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

## **Session 2: Deep dive into document and application at country level**

WHO HQ, Geneva

1 October 2024



# Background review on current policies and practices for pharmaceutical waste management

By

Stella Nanyonga

University of Oxford

1/10/2024

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# Introduction

- Pharmaceuticals waste (PW) includes pharmaceuticals that are expired, no longer needed, or contaminated (*Chartier 2014*).
- Generated along the life cycle of a drug : production, distribution, storage and use.
- Generated during emergencies: mismatched donations, short expiry dates of donated items, inadequate storage, and donations which are in excess of the local demand (*Schlottke et al. 2023*).
- Pharmaceutical products have a high potential for bioaccumulation and synergistic effect; contaminants of emerging concerns (CECs) for the ecosystem.
- Medicines have the characteristics of flammability, corrosiveness, reaction acceptability, and toxicity that are given in the same list.

# Methods

## Aim

To gather available data and identify best practices for the management of pharmaceutical waste both during routine healthcare and in emergency situations.

## Methods

1. Rapid review (MEDLINE and EMBASE and grey literature)
2. 72 publications included



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# Practices

- Global practices of PW minimisation and disposal differ due to varying resource capacities among countries (*Jangre, Prasad, and Patel 2023*).
- A review of 30 HCWM policies and guidelines from different countries showed that a total of 53% (16/30) of these policies and guidelines had no or only basic mention of PW without delving into the detailed handling and management practices for PW.
- There is limited data related specifically to PW management because it is generally managed mixed with other HCW (*Sapkota and Pariyatamby 2023*).

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# Practices

1. Waste minimisation at all stages of the supply chain : Manufacturing, procurement, distribution, storage, use (*Smale et al. 2021*).
2. The WHO recommends to return PW to the supplier/manufacturer (*WHO, 1999*) : Take back program ( 33 countries).
3. On-site receptacles at pharmacies constitute the most common collection system. One-day collection events or mail-back envelopes are also offered in some countries (e.g. United States).
4. Some programs rely only on government funding (e.g. Australia) while others are financed by contributions from the pharmaceutical industry or from pharmacies that provide support on a voluntary basis or driven by extended producer responsibility (EPR) legislation ( *OECD, 2024*).

# Management of pharmaceutical waste in emergency situations

- Return to the donor or manufacturer.
- Small quantities of liquid PW drain down the sewer.
- Small quantities of solid PW, use medium temperature incineration ( $\geq 850^{\circ}\text{C}$ ), encapsulation, high temperature incineration (greater than  $1200^{\circ}\text{C}$ ), chemical decomposition.



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# Challenges in PW management

- Limited data: pharmaceutical products, manufacturing facilities, warehouses, disposal capacity.
- Inadequate regulatory frameworks and compliance monitoring.
- Limited infrastructure for waste segregation and treatment (LMIC).
- Technological Limitations: Treatment facilities to neutralise PW.
- Cost of managing PW is high especially in LMICs.
- Lack of awareness / knowledge on the hazardous and risks of poor PW management.
- Uncoordinated donations .
- Expanded Producer Responsibility is not adopted



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# Opportunity

Regional Collaborations: ASEAN, Middle East Gulf Cooperation Council (GCC) Association of Southeast Asian Nations (ASEAN), The SADC Protocol on Health (1999) and the EAC Regional Health Sector Strategic Plan (2015-2020) have no mention of HCWM.

Strengthening Regulations: Developing and enforcing stricter regulations .

Standardizing Waste Segregation Protocols at source.

Innovative Technology for Tracking Waste ( we need to quantify the problem).

Public-Private Partnerships ( Industry).

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# Recommendations

- Map existing pharmaceutical products; consumption, manufacturing facilities , waste treatment capacities, waste volume.
- Incorporate PW guidelines into HCWM guidelines and policies.
- National emergency preparedness plan or medical counter measure plans; emergency warehouse capacity and emergency kits.
- Database of environmental risk assessments for new and existing pharmaceuticals; toxicity of the API, environmental risk, health impact and ease of degradability.
- Mapping and regular surveillance of pharmaceuticals in the environment; wastewater.
- Include API thresholds into the waste water and drinking water regulations

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# References

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# Thank you



# Opportunities and Challenges in Managing Pharmaceutical Waste

Nancy Muller,  
Independent Consultant

October 1, 2024



# Purpose and approach

## PURPOSE

- Landscape of gaps and opportunities in policies, technologies, and systems for managing pharmaceutical waste in lower-level public health facilities

## APPROACH

- Review of July 2024 Best Practices document; global Policies table; WHO Safe Disposal in Emergencies document (1999); literature (2012-present); technical experts
- Webinar - input from country-based experts
- Analyze and report – November 2024

# Review of literature – high level findings

- **Policies and literature represent middle- to high-income countries** – more research needed in LMIC
- Focus in LMIC literature is on **household management** of pharmaceutical waste
- **Insufficient awareness among community and health workers** regarding proper management of pharmaceutical waste
- **Prevention of pharmaceutical waste is most effective strategy**

# Policy - Gaps

- **Policies emphasize treatment and disposal technologies:** Greater attention needed for planning, management, data, procurement, training
- **Procurement guidance:** may contradict best treatment protocols
- **Human resource policies and budgets:** lack clarity
- **Safety protocols:** Inadequate for health worker/waste handler
- **Storage:** Acceptable conditions not clear



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# Policy - Opportunities

- **Clear, evidence-based information on human and environmental risks** needed to guide budgets and planning
- **Develop a risk-based approach by level of infrastructure level:** Identify high-risk pharmaceuticals (human and environmental health) and recommended waste management approaches
- **Ensure procurement guidance** offer optimal treatment protocols while considering environmental impact



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# Systems - Gaps

- **Insufficient attention to logistics management** - data needed to track inventory, locations, and status
- **Clarity needed on specifications for secure storage of pharmaceutical waste**
- **Inadequate training and awareness among healthcare workers and community** about risks and proper management of pharmaceutical waste



## Systems - Opportunities

- **Prevent waste generation** through credits/incentives eg. return of unused pharmaceuticals
- **Engage procurement expertise to reflect best practices** in process optimization
- **Explore digital collection of pharmaceutical waste data** for planning, evaluation, and informed decision-making
- **Involve cross-sector stakeholders in advisory committees**
- **Simple job aides and communication messages** – raise awareness of potential health and environmental risks

# Technology - Gaps



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- **Open burning and low-temperature incineration:** overreliance, especially at lower levels
- **Engineered sanitary landfills:** feasibility
- **Transport:** Insufficient systems to move volumes of waste
- **Availability of clear protocols and safe containers** for transporting immobilized/inertized ash residue waste to landfill
- **Labeling:** Unclear disposal information

# Technology - Opportunities

- **Identify regional manufacturing sources of equipment and technologies** including waste containers and PPE.
- **Explore reverse transport systems** eg. secure trailers attached to existing MOH vehicles.
- **Engage universities and schools of engineering in design** for feasible sanitary landfills and improved on-site treatment
- **Use of digital communication tools for tracking waste** and identifying possibilities for redistribution of returned or excess stock, as aligns with policy.



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# Future directions

- **Develop global best practices database** for all aspects of pharmaceutical waste management.
- **Explore the role of barcoding, artificial intelligence, and machine learning.**
- **Creative reimagining of waste as part of the circular economy** and not just an end-of-pipe disposal exercise



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## Next steps

- **Webinar** next month targeting country experts on pharmaceutical waste management-reality and best practices
  - All welcome
- Report findings – Nov 30

# Best Practices for Safe Disposal of Pharmaceutical Waste

Technical Consultation Meeting

Implementation case study: collection and treatment of unused medicines in Serbia

Viktor Hristov

WHO Geneva 1<sup>st</sup> October 2024



# Background

- First Project (Grontmij, Etlog, Eurohealth)- Technical assistance for Healthcare Waste Management Project 2007-2009 ( 78 treatment systems; 54 healthcare institutions, 25 vehicles and more than 4000 trained healthcare workers)
- Second Project (COWI, Eurohealth) – Technical Assistance for Treatment of Health Care Waste 2010-2013 (42 treatment systems, 29 healthcare facilities, 13 Veterinary institutes, 9 vehicles, more than 3500 trained healthcare and veterinary workers...
- Serious amounts of pharmaceutical waste were evidenced

# Situation analysis



# Situation analysis



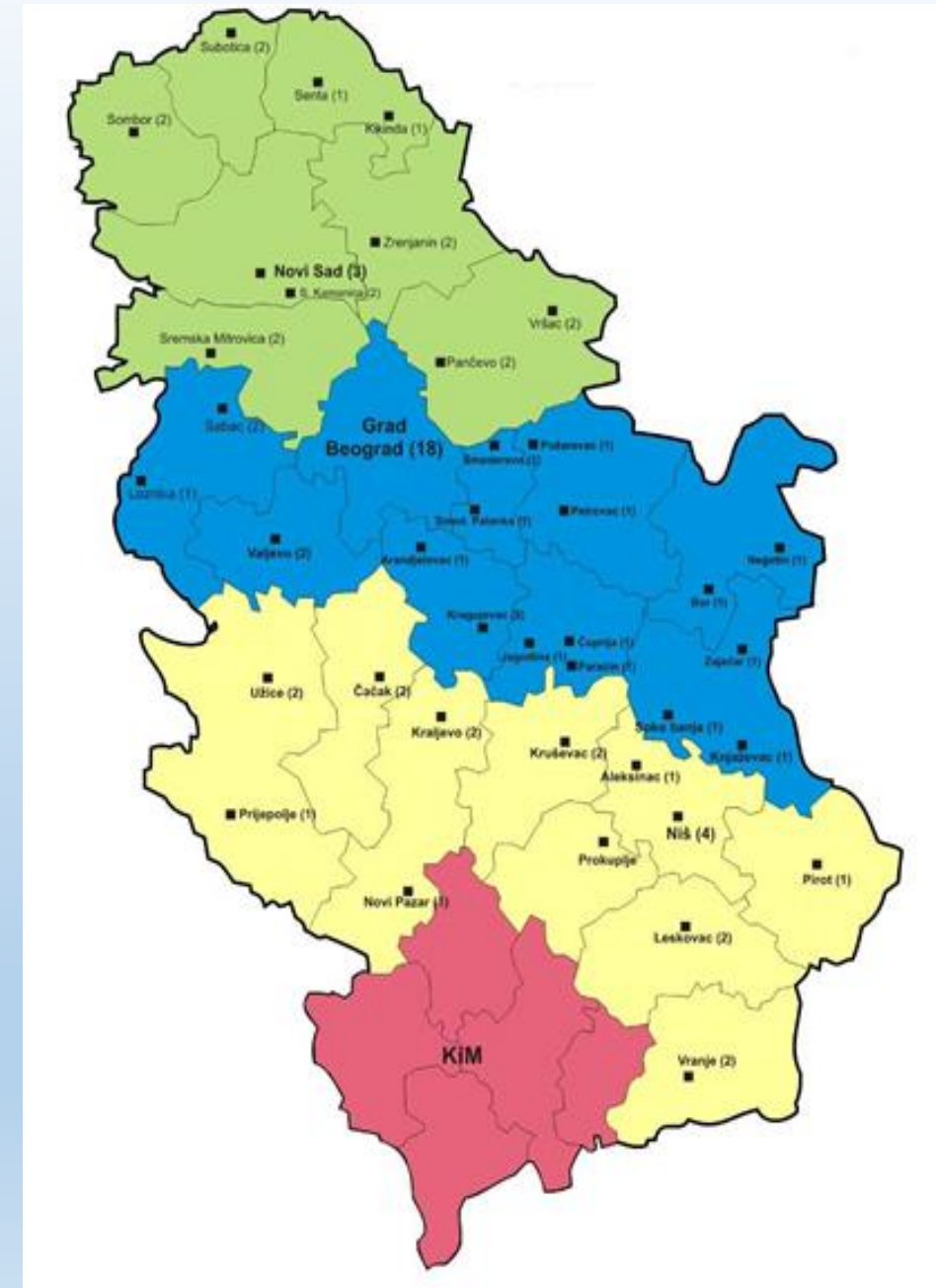
# Situation analysis

Defining the scope and objectives:

- **Ensuring Strong support and commitment from National stakeholders!!!**
- 25 Healthcare Districts
- More than 300 human healthcare institutions
- More than 50 veterinary healthcare institutions
- Military and civil defense facilities

Needs assessment:

- Professional company with competence and experience
- Permits, licenses, and certificates
- Collection requirements
- Packing materials and logistics arrangements
- In-country transport (ADR)
- Export procedure (Basel Convention and ADR)
- Import and destruction (incineration)
- Documentation and Evidence for completion of works



# Requirement

The Delegation of EU in Serbia, in cooperation with the Ministry of Health, launched a tender for Services with the following objectives:

To support the Ministry of Health, the Ministry of Agriculture, Forestry and Water Management (Veterinary Directorate) with the removal of accumulated pharmaceutical waste from healthcare facilities and veterinary institutes and to ensure the safe collection, transport, destruction, and disposal of said waste.

In particular, the services to be provided included:

- packing and preparing for the collection of around 300 tons of pharmaceutical waste stored in healthcare facilities and veterinary institutes throughout Serbia,
- collection and transportation of pharmaceutical waste followed by export to a country with adequate hazardous waste incineration/treatment facilities, and
- incineration or destruction and disposal by other means of the pharmaceutical waste collected in compliance with all applicable European and Serbian legislation.
- Execution of contract 18 months

**Technical Assistance project to provide supervision of the execution of the activities**

# Realization

**3 companies submitted the offers**

**Selection criteria:**

**1) Economic and financial capacity of the candidate:**

**2) Professional capacity of the candidate:**

- **Successfully completed 2 similar projects within the 3-year period**
- **Other projects that includes the elements (re)packing, international transport and incineration/destruction of pharmaceutical and/or hazardous waste**
- **Qualification and certification of employees**

**3) Adequate licenses and permits: ADR, Management, handling, treatment or incineration hazardous waste**

**4) Technical capacity of candidate**

- **Methodology**
- **Time schedule**
- **Project Team**
- **Technical resources that will be used in the activities**

**Award criteria: Best value for money**

**Contract awarded to: KEMIS DOO (Srb), KEMIS-TERMOCLEAN DOO (Cro) and WSA Waste Service GmbH (Aut)**

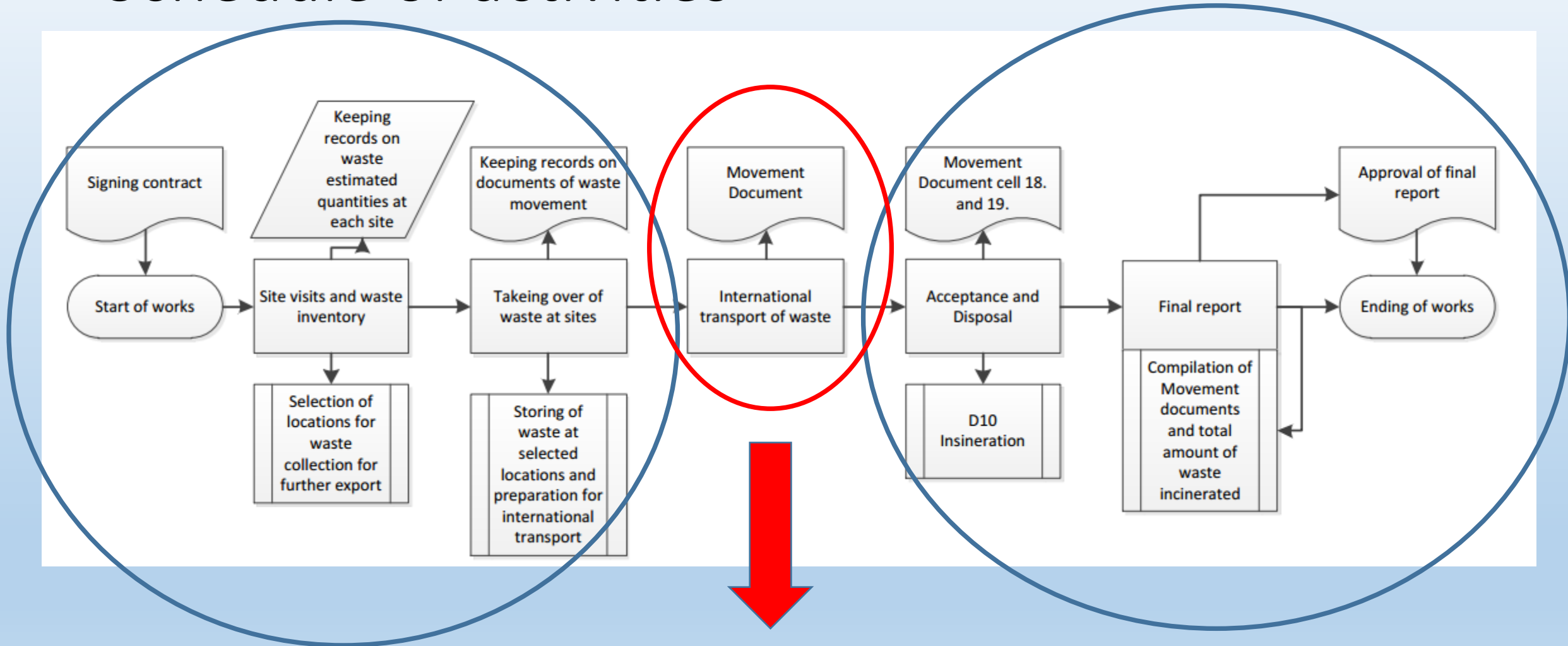
**[https://europa.rs/tenderi/zatvoreni/2011/EuropeAid\\_131768\\_4\\_Award.pdf](https://europa.rs/tenderi/zatvoreni/2011/EuropeAid_131768_4_Award.pdf)**

**Value of the contract:**

**Contract number: 289177.**

**Value of the contract: 484 185 EUR**

# Schedule of activities

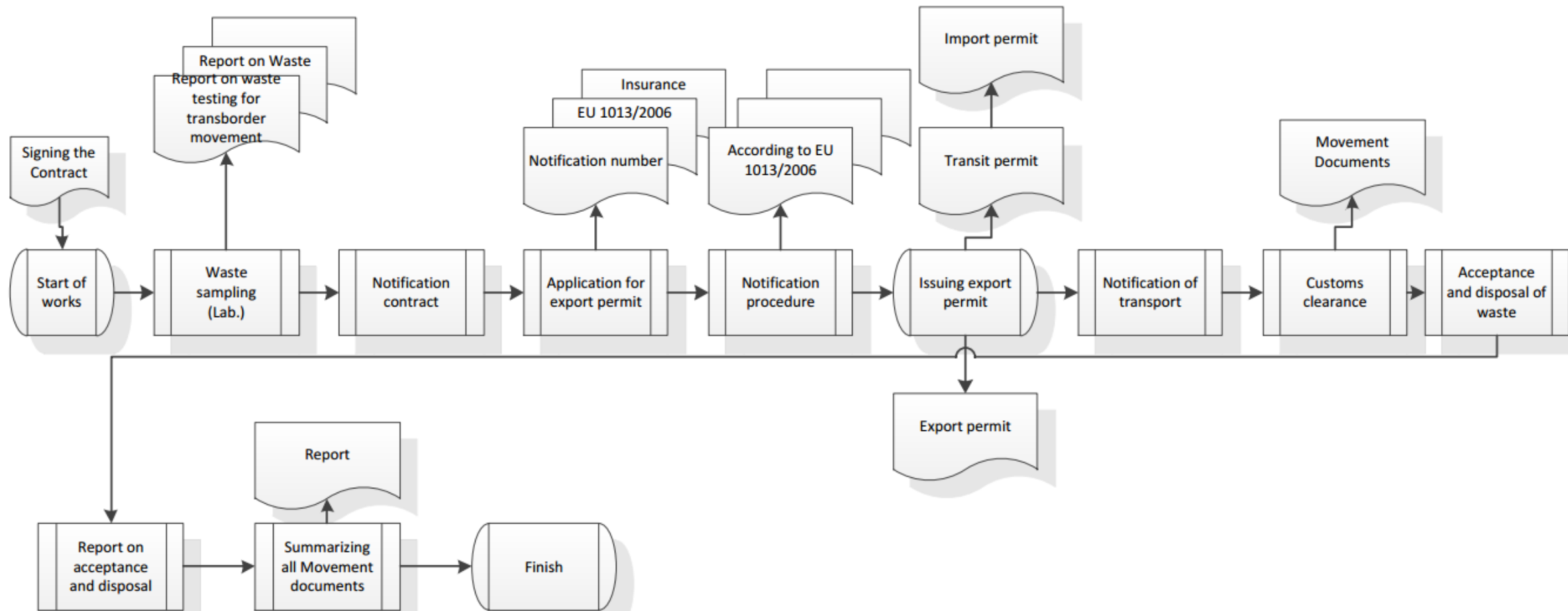


Collection packing and labeling Works

Export Notification Procedure

Export and Incineration

# Basel Convention - Export Notification Procedure





# Execution



Each storage was visited and assessed before the operations. Site Specific Action Plans will be developed for all storages with accumulated more than 1,000kg of waste. These must were reviewed and accepted by the Team Leader of the TA-HCW Project (Supervisor) prior to implementation and were implemented with high priority.

All packaging, labelling and collection of waste, along with the cleaning of storage site, if needed, was conducted according to site specific plans of actions. The plans were also submitted to the Labor Inspection in the city where activity is performed, as required by the Serbian legislation.

At locations with an accumulated waste amount of 1,000 kg or more the safety adviser will conduct direct, on-site supervision, while at healthcare facilities or institutes with less than 1,000 kg indirect supervision will be conducted. The verification will be conducted on the basis of documentation and photographs.

For storages that contain less than 1,000kg, the packaging, labelling and collection of waste will be performed without Site Specific Action Plan or supervision of DGSA.

# Execution – Logistics Arrangements



Bringing waste from smaller locations to Export Storage

Example: Waste from 61 locations in Vojvodina region was stored in 3 export storages

12 export storages were established across the whole Serbia



# Execution – Collection/Packing/Labeling



# Execution – Special attention



Chemical Waste



Not used vaccines



Regulated pharmaceuticals



Cytotoxic Waste

# Execution – Temporary storage



# Execution – Export for Incineration



# Execution – Waste Movement Document

**Movement document for transboundary movements/shippments of waste**

1. Corresponding to notification No: **SRB 19-00-0023/2013-05**

2. Serial/total number of shipments: **350**

3. Exporter - supplier Registration No: **RANK DOO**  
 Name: Rank doo  
 Address: Bulevar part brnca 915/2 br. 6, 14000 Vukovo, Serbia  
 Contact person: **Ms. Maja Milić**  
 Tel: +381 11 4142045  
 Fax: +381 11 2281434  
 E-mail: majam@rankdo.com

4. Importer - consignee Registration No: **WEN ENERGIE GMBH**  
 Name: WEN ENERGIE GMBH  
 Address: Hohenhofstrasse 21, A-1110 Wien, Austria  
 Contact person: **Mr. Thomas Leher**  
 Tel: +43 1 31326 010  
 Fax: +43 1 31326 016  
 E-mail: thomas.leher@wienenergie.at

5. Actual date of shipment: **18.11.2013**

6. Actual date of shipment: **18.11.2013**

7. Packaging: **251.458**

8. (a) 1st Carrier (SI): **JURICIC & Co.**  
 Registration No: **KR 50 747 / KE DC 873**  
 Name: Juricic & Co  
 Address: Plovidna cesta 445 SI  
 Contact person: **Mr. Andrej Magrac**  
 Tel: +386 41 711000  
 Fax: +386 41 711000  
 E-mail: andrea@juricic.com

9. (b) 2nd Carrier (SI): **JURICIC & Co.**  
 Registration No: **KR 50 747 / KE DC 873**  
 Name: Juricic & Co  
 Address: Plovidna cesta 445 SI  
 Contact person: **Mr. Andrej Magrac**  
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10. (c) 3rd Carrier (SI): **JURICIC & Co.**  
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**12. Designation and composition of the waste (2):**  
 Wastes from the MFSU (manufacture, formulation, supply and use) of pharmaceuticals and medicines – partly mixed waste

**13. Physical characteristics (1):** 1, 2, 3, 5

**14. Waste identification (6) in relevant codes:**

(i) Basel Annex VIII (or IX if applicable): A 4010

(ii) OECD code (if different from (i)): A 4010

(iii) EC list of wastes: 070513\*, 070503\*, 070504\*, 070514, 150110\*, 150202\*, 160303\*, 160306\*, 160108\*, 180109, 180207\*, 180208, 200131\*, 200132

(iv) National code in country of export: A4-1 A4010

(v) National code in country of import: 53502

(vi) Other (specify):

(vii) Y-code: Y2 /Y3

(viii) H-code (1): H361.1H12/H13

(ix) UN class (1): 3,9,6.1

(x) UN Number: 3007, 3082, 2811, 3248, 3248

(xi) UN Shipping name: Waste, medicines, envir hazard substance solid and liquid  
 N.O.S. toxic, flammable

(xii) Customs code(s) (HS): 3008 92 0000

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 Contact person: **Ms. Maja Milić**  
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 Fax: +381 11 2281434  
 E-mail: majam@rankdo.com

4. Importer - consignee Registration No: **WEN ENERGIE GMBH**  
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 Address: Hohenhofstrasse 21, A-1110 Wien, Austria  
 Contact person: **Mr. Andrej Magrac**  
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84. Date of receipt: **19.11.2013**

85. Date of receipt: **19.11.2013**

86. Date of receipt: **19.11.2013**

87. Date of receipt: **19.11.2013**

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89. Date of receipt: **19.11.2013**

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97. Date of receipt: **19.11.2013**

98. Date of receipt: **19.11.2013**

99. Date of receipt: **19.11.2013**

100. Date of receipt: **19.11.2013**

**19. I certify that the disposal/recovery of the waste described above has been completed.**

Name: **19.11.13**

Date: **19.11.13**

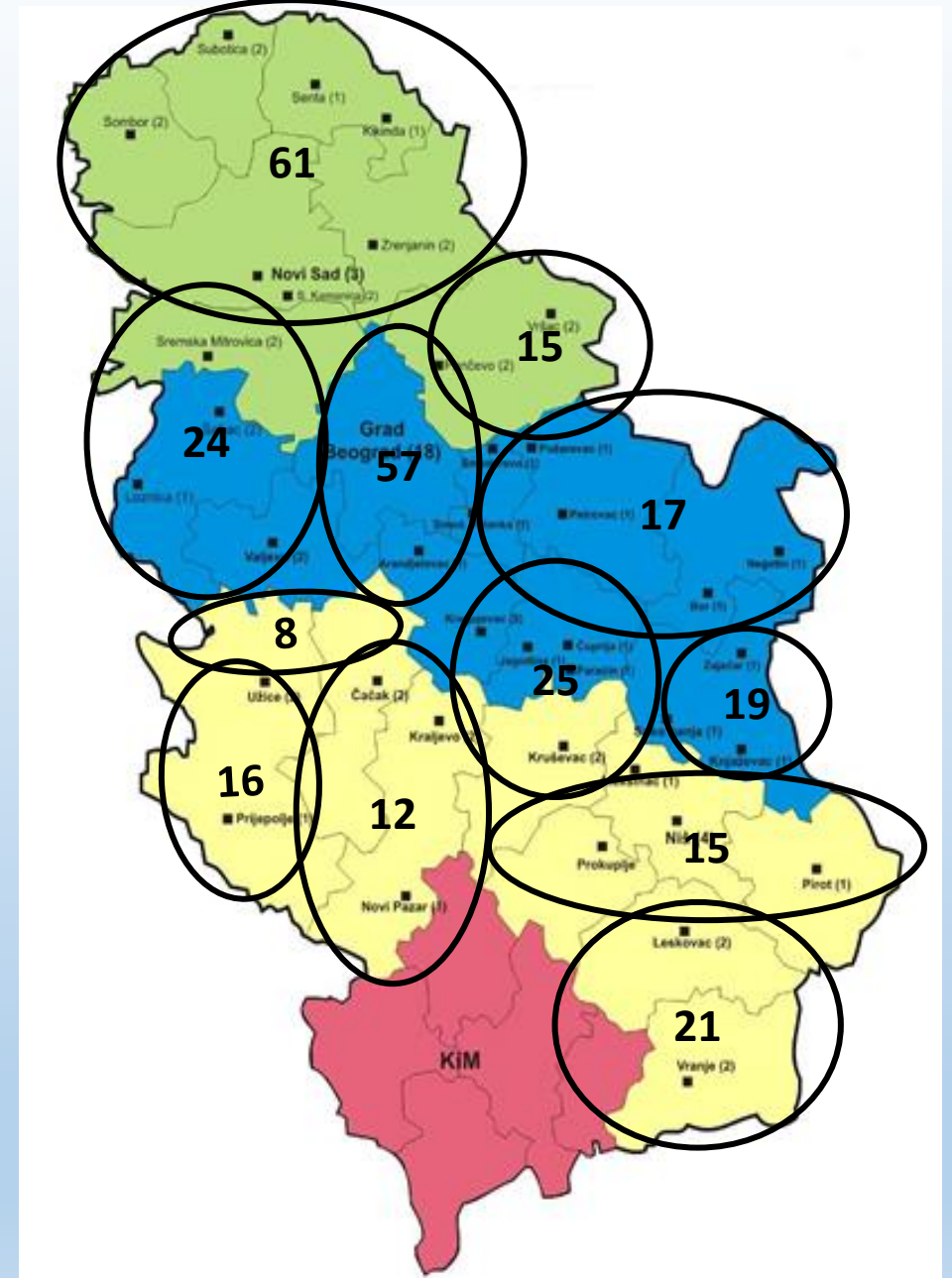
Signature: **[Signature]**

**Wien Energie GmbH**  
 Werk-Simmeringer Haide  
 Hohenhofstrasse 21, A-1110 Wien

(4) Required by the Basel Convention  
 (5) Attach to 4 more than one  
 (6) If required by national legislation

# Overall results

Total Transport				
No.	Region	Amount of waste (kg)	No. of transports (500kg)	Total km
1	Novi Sad	44,020	108	12,946
2	Pancevo	10,770	28	2,320
3	Pozarevac	10,590	28	1,814
4	Sabac	14,400	39	3,490
5	Valjevo	3,290	10	350
6	Kragujevac	19,290	47	3,090
7	Zajecar	15,570	40	3,814
8	Uzice	9,450	26	2,510
9	Kraljevo	21,650	58	6,660
10	Nis	23,530	56	3,090
11	Leskovac	12,580	35	3,990
12	Beograd	74,910	171	4,350
		260,050	646	48,424



TOTAL: 239 locations cleaned, Appx. 300 Tons of pharmaceutical waste was exported for incineration in less than 18 months



# Pharmaceutical waste – Beyond the project

Serbia developed Guidelines for the management of Pharmaceutical waste OGRS, No 78/10

Source segregation of pharmaceutical waste performed by healthcare institutions.

Healthcare institutions can contract services for pharmaceutical waste collection and disposal with licensed operators

Collection of pharmaceutical waste from households and residents is still a pending issue

Техничка подршка за третман медицинског отпада у Србији  
Пројекат финансира Европска унија

Министарство здравља  
Република Србија

Приручници за управљање медицинским отпадом  
Публикација бр: 13/005

**Препоруке за управљање  
фармацеутским отпадом**

*За већу безбедност пацијената и здравствених радника*

Новембар 2013. године

Препоруке су начињене од стране конзорцијума компанија

**COWI**  
и  
**EURO HEALTH GROUP**

и у сарадњи са  
Фармацеутским факултетом

и Фармацеутском комором Републике Србије

# Keynotes

- **It is imperative to ensure strong support and commitment from National stakeholders**
- **Not all pharmaceutical waste is hazardous waste**
- **In normal circumstances (natural or man-made emergencies and crises), pharmaceutical waste is not generated in high quantities in healthcare institutions.**
- **Once packed properly, pharmaceutical waste can be safely stored for longer and be inventoried.**
- **Always cooperate with professional, licensed, and permitted companies for the management of pharmaceutical waste**
- **Transboundary movement of waste usually takes a long time, but it is precisely regulated thus minimizing the potential for accident or error.**
- **Always involve DGSA whenever dangerous goods are to be managed**

It always seems impossible, until it's done.

Nelson Mandela

Thank you for your attention

[viktorhr@t.mk](mailto:viktorhr@t.mk)

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# Regional reflections from EMRO on challenges and solutions in emergencies

Rola Al-Emam, WASH Regional Advisor Eastern Mediterranean

1 October 2024

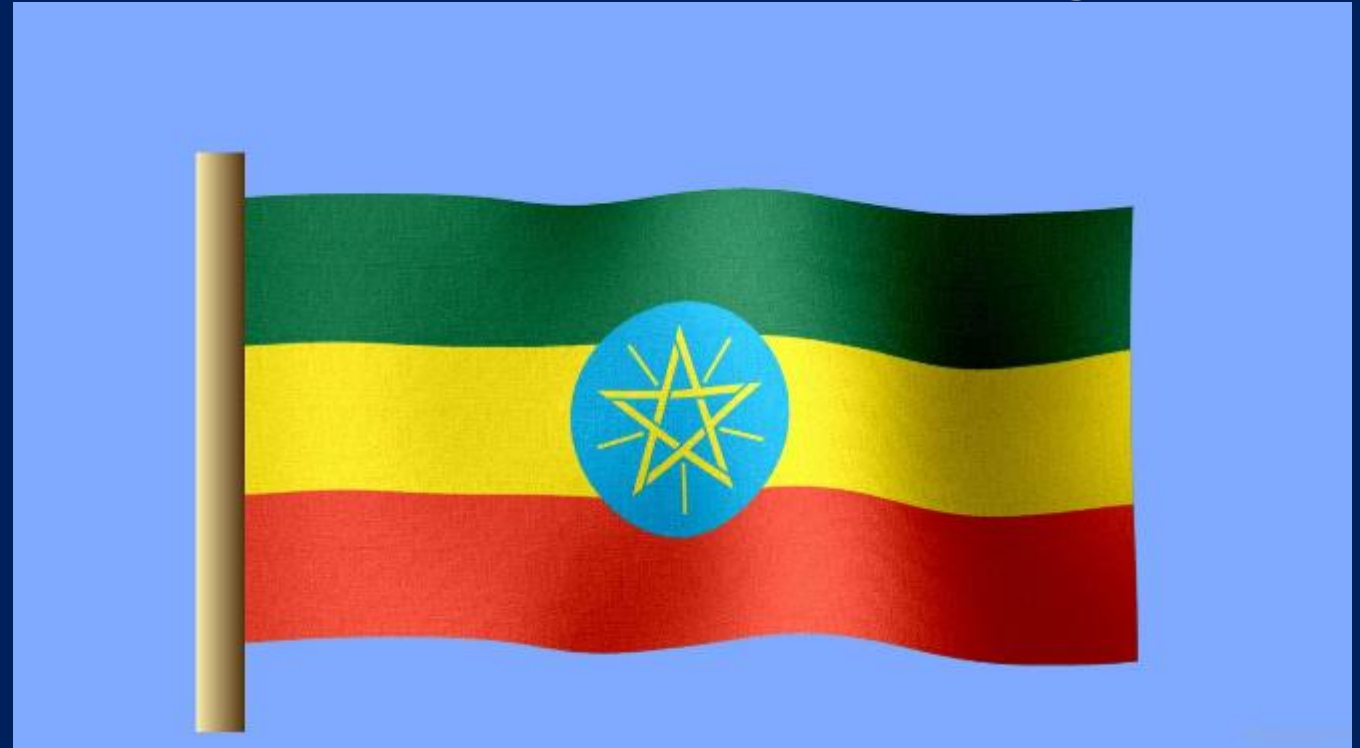
# Technical Consultation Meeting : WHO Safe Management of Pharmaceutical Waste from Healthcare Facilities

## Ethiopia Health Care Waste and Pharmaceutical Waste Management

Waltaji Terfa Kutane, NPO Health and Environment WHO, Ethiopia

1 October 2024

WHO Geneva



**ETHIOPIA**

# Presentation Outline

- Introduction
- Health Care Waste Management
- Pharmaceutical Waste Management
- Challenge
- Way for Ward

# Introduction



14 Regional Health Bureaus

District Health Offices/Zonal Health Department

Health Care Facilities (Hospital, Health Center and Health Post)



Normative, guidelines and SOPs development, Service Provision and Regulation/enforcement



# Introduction



## Ethiopia Health Tier system



**N: B - Primary level health care** includes Health post, Health center and primary hospital

Urban Health center served for 40,000 people

**Secondary level health care** = General hospital

**Tertiary level health care** = Specialized hospital

Private Health Care Facilities (Hospitals, clinics, specialized laboratories)



Medicine use by Household

Generation of HCW and Pharmaceutical Waste in Ethiopia



## Pharmaceutical Industries Ethiopia Vision

Ethiopia has identified strategic sectors for investment with a strong focus on Pharmaceutical manufacturing with a national strategy to develop the sector

**Strategic Sectors**

**National Strategy for the Pharmaceutical Manufacturing Sector**

National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)

- Ethiopia is one of the first African countries to develop national strategy for pharmaceutical manufacturing with a strategy to grow exports in addition to substituting imports and improving access to medicines
- Dual benefit of increasing access to medicines and promoting rapid industrialization of the country

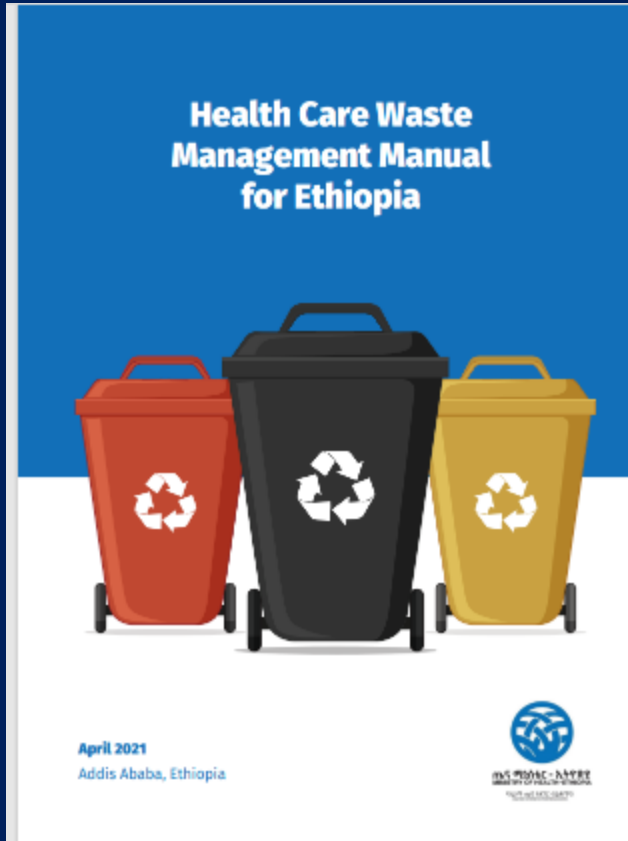
**Goal: To become a pharmaceutical manufacturing hub in Africa**



# Health Care Waste Management in Ethiopia

Health Care Waste Management in Ethiopian health care facilities are poor (ESPA 2021 Report Ethiopia)

- Only 23% of facilities have an incinerator,
- 15% have written guidelines for health care waste management,
- 23% have a placenta pit,
- 15% have a septic tank, and
- Just 7% of health facilities have staff trained on health care waste management



Pharmaceutical Waste well elaborated in this manual


WASH FIT Implementation Dilchora Referral Hospital, Dire Dawa Ethiopia , December 2023

Domain of WASH FIT	Number of indicators*	Baseline %	After 6 Months Implementation of WASH FIT
1 Water	17	42%	78%
2 Sanitation	13	57%	81%
3 Health care waste	20	48%	78%
4 Hand hygiene	5	30%	100%
5 Environmental cleaning	16	63%	84%
6 Energy & environment	13	75%	88%
7 Management & workforce	12	75%	79%
<b>TOTAL</b>	<b>96</b>	<b>55%</b>	<b>82%</b>

Ongoing WASH FIT Implementation are Contributing to HCWM Imprevdment

# Pharmaceutical Waste Management

**Medicines Waste  
Management and Disposal  
Directive**



**Food, Medicine and Healthcare  
Administration and  
Control Authority of Ethiopia**

August 2011  
Addis Ababa



Eight Randomly Distributed Pharmaceutical Waste Management Hubs

Environmentally friendly, modern incinerators capable of incinerating 500kg/hr. to 4500 kg/hr

# Challenges

- The incinerators in 8 hubs are not full functional
  - There is no established mechanism including service fee payment for the Ethiopian Pharmaceutical Service Agency who is managing the incinerators in 8 hubs
  - There is no logistics support to transporting the pharmaceutical waste to the hubs
  - Short fall of operation cost including high fuel consumption
  - Issues in relation to community 's perception, nature of the commodities to be disposed of, and equipment performance.
  - HR technical capacity
- Safe pharmaceutical waste disposal is weakly enforced and often managed by un efficient incinerators at health care facilities
- Pharmaceutical industries ?? Pharmaceutical waste management still not fully compliant with standard
- Donation of medicine with short life span specially in health emergency response
- Fragmentation of role and responsibility among government intuitions

# Way forward

- Delineate role and responsibilities among government institutions
- Put in place strategic framework with tools for progress monitoring for proper pharmaceutical waste management
- Establish a mechanism for sustained use of the hubs including vibrant mechanism for financing such reasonable payment for the service by public and private health care facilities, and pharmaceutical industries
- Capacitate health care facilities system and health workforce including capacity building training of health care waste management with due attention for pharmaceutical waste management in the context of WASH FIT implementation at scale