



Workshop

## **Drug lifecycle control in Sub-Saharan Africa**

**From production to responsible safe disposal and elimination in  
wastewater treatment plants**

(Med4Africa)

**Technical and Regulatory Challenges  
affecting Pharmaceutical Waste  
Management/Disposal**

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# **1.0 INTRODUCTION**

## **1.1 Problem: The Need for Pharmaceuticals**

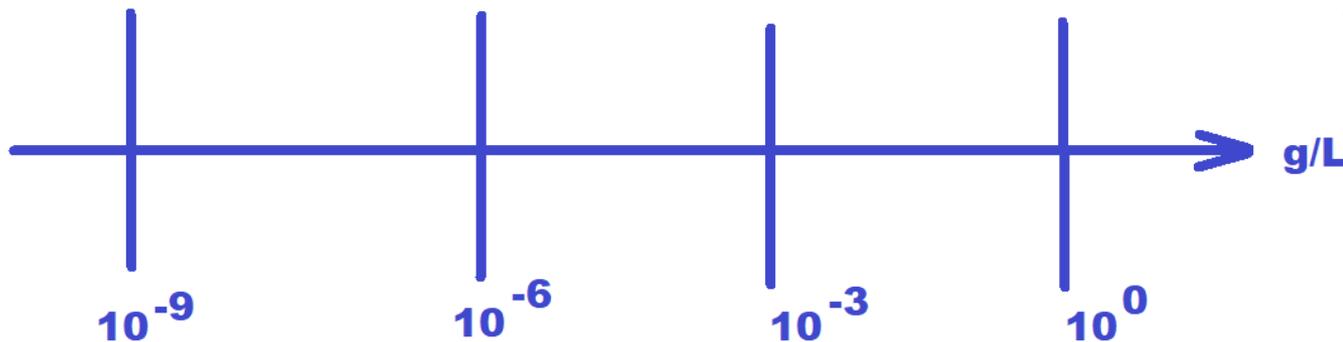
- 1. To support the national health framework**
- 2. Higher stocks required in each country**
- 3. Pharmaceuticals and personal-care products (PPCPs) used in large quantities**
- 4. One-time use for most PPCPs**
- 5. Externally vs. internally applied medicines**
- 6. Expiry dates around the corner**

# Volumes of UEMs

- 1. Most volumes of pharmaceuticals stocks end up in waste each year**
- 2. Need for proper waste management**
- 3. Skills required to manage the waste**
- 4. Some Pharm-Waste are reactive**
- 5. Pharm-Waste is NOT a conventional waste**

# Seepage of active substances into the environment

1. Found in soil and water bodies
2. Concentrations in ng/L to  $\mu\text{g/L}$

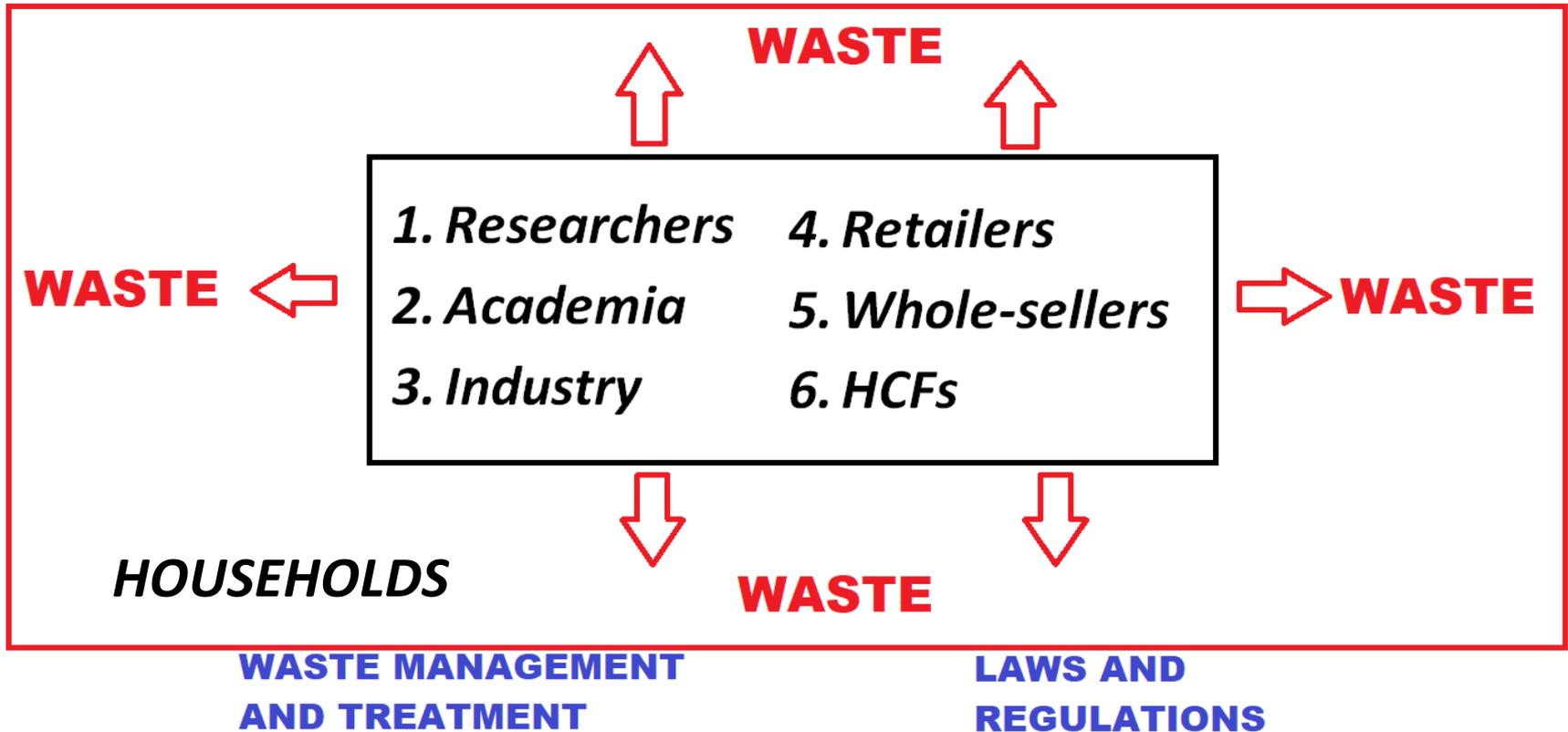


1. Low concentrations but highly toxic effects
2. Effluents in the vicinity of Pharm Industries
3. The market contains a wide range of Pharm Products  
- different complex chemicals (a challenge)

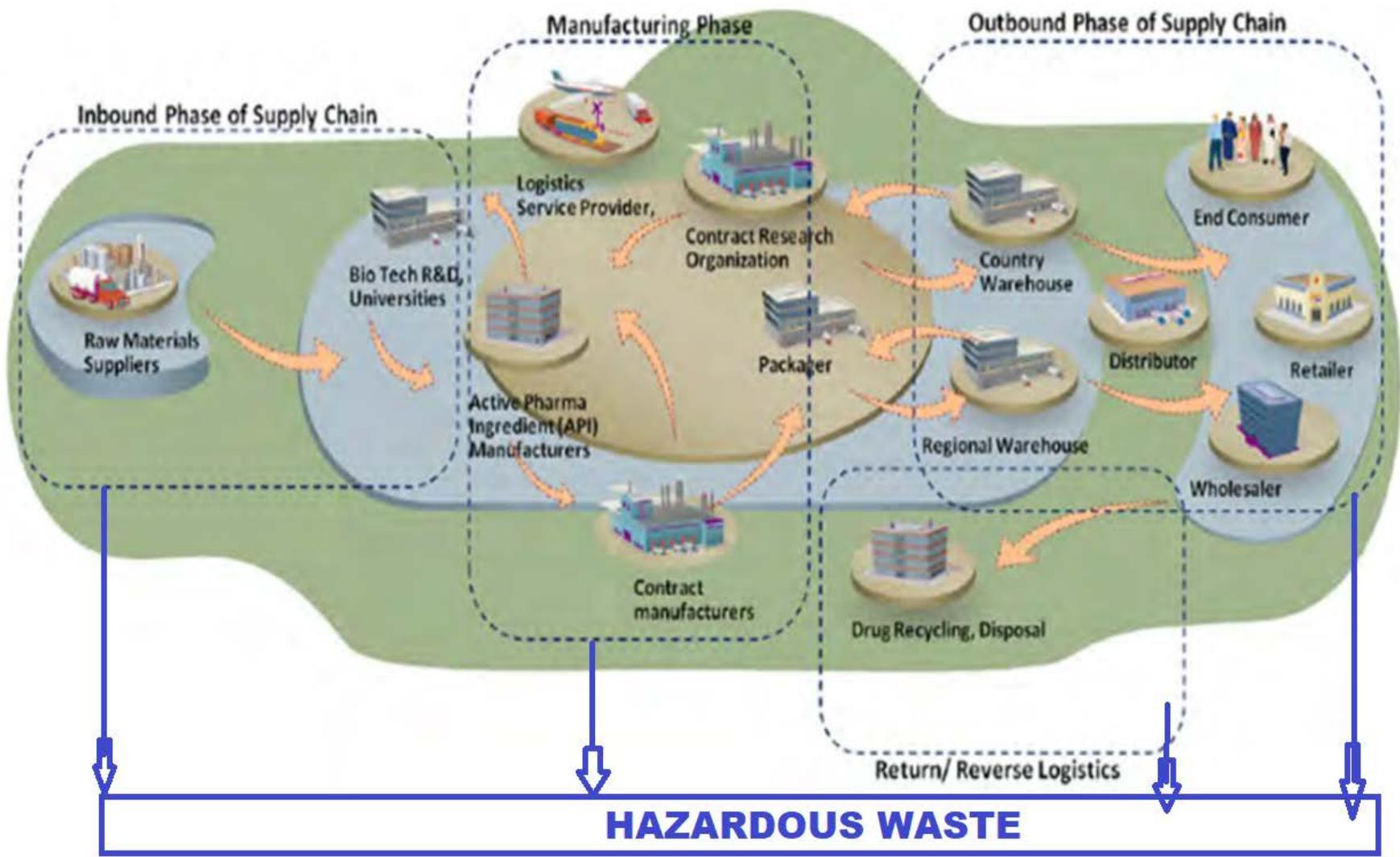
# The Whole Pharm SC

1. Are struggling to treat their waste products
2. Are manufacturers and researchers minimizing hazardous reagents/solvents (alternative synthetic pathways)
3. The Pharm-Waste Management is a key component that must be addressed by the whole supply chain
4. **Those with influence on products are responsible:**
  - Industry
  - Medical Stores
  - Regulators
  - Pharmacies
  - researchers

# Efforts by members in this Room – key generators



# Extended pharmaceuticals LCA and supply chain flow chart



# Types of Pharm-Waste Pharm-Waste generated

## 1. Hazardous

- U-Listed
- P-Listed
- Those containing heavy metals

## 2. Non-hazardous

- Covers most pharmaceutical products in the market, e.g., OTC.
- Antibiotics, contraceptives, prescription drugs

## 3. Inert

# 1.3 Hazards posed by Pharm-Waste

1. Hazardous chemicals content (as per national lists), most often we turn to US-EPA, EU lists
2. Hazardous characteristics –ignitable, corrosive, toxic, reactive
3. Pharmaceuticals contain wide range of chemistry – can affect humans, animals and plants
  - Genotoxicity, Cytotoxicity, mutagenicity, carcinogenicity, teratogenicity

# **Major Sources of Pharmaceutical Wastes**

- 1. Household Pharmaceutical Waste**
- 2. Pharmaceutical Waste from Healthcare Facilities**
- 3. Pharmaceutical Waste from Manufacturing Industries**
- 4. Research Centres and Laboratories**
- 5. Warehousing**
- 6. Packaging Waste from Pharmaceutical Products**

# Households as Sources of Pharm-Waste - UEM

1. Prescription and consumption practices
  2. Life style changes (ageing and growing population)
  3. Rise of chronic health conditions
  4. Availability of inexpensive generic treatments
  5. Changes in clinical practices
- **We observe: Lack of data on**
    - medicine consumption in SSA
    - Amount of drugs in circulation
    - Amount of medicine wasted

# **Why drugs become Waste? – UEM**

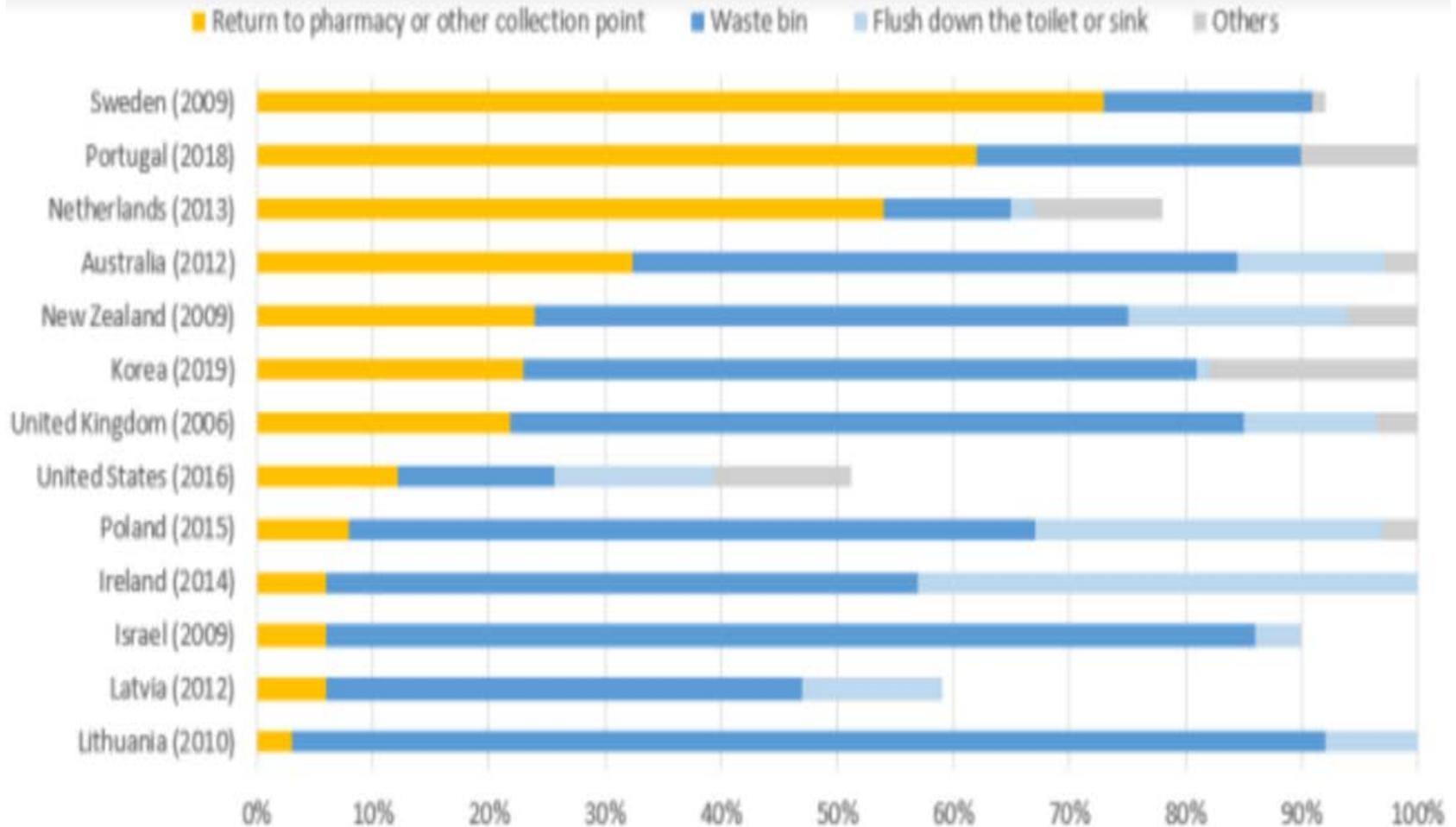
**[HCFs, Manufacturers, Pharmacy, Household]**

- 1. Having no effect**
- 2. Lack of adherence for patients**
- 3. Soon recovery or deceased**
- 4. Stockpiling followed by expiry**
- 5. Poor storage conditions (EEA @ MSD, HCFs)**

## Estimates of medicines becoming waste - UEM

1. In the EU – 3 to 8%
2. SSA – many cases, donated drugs, overstocking, bureaucratic distribution procedures leads to UEM
3. Finland: 3-4% of all medicines
4. With data: Expressed as *g EUM/capita*
5. France: EUM accounts for 0.05% of Household waste
6. USA: 8.1 mg API/kg of MSW in Florida

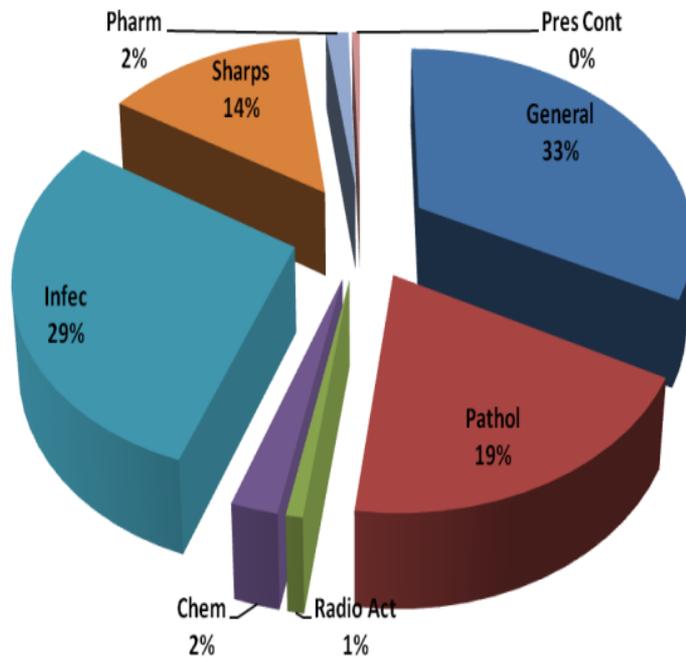
# Household EUM disposal practices



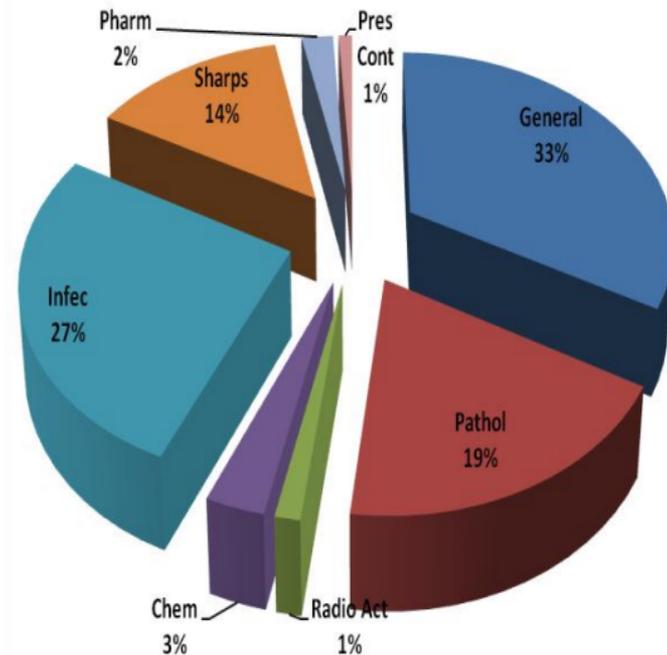
# Pharmaceutical Waste from HCFs

## *Generation rates in district hospitals*

Amana hospital



Ligula hospital



**Kagonji and Manyele (2011):**

- 1. 2% of HCW was pharmaceutical waste**
- 2. 45 and 50 kg/day for Amana and Ligula, respectively**
- 3. 16.2 to 18.0 tons/year for Amana and Ligula, respectively**

# **Why EUM in HCFs?**

- 1. Expiry**
- 2. Damage**
- 3. Patient own medicines**
- 4. Admission or assessment units**
- 5. Drug management during patient transfer**

# Packaging Waste from Pharm Products

- **Application of LCA of primary packaging**
- **Use ISO 14040 and ISO 14044 to make the LCA**
- **Proper selection of packaging leads to:**
  - **Reduced global warming**
  - **Reduced Primary energy consumption**
  - **Reduced respiratory organics**

# Pharmaceutical waste from Industrial Facilities

- **Large volumes**
- **Waste prevention**
- **Avoidance – re-use of products, repair, PPM, avoid disposables**
- **Considering value of waste, not only collection**

# Product Development and Research Facilities

- Regulations regard this group as HCFs, and they also hide behind the HCFs
- Waste management officers – look aside



Figure 4. Sample waste types from pharmaceutical formulation/testing laboratories.

## 2.0 PHARMACEUTICAL WASTE MANAGEMENT ISSUES FOR ALL GENERATORS

*The Hierarchy of Pharm-Waste Management*

## **2.1 Avoidance of Pharmaceutical Waste Generation**

- 1. EUM is preventable, Pharm-Waste is preventable.**
- 2. Resale procedures/possibilities**
- 3. Re-dispensing of unused medicine, not yet expired (concerns: counterfeit, QA, legal restraints), initiatives exist, lessons exit.**
- 4. Shipments as aid to Africa**

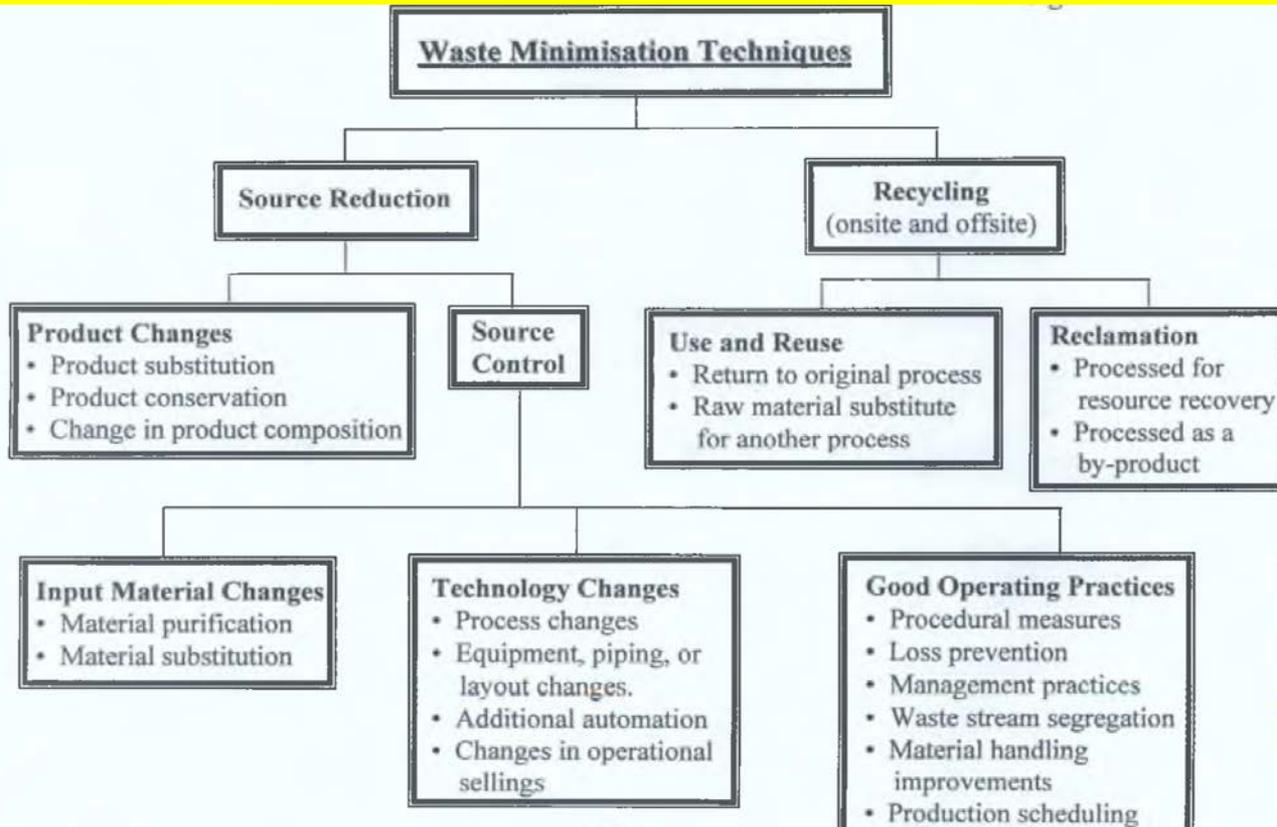
## **2.2    Pharmaceutical Waste Minimization Strategies**

- 1. The impact of medicines becoming waste – on Healthcare budget**
- 2. Prevent Pharmaceutical products from becoming UEM**
- 3. *Involve key stakeholders*: we suggest that laws and regulations do not become a burden to the waste generators**
- 4. *Pressure on MSD* leading to generation of UED (MoH procedures, PPRA, Internal challenges)**

## 2.2 Pharmaceutical Waste Minimization Strategies ....

5. Extend shelf-life of drugs
6. Re-distribute unused medicines (UM)
7. Marketing of close-to-expiry-date medicines (19% of UEM returned in the Netherlands is eligible for re-dispensing)
8. Digital network of UM for sharing stocks before expiry (**Prescription Promise**, **PharmSwap** are trying, why not)

# Pharm-Waste Minimization in the Industry



## Other technical issues:

- PPM
- Consistent power supply
- Well-trained personnel
- Switching from solvent- to water-base systems

## **2.4 Pharmaceutical waste collection system components**

- 1. National drug collection programme**
- 2. Collection method**
- 3. Legislation**
- 4. Funding options available**

## 2.4.1 National Pharm-Waste collection programs - characteristics

✓ Collection by Pharmacies

✓ Compulsory take back system (pharmacies or industry)

✓ Locally organised collection programs

✓ National collection system via pharmacies

✓ National EPR scheme

✓ Voluntary collection points in some pharmacies, or municipal offices

## **2.4.3 Legislation for Pharm-Waste collection**

- ✓ **Act on Maintaining Municipalities Clean**
- ✓ **Decree on expired drugs, cytotoxic and cytostatic drugs**
- ✓ **Environmental Management Act**
- ✓ **Legislation: National by the FDA, Provincial**
- ✓ **Official Gazette**
- ✓ **Regulations: Retail Pharmacy Businesses, National Health Service**
- ✓ **Municipal waste handling Rules**

## **2.4.4 Funding options available for Pharm-Waste collection**

- 1. EPR, financed by the pharmaceutical industry**
- 2. Government**
- 3. Pharmacies bear the cost**
- 4. Local government Authorities/municipalities**
- 5. Medicine wholesaler**
- 6. Pharmaceutical industry**

## **2.5 Reducing Pharmaceutical Waste in Pharmacies and Stores**

- 1. Prioritize Pharm-Waste management**
- 2. Keep track of medication expiry date**
- 3. Initiate and participate in drug take back days**
- 4. Engage in ongoing planning and education on proper Pharm-Waste management**

## **2.9 Pharmaceutical Waste Treatment and Disposal**

- 1. Impact of Improper Disposal of Pharmaceutical Waste**
- 2. Cost of Disposal for Pharmaceutical Waste**
- 3. Disposal Methods and Remedial Measures**
- 4. The Need for Secure Disposal of Pharmaceutical Waste**
- 5. Disposal of Pharmaceutical Waste by High Temperature Incineration**
  - The technical challenges**

## 2.9.1 Impacts of improper Pharm-Waste Disposal

1. Contamination of water supplies, water bodies and soil
2. Diversion into markets for resale, ,misuse, less efficacy, may develop different adverse reactions
3. EDCs in prescribed hormones may cause tumors in humans (emerging chemicals, emerging issues)
4. Antibiotics cause transfer resistance genes (harmless microbes becoming deadly pathogens)
5. Other problems: Lack of WWTPs in most parts of the cities in SSA: case of Dar es Salaam expansion

## **2.9.2 Cost of Disposal of Pharm-Waste**

- 1. The cost is higher, especially at lower volume, hence, dumping**
- 2. Higher than manufacturing**
- 3. For disposal at higher temperatures (WHO, 1999):**
  - US\$ 4.4 to \$8.2 million in the US**
  - 0.5 to 2% of total sale in India**
  - 25-35% of total burden of disease world wide**
  - US \$(2.2-4.1)/kg @ WHO**

# Disposal methods

Table 1: Pharmaceutical Waste Management Methods

Method	Safety	Ease	Cost
Landfill	High possibility to leak into waterways	Easiest method	N/A
Returning to Original Source	Depends on the source and how they dispose of the pharmaceuticals	Can be difficult if pharmaceuticals are expired and travel internationally	N/A
Incineration	Possibility for toxic gaseous by products	Access to able facilities is difficult	>US \$2.2/kg - US \$4.1/kg
Encapsulation	Can handle all types of pharmaceuticals in both solid and liquid states	Can send to an encapsulating company or use a machine	Machines can be purchased to complete this task



Information that inspired this table was compiled from World Health, 1999

## **2.9.3 The Need for Secure Disposal**

- 1. Brand integrity, reject prevented from finding their way to the market**
- 2. Danger of life for drugs that fail QA/QC**
- 3. Prevent environmental contamination**
  - Emissions from industrial discharge higher than emissions from consumption**
  - Point source pollution (API formulation into drugs products is done in specific locations)**

## **2.9.4 Challenges of Pharm-Waste Incineration**

- 1. Heavy metals in the incinerator ashes**
- 2. Glass bottles and vials in ashes**
- 3. Necessity of further treatment/disposal processes**
- 4. Poor waste segregation at the source or generation points**



# Technical Challenges of Pharmaceutical Waste Incineration



Scientific  
Research

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*Engineering, 2011, 3, 1045-1053*

doi:10.4236/eng.2011.310130 Published Online October 2011 (<http://www.SciRP.org/journal/eng>)

## **Assessment of Medical Waste Incinerator Performance Based on Physical Characteristics of Ashes**



# Assessment of the heavy metal - levels in the incinerators bottom-ash from different hospitals in Dares Salaam

A. Honest<sup>1\*</sup>, S. V. Manyele<sup>2</sup>, J. A. Saria<sup>3</sup> and J. Mbuna<sup>4</sup>

**Table 2.** Average heavy metals concentration in bottom ash from selected hospital incinerators (in mg/kg).

	<b>MNH</b>	<b>Ilala</b>	<b>Mwananyamala</b>	<b>Temeke</b>
Cr	0.16 ± 0.09	0.33 ± 0.27	0.17 ± 0.09	0.26±0.07
Cu	61.31± 13.91	52.04± 0.79	73.37± 4.73	83.01± 13.93
As	BDL	BDL	BDL	BDL
Pb	0.24 ±0.11	0.68 ± 0.58	0.25 ± 0.13	0.54 ± 0.26
Fe	409.62 ±52.98	213.33 ±58.32	344.42 ±54.37	556.32 ±55.71
Cd	0.019 ± 0.010	0.011 ± 0.005	0.016 ± 0.013	0.011 ± 0.005
Zn	77.32 ±19.32	89.58 ±10.13	67.09 ±8.20	87.30 ±19.51
Mn	68.04 ±21.25	42.22 ±07.17	53.03 ±03.10	43.02 ±06.00

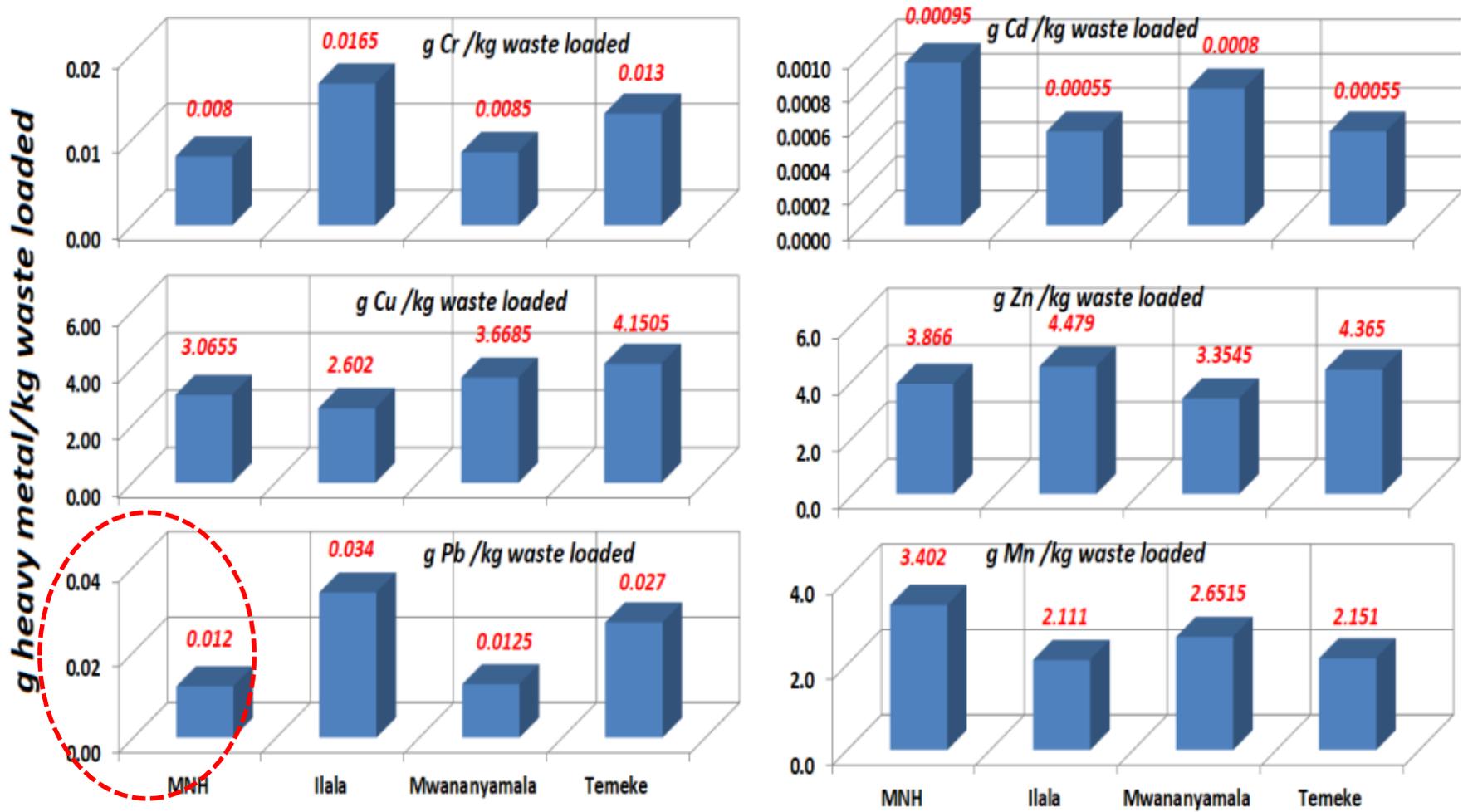


Figure 4. Quantities of heavy metals in the waste loaded per cycle based on concentration in the bottom ashes.

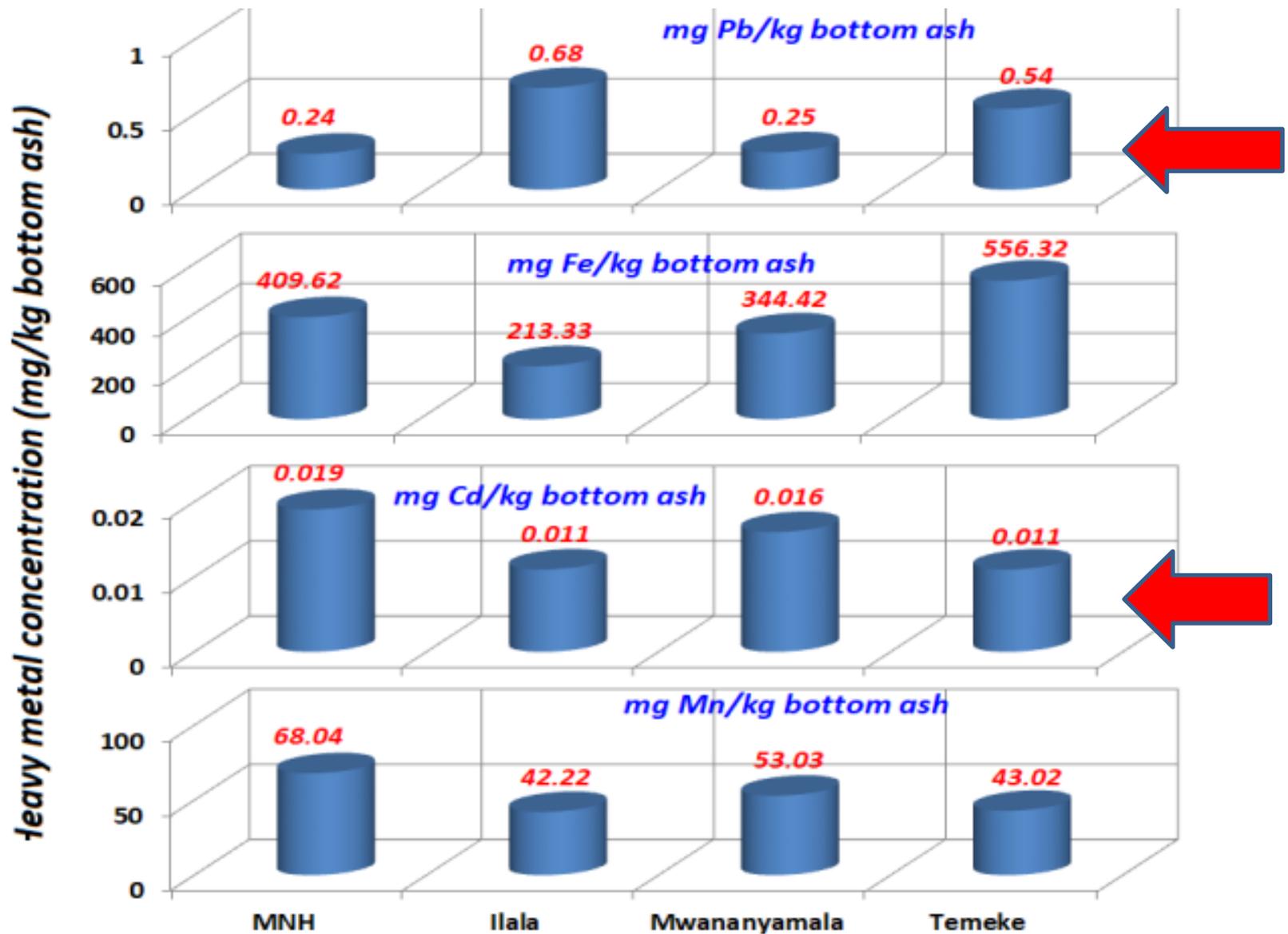
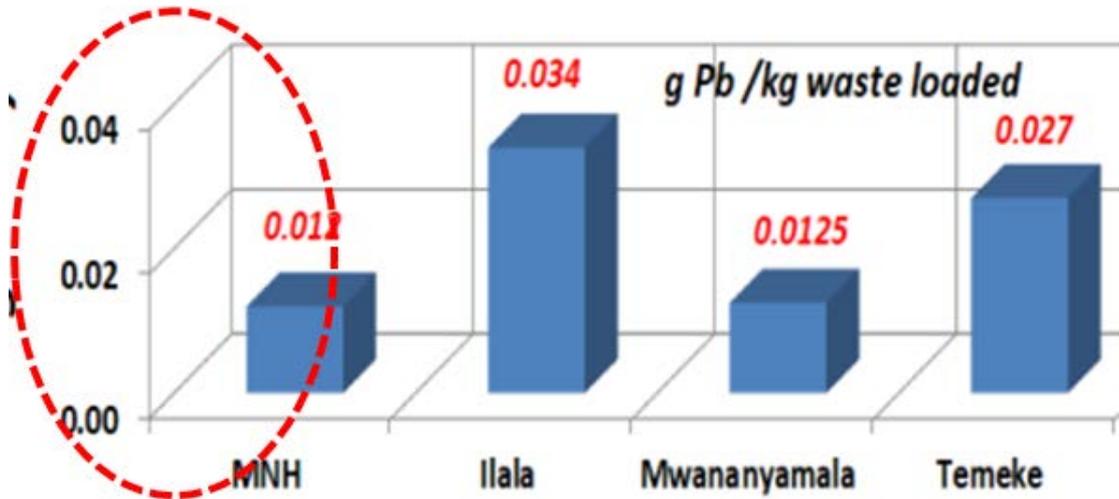
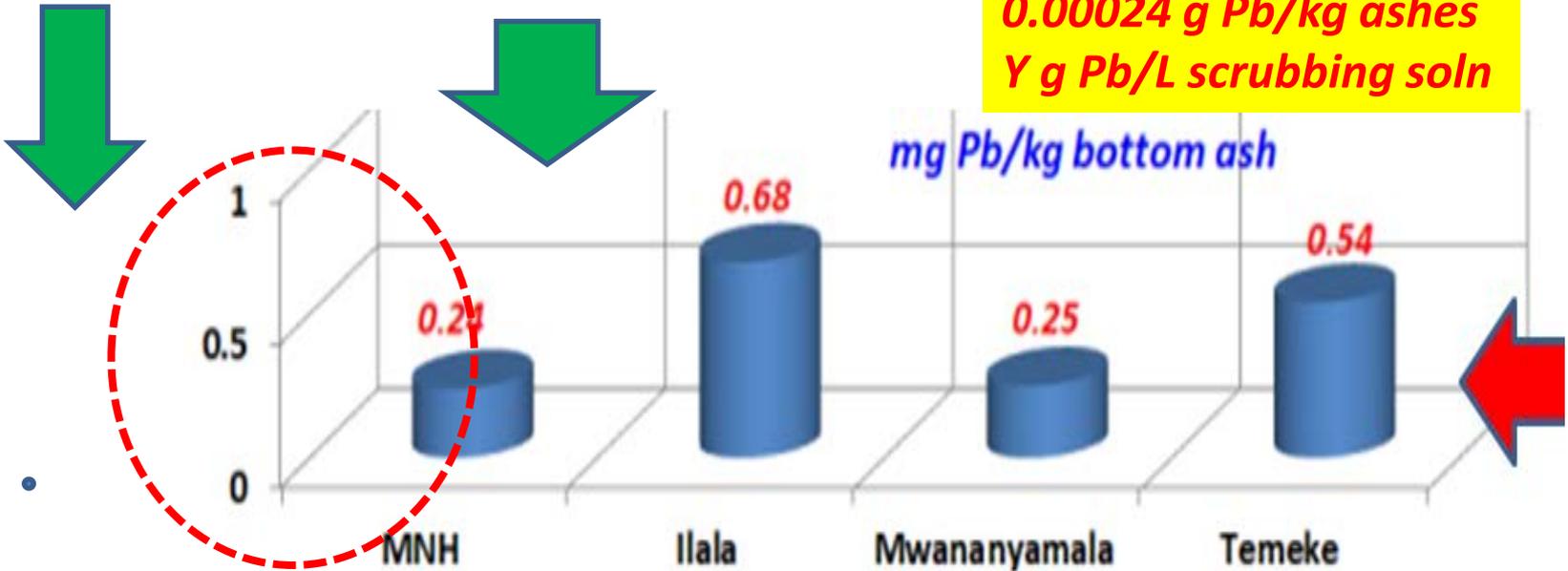


Figure 3. Comparison of the heavy metal concentration in bottom ash between different HCW incinerators.



1. Determine Pb in waste
2. Determine Pb in ashes
3. Determine Pb in scrubbing solution

**MNH:**  
*0.012 g/kg waste*  
*0.00024 g Pb/kg ashes*  
*Y g Pb/L scrubbing soln*



## **3.0 CROSS-CUTTING ISSUES IN THE PHARMACEUTICAL WASTE MANAGEMENT**

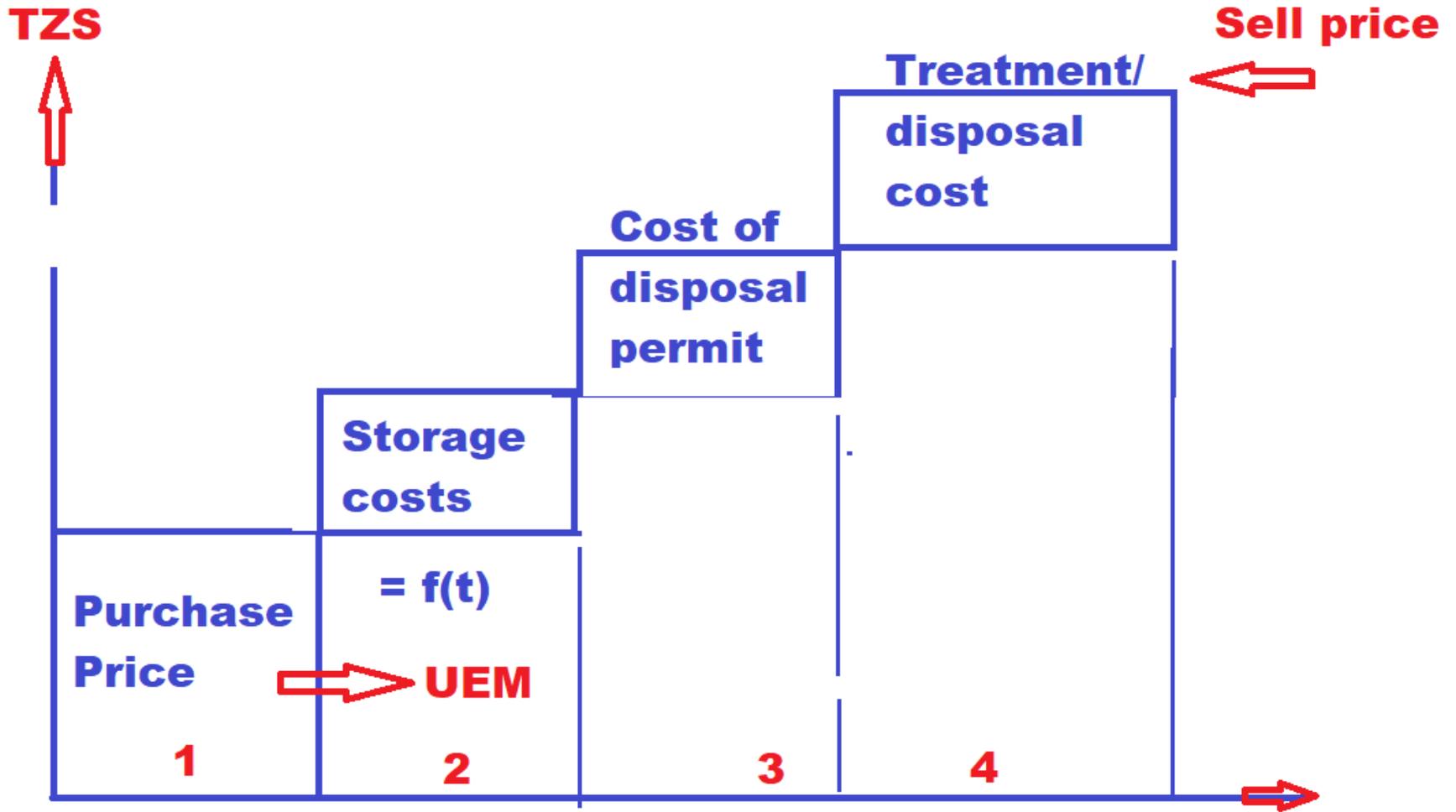
## **3.1 Challenges of Pharm-Waste Management**

- 1. Where Pharm-waste management is supervised by non-professionals of WM**
- 2. Lack of resources/expertise for managing waste**
- 3. Leachate from the landfills accepting Pharm-Waste:**
  - UK: 13% of WWTPs contain drugs (diclofenac, propranolol, buprofen, ethinylestradiol)**

## **3.2 Pharmaceutical Waste Management Practices in Pharmacies**

- **Challenging Experiences from Pharmacy Operators**
  - **They consider pharm waste as a loss**
  - **Treatment/disposal permit as additional loss**
  - **Treatment cost as an additional loss**
  - **Most pharmacies in SSA are small, not part of the chain, generate small quantities, high cost/kg**

# Disposal cost elements vs. price of medicines in pharmacies



## **3.2 Pharmaceutical Waste Management Practices in Pharmacies**

- **Need for awareness**
  - **Provide information on Pharm-Waste Management**
  - **Information campaigns, open day collection, TV, Radio**
  - **Incentives for returning medication**
  - **Product eco-Labeling**
  - **Environmental classification Schemes**

## 3.4 Key Policy Recommendations

1. Prevent unused or expired medicine
2. Marketplaces and redistribution platforms for
3. Customize the collection of unused medicines
4. Implement an EPR scheme
5. ePharmacies put in place
6. Develop a Drug take-back system and review it regularly
7. Awareness raising campaign

## 3.5 Economic Approaches to Pharmaceutical Waste Management in the Industry

- Circular economy (CE)
  - As part of the global SC
  - Promote reduction,
  - Maximize value of waste
  - Apply: 3R, 4R and 9R models
- Sufficiency economy philosophy (SEP)
  - Defined by the UN in 2012
  - Improve planning for sustainability

## 4.0 Regulatory Aspects of Pharm Waste

1. Analysis of Acts relating with Pharm-Waste management
2. Proper disposal of medicines is not only **important for compliance** but in consideration of public safety and the environment.
3. Regulatory distinction between hazardous waste, medical waste , Pharm Waste, chemical waste will hamper a environmental protection
4. Despite regulations in this respect, there has not been a single law that would clearly explain the procedures of **Pharm-Waste from Alpha to Omega**

# Environmental Management Act

## *Tanzania*

Pharmaceutical waste is still regulated under  
Healthcare/Medical Waste Category in Tanzania

### PART VIII

### PESTICIDES, RADIOACTIVE AND CHEMICAL WASTE

52. Management of pesticides waste.
53. Management of radioactive waste.
54. Management of industrial and consumer chemical waste.

# Environmental Management Act

## *Tanzania*

Pharmaceutical waste is still regulated under  
Healthcare/Medical Waste Category

### PART VII

#### HEALTH CARE WASTE

45. Segregation of health care waste.
46. Securing and packaging of health care waste.
47. Treatment of health care waste.
48. Storage of health care waste.
49. Transportation of health care waste.
50. Transfer stations.
51. Monitoring.

# Efforts by UNEP

- **Basel Convention – deals with hazardous waste (TBM, Responsibilities of the MS)**
- **Waste management guidance documents (EWG –ESM) – 2014-2018**
- **Decisions made by the CoP regarding Hazardous Waste**

# CONCLUSION

- 1. Current waste classification methods**
- 2. Analytical methods used in the identification of pharmaceuticals in the environment**
- 3. The public's awareness of the problem of Pharm-Waste**
- 4. The importance of the participation of society, governmental agencies and the entire productive chain is fundamental**
- 5. The guidance and monitoring of the habits of the population is part of the construction of an organized policy on the proper storage and disposal of residential medicines**