or warehouse) must be registered and reported to the relevant authority or committee. The waste is collected and transported to the identified treatment or disposal facility under the control of the relevant authority or committee and the transport and disposal process should be monitored by the police.

The UNODC deals with controlled substances, some of which are pharmaceuticals. The UN Toolkit on Synthetic Drugs has a module on the safe handling and disposal of controlled substances, which includes several guidance documents on waste management of illicit drugs *(80)*.

7.3 Options based on dosage form

7.3.1 Ampoules and vials

Glass ampoules and vials filled with nonhazardous pharmaceuticals can be disposed of in an engineered landfill. Another way of ensuring that vials cannot be reused is to crush them, which also reduces the volume of waste. Vial crushers are commercially available and are manually or pneumatically operated.

Médecins Sans Frontières has developed a manual glass crusher for empty vials and ampoules, which is connected to a sharps pit (*Glass crusher manufacturing & operation manual*, Médecins Sans Frontières,

unpublished data, 2017). The crushed vials and ampoules fall directly into the pit without further manipulation. Therefore, the crusher operator doesn't come into contact with the crushed glass and the volume of the waste is reduced. Fig. 17 shows the glass crusher in use.[5]

Fig. 17 Use of Médecins Sans Frontières glass crusher on empty vials and ampoules

Glass crusher | Loading of crusher | Crushing of empty vials and ampoules

Source: Médecins Sans Frontières (*Glass crusher manufacturing & operation manual*, unpublished data, 2017).

In emergencies, vials and ampoules 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 be trained and wearing PPE, such as a face shield, boots, clothing and gloves. The crushed glass and liquids should be placed in a container suitable for sharp objects, immobilized, sealed and disposed of in a landfill, or disposed of directly in a sharps pit/special pit for sharp objects. The remaining nonhazardous liquids can be diluted and disposed of in the sewer.

Ampoules and vials should not be burned or incinerated in medium- or small-scale incinerators, 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.

The optimal options for vials and ampoules containing hazardous substances are incineration in industrial-sized high-temperature incinerators, coprocessing, or encapsulation followed by burial in a landfill. Opening or crushing ampoules and vials that contain hazardous substances is not recommended due to risk of contamination.

7.3.2 Aerosol cans and compressed-gas inhalers

Aerosol cans, including compressed-gas inhalers, are pressure vessels, and many spray cans contain flammable liquid gases, such as the propellants hydrofluorocarbons (HFCs), propane and butane. The HFC propellants used in pressurized metered-dose inhalers have a global warming potential significantly

[5] The illustrations in Fig. 17 may be copied, reproduced or adapted to meet national needs, without permission from the copyright owner, provided that the parts reproduced are fully acknowledged and are not used for commercial purposes.

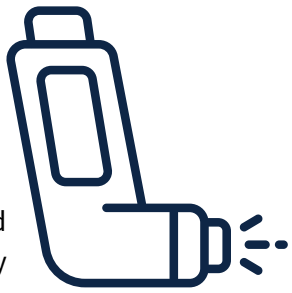
higher than that of carbon dioxide. Their usage, along with other emissive applications of HFCs, is being phased down under the Montreal Protocol *(81)*. Options for minimizing the use of HFC propellants in inhalers should be evaluated as much as possible.

Nonemptied aerosol cans containing hazardous substances can be treated by industrial high-temperature incinerators that are constructed and licensed to treat pressurized containers. Disposable aerosol cans and inhalers should not be burned in incinerators not licensed for this waste, as high temperatures may cause the aerosol cans and inhalers to explode, possibly causing injury to operators and/or damage to the furnace or incinerator.

Provided that the products do not contain hazardous substances, they should be disposed of in a landfill or dispersed among municipal solid waste. They should be completely emptied if there is a risk of scavenging. For safety reasons, the pressure cans and inhalers should be emptied in an accumulation container or into the sewerage system, the area should be ventilated and the staff must wear appropriate PPE. The aluminium and tinplate/steel of aerosol cans can be recycled.

7.3.2.1 Example: respiratory tract agents

(Anti-inflammatories, inhaled corticosteroids, bronchodilators, anticholinergics, mast cell stabilizers, respiratory tract agents)



The disposal of inhalers should follow the manufacturer's instruction, e.g.:

1. Ensure that the inhaler is empty or has expired (check the expiry date) before disposal.
2. Do not puncture or incinerate: metered-dose inhalers are pressurized containers and should not be punctured or incinerated, even when they appear to be empty, due to the risk of explosion.
3. Empty inhalers: if the inhaler is empty, it can be disposed of in the regular household waste. To check whether an inhaler is empty, follow the manufacturer's instructions. Typically, shaking the canister or checking the dose counter can help to determine whether the inhaler is empty.

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Annex 1: pharmaceutical categorization

1 *United States Pharmacopeia drug classification*

The non-profit, nongovernmental organization United States Pharmacopeia (USP) classifies drugs by:

- therapeutic use
- mechanism of action
- formulary classification.

The USP classification system *(1)* comprises 50 drug categories and more than a hundred classes within those categories. Pharmacists can use Table A1.1 to assist with classifying pharmaceutical waste in the event that national guidance is not available.

Table A1.1 Categories for the classification of pharmaceutical waste

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
1 .	Analgesics	Nonopioid analgesics	L, S, SS		x	
		Opioid analgesics	L, S, SS		x	x
2.	Anaesthetics	Local anaesthetics	L, SS		x	
		General anaesthetics	G, L, S		x	
3.	Antibacterials	Aminoglycosides	L		x	
		Beta-lactam, cephalosporins	L, S, SS		x	
		Beta-lactam, penicillin	L, S, SS		x	
		Macrolides	L, S, SS		x	
		Quinolones	L, S, SS		x	
		Sulfonamides	L, S, SS		x	
		Tetracyclines	L, S, SS		x	
		Antibacterials, other	L, S, SS		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
4.	Anticonvulsants	Calcium channel modifying agents	S		x	
		Gamma-aminobutyric acid augmenting agents	L, S		x	x
		Glutamate reducing agents	L, S		x	
		Sodium channel inhibitors	L, S		x	
		Anticonvulsants, other	L, S		x	
5.	Antidementia agents	Cholinesterase inhibitors	L, S		x	
		Glutamate pathway modifiers	L, S		x	
		Antidementia agents, other	L, S		x	
6.	Antidepressants	Monoamine oxidase inhibitors	S		x	
		Serotonin/ norepinephrine reuptake inhibitors	L, S		x	
		Tricyclics	S		x	
		Antidepressants, other	L, S		x	
7.	Antidotes, chelators, deterrents and toxicologic agents	Antidotes	L, S		x	
		Deterrents (smoking cessation agents, alcohol deterrents)	L, S		x	
		Toxicologic agents (opioid antagonists)	L, S		x	
8.	Antiemetics	Antiemetics	L, S		x	
9.	Antifungals	Antifungals	L, S, SS		x	
10.	Antigout agents	Antigout agents	L, S		x	
11.	Anti-inflammatory agents	Glucocorticoids	L, S		x	
		Nonsteroidal anti-inflammatory drugs	L, S, SS		x	
12.	Antimigraine agents	Abortive	L, S, SS		x	
		Prophylactic	L, S, SS		x	
13.	Antimyasthenic agents	Parasympathomimetics	L, S		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
14.	Antimycobacterials	Antituberculars	L, S		x	
		Antimycobacterials, other	L, S		x	
15.	Antineoplastics	Alkylating agents	L, S		x	
		Antiangiogenic agents	L		x	
		Antiestrogens/modifiers	L		x	
		Antimetabolites	L, S		x	
		Aromatase inhibitors, third generation	L		x	
		Molecular target inhibitors	L		x	
		Monoclonal antibodies	L		x	
		Retinoids	L		x	
		Antineoplastics, other	L		x	
16.	Antiparasitics	Anthelmintics	L, S, SS		x	
		Antiprotozoals	L, S, SS		x	
		Pediculicides/ scabicides	L, S		x	
17.	Antiparkinson agents	Antiparkinson agents	L, S, SS		x	
18.	Antipsychotics	Atypicals	L, S		x	
		Conventional	S		x	
19.	Antispasticity agents	Antispasticity agents	L, S		x	
20.	Antivirals	Anticytomegalovirus agents	L, S		x	
		Antihepatitis agents	G, L, S		x	
		Antiherpetic agents	L, S		x	
		Anti-HIV agents, fusion inhibitors	S		x	
		Anti-HIV agents, non-nucleoside reverse transcriptase inhibitors	S		x	
		Anti-HIV agents, nucleoside and nucleotide reverse transcriptase inhibitors	S		x	
		Anti-HIV agents, protease inhibitors	S		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
21.	Anxiolytics	Antidepressants	S		x	
		Benzodiazepines	S		x	x
		Anxiolytics, other	L, S		x	
22.	Bipolar agents	Bipolar agents	L, S		x	
		Benzodiazepines	L, S		x	x
23.	Blood glucose regulators	Antidiabetic agents	L, S		x	
		Glycemic agents	L, S		x	
		Insulins	L		x	
24.	Blood products	Anticoagulants	L, S		x	
		Blood formation products	L		x	
		Coagulants	L, S		x	
		Platelet aggregation inhibitors	L, S		x	
25.	Cardiovascular agents	Alpha-adrenergic Agonists	S		x	
		Alpha-adrenergic blocking agents	S		x	
		Antiarrhythmics	L, S		x	
		Beta-adrenergic blocking agents	L, S		x	
		Calcium channel blocking agents	L, S		x	
		Diuretics	L, S		x	
		Dyslipidemics	L, S		x	
		Renin-angiotensin-aldosterone system inhibitors	L, S		x	
		Vasodilators	L, S		x	
		Cardiovascular agents, other	L, S		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
26.	Central nervous system agents	Amphetamines	L		x	x
		Nonamphetamines, attention-deficit/ hyperactivity disorder (ADHD)	L		x	
		Nonamphetamines, other	L		x	
27.	Dental and oral agents	Dental and oral agents	L, S, SS		x	
28.	Dermatological agents	Dermatological agents	L, SS		x	
29.	Enzyme replacements/ modifiers	Enzyme replacements/ modifiers	L, S, SS		x	
30.	Gastrointestinal agents	Antispasmodics, gastrointestinal	L, S, SS		x	
		Histamine2 blocking agents	L, S		x	
		Irritable bowel syndrome agents	L, S		x	
		Protectants	S, SS		x	
		Proton pump inhibitors	L, S		x	
		Gastrointestinal agents, other	L, S, SS		x	
31.	Genitourinary agents	Antispasmodics, urinary	L, S		x	
		Benign prostatic hypertrophy agents	L, S		x	
		Phosphate binders	S		x	
		Genitourinary agents, other	L, S		x	
32.	Hormonal agents, stimulant/ replacement/ modifying (adrenal)	Glucocorticoids/ mineralocorticoids	L, S		x	
33.	Hormonal agents, stimulant/ replacement/ modifying (pituitary)	Hormonal agents, stimulant/replacement/ modifying (pituitary)	L		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
34.	Hormonal agents, stimulant/ replacement/ modifying (prostaglandins)	Hormonal agents, stimulant/ replacement/modifying (prostaglandins)	L, S		x	
35.	Hormonal agents, stimulant/ replacement/ modifying (sex hormones/ modifiers)	Anabolic steroids	L, S		x	x
		Androgens	L, S		x	x
		Estrogens	S		x	
		Progestins	L		x	
		Selective estrogen receptor modifying agents	S		x	
36.	Hormonal agents, stimulant/ replacement/ modifying (thyroid)	Hormonal agents, stimulant/replacement/ modifying (thyroid)	S		x	
37.	Hormonal agents, suppressant (adrenal)	Hormonal agents, suppressant (adrenal)	L, S		x	
38.	Hormonal agents, suppressant (parathyroid)	Hormonal agents, suppressant (parathyroid)	L, S		x	
39.	Hormonal agents, suppressant (pituitary)	Hormonal agents, suppressant (pituitary)	G, L, S		x	
40.	Hormonal agents, suppressant (sex hormones/ modifiers)	Antiandrogens	S		x	
41.	Hormonal agents, suppressant (thyroid)	Antithyroid agents	S		x	
42.	Immunological agents	Immune stimulants	L		x	
		Immune suppressants	L, S		x	
		Immunizing agents, passive	L		x	
		Immunomodulators	L, S		x	
43.	Inflammatory bowel disease agents	Glucocorticoids	L, S		x	
		Salicylates	S		x	
		Sulfonamides	S		x	

#	Category	Pharmacologic classes	Dosage form: gaseous (G), liquid (L), solid (S), semisolid (SS)	Nonhazardous	Hazardous	Controlled
44.	Metabolic bone disease agents	Metabolic bone disease agents	L, S		x	
45.	Ophthalmic agents	Ophthalmic antiallergy agents	L		x	
		Ophthalmic antiglaucoma agents	L		x	
		Ophthalmic anti-inflammatories	L		x	
		Ophthalmic prostaglandin and prostamide analogues	L		x	
		Ophthalmic agents, other	L		x	
46.	Otic agents	Otic agents	L		x	
47.	Respiratory tract agents	Antihistamines	L, S, SS		x	
		Anti-inflammatories, inhaled corticosteroids	G, L, S, SS		x	
		Antileukotrienes	S		x	
		Bronchodilators, anticholinergic	G, L		x	
		Bronchodilators, phosphodiesterase inhibitors (xanthines)	L, S		x	
		Bronchodilators, sympathomimetic	L		x	
		Mast cell stabilizers	G, SS		x	
		Pulmonary antihypertensives			x	
		Respiratory tract agents, other	G, L, S, SS		x	
48.	Sedatives/ hypnotics	Sedatives/hypnotics	L, S		x	x
49.	Skeletal muscle relaxants	Skeletal muscle relaxants	L, S		x	
50.	Therapeutic nutrients/minerals/ electrolytes/metals	Electrolytes	L, S	x		
		Minerals	L, S	x		
		Vitamins	L, S	x	(x)	
		Metals	L		x	

Source: adapted from the *USP therapeutic categories model guidelines (2)*.

2 List of halogenated pharmaceuticals

Halogenated pharmaceuticals are drugs that contain halogen atoms – any of the elements fluorine, chlorine, bromine, iodine, and astatine (occupying group VIIA (17) of the periodic table) – in their chemical structure. Examples are:

Fluorinated pharmaceuticals:

- fluoxetine (Prozac): an antidepressant used to treat major depressive disorder, obsessive-compulsive disorder and other conditions;
- ciprofloxacin: an antibiotic used to treat a variety of bacterial infections; and
- fluticasone: a corticosteroid used to treat asthma and allergic rhinitis.

Chlorinated pharmaceuticals:

- chloramphenicol: an antibiotic used to treat serious bacterial infections
- chlorpromazine: an antipsychotic medication used to treat schizophrenia and bipolar disorder
- clonazepam: a benzodiazepine used to treat seizures, panic disorder and anxiety
- diazepam: a benzodiazepine used to treat anxiety.

Brominated pharmaceuticals:

- bromocriptine: a medication used to treat Parkinson's disease, hyperprolactinemia and type 2 diabetes;
- brompheniramine: an antihistamine used to treat symptoms of allergy, hay fever and the common cold; and
- bromhexine: a mucolytic agent used to treat respiratory disorders associated with viscid or excessive mucus.

Iodinated pharmaceuticals:

- amiodarone: an antiarrhythmic medication used to treat and prevent various types of cardiac dysrhythmias;
- iodixanol: a radiocontrast agent used in diagnostic imaging procedures; and
- levothyroxine (Synthroid): a synthetic form of the thyroid hormone thyroxine, used to treat hypothyroidism.

3 List of potentially fetotoxic vitamins

The vitamins in the following list have the potential to be fetotoxic if misused or taken in concentrations that are too high (must be evaluated by the pharmacist):

- vitamin A – retinol ($C_{20}H_{30}O$) – may be teratogen at high doses
- vitamin B6 – pyridoxine ($C_8H_{11}NO_3$)
- vitamin B12 – cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$)
- vitamin D3 – cholecalciferol ($C_{27}H_{44}O$)
- vitamin K – phytomenadione ($C_{31}H_{46}O_2$).

References

1 United States Pharmacopeia drug classification (USP DC) 2024. Silver Spring: United States Food and Drug Administration; 2023 (https://www.usp.org/health-quality-safety/usp-drug-classification-system, accessed 8 January 2025).

2 USP therapeutic categories model guidelines. In: U.S. Food and Drug Administration [website]. Silver Spring: United States Food and Drug Administration; 2018 (https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines, accessed 8 January 2025).

Annex 2: pharmaceutical waste registration template – example

#	Name and description of pharmaceutical wastes*	Manufacturer/ supplier	Unit type and size	Number of units	Batch number(s)	Expiry date	Physical form**	Packaging***	Reason for disposal****	Nonhazardous or hazardous	Hazardous waste class*****
1	Brufen – ibuprofen tablets, 400 mg	Viatris	Box with 100 tablets	1	3161245	15.04.2024	Solid	Plastic box	Expired	Hazardous	Other hazardous waste: analgesics

* Generic name, brand name, strength and dosage

** Solid/liquid/semiliquid

*** Glass bottle, plastic box, sachet etc.

**** Expired, damaged, spilled etc.

***** Controlled, antineoplastics, anti-infective, other

Annex 3: standard operating procedure – pharmaceutical waste

1 Purpose

The purpose of this standard operating procedure is to describe the process for managing unused/unusable pharmaceutical waste. The standard operating procedure provides clear instructions on how to classify, pack, register, store and treat/dispose of the different types of pharmaceutical waste while minimizing any associated health risk and taking into consideration the local context.

2 Definition and scope

Pharmaceutical waste is defined as pharmaceutical products that are expired, unused, spilt or contaminated and prescribed and proprietary drugs, vaccines and sera that are no longer required and, due to their chemical or biological nature, need to be disposed of carefully. Pharmaceutical waste can be produced in wards, pharmacies and warehouses or during emergencies. This standard operating procedure deals with the general waste management process of pharmaceutical waste generated in the health sector in a routine situation as well in and after emergencies.

The head/director of the facility generating pharmaceutical waste has overall responsibility. A designated person responsible for waste management should be appointed, trained and knowledgeable about the processes for safely handling pharmaceutical waste.

3 Procedures

3.1 Identification and packaging

Waste must be identified, and safely packaged at the place of generation: in the ward, pharmacy or warehouse.

Pharmaceutical products that must be classed as waste:

- expired pharmaceuticals;
- unsealed pharmaceutical products such as syrups, eye drops, tubes of creams, ointments etc. (expired or unexpired);
- bulk or loose tablets and capsules, which are not anymore in their original packaging;
- cold-chain-damaged unexpired pharmaceuticals such as insulin, polypeptide hormones, gamma globulins and vaccines; and
- pharmaceuticals that are no longer used.

Packaging:

- The identified pharmaceutical waste should remain in the original packaging if possible.
- Package bulk or loose tablets and capsules in cardboard boxes and label the box with "Solid pharmaceutical waste – unknown product", the date, the location (name of ward, warehouse etc.) and the person who packed the waste in case further clarifications are needed. Ensure that you wear proper personal protective equipment (PPE) such as gloves, goggles and a coat.

Who is responsible?

- Medical staff working in health care facilities
- pharmacists working in the pharmacy
- pharmacists/trained logistics staff working in warehouses.

3.2 Registration

The disposal of pharmaceutical waste involves obtaining administrative approval. Unwanted and expired medicines should be written off administratively in a well-documented process.

Each item of pharmaceutical waste product must be recorded in the register book in accordance with the national regulations. The information to be recorded may include:

- general description (brand name, strength and dosage);
- manufacturer/supplier;
- unit type and size;
- quantity;
- batch number;
- expiry date;
- reason for disposal;
- physical form (solid, liquid, gaseous);
- category and associated information, i.e.: controlled substance, hazardous (ignitable, toxic, corrosive, reactive, explosive, ecotoxic) or nonhazardous; and
- if applicable: return to manufacturer/donor / extended producer responsibility (EPR) – yes/no, if yes which process to be followed).

3.3 Sorting and labelling

The objective of sorting is to separate the pharmaceuticals into the different categories for which different disposal methods are required.

- Return to manufacturer: sort and label in accordance with instructions received from the manufacturer/donor/service provider.
- Based on its identified characteristics, the waste should be sorted into the following categories and labelled accordingly:
  - nonhazardous waste (sorting within the classes: solid, fluid, gaseous):

        - not expired but not used anymore (usable)
    - hazardous waste (sorting within the classes: solid, fluid, gaseous):
        - controlled substances
        - antineoplastics
        - anti-infective products
        - other hazardous waste.

Who is responsible?

- Pharmacists of the facility.

3.4 Waste storage

Once the generated pharmaceutical waste has been sorted and registered, the waste must be stored before being handed over for return to manufacturer/donor/service provider or treatment and disposal. In emergencies, the waste may need to be stored for longer periods until proper treatment and disposal options are available.

- Store pharmaceutical waste in the pharmacy warehouse or in a designated area in the facility:
    - interim storage for small amounts and regular collection for treatment and disposal: a designated area (such as a quarantine area) in the warehouse or labelled cardboard boxes; and
    - for larger amounts: an enclosed room (ventilated, equipped with lighting, and with a locked and labelled door).
- The following storage compartments are required:
    - nonhazardous
    - hazardous
    - controlled drugs may need to be stored in a locker for security reasons.
- All storage areas should be labelled. It is recommended that liquid waste be stored on a shelf that is equipped with collection trays to catch any liquid from leakages.

Who is responsible?

- Storage in the pharmacy: pharmacists; and
- storage in a warehouse or designated storage facility: designated person such as the pharmacists/ trained logistics staff/person responsible for health care waste management in the facility.

3.5 Treatment and disposal

If pharmaceutical waste is generated and there is no take-back/EPR system in place, the waste must be safely treated before being disposed of, or directly disposed of without prior treatment. If the waste is collected/treated/disposed of by an external company, there must be a written agreement (prior informed consent).

- Transport of pharmaceutical waste via public roads:

  - Nonhazardous waste can be transported without specific legal requirements, but it must be ensured that the transport is safe and reliable, preventing illicit selling or disposal of the waste.
  - The transport of hazardous pharmaceutical waste should comply with national legislation. Where there are no such regulations, responsible authorities should refer to the latest revised edition of the United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations *(1)*.
  - Controlled pharmaceutical products must be transported to the identified treatment or disposal facility under the control of the relevant authority or committee and the transport and disposal process should be monitored by the police.
- Treatment/disposal:
  - options (see Box A3.1 for information on prioritization):
    - optimal options: high-temperature incineration with flue gas cleaning that complies with the Stockholm Convention *(2)*, coprocessing in a high-temperature process (cement kiln), or waste immobilization followed by disposal in an engineered landfill;
    - interim options: high-temperature incineration with no or limited flue gas treatment, medium-temperature dual-chamber incineration with auxiliary burners, burial in engineered landfill, or immobilization followed by burial in a controlled landfill; and

Box A3.1 Prioritizing the optimal methods

Hazardous waste should be treated and disposed of by the recommended, optimal methods. If not available, consideration should be given to interim methods or safe and secured storage of the waste until the optimal treatment and disposal options become accessible.

Source: WHO *(3)*.

    - immediate response in emergency situations: encapsulation followed by burial in an uncontrolled landfill;
  - exemptions:
    - Antineoplastics should only be disposed of via the following methods (no interim or immediate response options): burning via high-temperature dual-chamber incineration with flue gas treatment (no low-/medium-temperature incinerators), coprocessing in cement kilns, waste encapsulation followed by disposal in an engineered landfill, or chemical decomposition followed by disposal in a sewerage system.
    - Hazardous anti-infective drugs should only be disposed of via the following methods (no interim or immediate response options): burning in a high-temperature incinerator with flue gas treatment, coprocessing in cement kilns, or immobilization followed by disposal in an engineered landfill or a controlled landfill.
    - Aerosol cans and ampoules should only be disposed of via burning in high-temperature incinerators that have flue gas treatment and are capable of withstanding explosions in the burning chamber. As an interim option, glass ampoules and vials containing hazardous materials can be encapsulated and buried in a controlled landfill. Aerosol cans can be incinerated if empty (no pressure).

- Staff safety:
  - Staff must be trained in risks and safe practices.
  - Sufficient and adequate PPE must always be available.
- Documentation:
  - A consignment/transfer note must be filled in to verify the safe and reliable transport, treatment and disposal of the waste.
  - Keep the copies of all documentation supplied or completed by the approved waste collector, including the consignment note (signed by all parties) in your files.

Who is responsible?

- Storage in warehouse or designated storage facility:
  - designated person such as pharmacists/trained logistics staff/person responsible for health care waste management in the facility;
- transport:
  - the person responsible for the health care waste management of the hospital/pharmacists/trained logistics staff; and
  - at the transport company: the transport staff, the owner of the company;
- treatment and disposal:
  - the person responsible for the health care waste management of the hospital/pharmacists/trained logistics staff (who signed the consignment note); and
  - at the treatment/disposal company: the person who signed the waste receipt at the treatment/disposal company, the owner of the company.

References

1 UN Model Regulations Rev. 23 (2023) [United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations]. In: UNECE [website]. Geneva: United Nations Economic Commission for Europe; 2023 (https://unece.org/transport/dangerous-goods/un-model-regulations-rev-23, accessed 8 January 2025).

2 Stockholm Convention on Persistent Organic Pollutants (POPs). Text and Annexes. Geneva: Secretariat of the Stockholm Convention; 2023 (https://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx, accessed 8 January 2025).

3 Safe management of wastes from health-care activities, second edition. Geneva: World Health Organization; 2014 (https://www.who.int/publications/i/item/9789241548564, accessed 8 January 2025).

Annex 4: hazardous waste incineration requirements – specifications

1 General requirements

- National regulations are met.
- The incinerator is suitable for treating liquid, semi-solid and solid hazardous pharmaceutical waste.
- The incinerator can treat waste of calorific values between 5000 kJ/kg and 40 000 kJ/kg with an expected average heating value of the waste of 14 000 kJ/kg.
- The unit is totally piped and tested; all surfaces are heat resistant.
- A dual-chamber system is used.
- The combustion chamber is lined entirely with high-quality fireproofed refractory lining that can durably withstand the required temperatures (first chamber: 850 °C; second chamber: 1100 °C).
- The burner must be switched on automatically when the temperature of the combustion gases falls below the required temperatures (first chamber: 850 °C; second chamber: 1100 °C) after the last injection of combustion air.
- Optional: the incinerator is equipped with an injection system for liquid hazardous waste (if liquid waste is treated).
- Chimney:
  - The chimney is at least 10 m in height – higher than the surrounding housing.
  - The chimney has been chosen for use with an incinerator. It should be manufactured from refractory-lined mild steel or high-quality air-cooled stainless steel.
  - The chimney has a sampling socket to allow the testing of flue gases.
- An adequate fuel tank is available (capacity based on the size of the incinerator).

Based on the Stockholm Convention *(1)* and the related United Nations Environment Programme *Guidelines on best available techniques and provisional guidance on best environmental practices (2)*, a summary of what constitutes best environmental practice and the best available techniques for medical waste incineration is presented in the remainder of this annex.

2 Primary measures

- Two combustion chambers:
  - first combustion chamber: 850 °C; and
  - second combustion chamber: sufficient residence time (minimum 2 s) in a secondary combustion chamber after the last injection of air and temperature above 850 °C (1100 °C for highly chlorinated wastes, i.e. wastes with more than 1% halogenated organic substances) and 6% oxygen;
- automatic system to prevent waste feed before the appropriate temperature is reached;

- installation of auxiliary burners (for startup and shutdown operations);
- continuous (online) monitoring for combustion control of:
  - temperature: first chamber ≥ 850 °C and second chamber ≥ 1100 °C
  - oxygen content
  - carbon monoxide
  - gust by total organic carbon
  - hydrochloric acid
- regulation of the incineration process from a central console.

3 Secondary measures

- Avoidance of particle deposition equipment using e.g. soot cleaners/mechanical rappers/sonic or steam soot blowers/frequent cleaning of sections that are passed by flue gas at the critical temperature range;
- dust removal: < 10% remaining emission in comparison to uncontrolled mode (removal of polychlorinated dibenzo-p-dioxins (PCDDs)/polychlorinated dibenzofurans (PCDFs) adsorbed onto particles):
  - use of cyclones (only for precleaning of flue gases);
  - fabric filters or ceramic filters;
  - electrostatic precipitation; and
  - high-performance adsorption unit with added activated charcoal particles (electrodynamic venturi) – for fine dust removal;
- reduction of PCDD/PCDF emissions:
  - gas quenching: temperature reduced < 250 °C and emission < 0.1 ng TEQ/m^3 at 11% oxygen;
  - fabric filter coated with catalyst: (< 0.1 ng TEQ/m^3 at 11% oxygen); and
  - different types of wet and dry adsorption methods with mixtures of activated charcoal, open hearth coke, lime and limestone solutions in fixed bed, moving bed and fluidized bed reactors: < 0.1 ng TEQ/m^3 at 11% oxygen.

The residuals from the flue gas cleaning process (e.g. bottom ash, fly ash, filter cake from process wastewater treatment) must be treated. In particular, fly ash and filter cake contain relatively high concentrations of heavy metals, organic pollutants (including PCDDs/PCDFs), chlorides and sulfides. Therefore, their method of disposal has to be well controlled.

4 Treatment/disposal options for residuals from the flue gas cleaning process

- Disposal in safe landfills (e.g. hazardous waste landfill);
- use of fly ash and bottom ash in stabilization-solidification processes;
- catalytic treatment of fabric filter dust under conditions of low temperatures and lack of oxygen;
- scrubbing of fabric filter dusts by the 3-R process (extraction of heavy metals by acids): 1) recovery of fly ash and hydrochloric acid from the flue gases; 2) removal of heavy metals from the fly ash by extraction with hydrochloric acid; and 3) returning of a pelletized fly ash to the incinerator;

- combustion for destruction of organic matter (e.g. rotary kiln) with subsequent fabric filter, scrubber; and
- vitrification of fabric filter dust or other immobilization methods (e.g. solidification with cement) and subsequent landfilling.

References

1 Stockholm Convention on Persistent Organic Pollutants (POPs). Text and Annexes. Geneva: Secretariat of the Stockholm Convention; 2023 (https://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx, accessed 8 January 2025).

2 Guidelines on best available techniques and provisional guidance on best environmental practices relevant to Article 5 and Annex C of the Stockholm Convention on Persistent Organic Pollutants. Geneva: Secretariat of the Stockholm Convention; 2007 (https://nips.pops.int/Guidance_docs/Document_2_4_1.pdf, accessed 8 January 2025).

Annex 5: summary of relevant tools and guidance

Table A5.1 summarizes key tools and guidance that are available on the topic of pharmaceutical waste management.

Table A5.1 Summary of relevant tools and guidance

Area	Name and weblink of document
Databases	
Pharmaceuticals	United States Pharmacopeia classification system: https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines
Pharmaceuticals	World Health Organization (WHO) *Model list of essential medicines*: https://list.essentialmeds.org/
Controlled drugs	Drug Enforcement Administration of the United States list of controlled substances: https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf
Controlled drugs	United Nations Single Convention on Narcotic Drugs of 1961: https://www.unodc.org/pdf/convention_1961_en.pdf Its updates: https://www.incb.org/incb/en/narcotic-drugs/index.html
Antineoplastics and others	National Institute for Occupational Safety and Health of the United States (NIOSH) *NIOSH list of antineoplastic and other hazardous drugs in healthcare settings*: https://www.cdc.gov/niosh/healthcare/hazardous-drugs/index.html
Environmental impacts	Stockholm County Council database of the environmental impact of pharmaceuticals: http://janusInfo.se
General guidance on health care waste management	
Health care waste management	WHO *Safe management of wastes from health-care activities*: https://www.who.int/publications/i/item/9789241548564
Health care waste management	Basel Convention – *Technical guidelines on the environmentally sound management of biomedical and healthcare wastes (Y1; Y3)*: https://www.basel.int/TechnicalGuidelines/tabid/8025/Default.aspx
Health care waste management	United Nations Environment Programme *Compendium of technologies for treatment / destruction of healthcare waste*: https://www.unep.org/ietc/resources/report/compendium-technologies-treatment-destruction-healthcare-waste
Technologies	WHO *Overview of technologies for the treatment of infectious and sharp waste from health care facilities*: https://apps.who.int/iris/handle/10665/328146

Area	Name and weblink of document
Specific guidance	
Donations	Inter-agency *Guidelines for medicine donations*: https://www.who.int/publications/i/item/9789241501989
Procurement	United Nations Development Programme *Sustainable Procurement Index for Health (SPIH): user guidance*: https://api.savinglivesustainably.org/documents/file/764e233134ffe62af43550927d10c2eb/full/hash
Tools	
Implementation	United Nations Children's Fund/WHO WASH FIT implementation tool: https://www.who.int/publications/i/item/9789240043237
Controlled substances	United Nations Toolkit on Synthetic Drugs – safe handling and disposal: https://syntheticdrugs.unodc.org/syntheticdrugs/en/safe-handling-and-disposal/index.html

Water, Sanitation, Hygiene and Health Unit
Department of Environment, Climate Change and Health
World Health Organization
20 Avenue Appia, 1211-Geneva 27 | Switzerland
https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health