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# **Technical consultation on safe management of pharmaceutical waste**

## **Session 1: Opening, document and key issues**

WHO HQ, Geneva

1 October 2024

# A growing attention **to health care waste** within wider, global efforts on WASH, waste and electricity

Ongoing country implementation (75+) of standards, regular monitoring, WASH FIT, roadmaps



## **Global Efforts co-led** by WHO and UNICEF

**Contributions from 50+ Partners** (e.g. World Bank, UNDP, IFRC, Global Fund, Gavi, WaterAid, World Vision, Save the Children, Helvetas)

**Strategic Inputs from Core Partners** (trailblazer countries+ UN/NGOs + academia + donors e.g. FCDO, USAID, ROK, SIDA, GIZ)

## **Global Knowledge Portal** **([www.washinhcf.org](http://www.washinhcf.org))**

- *Training and resource materials*
  - *Country tracker*
- *Latest news and case studies*

# Leveraging WASH and Health Global Strategies

## 1. Country commitments: 2019 World Health Assembly and 2023 UNGA Resolutions

- Develop **roadmaps** and allocate **adequate budgets**
- Articulates need for enhanced **collaboration, leadership and partner** investments
- Integrate WASH and IPC **standards and indicators** into health programming and monitoring and increase domestic funding

## 2. Partner actions: Global Framework for Action (2024-2030) and Consensus Statement

- Focus on **equity, climate resilience/sustainability, and integration**
- Regular **monitoring and reporting** of national actions + service levels
- **Double number of people benefitting annually** from domestic and external investments in improved WASH + waste services

## 3. Global health and climate commitments and actions

- Health waste indicators and actions featured in **Global Action Plan for IPC and AMR High Level Declaration**
- Health care waste core area of efforts on **climate resilient and low carbon health care facilities**

# Meeting objectives and agenda

## Objectives

- Provide summary of main recommendations and remaining needed updates/areas for agreement in the Best Practices for Safely Managing Health Care Waste
- Present successes and challenges from country implementation and implications
- Articulate a plan to disseminate the document and collective scale-up best practices

## Agenda

- Session 1: Document summary
- Session 2: Summary of key issues to dissect and reconcile; implementation case studies from Serbia, Nepal, Middle East and Ethiopia
- Session 3: Linking with related policy, technology, wastewater and antimicrobial resistance efforts
- Session 4: Supporting effective implementation, including in Emergencies
- Session 5: Consolidation, dissemination and way forward

# Meeting outcomes

- Updated **Best Practices for Safely Managing Health Care Waste** (for publication in Q 1 2025)
- **Dissemination plan** (including capacity building activities) to improve pharmaceutical waste management
- **Agreed, collective actions for implementing** best practices



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# Best practices for safe management of health care waste: an overview

Ute Pieper, expert consultant WHO

1 October 2024

# Content

- **Document structure and content**
  - Sources and risk, purpose, target audience
  - Waste prevention and minimization
  - Components:
    - Administration and management
    - Classification, storage, transport
    - Categorizing of treatment and disposal options
  - Treatment and disposal options
  - Annex: Pharma list, templates, SOP, specs
- **Case studies**



# Purpose and scope

- focuses on pharmaceutical waste generated in health care facilities, including secondary and tertiary hospitals, primary health care facilities, dental clinics and laboratories
- pharmaceutical waste generated during development/peace-time activities and in outbreaks and emergencies
- pharmaceutical waste in solid, fluid or gaseous form.
- illustrates through case studies best practices for safe management

Waste types included	Details
Unused pharmaceuticals	Pharmaceuticals which are not used anymore, have been partially used but no longer needed or are expired.
Unsealed pharmaceutical products	Opened or damaged packaging such as open boxes or blister packs.
Bulk or loose tablets and capsules	Packaging / leaflet is missing.
Cold chain damaged pharmaceuticals	Cold chain of the pharmaceuticals during storage or transport was interrupted and cannot be used anymore.

Note: Pharmaceutical waste generated from households, manufacturing facilities, and veterinary pharmaceuticals used for aquaculture, companion animals, and livestock are beyond the scope of this document.



# Waste prevention and minimization

## Legislative framework

- Pharma waste to be included in the legal framework (defined roles, Extended Producer Responsibilities, stock management, procurement indicators include environment and disposal)

## Process optimization

- Rational use, procurement (selection of the least harmful options for prescription, procurement or donation policies), marketplace and redistribution, recycling and reuse

## Appropriate Donations

- National guidelines for drug donations, cooperation & communication
- Recipients should have defined procedures for valuation, for entering donations in their budget records, and for rejection of donations or the disposal of inappropriate donations

## Emergency preparedness and response

- National guidelines for drug donations, cooperation & communication
- Following donation guidelines and using emergency kits
- Including of pharmaceutical waste management in the national and local “Emergency and Preparedness Plans”

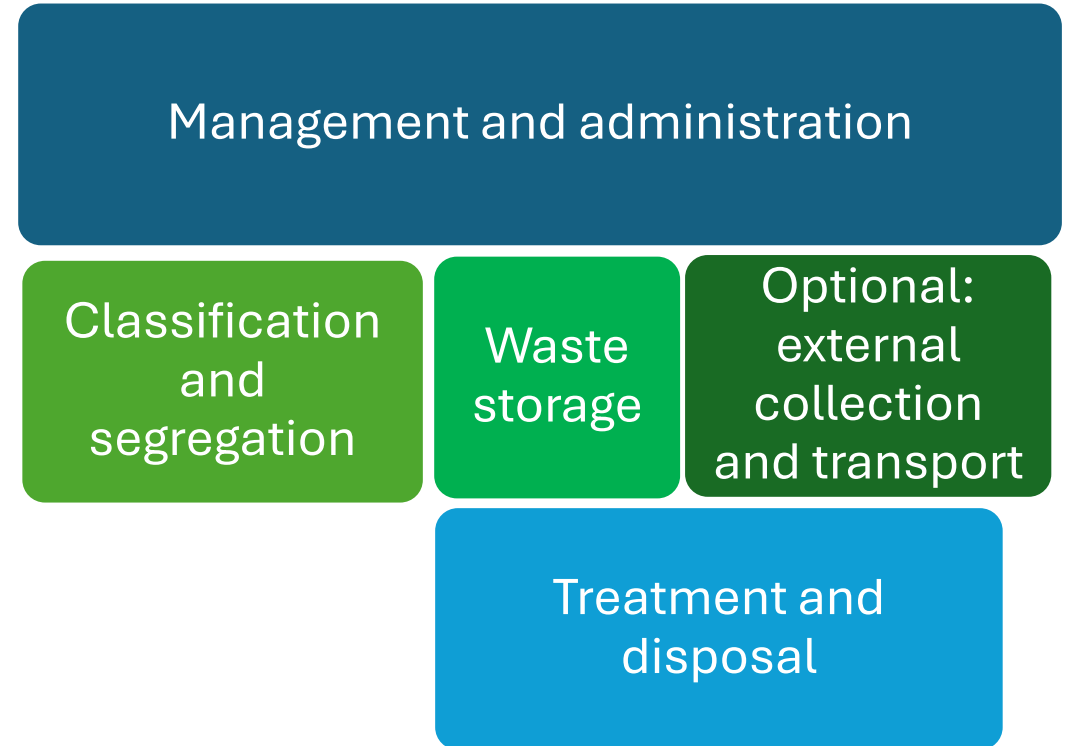
## Cost Considerations

- Efficient procurement, use of oral medications, prevent expired drugs by efficient storage (first in first out), segregation, recycling etc.

**Case studies:** Indonesia on awareness, Australia on advocacy, Nepal on legislation, Columbia on EPR, Netherland on marketplace, Australia and Oman on recycling

# Pharmaceutical waste management components

- New subchapter:
  - External collection and transport added (Transport of hazardous waste on public roads (ADR), Basel / Bamako Convention, transport documents etc.)
  - Storage: standard procedure and large amounts
  - Moved the decision tree to this chapter
- Revised treatment and disposal hierarchy

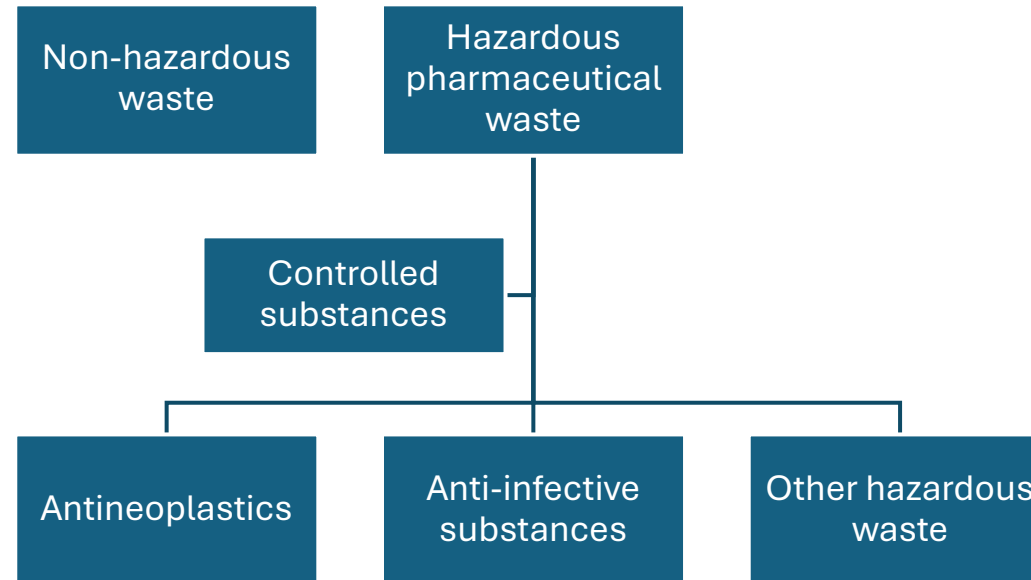


# Classification and sorting

- Sorting categories

List of pharmaceutical categories and classes based on “United States Pharmacopeia” (USP) – annex.



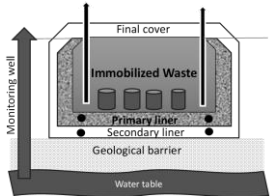
Further information from WHO Model List of Essential Medicines.



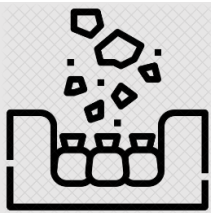
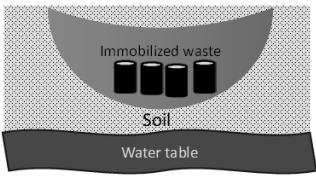

- Sorting can also depend on the dosage form (solid, fluid, gaseous)
- Segregation of large amounts of pharmaceutical waste after emergencies or long-term piling up of waste

# Treatment and disposal options

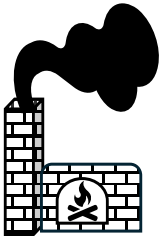


## 1. Preferred options

		
<p>High temperature incineration with flue gas treatment</p>	<p>Co-processing: Cement kiln</p>	<p>Engineered sanitary / controlled landfilling after waste immobilization</p>

## 2. Interim solutions

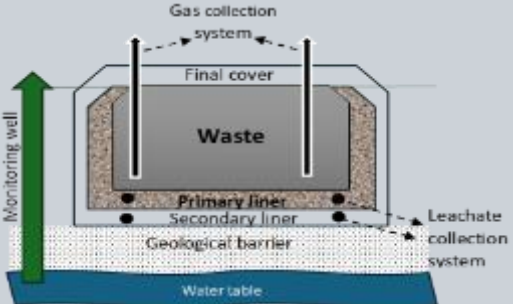
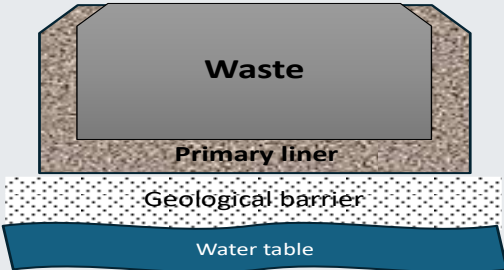
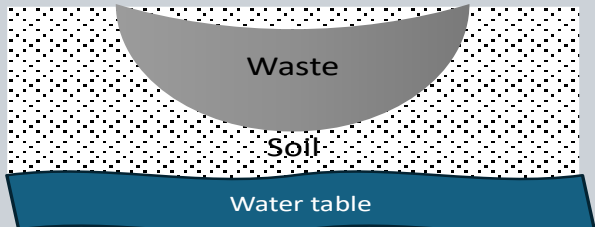
		
<p>Safe burial on controlled landfill</p>	<p>Uncontrolled landfilling after waste immobilization</p>	<p>Incineration with limited or no flue gas treatment</p>

## 3. Immediate response in emergency situations

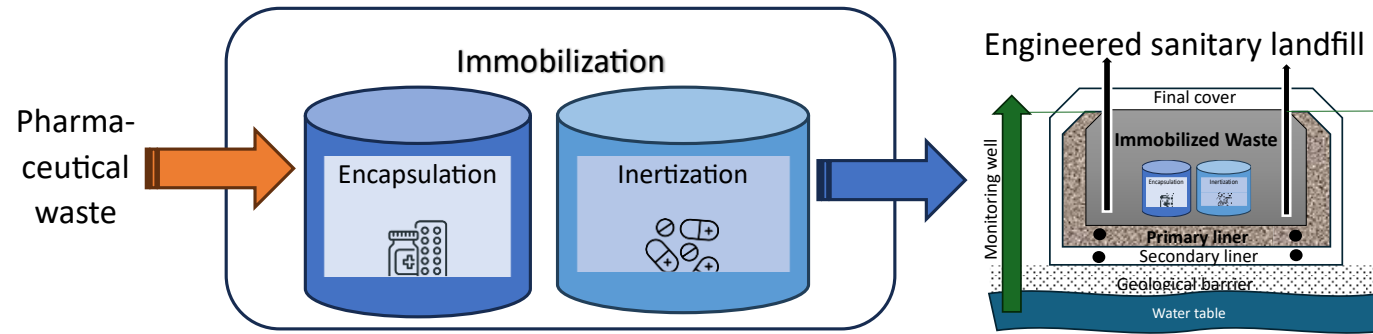
		
<p>Burning of waste – SSI</p>	<p>Burial on uncontrolled landfill</p>	<p>Dilution</p>

Case studies: EU on co-processing, Nepal on inertization

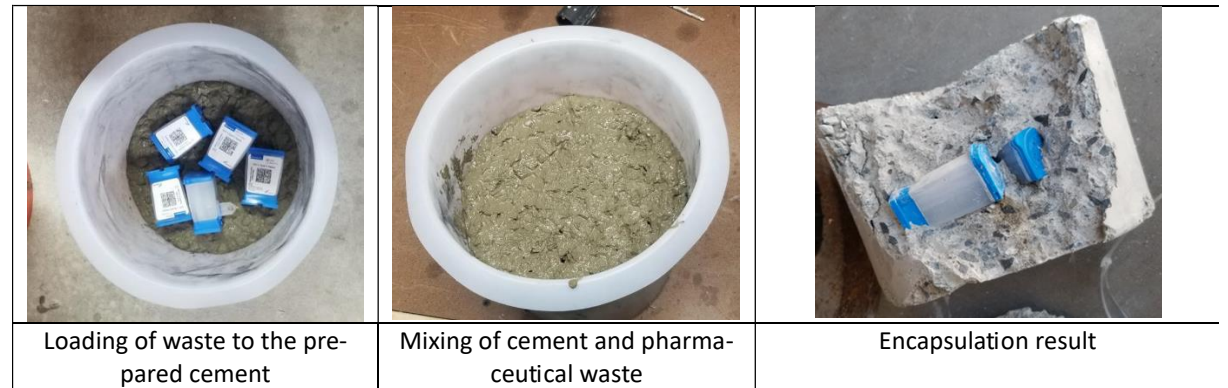
# Technical Terms: different kinds of disposal

Kind of landfill	Outline	Description
<b>Engineered sanitary landfill (preferred)</b>		<p><b>Complete isolation</b> of waste from the environment.</p> <p>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 monitoring of groundwater contamination. No public access.</p>
<b>Controlled landfill</b>		<p><b>Partly isolation</b> of waste from the environment.</p> <p>One or more safety measures as outlined above are lacking (e.g. no leachate and gas collection, no monitoring of groundwater and limited barrier system to prevent leachate). Open or limited public access.</p>
<b>Uncontrolled landfill (dumpsite)</b>		<p><b>No isolation</b> of waste from the environment.</p> <p>Waste is in direct contact with the environment - immobilization of waste before disposal is necessary. Safety measures are lacking. Open access to the public.</p>

# Immobilization: encapsulation & inertization



- Encapsulation  
(Immobilization of complete Package)



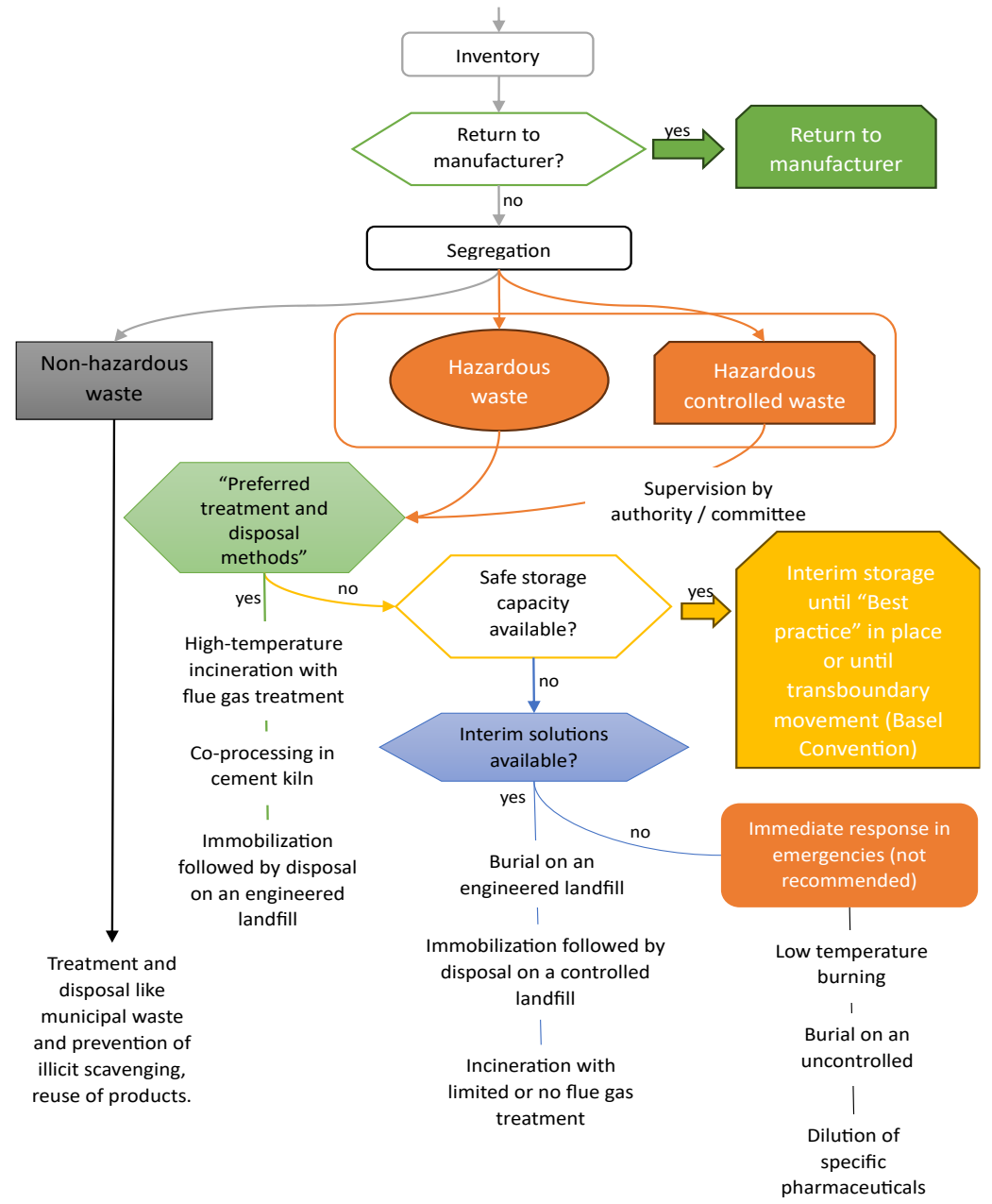
- Inertization (unpacking of drugs)



**Prevention and minimization!**

**Pharmaceutical waste**

**Decision Tree**



# Treatment and disposal methods by sorting category and physical form (liquid, solid, gaseous) – summary table

Hazardous pharmaceutical waste		
<b>Solid, liquid</b>	High temperature incinerator (>1,100°C) with flue gas treatment or co-processing in cement plant.	Preferred options. Safe disposal of ash
	Immobilization followed by disposal preferably on an engineered landfill or a controlled landfill.	Preferred option. Prevention of scavenging. Designated area.
	High temperature incinerator (>1,100°C) without flue gas treatment	Interim solution. Safe disposal of ash.
	Disposal on an engineered or controlled landfill.	Interim solution. Prevention of scavenging. Designated area
	Medium temperature incineration (>= 850 °C).	Interim solution. No liquids. Safe disposal of ash.
<b>Ampoules / vials</b>	High temperature incinerator (>1,100°C) with flue gas treatment or co-processing.	Preferred options. Safe disposal of ash.
	Encapsulation followed by disposal preferably on an engineered landfill or a controlled landfill.	Preferred option. Prevention of scavenging. Designated area.
<b>Aerosols / inhaler</b>	High temperature incinerator with flue gas treatment.	Preferred option. Incinerator is constructed / licensed for the treatment of gaseous waste. Safe disposal of ash.

## Specific hazardous waste

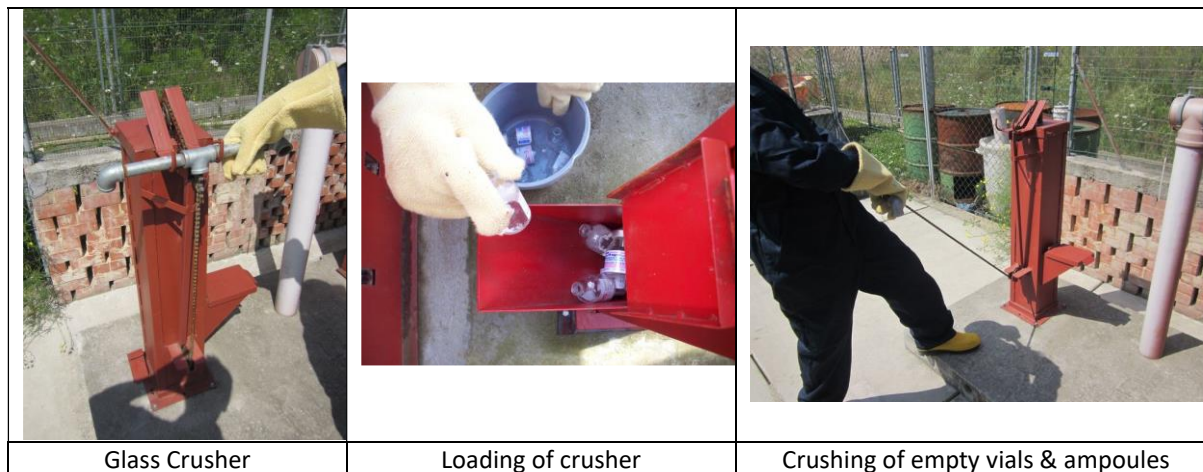
- Antineoplastics
  - No inertization
  - Chemical decomposition possible
  - Interim and emergency solutions to be prevented
- Anti-infective drugs
  - All preferred options
  - Interim and emergency solutions to be prevented
- Controlled drugs
  - Supervision of treatment and disposal (authorities, committee,...)

Preferred options not available: **secure storage** of this waste should be considered before moving to interim solutions or immediate response in emergency situations.



# Options based on dosage: ampoules and vials

- Glass ampoules and vials filled with non-hazardous pharmaceuticals can be disposed of in an engineered sanitary landfill.
- Another possibility to ensure that vials cannot be reused is the crushing of vials, at the same time as reducing the volume of waste.
- Vial crushers are commercially available and are manually or pneumatically operated.



Use of MSF glass crusher

# Case studies (14)

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Chapter	Countries	Guidance, awareness, training	Prevention & Minimization	Collection & storage	Transport	Treatment & disposal
3 prevention and mini	Indonesia	Campaign				
3 prevention and mini	Australia	Advocacy				
3 Legal framework	Nepal	Guideline				Inertization
3 Legal framework	Columbia	Resolution - take back program				
3 Marketplace and redistribution	Netherland		Sharing marketplace			
3. Recycling and reuse	Australia		Recycling – carbon footprint			
3. Recycling and reuse	Oman		Recycling			
4 Management and Admin	Canada	Administration, take back				
4 Waste storage	Guinea			Clean-up	Transboundary	
4 Waste storage	Haiti			Clean up		
4 Waste storage	Serbia			Clean up	Transboundary	
4 Waste storage	Benin	Training		Clean up		Inertization
4 Transport	Yemen				Reverse logistics	
5 Co-processing	Europe					

# Annex

- 7.1 Pharmaceutical categorization
  - 7.1.1 USP Drug Classification
  - 7.1.2 List of halogenated pharmaceuticals
- 7.2 Pharmaceutical waste registration template – example
- 7.3 Safety Operation Procedure – Pharmaceutical waste
  - 7.3.1 Purpose
  - 7.3.2 Definition and scope
  - 7.3.3 Procedures
- 7.4 Hazardous waste incineration requirements - specifications

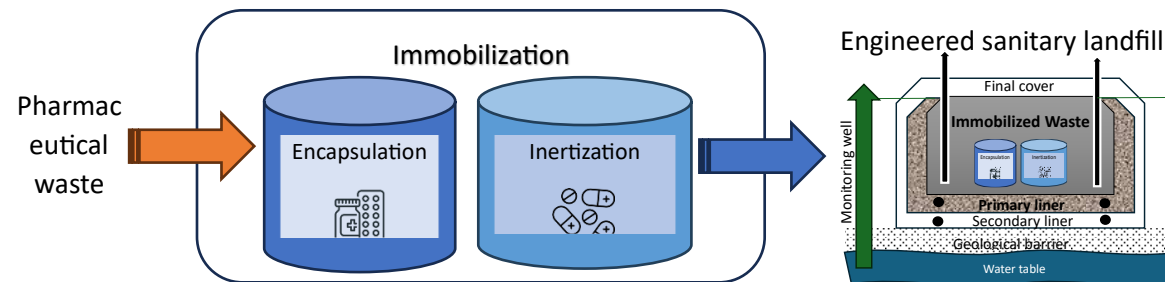


# Remaining topics to consolidate/agree

- Classification:
  - “non-hazardous” or better “low-risk hazardous waste” (MSF) – some non-hazardous pharmaceutical might be potentially risky like fetotoxic vitamins
  - Add list of fetotoxic vitamins – any other “low-risk” non-hazardous examples?

# Treatment and disposal hierarchy

- Preferred – interim – immediate response
  - Preferred options: encapsulated products could possibly be retrieved afterwards for illegal resale, even when buried at a controlled landfill – should be considered as last resort
  - Immediate response: Authorities and aid-agencies may misunderstand and/or misuse it, to do the strict minimum effort to eliminate their pharmaceutical waste under the pretext that a precarious situation within a country (often present in LMIC) is an emergency.



# Inertization of waste

- Inertization raises concerns
  - lack of extensive experience around this practice
  - lack risk assessments
  - More research needed
- Is there a need to remove drugs from blister packs? is this a best management practice?



# Co-processing of waste in a cement kiln

- The use of suitable waste materials like pharmaceutical waste in manufacturing processes for the purpose of energy and/or resource recovery and resultant reduction in the use of conventional fuels and/or raw materials through substitution (e.g. cement plants).
- Added a box on “Practical considerations in co-processing of pharmaceutical waste at cement plants”
  - Inventory, prevention of occupational risk, availability of appropriate feeding points, control of emissions, capacity building
- Revised by waste manager from relevant industry (Holcim)



# Dilution of pharmaceutical waste

- Dilution of liquid pharmaceutical waste:
  - During emergencies in places without any storage capacity, small quantities of well-diluted liquid pharmaceuticals can be disposed into the sewer. Exceptions are anti-infective drugs, anti-cancer medication, hormones/steroids and controlled drugs, which must not be discarded to sewer.
- Taken from the “old” pharma waste guideline 1999:
  - Some liquid pharmaceuticals, which are categorized as non-hazardous as syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers (**< 1 liter at a time**) with-out serious public health or environmental affects.
  - During emergencies in places without any storage capacity, **small quantities** of well-diluted liquid pharmaceuticals can be disposed into the sewer.
    - Exceptions are anti-infective drugs, anti-cancer medication, hormones/steroids and controlled drugs, which must not be discarded to sewer

Steps / process of dilution – how much of which waste ? Also depending on the followed wastewater treatment.





# Thank you

WHO/UNICEF knowledge portal:  
[www.washinhcf.org](http://www.washinhcf.org)

WHO/UNICEF Joint Monitoring Programme:  
[www.washdata.org](http://www.washdata.org)

# Updating guidance on best practices on safe disposal of pharmaceuticals

- Basis for document
  - Focus on health sector and health care facilities
  - Including all pharmaceuticals - not only focus on emergencies
  - More information on waste prevention and minimization
  - Systems approach: policies, processes, treatment technologies
  - New emerging trends on AMR, emergencies, pandemics

Safe management of waste  
from health-care activities

Second edition

Edited by Yves Chartier, Jorge Emery,  
Annette Prüss, Philip Rushbrook, R.  
William Townsend, Susan Wilburn

GUIDELINES FOR SAFE  
DISPOSAL OF UNWANTED  
PHARMACEUTICALS IN AND  
AFTER EMERGENCIES



# Target audience



Health authorities and health facility staff trained to use pharmaceuticals and manage pharmaceutical waste and 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 (NRA), the Food and Drug Administration (FDA), a regional or local health authority (pharmaceutical officer) or the ministry of environment.

# Which pharmaceutical products are not included?

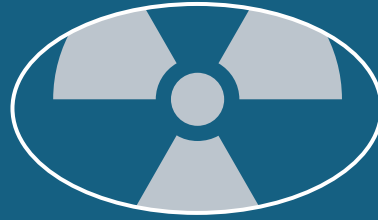
Category	Description	Examples
<b>Radio-pharmaceuticals</b>	This is radioactive waste and requires specific procedures. Specialized guidance is available from WHO.	Gallium-67 citrate Indium-111 chloride, Iodine-125 human serum albumin, Technetium-99m bicisate etc.
<b>Certain types of vaccines</b>	Vaccines which are considered as potentially infectious. Managed and disposed as infectious waste.	Measles-mumps-rubella (MMR combined vaccine), rotavirus, smallpox, chickenpox, yellow fever, shingles, varicella-zoster, oral poliovirus (OPV) vaccine, live attenuated Japanese encephalitis and live-attenuated influenza vaccines.

# Risks and mitigation measures



## Unsafe practices

- Over and/or un-needed consumption
- Inappropriate medicine donations
- Low-temperature or inadequate burning
- Inadequate and poorly managed landfills and dump sites
- Disposal of hazardous pharmaceuticals (e.g. antibiotics and antineoplastics) in sewerage system
- Unsafe management of wastewater and sludge



## Risks

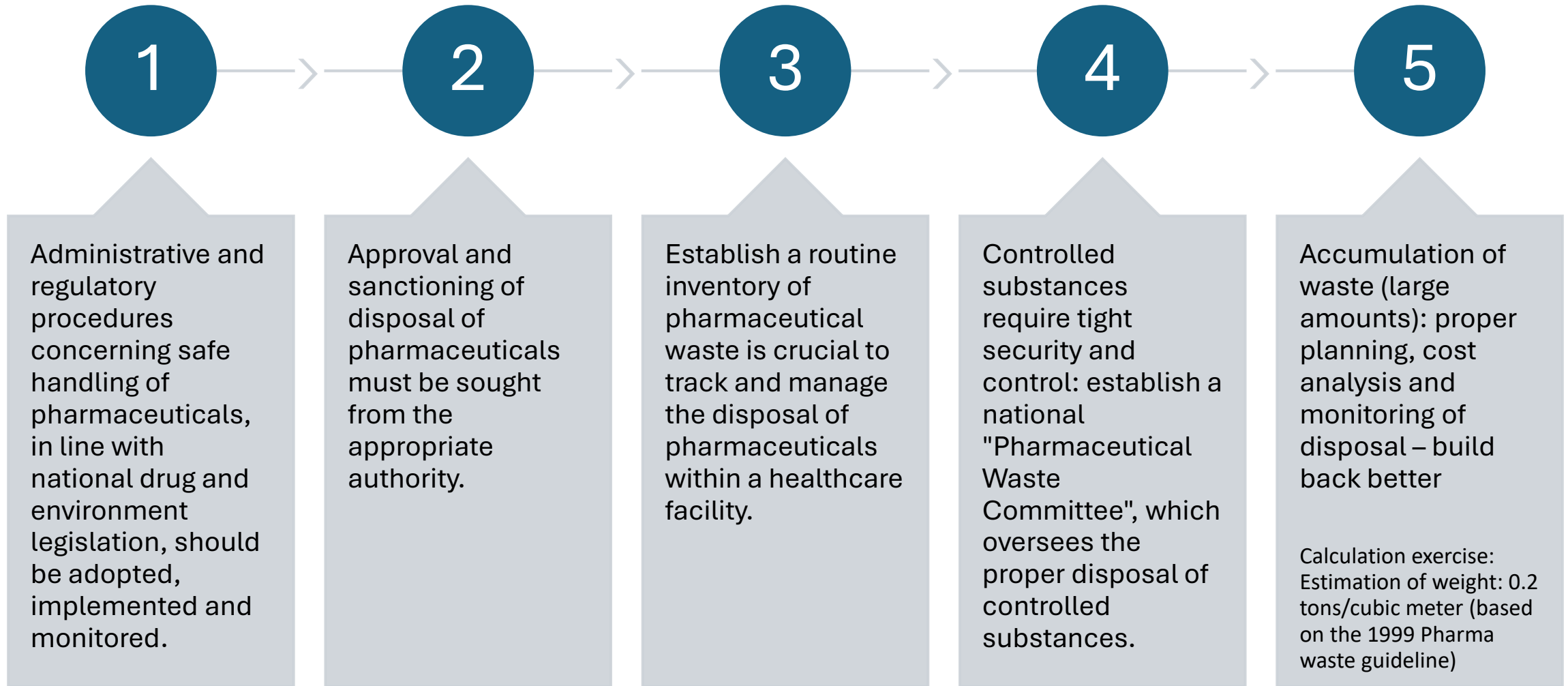
- Spread of AMR in humans
- Additional volume of pharmaceutical waste
- Exposure of animals and humans to harmful substances
- Contamination of water bodies and soil
- Re-sell in markets
- Release of toxic pollutants in air, water and soil
- “Good” microorganisms which facilitate biotreatment of sewage are killed
- Contamination of waterbodies and the environment



## Mitigation measures

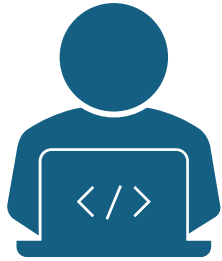
- Avoidance and minimization strategies
- National guidelines and legal framework for drug donations
- Awareness raising on principals of donation
- Site landfills to minimize leachate entering aquifers and surface water
- Fence and manage landfills to prevent illegal entry
- Install and manage high temperature incinerators with flue gas scrubbers to remove toxins
- Employ reverse logistics
- Set up and encourage use of take-back schemes for consumers
- Strengthen laws and regulation to ensure safe management of wastewater
- Support risk-based treatment and monitoring of wastewater including at least secondary treatment

# Management and administration



**Case study:** Canada on Improved administrative procedures and take back system

# Storage



## **General storage requirements (routine processes)**

Inventory, separate area / room,  
labelling of door, restricted access,  
training, responsible person, non-  
hazard and hazardous compartments  
etc.



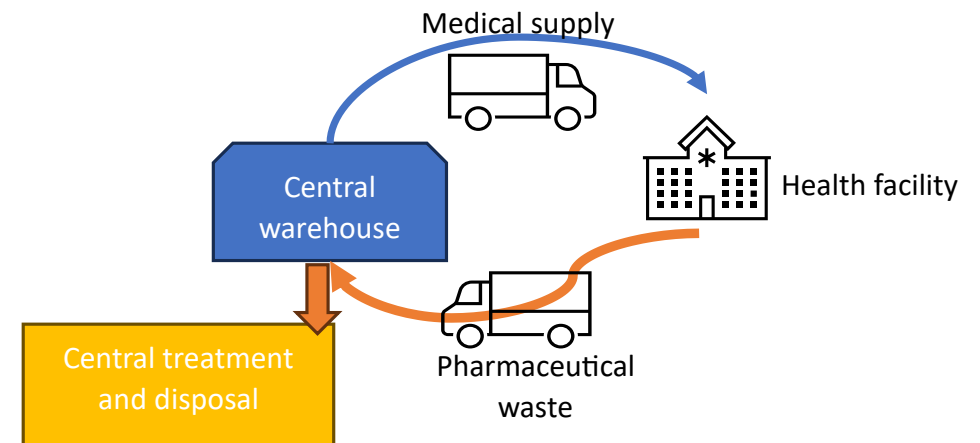
## **Storage and handling of large amounts of pharmaceuticals (e.g. during emergencies)**

Preparing of specific action plan which  
includes an inventory / hazards  
identification, clean up of spills,  
occupational safety measures, training,  
packaging material,  
  
organization of treatment and disposal  
or proper storage

Case studies: Clean-up of pharmaceutical after Ebola outbreak in Guinea 2014, Haiti after earthquake 2010, Serbia after conflict 2012, Benin clean up of counterfeit pharmaceuticals 2017

# External collection and transport

- Routine collection
  - Use of external central safe treatment / disposal facilities: documentation, packaging, labelling etc.
  - Consider reverse logistics
- Transport of large amounts of hazardous pharmaceutical waste
  - Consider national / international regulations like United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations or ADR
  - Transboundary transport of hazardous pharmaceutical waste
    - Basel Convention / Bamako Convention



Case study: Yemen on reverse logistics (ICRC)



# Options based on dosage: aerosols

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- Provided the products do not contain hazardous substances they should be disposed of in a landfill, dispersed among municipal solid wastes or completely empty the products in case of scavengers.
- For safety reasons the pressure cans / inhaler 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 aluminum and tinplate / steel of aerosol cans can be recycled.



# USP Drug Classification

Category	Pharmacologic Classes	Dosage form: liquid (L), solid (S), semi-solid (SS), gaseous (G)	Non-hazardous	Hazardous	Controlled
<b>Analgesics</b>	Non-opioid Analgesics	L, S, SS		X	
	Opioid Analgesics	L, S, SS		X	X
<b>Anesthetics</b>	Local Anesthetics	L, SS		X	
	General anesthetics	L, S, G		X	
<b>Antibacterials</b>	Aminoglycosides	L		X	

<https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines>

# Annex: Halogenated pharmaceuticals

- Why is this relevant?
  - Halogens are used in several classes of pharmaceuticals, including antibiotics.
  - Generation of dioxin and furan by medium or low temperature incinerators with limited or no flue gas treatment system – halogenated waste should be removed from the waste stream
  - Stockholm Convention – BAT: High temperatures are needed (1100 °C) for waste with more than 1% halogenated organic substances
- Annex provides a list of fluorinated, chlorinated, brominated, iodinated pharmaceuticals
  - Fluoxetine (Prozac), Diazepam, Bromhexine



# Pharmaceutical waste registration template – example

#	Name and description *	Manufacturer / supplier	Unit type and size	Number of units	Batch Number(s)	Expiry date	Physical form **	Packaging ***	Reason for disposal ****	Non-hazardous or hazardous	Hazardous waste class *****
1	Brufen – Ibuprofen tablets 400 mg	Viartis	Box with 100 tablets	1	3161245	15.04.2024	Solid	Plastic box	Expired	Hazardous	Other hazardous waste: Analgesics

\* generic & brand, name, strength and dosage

\*\* solid / liquid / semi liquid

\*\*\* glass bottle, plastic box, sachet etc.

\*\*\*\* expired, damaged, spilled, etc.

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

# Annex: Safety Operation Procedure (4 pages)

- Purpose
- Definition and scope
- Procedures
  - Identification and packaging
  - Registration
  - Sorting and labelling
  - Waste storage
  - Treatment and disposal
- Responsibilities

