EAST AFRICAN COMMUNITY

PHARMACEUTICAL WASTE MANAGEMENT IN THE EAC

SCOPING STUDY, April 2024

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Abbreviations

ABREMA	Burundi National Medicines Regulatory Authority
ADDO	Accredited drug Dispensing Outlets
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral Drug Optimization
BI	Republic of Burundi
CAG	Chief Auditor General
CAMEBU	Burundi Central Medical stores
CMS	Central Medical Supplies, Juba
DFCA	Drug and Food Control Authority
EAC	East African Community
EIA	Environmental Impact Assessment
EMCA	Environment Management and Coordination Act
EPA-US	Environmental Protection Agency
FDA	Food and Drugs Authority
FIFO	First in and first out
HCWM	Health Care Waste Management
HIV	Human Immunodeficiency Virus
HPF	Health Pooled Fund Store
KE	Republic of Kenya
KEMSA	Kenya Medical Supplies Authority
LGA	Local Government Authorities
MOH	Ministry of Health
MSD	Medical Stores Department
NDA	National Drug Authority
NDP	National Development Plan
NEMA	National Environment Management Authority
NEMC	National Environment Management Council
NGO	Non-Governmental Organization
NMS	National Medical stores
OSH	Occupational Safety and Health
PCPs	Polychlorinated products
PPB	Pharmacy and Poisons Board
PW	Pharmaceutical Waste
REMA	Rwanda Environment Management Authority
RMS	Rwanda Medical Supply
RPMPOA	Regional Pharmaceutical Manufacturing Plan of Action
RW	Republic of Rwanda
SS	Republic of South Sudan
TMDA	Tanzania Medicines and Medical Devices Authority
TZ	United Republic of Tanzania
TZS	Tanzanian Shillings
UG	Republic of Uganda
UNDP	United Nations Development Program
URT	United Republic of Tanzania
USD	United States Dollar

FOREWORD

The urgent need for sustainable Pharmaceutical Waste Management in the EAC

The East African Community (EAC) is a dynamic region comprising eight partner states, currently experiencing rapid economic growth and development. This growth, coupled with increasing access to healthcare, has led to a significant rise in the consumption of pharmaceuticals and relevant medical products. While this trend is encouraging, it brings with serious challenges resulting from inadequate and improper management of pharmaceutical waste, across various levels, covering households, drug shops, pharmacies, healthcare facilities and pharmaceutical industries among other sources.

Pharmaceutical waste, if not handled correctly, poses a serious threat to human health and the environment. Improper disposal can contaminate water sources, soil, and air, leading to adverse health and environmental effects. Additionally, it can contribute to the development of antimicrobial resistance, a global health crisis that need to be urgently addressed.
This scoping study on pharmaceutical waste management within the EAC Partner States serves as a critical step towards in addressing these pressing issues at the intersection of health and environmental sustainability. It provides valuable insights into current practices of pharmaceutical waste management, highlights key challenges and opportunities, and offers recommendations for sustainable solutions.

By understanding the scope of the problem and exploring potential solutions, as a region, we can start working together to develop effective policies, regulations, and establish the required infrastructure to ensure the safe and responsible disposal of pharmaceutical waste. This will not only protect public health and the environment, but also contribute to the sustainable development of the EAC region.

I would like to commend the partner state institutions for their unwavering support throughout the study. My gratitude extends to the short-term experts and regional consultants for their invaluable technical guidance, to the GFA team for their administrative and technical oversight, and to the GIZ regional program for their financial support in conducting this study. I also appreciate the efforts of the team responsible for report editing, layout, and design whose inputs, dedication, and expertise have been instrumental.

The EAC Secretariat is confident that the findings and recommendations of this study will inform policy decisions and inspire actionable steps to tackle the challenges of pharmaceutical waste management in our partner states.

Hon. Andrea Aguer Ariik Malueth
Deputy Secretary General
(Infrastructure, Productive, Social and Political Sectors)

ACKNOWLEDGEMENT

On behalf of its Partner States, the East African Community Secretariat thanks the Government of Germany for its ongoing financial and technical support through GIZ and GFA Consulting Group, during the pharmaceutical waste management scoping study. Special thanks to Prof. Anthony Ngure Gachanja from Jomo Kenyatta University in Kenya for his leadership, and the following experts namely Pierre Claver Niyonzigiye (Burundi), Dr. Innocent Hahirwa (Rwanda), Dr. Moses Deng Malual Dhol (South Sudan), Alambo Mssusa (Tanzania), and Dr. Denis Kibira (Uganda) for their outstanding contributions to the study.

The study highlights the serious dangers of inadequate pharmaceutical waste management, including risks to human and animal health, environment, and its contribution to antimicrobial resistance. Key issues identified include inadequate incinerators, exclusion of household waste from policy and poor record-keeping, making it difficult assess waste generation in each Partner State. Additional challenges such as lack of information sharing, lengthy approval processes, high costs, and multiple stakeholders complicate waste management.

Moving forward, we will continue to collaborate with our Partner States, responsible institutions, development partners, and stakeholders to address the challenges above identified by the study. We will create work plans and regional guidelines based on the 2018 Regional Pharmaceutical and Health Technologies Policy, supporting relevant frameworks in each Partner State. Our holistic approach will tackle antimicrobial resistance through multi-sectoral engagement, integrating human. animal and plant health to guide the region toward effective solutions.

Mr. Jean Baptiste Havugimana
Director Productive Sector
East African Community Secretariat

EXECUTIVE SUMMARY

Pharmaceutical waste is classified as hazardous waste, unsafe disposal into the environment may result in serious environmental contamination, microbial resistance and impacts on human health, including the biosphere. Apart from handling of the pharmaceutical ingredients, production, storage and warehousing, the activities during healthcare system including expired drugs, damaged drugs and discarded personal medications are all major and important sources of pharmaceutical waste.

The East African Community adopted the EAC Regional Pharmaceutical Manufacturing (EACRPMPOA) plan of Action 2017-2027[1]. As part of the implementation of this action, the secretariat commissioned a scoping study on pharmaceutical waste management in six of the seven EAC Partner States.

The scoping study was commissioned in the EAC Partner States to advise on the policy and guidelines in the region using a harmonized approach. The study was conducted during the April 2023 in Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda.

The objective of the scoping study was to understand the current status of pharmaceutical waste management in the EAC and to make meaningful recommendations on how the waste can be effectively managed in a safe and sustainable manner. In addition, the study was expected to establish indicative figures and data on pharmaceutical waste and the methods of disposal for the manufacturers, national medicines regulatory agencies and national medical stores, hospitals and health care facilities, pharmacies (retail and wholesale), and EAC households. Data and qualitative information were collected from the selected facilities using tailor-made data collection tools that had been endorsed before deployment.

This report presents information gathered during the scoping study. The findings, though limited due to a fraction of the number of facilities sampled is, however, indicative and guiding in the current practices of handling of pharmaceutical waste in the region.

The study included a total of 312 facilities across the six EAC Partner States, including national ministries of health, medicines regulatory agencies, medical/pharmaceutical stores, environment agencies, pharmaceutical manufacturers, pharmacies, hospitals/clinics, pharmaceutical stores, and garbage collectors.

The types of pharmaceutical waste disposed by the respondents include the full range of pharmaceuticals and related devices. These included, among others: Tablets and capsules, liquid bottles, used/contaminated packaging, used syringes and needles, all of which were visible in the waste dump sites and incineration sites.

Estimated cumulative annual pharmaceutical waste volumes disposed were tabulated as given in Table 1. It is important to note that waste volumes recorded only represent a preliminary showing of the actual volumes.

1 http://repository.eac.int/handle/11671/24343

Some Partner States did not have quantitative records for their waste disposed from the different facilities sampled. The study recorded an overall estimated annual quantity of 33.4 thousand metric tons.

Table 1
Estimated Cumulative Annual Pharmaceutical Waste Quantities in Six EAC Partner States

Facility	Pharmaceutical Waste
National Regulators	31,208,750
National Medical Stores	1,842,473
Manufacturers	123,411
Pharmaceutical Warehouses and Stores	90,433
Hospitals and Health Facilities	127,937
Retail Pharmacies and Chemists	6,800
Garbage Collectors	--
Cumulative	**33,399,804**

-- no data available

Waste segregation is widely practiced among facilities such as manufactures and hospitals, but unfortunately is not common practice amongst the respondent who interacted with the households, which include the retail chemist and garbage collectors.

A very small percentage (less than 1%), almost negligible, of households return unused or expired medicines to the chemists, hospitals, stores, or the relevant authorities. Almost all the pharmaceutical waste from households is taken by garbage collectors. Garbage collectors do not segregate pharmaceutical waste from the other household waste for purposes of safe disposal. All waste from garbage collectors is mixed and disposed of as household / general garbage.

The most prevalent mode of solid waste disposal by the manufacturers, regulators, health facilities and pharmaceutical stores is incineration. Hospitals and Warehouses, however, employ more than one disposal method, which include, burning, landfill, and handing over to garbage collectors. For retail chemists and pharmacies, burning, landfill and handing over to the garbage collectors are the most common waste disposal methods used. Liquid waste is diluted and poured into the sinks, sewer, or the environment.

The cost of disposal varies from Partner State to Partner State and within the individual states, and facility to facility. There is no harmonized costing for disposal within the individual countries and across the entire region. The cost of pharmaceutical waste disposal is high across the region and there is need for harmonization to achieve appropriate waste disposal.

Unsafe disposal of expired/unwanted pharmaceuticals and pharmaceutical wastes, presents a challenge to the safety of the environment and a serious health risk to both humans and animals. Guidelines and regulations exist in each Partner State, however, there are no harmonized guidelines for the EAC. There is a need for harmonized regulations and guidelines on pharmaceutical waste under the guardianship of the EAC secretariat, to complement the already available guidelines and regulations in each Partner State.

There are huge quantities and volumes of pharmaceutical waste being generated across the region and a high percentage of these volumes are not being propery disposed of. There are only a small number of incinerators with the required specifications and capacity to handle the volumes of pharmaceutical waste being generated within the EAC. Some Partner States do not have such equipment installed and therefore result to burning the pharmaceutical waste. Pharmaceutical waste disposal methods being used are inadequate, improperly disposed pharmaceutical waste poses a danger to environmental and human health.

There is a knowledge gap in pharmaceutical waste management across all sectors engaged during the study and, therefore, a need to train and retrain players and stakeholders on pharmaceutical waste management.

Waste segregation is not common practice amongst households. Almost all the pharmaceutical waste from households is taken by garbage collectors

Waste segregation is widely practiced among facilities such as manufactures and hospitals,

1. Introduction

1.1 Background

The East Africa community Secretariat headquarters is based in Arusha, Tanzania, and the Community is currently made up of seven partner's states: The Republic of Kenya, The United Republic of Tanzania, the Republic of Uganda, The Republic of Rwanda, The Republic of Burundi, and the Democratic Republic of Congo. The community was established through its Treaty, signed on 30th November 1999, and enforced on 7th July 2000, after it was ratified by the original Partner States, Kenya, Tanzania, and Uganda. Burundi and Rwanda became full members from 1st July 2007, having acceded to the Treaty on 18th June 2007. South Sudan acceded to the Treaty on 15th April 2016, and attained full membership on 15th August 2016. The newest member, Democratic Republic of Congo, acceded to the Treaty on 8th April 2022 and became a full member on 11th July 2022. Data from the EAC community estimates that the community population stands at 283.7 million citizens, with an estimated 12 million households, 30% of this is urban population. The combined community occupies 4.8 million square kilometers land area.

Considering the ever-increasing population, partner states have made a deliberate effort to engage programs that facilitate access to safe, effective, and quality essential medicines, vaccines, and medical devices for treatment, for their population. At the tail end of achieving these efforts lies the management of pharmaceutical waste (generation, storage, transportation, and proper disposal).

Environmental pollution through disposal of chemicals is an emerging crisis in Africa. Among the emerging chemical pollutants are active pharmaceuticals, which will be found in the hydrosphere and lithosphere, including agricultural chemicals (pesticides, veterinary drugs), body care products and pharmaceuticals (pharmaceutical devices, prescriptions and over the counter drugs).

In the value chain of pharmaceutical products, waste will be generated. This comes from the handling of raw materials, during production (formulation), warehousing and dispensing.

Pharmaceutical waste is classified as hazardous waste and unsafe disposal into the environment may result in serious environmental contamination, microbial resistance and impacts on human health including the biosphere. In additionl to handling the pharmaceutical ingredients, production, storage and warehousing, expired drugs, damaged drugs and discarded personal medications all constitute major and important sources of pharmaceutical waste.

The East African Community adopted EAC Regional Pharmaceutical Manufacturing (EACRMPOA) plan of Action 2017-2027, as part of the implementation of this action, the secretariat commissioned a scoping study on pharmaceutical waste management in six of the seven EAC Partner States.

The objective of the scoping study is to understand the current status of pharmaceutical waste management in the EAC, and to make meaningful recommendations on how the waste can be effectively managed in a safe and sustainable manner.

The objective of the scoping study is to understand the current status of pharmaceutical waste management in the EAC, and to make meaningful recommendations on how the waste can be effectively managed in a safe and sustainable manner. In addition, the study is expected to establish indicative figures and data on pharmaceutical waste and the methods of disposal for the EAC households, manufacturers, pharmacies (retail and wholesale), hospitals, national medicines regulatory agency and national medical stores among others. The product will be a regional harmonized framework and approaches on pharmaceuticals waste disposal and management.

A scoping study is an exploratory study that will systematically map data available, identify key issues and concepts on pharmaceutical waste management, sources of evidence, policy, and gaps. The strength of the scoping study was to provide an overview of the evidence available on pharmaceutical waste management, the breadth and scope of evidence available. The study methodology was flexible, including new and unpublished data (questionnaires), and published literature for collation of qualitative and quantitative data. The systematic process of the scoping study provided the ability to explore and synthesize evidence on pharmaceutical waste management in the region. The scoping study provided a focus on the state of the subject in the region, rather than the already existing literature, and will

assist policy makers to make evidence-informed decisions and engagement of stakeholders with experts in the area. However, the study faced difficulties in establishing the scope and sample size, since the spectrum of facilities is wide, there are large populations and communities/ facilities are diverse.

Scoping studies in general face challenges of flexibility, broad scope, and lack of guidance standards i.e. time and depth. The flexibility and iterative process of defining (and redefining) the question, strategy and selection criteria required increases time and resources, which are difficult to ascertain at the design stage of the study.

A scoping study was commissioned in the EAC Partner States by GFA consulting group, to inform on policy and guidelines in the region using a harmonized approach. The study was conducted in Burundi, Kenya, Rwanda, Uganda, United Republic of Tanzania, and Republic of South Sudan during April 2023. The report presents information captured in the study. The findings, though limited due to the fraction number of facilities sampled, is however indicative and guiding in the current practices in the handling of pharmaceutical waste in the region.

1.2 Problem Statement

Pharmaceutical waste is potentially generated from a wide variety of activities in the health care system, including expired drugs, discarded personal medications, waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.), chemotherapy drug residues, etc., which are classified into 3 categories.

- Hazardous waste
- Non-hazardous waste
- Chemo waste.

Unsafe disposal of expired/unwanted pharmaceuticals and pharmaceutical wastes, presents a challenge to the safety of the environment and a serious health risk to both humans and animals. Quantifying pharmaceutical waste may be difficult particularly in institutions where records of the waste disposed are not kept very well and the pharmaceutical waste originating from households is not captured.

Significant research has been performed worldwide and data has been collected regarding the complex issues associated with this waste stream. In the United States, the EPA has performed multiple studies and research relating to the existence and effects of PPCPs in the environment. Links to important worldwide research, data, and literature references can be found on the EPA website (https://www.epa.gov). From the studies, the most common practice for pharmaceutical waste disposal by consumers is to discard it along with household waste (between 60% and 80%). Disposing pharmaceuticals into the sewage system is the secondmost common practice (between 5% and 30%). Very few consumers return unused pharmaceuticals to the pharmacy. Of course, these figures depend on how stringently the disposal systems for pharmaceuticals are applied and communicated. We need to establish these figures for EAC households, but also for manufacturers, pharmacies, hospitals, and medical stores.

A huge amount of pharmaceutical waste is amassed yearly, because of consumption, overproduction, donations, and over-prescription. Numerous studies have shown the presence of trace amounts of pharmaceuticals in soil, water supply systems and rivers. Due to improper disposal, these active APIs enter the food chain and are transferred back to humans, animals, and plants. The critical shortcomings in pharmaceutical waste disposal are inadequate storage space, insufficient funds, weak infrastructure, and insufficient awareness among healthcare staff, patients, and the public. Introduction of national guidelines, cost-effective solutions to disposal, training personnel, and educating the public are crucial to achieving a reduction in pharmaceutical waste-related hazards. Pharmaceutical industries should balance manufacturing and consumption rates of pharmaceuticals to avoid expiry. Take back options, collection events, and approved collection sites should be implemented and popularized through awareness campaigns. To avoid environmental pollution and the associated health threats, wastewater and drinking water treatment plants should upgrade technology to eliminate traces of the pharmaceuticals in aquatic systems. Further research should be conducted across all nations to assess the magnitude of unsafe disposal practices. As part of the resolution of reducing pharmaceutical waste across the Partner States, quantification and forecasting of needs by health facilities should also be strengthened, to avoid excess quantities.

We are not aware of any recent study/survey regarding pharmaceutical waste in the EAC. In addition, there are no regional harmonized guidelines to provide scientific guidance to the Partner States, implementing institutions and stakeholders on the management and disposal of pharmaceutical waste.

CONSUMERS

60% to 80%
Discarded with Household waste

5% to 30%
Discarded into the sewage system

1.3 Objective and Purpose

The overall objective of the assignment was to submit a final report that has undergone national and regional validation and give a comprehensive overview of the pharmaceutical waste management situation in the EAC, as well as recommendations and samples on the way forward by end of July 2023.

Purpose of the exercise was to:

- Understand the status of pharmaceutical waste management in the EAC, including common practices of EAC households, pharmacies, hospitals, medical stores, and manufacturers.
- Establish a quantitative and qualitative estimate of pharmaceutical waste in the EAC per annum.
- Determine existing capacity to manage pharmaceutical waste across the EAC Partner States, incl. available technologies (i.e. incinerators).
- Provide an overview of existing national policies and guidelines on pharmaceutical waste management.
- Estimate the costs of pharmaceutical waste disposal.
- Benchmark international policies and guidelines.
- Make meaningful recommendations to the EACS on pharmaceutical waste management,
- Develop sample draft EAC policy on pharmaceutical waste management and/or respective guidelines (pharmacies, hospitals, manufacturers).
- Provide a Policy Brief for the EAC (max. 2 pages).
- Provide an overall regional report covering the outcomes from the Partner States that participated in the study.

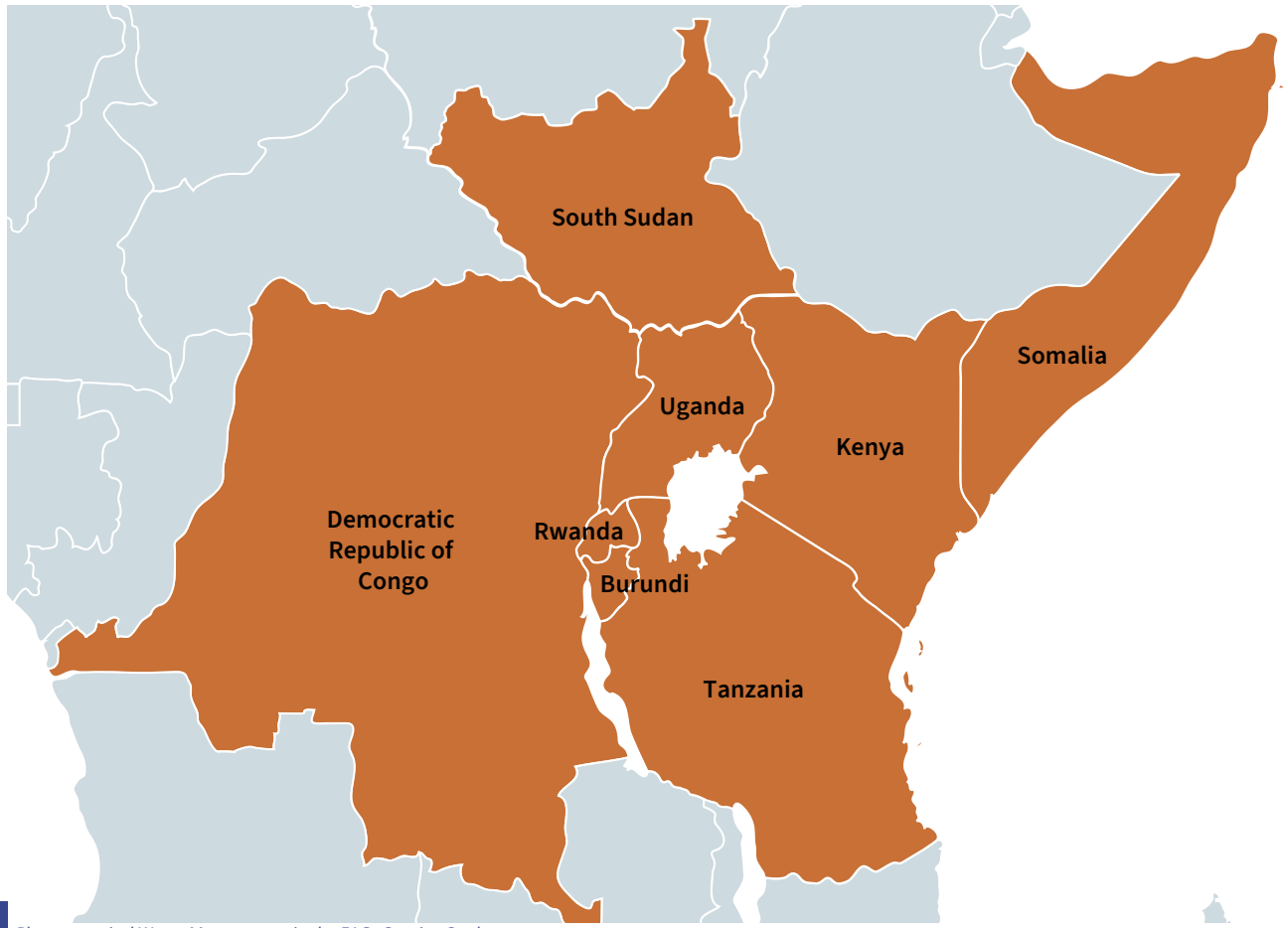
1.4 Methodology

This chapter described the methodologies used to collect and analyse the data included in this pharmaceutical waste management scoping study report.

The study was based on secondary sources, such as existing literature, studies, policies, etc. as well as primary data/information from in-depth interviews with key stakeholders. The study and data collection were conducted across the EAC Partner States (excl. DRC) (See Map 1). Data and information collection and gathering was facilitated by the Partner States institutions and stakeholders that include National Medicines Regulatory Agencies, National Medical Stores, Pharmaceutical Products Manufacturers, not for profit medical stores, importers and distributors of pharmaceutical products, dispensing pharmacies, and big hospitals across the Partner States.

A regional/international lead consultant was contracted to work alongside six national short-term experts, who supported the lead consultant with regards to national data/information collection, facilitation of national meetings, and any other support required by the lead consultant. The lead consultant worked closely with the national short-term experts to ensure smooth running of the exercise, engagement of the right stakeholders from the public and private sectors, usage of appropriate tools in data/information collection, etc. All consultants worked closely with the GFA pharmaceutical expert, John Patrick Mwesigye (patrick.mwesigye@gfa-group.de), who involved the EACS when it was appropriate, and their input was required.

Map 1:
Map showing the different EAC Partner States involved (shaded red)



Purposive sampling was used for all groups other than sampling in the homesteads, where probability sampling was more suitable in order to guarantee the representation of different subgroups within the population. Data collection tools were designed for each of the different groups to collect both qualitative and quantitative information, the tools were validated through the experts in the EAC Partner States and were piloted before administration in the field.

The data collected from the respondents was processed and reports for each of the groups across participating Partner States is presented below. Table 2 and 3 show the number of institutions/ organizations in the EAC Partner States and the total number of facilities sampled in the region. Table 4 shows the number of different types of facilities sampled.

Table 2:
Number of Relevant Institutions/Organizations in the EAC Partner States

No.	Facilities	Number of facilities in each of the Partner States						Total
		BI	KE	RW	SS	UG	TZ	
1	National medical regulatory Agencies	1	1	1	1	1	1	6
2	National medical/ pharmaceutical stores	1	1	1	5	1	1	10
3	National environment Agencies	1	1	1	0	1	1	5
4	Pharmaceutical products manufacturers	2	39	0	0	43	10	94
5	Dispensing pharmacies and chemists	300*	6,000	809	>185	1,557	16,191	25,042*
6	Hospitals and clinics	1,229	17,000	2,247	>10	6,937*	11,093	38,516
7	Pharmaceutical stores	30*	600	185	35	786	1,213	2,849*
8	Garbage collectors' companies	50*	1,500**	70**	30**	76	1,267[2]	2,993*
9	Ministry of Health	1	1	1	1	1	1	6
	Totals	**1,615**	**25,143**	**3,315**	**267**	**9,403**	**29,778**	**69,521**

* Indicative number as there are no records available

2 https://globalrec.org/2015/05/13/a-study-about-waste-pickers-in-dar-es-salaam-tanzania/ (Dar es Salaam only)

Table 3:
Number of Institutions/Organizations Sampled in the Partner States

No.	Facilities	Number of sampled facilities in each of the Partner States						Total
		BI	KE	RW	SS	UG	TZ	
1	National medical regulatory Agencies	1	1	1	1	1	1	6
2	National medical/pharmaceutical stores	1	1	1	4	2	1	10
3	National environment Agencies	0	1	1	0	1	1	4
4	Pharmaceutical products manufacturers	1	3	0	0	3	4	11
5	Dispensing pharmacies and chemists	5	41	27	10	15	23	121
6	Hospitals and clinics	6	23	3	5	7	16	60
7	Pharmaceutical stores	3	31	21	10	1	9	75
8	Garbage collectors' companies	5	11	1	0	4	3	24
9	Ministry of Health	0	0	0	0	1	0	1
	Totals	**22**	**112**	**55**	**30**	**35**	**58**	**312**

Table 4:
Total number and types of sampled facilities

Type Facility	Number of facilities	Number Sampled
National medical regulatory Agencies	6	6
National medical/pharmaceutical stores	10	10
National environment Agencies	5	4
Pharmaceutical products manufacturers	94	11
Dispensing pharmacies	25,042**	121
Hospitals and clinics	38,516	60
Pharmaceutical stores	2,849**	75
Garbage collectors' companies	2,993**	24
Ministry of Health	6	1
Total facilities	**69,521**	**312**

* Indicative number as there are no records available

Despite the successful preparations, and stakeholders' engagement, the study being a scoping or pilot study had significant number of **limitations** in several aspects, which include:

- The period to conduct the exercise in terms of data collection was very short and did not have adequate time to gather and input data from the large number of stakeholders across the Partner States.
- Absence of a centralized mechanism in each Partner State and later, at a regional level, limited data collectors and meant getting data from different stakeholders.
- Involvement of a number of stakeholders (NMRAs, NEMAs, Police, Revenue Authorities, some Bureau of Standards) in the process, made it difficult to access the actual and real time data.
- Household level data, which is considered one of the main sources of pharmaceutical waste, was only accessed through secondary sources via the garbage collectors.
- In some Partner States not all data for all the four years sampled was available and where it was available, still not all data was recorded,and records kept well.

2. Legal and Regulatory Framework

Each Partner State has, to some extent, developed policies and guidelines for management of pharmaceutical waste. In the member Partner States, some policies are more elaborate, while other are in their infancy, however, there is no harmonized policy for the EAC Partner States as a block.

The study listed the below **policies and guidelines** from each of the Partner States:

Burundi

- The National Health Policy, 2016-2025.
- The National Health Development Plan 2018-2023.
- The National Sanitation Policy and Operational Strategy, Horizon 2025.
- National Environment Strategy, 1997.
- The National Water Policy, 2009.
- The Code of Healthcare Provision and Health Services, 2018.
- The Code of Hygiene and Sanitation, 2018.
- The environment Code, 2021.
- The Water Code, 2012.
- The Tax Code of Burundi, 2013 (Deduction of the value of Pharmaceuticals and related devices from tax of the financial year).
- The Labor Code,2020 (OSH: Occupational Safety and Health).
- The Code of Commerce, 2015 (Pharmaceuticals and other medical products remain trading items).

Kenya:

- Environmental Management and Coordination act, 1999, and the revised act, 2019 and implemented by the waste regulations, 2009.
- Pharmaceutical waste is covered under the hazardous waste regulations 2009, in which the treatment of such waste is by incinerator. Permits or licensing procedures for systems and waste handling are covered under EMCA, 1999, and the Waste Regulations, 2009.
- Public Health Act, Chapter 242 of the Laws of Kenya.
- The sustainable waste management act, 2022 requires the classification and segregation of all waste. Also, the extended responsibility obligations apply to reduce pollution and environmental impacts of all products they introduce into the Kenyan market

and waste arising. Among the objects of the act are to reduce pollution, establish a system for sustainable waste management and inculcate responsible public behavior on waste and environment.

- The ministry of Health, through the PPB produced the most recent guideline, Guidelines for safe management of pharmaceutical waste, in January 2022. This guideline recommends the most appropriate methods and practices for safe management of pharmaceutical waste, which covers waste containing pharmaceuticals e.g., expired or no longer needed pharmaceuticals, items containing or contaminated with pharmaceuticals.

Rwanda:

- The country has regulations and guidelines on the management of pharmaceutical waste, especially those from health facilities and pharmaceutical companies. However, there are no clear regulations for the management of pharmaceutical waste from households. The available regulations are:
- Rwanda Food and Drug Authority, guidelines on Recall, Treatment and Disposal of Unfit Pharmaceutical Products, November 2021: These guidelines are followed for the disposal of pharmaceutical wastes is the “Rwanda FDA regulations governing recall treatment and disposal of unfit regulated products.
- Other regulations/guidelines that may be relevant to pharmaceutical waste management include “Regulations governing the provision of services for hazardous waste disposal” published by Rwanda Utilities Regulatory Authority are; “The National guidelines on Health care waste management, February 2016”.
- The National Guidelines on Health care Waste Management, Rwanda: “Regulations governing the provision of services for hazardous waste management Number 002/R/SAN”.

South Sudan:

- DFCA act (guidelines): 2012.
- Pharmaceutical Policy: April 2022 - Disposal of medicines (5.3.5.1): Disposal of medicines shall be guided by clear protocols as detailed by the National MOH in collaboration with relevant stakeholders in a manner that is safe to the environment.
- Pharmaceutical Strategy: May 2022- Activity Ref. (61): Develop drug disposal protocol for South Sudan, with dissemination/orientation for all stakeholders.
- Draft Guidelines for Disposal of Expired Medicines/ Health Commodities: Oct 202.

Tanzania:

- Pharmaceutical waste is part of hazardous waste as described in the Environmental Management (Hazardous Waste Control and Management) Regulations, 2019) made under The Tanzania Environmental Management Act (Cap. 191).
- In Tanzania control of disposal of pharmaceutical waste is mandated to the Tanzania Medicine and Medical Devices Authority through the Tanzania Medicine and Medical Devices Act, Cap 219.
- The Tanzania Medicines and Medical Devices (Good storage and distribution practices) Regulations, 2021 prescribes requirements for disposal of pharmaceutical waste. Section 25(5) of the regulation states that "Any expired product shall be declared to the authority and disposed off within 3 months after its expiration.
- The Authority has developed "TMDA Guidelines for Recall, Handling and Disposal of Unfit Medicinal Products, Third Ed, October 2020" which guides community and other players or stakeholders such as manufacturers, pharmaceutical dealers, public and private health facilities, Local Government Authorities (LGAs), Non-Governmental Organizations (NGOs) and drug inspectors on proper management and disposal of pharmaceutical waste and related products.
- Since pharmaceutical waste is part of healthcare waste in health facilities, The Tanzania Ministry of Health (MoH) has "The National policy guidelines for healthcare waste management in Tanzania" and "Guidelines for Management of Unserviceable Medicines and Related Medical Supplies in Public Health Facilities, 2016 "(under review) which are also used for management of waste at the healthcare facilities before disposal.
- The Environmental Management (Hazardous Waste Control and Management) Regulations, 2019 also tasks the LGAs to be responsible for proper waste management in their jurisdiction.

Uganda:

The Constitution of the Republic of Uganda (1995) entrusts the Government with the duty of ensuring that Ugandans enjoy a healthy environment [Chapter 3, Article 17J]. The "Second National Development Plan (NDPIII) objective is to improve health and well-being of Ugandans. According to the Uganda National Integrated Waste Management Policy and Systems Regulatory Assessment Report 2020, the existing policy framework is shown below:

Health Sector:

Health in general:

- Public Health Act 1935
- Occupational Safety and Health Act 2006
- Local Government Act 1997
- Medical and Dental Practitioners Act 1998
- National Infection Prevention and Control Guideline 2013

Healthcare waste:

- National Policy on Health Care Waste Management and injection safety 2004
- National Health Workers Guide – HCWM Guideline 2013
- Health Care Waste Management Strategic Plan 2010

Biosafety and Biosecurity:

- Biosafety and Biosecurity Policy 2017
- Biosafety and Biosecurity Manual 2015

Environmental Sector:

Environment and waste in general

- National Environmental Act 2019
- National Climate Change Policy 2015
- Electronic Waste Policy 2012
- Waste management regulation 1999
- Environmental Impact Assessment (EIA) regulation 1998

Radioactive Waste

- Atomic and Energy Act 2008
- Atomic and Energy Regulation 2012

Wastewater

- Water Act 1997
- Wastewater discharge regulation 1998
- Effluent discharge regulation 1999

The National Policy on Health Care Waste Management and Injection Safety 2004,

provided the implementation mandate to Ministry of Health (MoH) and regulation to NDA and NEMA. However, the roles on collection and disposal of healthcare waste remained silent. A new policy the National Healthcare Waste Management Policy (2020 draft) has provided healthcare and pharmaceutical waste management responsibilities as below:

- MoH will be responsible for: dissemination, resource mobilization and coordination, supervision of implementation, monitoring and evaluation. The Department of Curative Services of the MoH will be the central co-ordination point. In addition, the infection control units of the Referral hospitals shall be responsible for implementing this policy.
- At the district level, the directorate of health services shall serve as the responsible coordinating body for ensuring the implementation of this policy in all health facilities. At all levels national interests will be taken care of both in the public and private sector in the delivery of health care.

- At the health sub-district, the Department of Community Health shall be responsible for ensuring implementation in all health facilities and the community.
- The National Medical Stores shall ensure that waste management commodities are provided in adequate numbers and comply with national regulations and standards. The Central Stores are responsible for organizing the collection, treatment, and disposal of expired and obsolete items at the store and the destruction is witnessed by an inspector from the National Drug Authority.
- NEMA is responsible for supervisory, monitoring, and regulatory matters related to environmental control standards associated with management of healthcare waste. NEMA is responsible for giving permits and licensing hazardous waste transporters, hazardous waste treatment and disposal facilities, new health facilities and all companies involved in HCWM. Both the Ministry of Water and Environment and NEMA impose and enforce penalties to entities which do not follow the stipulated waste management guidelines relevant to their responsibilities.

The implementation of the policy shall be funded primarily by the government of Uganda, with contributions from development partners, individuals, and the private sector when applicable.

3. Public Institutions and Private Organizations

3.1 Public Institutions

3.1.1. Regulatory Bodies

The National regulatory bodies are established by specific acts of parliaments in each member state in the region. They are mandated to regulate the practice of pharmacies, the manufacture and trade in drugs and poisons within their territories, furthermore, they are custodians of regulations that prescribe the standards in pharmaceutical waste management operations from generation, handling, storage, collection, transport, treatment, and final disposal.

In addition, the national central stores within the region in each Partner States warehouses and distributes drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals.

The National Environmental Management Authorities implement policies that guarantee a safe environment, among other regulations, the waste regulations in each Partner States, prescribes the standards in waste management operations from generation, handling, storage, collection, transport, treatment, and final disposal. Pharmaceutical waste is classified as hazardous waste and should be treated and disposed of strictly in accordance with the specific regulations.

The scoping study engaged 19 national regulatory bodies and central stores within the EAC region. Among these, six were national medicine regulatory authorities, four national environmental management Authorities and nine national medical stores as listed in Table 5 below.

The scoping study engaged 19 national regulatory bodies and central stores within the EAC region.

National regulatory bodies:

- are established by specific acts of parliaments in each member state in the region.
- are mandated to regulate the practice of pharmacies, the manufacture and trade in drugs and poisons within their territories
- are custodians of regulations that prescribe the standards in pharmaceutical waste management operations from generation, handling, storage, collection, transport, treatment, and final disposal

Table 5:
National Regulatory Bodies and Central Stores within the EAC

Partner State	Regulator
Burundi	National Medicines Regulatory Authority, ABREMA Central Medical stores, CAMEBU
Kenya	The Pharmacy and Poisons Board, PPB Kenya Medical Supplies Authority, KEMSA National Environmental Management Authority, NEMA
Rwanda	Rwanda Food and Drugs Authority, Rwanda FDA Rwanda Medical Supply, RMS Rwanda Environment Management Authority, REMA
South Sudan	Drug and Food Control Authority, DFCA Continental Medical Supplies, CMS-Juba Wau Regional Store, WRS UNDP Store Health Pooled Fund Store, HPF
Tanzania	The National Medicine Regulatory Authority (TMDA) Medical Store Department (MSD) The National Environmental Council (NEMC)
Uganda	National Drug Authority, NDA National Medical stores, NMS National Environmental Management Authority, NEMA

From the engagements, **the study sought to find out** the extent to which these regulatory bodies are involved in pharmaceutical waste management and offer training. The information required included:

- The number of health facilities who return expired, recalls, and rejected, damaged pharmaceuticals to the regulators for proper disposal?
- To what extent regulators are involved in management of disposal of pharmaceutical wastes and more so pharmaceutical waste from households.
- Regulations and Guidelines in place in the Partner State for pharmaceutical waste management.
- Their role in trainings, assessments and audits of personnel and facilities that either generate, handle, store, collect, transport, treat and dispose pharmaceutical waste.
- Approximate amount of pharmaceutical waste delivered to regulators annually for disposal.
- Challenges they encounter as regulatory bodies in pharmaceutical waste management.
- Way forward to achieve a regional policy recommendation that ensures sustainable pharmaceutical waste management.

3.1.1.1 National Medicine Regulatory Authorities

Six National Medicine Regulatory Authorities (NMRA) were sampled, one in each of the Partner States. These included:
Burundi: National Medicines Regulatory Authority, ABREMA.
Kenya: The Pharmacy and Poisons Board, PPB.
Rwanda: Rwanda Food and Drugs Authority, Rwanda FDA.
South Sudan: Drug and Food Control Authority, DFCA.
Tanzania: The National Medicine Regulatory Authority, TMDA.
Uganda: National Drug Authority, NDA.

The national regulatory authorities, a representative from the waste generator and the incinerator staff take charge in the supervision of pharmaceutical waste disposal during incineration. For disposal that has been commissioned through a court order, the police, court representative, and counterfeit agency representative together the regulatory authority, waste generator representatives and the incinerator staff supervise such waste disposal. After disposal, the final disposal certificate is issued by the regulatory authority in each of the member's state. A supervision fee is charged by the regulator in all the Partner States.

Over the last four years, 3,768 disposal requests were received, and 2,555 approvals issued representing a 67.8% approval rate in the region. Table 6 below shows a 4-year cumulative disposal applications and approvals from each member states and the entire region.

Table 6:
4-Year Disposal Applications and Approvals from Partner States

Country	Number of Applications Received	Number of Applications Approved	Approval Rate
Burundi	2	2	100%
Kenya	1,587	1,587	100%
Rwanda	130	124	95%
South Sudan	20	20	100%
Tanzania	1,492*	285	19%
Uganda	537	537	100%
EAC	3,768	2,555	67.80%

* many applications were replicated as they moved from manual to electronic approval system

In five of the six Partner States sampled, the approval of applications for disposal of pharmaceutical waste is above 95%.

The total annual amount of pharmaceutical waste processed through incinerators, based on NMR approvals, is an estimated 31,209 tons for the six EAC Partner States. However, it must be noted that this figure is only a rough estimate, due to lack of proper records in most Partner States.

Table 7 shows the estimated annual total and per capita amount of pharmaceutical waste across the EAC Partner States, based on disposal approvals.

Table 7:
Estimated Annual Amount of Pharmaceutical Waste Processed Based on NMRA Approvals

Partner State	Estimated Annual Total Amount of Pharmaceutical Waste (kg) through NMRAs
Burundi	37,500
Kenya	16,250,000
Rwanda	37,500
South Sudan	8,750
Tanzania	12,500,000
Uganda	2,375,000
Total	**31,208,750**

The regulators provide guidelines for the disposal of pharmaceutical waste by manufacturers and warehouses, however, there is limited or no engagement between the regulators and the households, and garbage collectors including guidelines, inspections, trainings, and assessments.

There is an indication of the huge volumes of pharmaceutical waste that is being disposed across the EAC and evidently the need to have a harmonized pharmaceutical waste disposal policies and guidelines.

3.1.1.2 National Environmental Management Authorities

National Environmental Management Authorities in four of the Partner States were engaged.
Kenya: National Environmental Management Authority, NEMA.
Tanzania: The National Environmental Council (NEMC).
Uganda: National Environmental Management Authority, NEMA.
Rwanda: Rwanda Environment Management Authority, REMA.

The other two countries involved in this study do not have a national environmental management authority.

The national environmental authorities receive environmental audits from manufacturers, hospitals, stores, and incinerators. However, there is no quantifiable data on pharmaceutical waste provided in these submissions, a challenge already flagged by the environmental authorities in the Partner States.

Across the region, there are 27 incinerators licensed by the Environmental Authorities, with the required specifications for disposal of pharmaceutical waste and related used devices. There were no registered burial sites or specific disposal sites for pharmaceutical waste.

Table 8:
Number of Environmental Authority Incinerators for Pharmaceutical Waste in the EAC Partner States

Partner State	No. of Incinerators
Burundi	0
Kenya	15
Rwanda	3
South Sudan	2
Tanzania	5
Uganda	2
Total	**27**

Training for personnel in institutions/health facilities, on hazardous waste management including pharmaceutical waste management was reported to be done, however there was no available data on the number of trainings conducted. The National Environment Authorities do not conduct training to communities and garbage collectors on pharmaceutical waste disposal in households.

Data on the number of applications and approvals for pharmaceutical waste could not be established from the data collected from national environment agencies. There is a need to have a management information system/database for keeping records and monitoring trends of pharmaceutical waste disposal at local government representatives and at National level.

3.1.2 National Medical Stores

Nine National Medical stores were engaged during this study. It is important to note that, in Republic of South Sudan the three medical stores are private and non-governmental medical stores, while WAU regional stores is a branch of the national medical central stores.

- Kenya Medical Supplies Authority, KEMSA, Kenya.
- Medical Store Department (MSD), Tanzania.
- National Medical stores, NMS, Uganda.
- Central Medical stores, CAMEBU, Burundi.
- Medical Supplies, CMS-Juba, Republic of South Sudan.
- Wau Regional Store, WRS -Republic of South Sudan..
- Store – Republic of South Sudan.
- Health Pooled Fund Store, HPF – Republic of South Sudan.
- Rwanda Medical Supply, RMS, Rwanda.

The central medical stores supply pharmaceuticals to public health facilities. Among the Partner States, the return of pharmaceuticals to the central store is usually occasioned by recalls or due to expiration. In Rwanda for instance, data from Rwanda Medical Supply shows that 394 facilities returned pharmaceuticals to the central stores between 2019 and 2022. In South Sudan, data from the medical stores shows that 910 facilities returned pharmaceutical drugs to the central stores in the period between 2019 and 2022. Partner States have different thresholds for the return of pharmaceuticals to their central store, ranging from expiry, quality defect to government recalls. In other Partner States, there were no records on returns to the central stores and therefore no data was available to permit analysis of return/non return trend.

The respondents reported inadequate storage facilities in the central stores for the handling of expired/unwanted pharmaceuticals across the region.

Central medical stores generate substantial amounts of waste. Over the last four years, the following approximate waste quantities, in Table 9, were recorded by the National Medical Central Stores.

Table 9:
Estimated Annual Waste Quantities Generated by the National Medical Central Stores

Partner State	Estimated Annual Total Amount of Pharmaceutical Waste (kg) through National Medical Stores
Burundi	--
Kenya	94,500
Rwanda	36,797
South Sudan	1,509
Tanzania	303,667
Uganda	1,406,000
Total	**1,842,473**

-- No records available

From the available data, about 2,000kg of pharmaceutical waste, (solid medicines, liquids, and other pharmaceutical waste) are delivered for disposal by the central stores annually in the EAC. Again, there are no proper records, which is also reflected in the huge difference between Uganda and all other Partner States.

There is no training conducted by the central stores, especially to communities and garbage collectors, on pharmaceutical waste disposal in households. Some, however do minimal training to institutions and health facilities, even so, there are no records on the number of trainings done to the health facilities.

3.1.3 Public Institution Challenges

- Lack of sufficient incinerators that are capable of completely disposing pharmaceuticals. The available incinerators lack capacity to handle the volumes generated.
- Bureaucracy in the process of disposal and too many licenses required for disposal along the disposal chain.
- Transportation to the site.
- Insufficient budgets.
- Temporary storage space at the disposal site.
- Lack of policies and guidelines on pharmaceutical waste management and related used devices. The available guidelines are poorly implemented, and there is no proper follow up on their adherence. There are no common guidelines harmonized for the EAC.
- Lack of knowledge on the collection and proper disposal of pharmaceutical waste.
- The public do not have training on the handling of pharmaceutical waste, which is also classified as hazardous waste. In addition, improper waste sorting at source which ends up with mixture of pharmaceutical wastes with other household/institutional wastes.
- Disposal in undesignated areas (e.g. as seen by some retail pharmacies that dispose of in dustbins and also at household level in domestic garbage) and smuggling of expired pharmaceuticals onto the market.
- Declaration of waste quantities was a voluntary aspect; this results in under declaration because of associated cost in waste disposal.
- There is no budget for disposal of pharmaceutical waste, vast amounts of waste collected from facilities are not sourced from national medical stores but are dumped at public facilities by private pharmacies/NGOs through short expiry donations.
- Negligence in disposal of pharmaceutical waste.

3.1.4 Public Institution Recommendations

- The National regulators, stores and environmental management therefore recommends the following.
- Automation of pharmaceutical waste loading process to the incinerator.
- There is need for more public awareness and education including households.
- Incorporate more stakeholders including local authorities (Chiefs) and garbage collectors for effective management of pharmaceutical waste.
- Focus to widen to capture veterinary pharmaceutical products and carcasses of poisoned animal disposal.
- Target also agricultural chemical disposals.
- Increase of licensed and operational incinerators within the country.
- Adopting a proactive and vigilant approach to pharmaceutical waste management.
- To improve compliance, have declaration of waste as a requirement for annual license renewal for pharmacies.
- Training of lower-level healthcare cadres.

- Public sector approach to collect from facilities and households, pharmaceutical waste management needs a dedicated budget from Government.
- NEMA recommended compulsory escorts for disposal of pharmaceutical and hazardous waste and use of waste manifest or tracking system.
- Provide sufficient budget as per the volume of expired medicine.

DISPOSAL APPLICATIONS & APPROVALS

3,768
Disposal Requests

2,555
Approvals Issued

3.2 Pharmaceutical Manufacturing Companies

Pharmaceutical manufacturing companies are the main source of pharmaceuticals in each economy and are at the top of the pharmaceuticals' distribution chain. All the manufacturing facilities in the region undertake product formulation after sourcing the raw materials, including the active molecules, and excipients. Their main activities are formulation, processing, and packaging of pharmaceuticals.

Unlike distribution channels, e.g. Warehouses, pharmacies and hospitals, manufacturers have no direct link with the end users (citizens), though they target to have above 99% of their products reach the consumers through the various distribution channels. Manufacturers also generate waste in form of expired/unused pharmaceuticals as well as process waste.

Every manufacturer targets a 99% uptake of their production networks. This is achieved by actively signing up clients who include pharmaceutical warehouses, hospitals and health facilities and, to an extent, wholesale and retail pharmacies (chemists). In addition, they, from time to time donate to NGOs and Government community programs.

During in-house activities, i.e., production processes and warehousing activities, waste will be generated. Documenting the quantities of this waste will give an indicative picture of the levels of pharmaceutical waste being generated by manufacturers, who are at the top of the distribution triangle. In addition, since they are the originators of pharmaceuticals, it would be necessary to understand whether they are actively involved in tracking down their products including waste generated down the distribution channels.

The study engaged 11 pharmaceutical manufacturing companies across the EAC region as shown in Table 10. There were no respondents in two of the six Partner States where the scoping study was conducted. These are Rwanda and Republic of South Sudan.

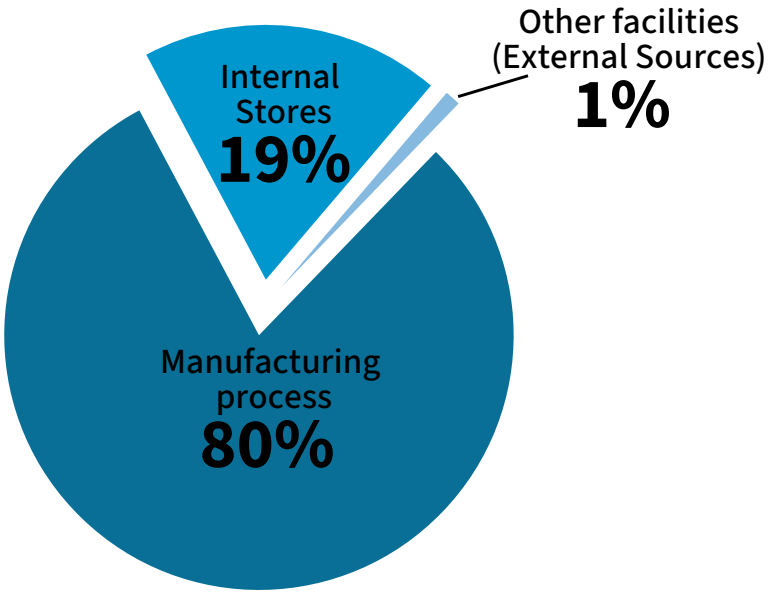
Table 10:
Pharmaceutical Manufacturing Companies in the EAC

Partner State	Number of Facilities	Number of Facilities Sampled
Burundi	2	1
Kenya	35	3
Tanzania	10	5
Uganda	23	3
Total	**70**	**12**

From the facilities engaged, 10 out of the 11 do not collect expired or unused medicines from hospitals and wholesales outlets for disposal.

80% of solid waste from the manufacturers is self-generated, while 19% comes from their own internal stores and warehouses (Figure 5). This therefore accounts for 99% of all the waste from manufacturers.

Figure 1:
Comparison of Waste Sources for Manufacturers



Among the most notable **reasons** given for **not collecting waste from other sources** were:

- The manufacturers notes that, it is not within their mandate to do so.
- Internal policies that prevent selling on near-expiry products to their customers.
- For unused products, the manufacturers have indicated proper disposal methods on the product packaging.
- Manufacturers have transferred the responsibility of managing expiry to the distributors.
- The manufacturers only collected medicines from hospitals and wholesalers for disposal in case of a recall issued by the regulatory authorities, or if there were rejects by clients following quality issues suspected or known after sale of the products, which is not frequent but did not collect expired medicines.

Apart from the pharmaceutical waste from products in the various distribution levels, the manufacturers will also generate waste from their own activities. This waste comes from production and warehousing activities within their premises. The study sort to understand the type of waste and noted the following:

3.2.1 Type of Waste Disposed by Manufacturers

Manufacturers disposed a variety of waste. From the respondents, they gave the list below of the wastes they disposed:

MANUFACTURER'S WASTE

- Product Waste from Machine setting
- Contaminated primary packaging material
- Expired raw Materials and Products
- Effluent and Process waste
- Expired chemicals
- Analysis test solutions
- Expired APIs
- Market recalls
- Retained samples
- Sample after analysis
- Microbiology culture media/Inoculums
- Obsolete analytical equipment
- Active ingredients,
- Excipients,
- Finished products,
- Packing material.
- In-process control samples
- Production process waste (solids and liquids)

3.2.2 Solid and Liquid Waste

Solid waste, at 95%, accounts for the largest share pharmaceutical waste disposed by the manufacturers (Table 11). From the respondents, the amount indicated is inclusive of expired/ unused medicines, as well as other types of waste, including packaging. From the data provided, the liquid waste is included together with the domestic and sanitary waste. Liquid waste accounts for 5% of the disposed waste, although the figure is much higher since some percentage is mixed with sewerage during domestic waste disposal through the sewers.

Table 11: Solid and Liquid Waste

Type	BI	KE	RW	SS	TZ	UG	EAC
Solid (kg)	NA	21,000	NA	NA	32,000	15,500	68,500
Liquid (l)	NA	1,000	NA	NA	900	900	2,800

NA: no respondents

* - data for 3 years

3.2.3 Process Waste

All the manufacturers responded that the wastewater goes to an effluent wastewater treatment plant at their factory, from there, the wastewater is channeled into the sewer after treatment.

Table 12:
Annual Amount of Pharmaceutical Process Wastewater Delivered for Disposal by Manufacturers in the EAC (m3)

Partner State	Estimated Annual Total Amount of Pharmaceutical Process Water (m^3)
Burundi	NA
Kenya	6,105
Rwanda	NA
South Sudan	NA
Tanzania	34,006
Uganda	12,000
Total	**52,111**

NA: no respondent

Only four facilities out of 11 undertake testing of APIs in process wastewater. One facility in the region is undertaking pilot testing of antibiotics in their process wastewater. Testing ensures that the released treated water is safe to the environment.

Analysis of vent dust within the facilities in not undertaken by most of the manufacturers. Only two out of the 11 respondents conducted the analysis of the vent dust. The manufacturers in Tanzania for instance, noted that analysis of APIs in vent dust was not part of the standard required by the authorities in Tanzania. In Uganda and Kenya, none of the respondents do the test, the reasons cited are lack of expertise and associated resources as the limiting factors. This points to a gap in the analysis of APIs both in vent dust and process wastewater.

On cost, manufacturers were reluctant to incur the cost of disposal for waste that they have not generated, in their submission, the responsibility for the cost of disposal of unused, expired, or damaged pharmaceuticals should be incurred by the entity that owns or possesses the pharmaceuticals at the time the product converts to be a waste requiring disposal.

3.2.4 Pharmaceutical Manufacturer Challenges

The main **challenges** that pharmaceutical manufacturers experienced in the handling and disposal of pharmaceutical waste were:

- Waste disposal is a very bureaucratic and expensive process requiring multiple licenses from different authorities.
- Lack of technical expertise more so to the waste handlers who collect waste from the manufacturers for disposal.
- Cost of disposal and analysis of APIs.

- Lack of regulations.
- Multiple licenses are required for disposal of waste which increases the cost of disposal.

3.2.5 Pharmaceutical Manufacturer Recommendations

- Carbon trading initiatives for manufacturers who are producing less waste as an incentive.
- Provision of expertise including technology transfer.
- Conduct bench marking studies for approaches and mechanism for management of pharmaceutical waste.
- Create a centralized control body for all pharmaceutical waste in a Partner State.

3.3 Pharmaceutical Stores and Warehouses

In most instances, wholesalers have an indirect link with the citizens through chemists, health centers and other distribution channels, however, they occasionally interact directly with the citizens. This direct contact generates pharmaceutical waste, in addition, waste disposal arrangements between the wholesalers and their clients, including chemist's results in unused/ expired pharmaceutical waste.

Across the EAC, there are well over 1,000 registered pharmaceutical stores and warehouses. From this number, the scoping study engaged 75 facilities within the EAC.

Table 13:
Pharmaceutical Stores and Warehouses Sampled Across the Region

Partner State	No. of Incinerators
Burundi	3
Kenya	31
Rwanda	21
South Sudan	10
Tanzania	9
Uganda	1
Total	**75**

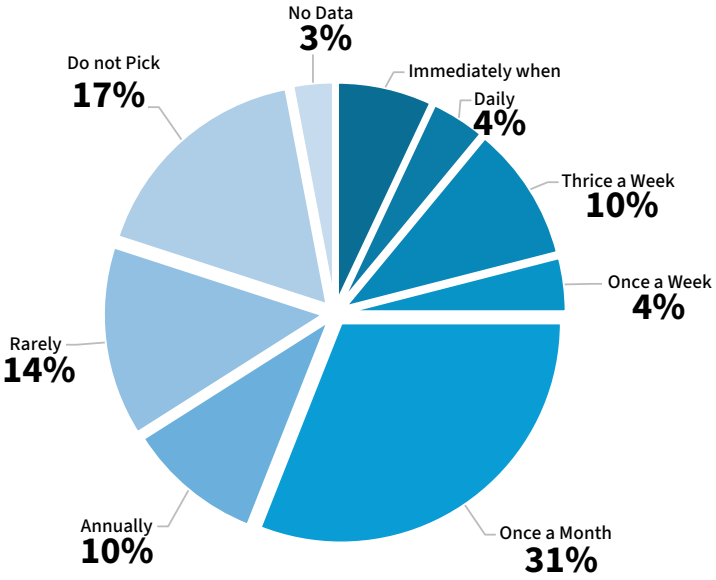
62 out of the 75 respondents indicated that, they do not collect unused or expired pharmaceuticals from clients.

Waste sources from pharmaceutical warehouses and stores account for the largest share of waste delivered for disposal by the warehouse/stores. This corresponds with their response on waste collection from their clients and citizens, even so, there is still a considerable amount of waste that comes from their clients and a smaller portion from citizens.

Asked what intervals they are requested to take over pharmaceutical waste from their clients and citizens, the respondents gave varied intervals. These intervals ranged from as soon as the request is made, to once per year. The majority of warehouses, however, do not take over expired or unused pharmaceuticals from their client or citizens. In Kenya, for instance, every facility had its scheduled interval for collection ranging from immediately noted to once a year. In South Sudan, the majority collects once in a month, while in Burundi, none of the sampled facilities accepts any waste from their client or citizens. The trend shows a similar pattern in the entire EAC Partner States.

Figure 2 below, shows the distribution of intervals that pharmaceutical stores collect pharmaceutical waste from their clients and citizens, in Kenya.

Figure 2:
Intervals for Collection of Expired/Unused Pharmaceuticals from Clients through Pharmaceutical Stores and Warehouses (Kenyan Case)



3.3.1 Quantities of Waste Generated by Pharmaceutical Stores and Warehouses

From the study, most of the facilities engaged provided estimate figures of the quantities of waste they generate annually. In Rwanda for instance, of the 21 companies engaged, 17 were able to provide approximate amount of solid pharmaceutical wastes disposed of annually. In Kenya and Tanzania, all facilities indicated estimate amounts annually disposed. It is important to note that the quantities provided under solid wastes for some facilities included liquids volumes.

78,853kg of solid pharmaceutical waste and 11,580litres of liquid pharmaceutical waste was disposed by pharmaceutical stores across the EAC Partner States as shown in Table 14.

Table 14:
Approximate Waste Disposed by Pharmaceutical Stores in the EAC

Partner State	Solids	Liquids	Others
Burundi	--	--	--
Kenya	9,656	2,069	940
Rwanda	41,620	6,300	250
South Sudan	335	2,200	--
Tanzania	15,801	11	10,001
Uganda	250	1,000	--
Total Waste Reported	**67,662**	**11,580**	**11,191**

-- no data provided

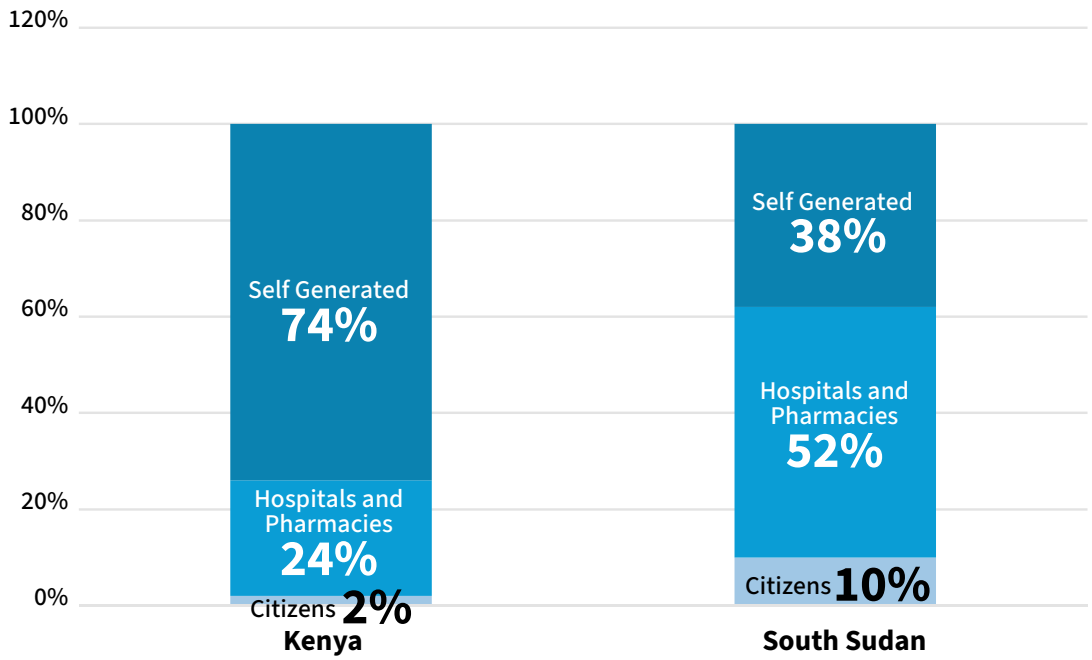
Pharmaceutical solid waste accounts for the largest portion of waste generated by pharmaceutical warehouses and stores.

Pharmaceutical waste delivered by pharmaceutical stores for disposal comes from three sources:

- Citizens
- Hospitals and Pharmacies
- Self-generated

The largest percentage of waste is self-generated, with waste from citizens accounting for the least percentage; South Sudan for instance, only 10% waste and Kenya 2% waste coming from the citizens as illustrated in Figure 3.

Figure 3:
Sources of Pharmaceutical Waste in Pharmaceutical Warehouses and Stores



The cost for disposal of the pharmaceutical waste varies from Partner State to Partner State. It is important to understand how the respondents view the cost implication, as well as who should bear the costs. The cost determines, to some degree, the disposal method a facility chooses. The Partner States use different currencies, which are valued differently as well, however, using an accepted common currency, United States of America currency (USD), the cost ranged between 1.2 USD and 300 USD. Most of the respondents paid a fee of 1.5 USD per kg for solid waste disposal.

Asked who they thought should bear the cost of pharmaceutical waste disposal, the majority felt that the holder of expired stock should pay for its disposal, as this would encourage proper disposal and improve responsibility. An equally large number consider it an expense they would rather not incur.

All respondents have the opinion that the following should bear the cost:

- Waste generator.
- The Government and the regulatory authorities.
- The importer.
- The industry.

The NGOs, for instance, noted that they have a responsibility to ensure proper stock management, which in turn minimizes the expiration and damage rate. Furthermore, those that view pharmaceutical waste disposal as their responsibility noted that they had a duty to protect the environment, as well as it being their corporate social responsibility.

Most of the respondents indicated that they do conduct some form of assessment on the technical competence in the management of pharmaceutical waste for their waste handlers, the main driving force for the assessment being to ensure safety of their staff. Those that do not carry out an assessment cite high cost associated with the exercise, while others believe that the responsibility to train and assess lies elsewhere, particularly with regulatory authorities and pharmaceutical waste handler contractors.

3.3.2 Challenges for Pharmaceutical Stores and Warehouses

- Lack of storage areas.
- Delayed waste collection by Regulatory Authority.
- Cost of disposal is high, which includes provision of transport and other disposal requirements.
- No competent companies for healthcare related waste management.
- The handling and disposal of pharmaceutical waste is complicated/ bureaucratic, time consuming and costly.

3.3.3 Recommendations for Pharmaceutical Stores and Warehouses

- Rules and regulations should be put in place to follow the pharmaceutical products from the wholesaler to the retailer or hospital and finally to the patient, who is the end user and know its final status, if used or not used, expired in which case it needs to be disposed,
- Rules and regulations should not overlook the household level.
- Mass education on usage of pharmaceuticals to the public, hence eliminating the need for excessive drugs in households.
- Just in Time purchases by distributors, as this will reduce chances of pharmaceuticals expiring in Partner State. Monitoring the expiry dates on pharmaceutical products by distributors and donating all that is due to expire within 3 months.
- Fine and penalty system to discourage the attitude of having expired drugs into the store,
- Do monthly inspection in pharmacies for expired pharmaceutical products.

- Government and partners in the health sector to provide facilities for safe disposal of pharmaceutical waste.
- The government should regulate the cost for pharmaceutical waste disposal and put some incentives.
- Public awareness campaigns, training of stakeholders, and improvement in efficiency of the process and reduction of disposal cost.

3.4 Hospitals and Health Facilities

3.4.1 Sample Size and Distribution of Hospitals and Health Facilities

Samples were collected across all six Partner States, a total of 63 health facilities were sampled. The facilities sampled included referral hospitals, teaching hospitals, health centers in public, non-governmental, missionary, and private sectors. The distribution of the sampled facilities in the partner's states is given below in Table 15 and Figure 4:

Table 15:
Distribution of the Sampled Facilities in the EAC

Partner State	No. of Facilities Sampled	Comments
Burundi	6	4 hospitals and 2 health centres
Kenya	23	8 x level 5 and 6 hospitals 15 x level 3 and 4 hospitals
Rwanda	3	3 x big referral hospitals, one is a teaching referral hospital
South Sudan	5	Facilities from 5 states (Central Equatoria, Western Equatoria Western Bahr Elgazal, Northern Bahr Elgazal and Upper Nile state)
Tanzania	16	6 x public referral hospitals 6 x Public district hospitals 2 x private hospitals 1 x Faith based organization Hospital 1 x public super specialized hospitals
Uganda	7	All big hospitals

3.4.2 Waste Segregation in Hospitals and Health Facilities

All the hospitals and health facilities sampled, indicated that they segregate hospital waste into different color bags, except for one facility. In 98% of the facilities sampled, pharmaceutical waste including used drugs vials, and syringes is segregated from other medical waste. The 2% (1 out of 60) who do not segregate, stated that they mix all waste.

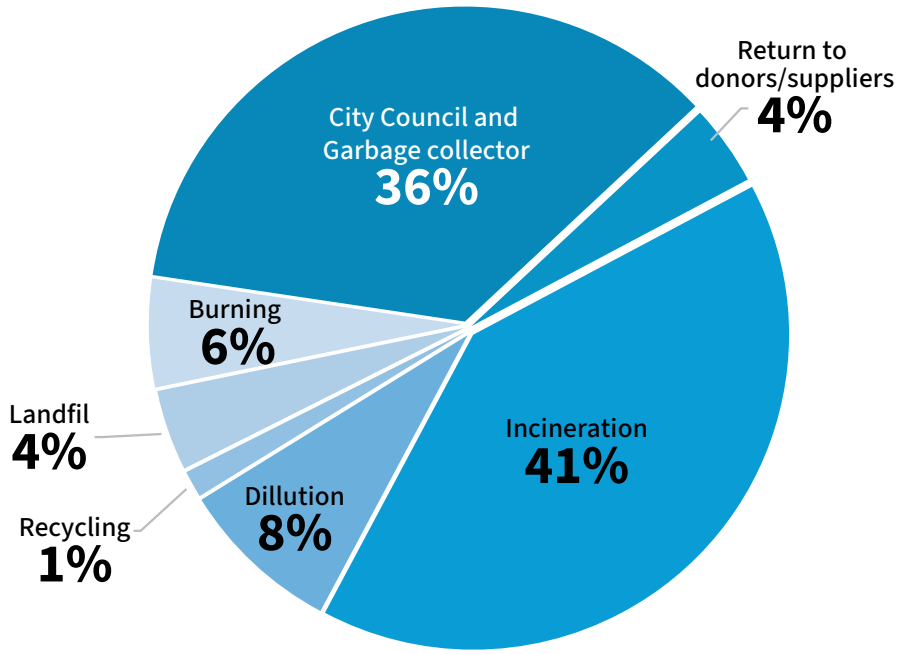
Most of the hospitals (92%) sampled have storage facilities for pharmaceutical waste and related devices. Only five facilities out of the 60 sampled (8%) did not have storage facilities for pharmaceutical waste and related devices disposal.

From the facilities sampled, chemical treatment and autoclaving are sometimes used (Note: autoclaving is used for infectious waste and not a pharmaceutical waste disposal method). It is noted that 78% of health facilities do not employ any pharmaceutical waste treatment methods before disposal. No treatment of pharmaceutical waste was recorded in respondents in five of the Partner States. This shows that pretreatment of the pharmaceutical waste is not practiced in the region. However, chemical treatment is a well-documented method[3] for pharmaceutical waste pretreatment before disposal.

3.4.3 Waste Disposal Methods of Hospitals and Health Facilities

Several waste disposal methods are used by the health facilities to dispose of their waste, these are dilution and drainage into sewer, landfill, burning, and incineration. Hospitals employ one or more of these waste disposal methods. Empty drug containers are recycled, while expired drugs/ medicines are returned to the suppliers by some facilities. Waste Collectors and local government garbage collectors are also used for disposal of pharmaceutical waste (36%).

Figure 4:
Pharmaceutical Waste Disposal Methods in Hospitals and Health Facilities

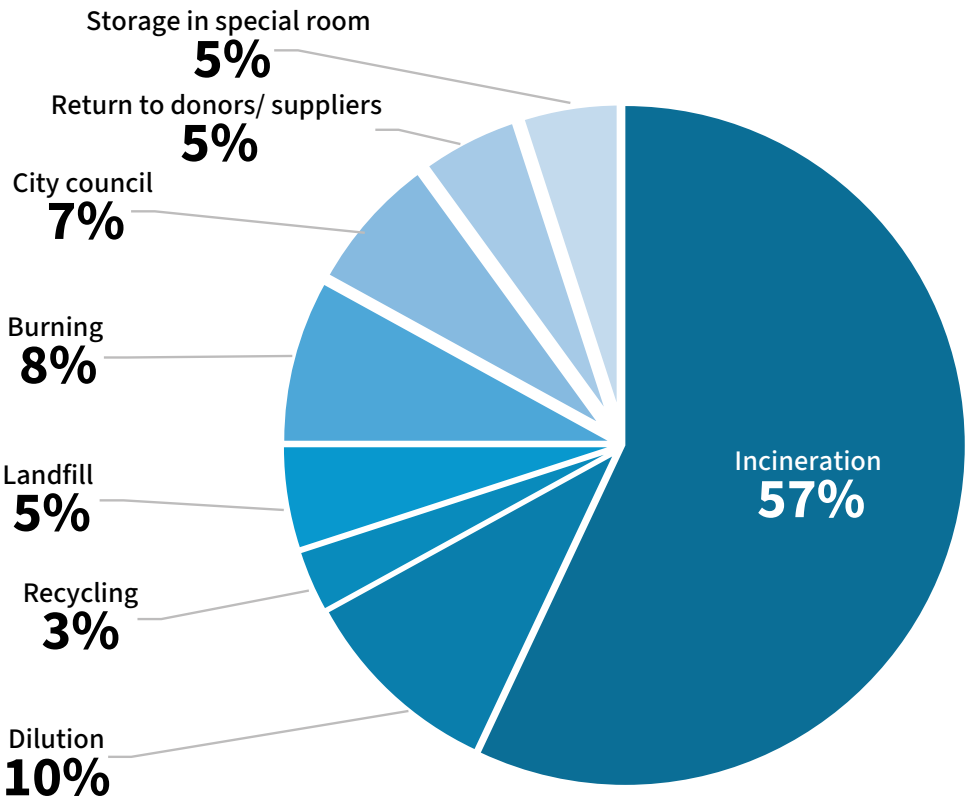


3 https://nepis.epa.gov/Exe/tiff2png.cgi

3.4.4 Treatment of Pharmaceutical Waste in Hospitals and Health Facilities

Over 78% of hospitals and health facilities in the region do not apply any treatment to pharmaceutical waste. Figure 5 shows that the most common mode of solid waste disposal is through incinerations (57%), some facilities however do burn, while a few return their expired pharmaceutical waste to their suppliers. Liquid waste is disposed of through dilution and exhaustion to sewer. Recycling is undertaken for packaging materials. However, the respondents in 50% of the Partner States avoided this aspect of waste treatment and did not respond to the question on how they treated their pharmaceutical waste. Practices of burning, dilution, and landfill for disposal of pharmaceutical waste are likely to be more prevalent than presented in this data set.

Figure 5:
Treatment of Pharmaceutical Waste in Hospitals and Health Facilities in the EAC



3.4.5 Quantities of Disposed Unused/Expired Pharmaceuticals in Hospitals/Health Facilities

The records of pharmaceutical waste in hospitals and health facilities are poorly kept and this data was not readily available during the data collection. Table 16 shows pharmaceutical waste disposed of by the hospitals/health facilities that recorded figures.

Table 16:
Quantities of Disposed Unused/Expired Pharmaceuticals in Hospitals and Health Facilities in the EAC

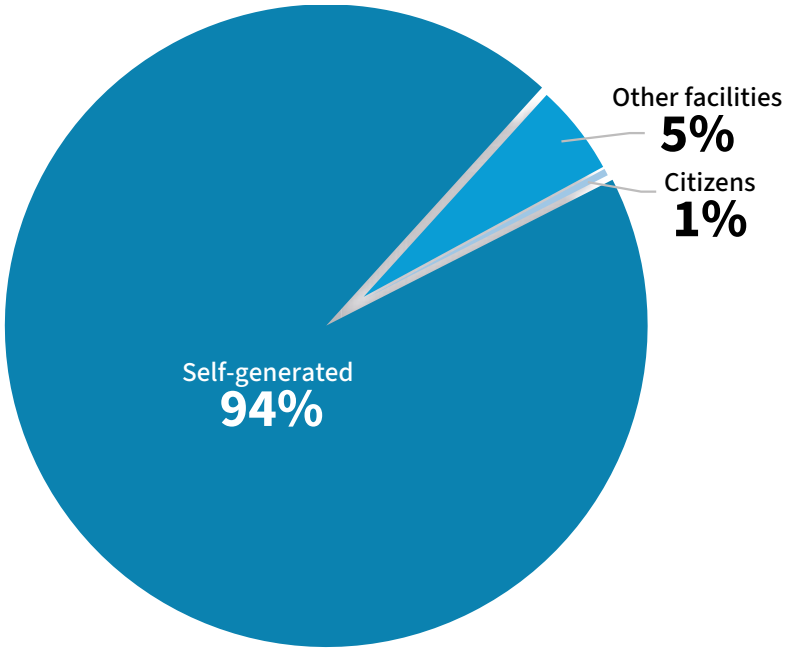
Partner State	Quantities Reported	
	Solid PW (kg)	Liquid PW (Litre)
Burundi	450.00	--
Kenya	21,247.00	7,946.00
Rwanda	3,352.00	3,450.00
South Sudan	6,345.00	170.00
Tanzania	37,827.00	46,720.00
Uganda	400.00	30.00
Total	**69,621.00**	**58,316.00**

Under 60% of hospitals/health facilities report the quantities of pharmaceutical waste in the EAC. The cost of disposal of pharmaceutical waste varies from state to state. The cost is reported to go up to USD 20 per kg of liquid waste. The general feeling of the respondents is that the waste generator, the government, local and national, as well as the regulatory bodies including Pharmacy and Poisons Board (PPB), should bear the cost of pharmaceutical waste disposal.

3.4.6 Sources of Pharmaceutical Waste in Hospitals/Health Facilities in the EAC

Pharmaceutical waste originates from health facilities, citizens, and other facilities. The collection and documentation of pharmaceutical waste from citizens is not practiced in most parts of the region. Self-generated pharmaceutical waste accounts for the largest source of waste within the health facilities, with waste coming from the citizens accounting for less than 1% of the total pharmaceutical waste disposed by the health facilities.

Figure 6:
Sources of Unused/Expired Pharmaceutical Waste in Hospitals/Health Facilities in the EAC



Health facilities are rarely asked to take over expired/ unused pharmaceuticals from the citizens, with a majority never having taken over expired/unused pharmaceuticals from the citizens at 74% and 56% in Kenya and Tanzania respectively. In the Kenya scoping study, three respondents collected pharmaceutical expired / unused medicines and used related devices from citizens for disposal, in particular HIV -ARVs and TB drugs. Respondents acknowledge that expired and unused drugs are not collected from the citizens because they do not have a policy to do so, and also requests to take the expired drugs from citizens are rare. In addition, the collected waste will be expensive to dispose of. One facility accepts pharmaceutical waste from the nearby facilities. For safe disposal, the public is asked to deliver the expired drugs to the Pharmacy in the health facility. The expired products are also collected from patients at service points organized through PSK /PPB sensitization. However, the respondents (3) noted that low percentages of their total pharmaceutical waste came from citizens, <2%, 5%, 23%. In all three facilities, they collected the pharmaceutical waste brought to them by the citizens, explaining the reasons for the low levels to be lack of information and ignorance.

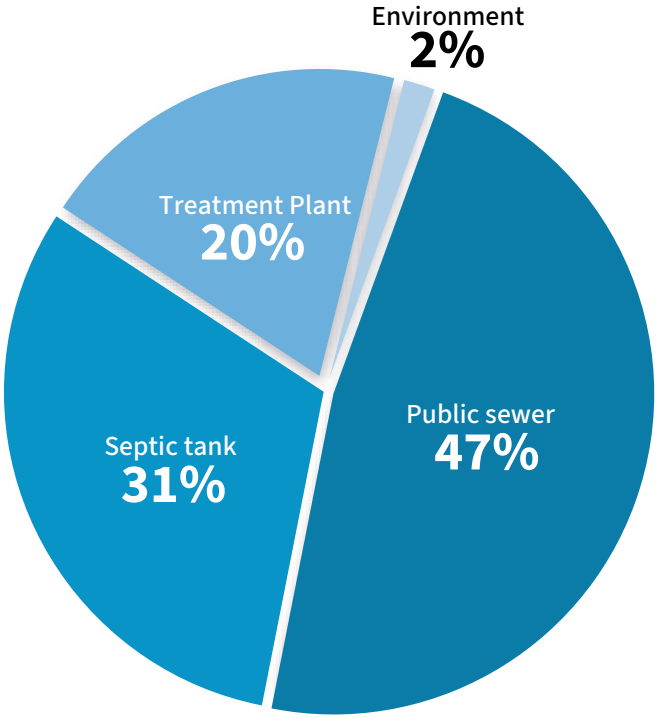
In the Tanzania study report, the majority (56%) of the health facilities/hospital did not receive waste from citizens with varying frequency of collection as demonstrated in figure 26. The amount of pharmaceutical waste originating from citizens was very small (negligible) amounting to 5% of the total pharmaceutical waste of a Health facility. This finding shows that the citizens do not send the expired/unwanted products as per the TMDA guidelines, which requires the citizens/ households to send their expired products to the nearest health facility which implies the products are disposed with other general waste.

Wastewater (effluent) from health care facilities will contain pharmaceutical residues. It is therefore important to investigate the options available for effluent discharge into the environment for the health facilities. Wastewater is disposed of either into a wastewater treatment plant, municipal sewer line, or septic tank. Also, liquid medicines are recorded to undergo dilution and disposal

through the effluent discharge facility. Disposal of improperly treated health care effluent into the environment presents a high chance of environmental contamination from drug residues, human infection and spread of waterborne diseases.

From the respondent data collected, there was one facility that indicated that it disposed of its wastewater directly into the environment before treatment. The available disposal sites include septic tanks, wastewater treatment plants and municipal sewers. Treatment plants (20%) are least used with majority of health facilities (50%) with direct connection to the municipal sewer (Figure 7). The septic tanks are exhausted using boozers into municipal sewer lines for onward treatment through biological wastewater treatment facilities.

Figure 7:
Wastewater Disposal Methods in Hospitals/Health Facilities in the EAC



3.4.7 Technical competence assessments

Many health facilities indicate training their personnel on pharmaceutical waste management (45%), however, there is an equally large number of facilities that do not train their personnel at 55%. Table 17 below shows health institutions that do training on pharmaceutical waste handling.

Table 17:
Hospitals/Health Facilities that Conduct Training on Hazardous Waste Management and Assessment of Technical Competence in the EAC

Partner State	No. of Healthcare Facilities	No. Conducting Training	No. Conducting Assessment	Comments
Burundi	6	None	None	1 hospital has committee for hospital waste management.
Kenya	23	13	15	
Rwanda	3	3	2	
South Sudan	5	1	2	Training done as part of training for hospital cadre in training program
Tanzania	16	9	7	Conduct training on pharmaceutical waste management during their supervision of other health facilities, on job trainings and coaching
Uganda	7	1	1	Assessment on technical competence done through internal supervision.

3.4.8 Challenges

- Lack of adequately trained personnel.
- Limited disposal options. Lack of storage space.
- Delayed response from authorities for disposal permissions.
- Transportation costs to disposal facility.
- Lack of adequate infectious waste disposal equipment.
- No modern and advanced equipment. Small capacity incinerators resulting in waste pilling up.
- Smoke from incinerator causes air pollution.
- Inadequate knowledge on pharmaceutical waste handling and management.
- Inadequate personal protective equipment's for handling infections and pharmaceutical waste.
- Costs for Supervision and lack of budget.
- No guidelines on pharmaceutical waste disposal. Regulatory negligence and ambiguous on responsibility.
- Poor documentation of pharmaceutical waste including expired medicines.
- Lack of guidelines of cytotoxic/chemotherapy waste management.
- Inefficient waste collection system that often result in piling of pharmaceutical waste.

3.4.9 Recommendations

- Provision of adequate infection waste disposal equipment.
- Regular trainings of new employees on pharmaceutical and infectious waste handling and management.
- Public awareness on expired/unused pharmaceutical waste disposal methods including returning them to the nearest health facilities.
- Ensure controlled disposal of pharmaceutical waste.
- Create a smooth disposal trend for pharmaceutical waste to reduce waste piling.
- Harmonize the cost of handling pharmaceutical waste.

3.5 Pharmacies and Chemists Outlets

Retail pharmacies include chemists, retail drug shops and wholesalers, both are a key pathway for pharmaceuticals to reach the consumers (citizens). The outlets are located across the region in all the Partner States, both rural and urban centers, making them a major source and sometimes the only source of pharmaceuticals to the citizen, especially in remote areas. Retail pharmacies and chemists offer a direct link of pharmaceuticals to the citizens. They are at the bottom of pharmaceuticals products distribution, remain the most easily accessible to public and often accounts for the lion's share of interaction between the citizens and pharmaceuticals retail pharmacies. This link is mainly through doctor's prescriptions or over the counter self-medication. This demonstrates the key role played by this sector, and thus the importance of information collected from them on pharmaceutical waste management.

Taking into consideration their large numbers in the region, and the role they play in the pharmaceutical products distribution network, a total of 112 outlets across the region were sampled.

Table 18:
Number of Chemists and Pharmacies Sampled in the EAC

Partner State	No. of Pharmacies & Chemists	% allowed to return to Supplier	% Collection from Citizems	Comments
Burundi	5	0	0	No reverse logistics in place
Kenya	41	68%	24%	Citizens unaware of option to return unused/ expired medicines
Rwanda	27	26%	4%	1 out of 27 reported to receive from citizens. All data collected from Kigali
South Sudan	10	70%	10%	1 out of 10 reported to have collected from citizens
Tanzania	14	78%	22%	
Uganda	15	27%	0%	Allowed return was for short expirely times and damaged items
EAC	112			

To understand the interaction with their suppliers and wholesalers, the study sought to find out whether they are allowed to return damaged, expired, and slow-moving pharmaceuticals to them. Indicatively, (74 out 112, representing 66.07%) most of the chemists and pharmacies are not allowed to return products to their suppliers. The average percentage of outlets who can return their expired, unused, and damaged pharmaceuticals in the region is 44.8% and in the range of 0-78% (Table 26).

The statistics highlight a gap across the region between the suppliers (wholesales, warehouses, importers, and manufacturers) and the outlet pharmacies to the citizen.
Furthermore, being a major pathway of pharmaceuticals to households, the study sought to find out whether chemists and pharmacies accept or have a mechanism to receive expired/unused

pharmaceuticals from citizen for disposal. From the study, 51 out of 112 (45.5%) scoped outlets do not accept or collect unused and expired pharmaceuticals from citizens.

Considering the large number of chemist in the region, about half of the dispensing pharmacies do not collect unused/ expired pharmaceuticals from citizens. This projects to huge volumes of expired/unused pharmaceuticals that are left for citizens to dispose of into the environment without any guidelines.

3.5.1 Approximate Waste Quantities

Sampled chemists and pharmacies recorded an estimated 5,000kg of solid pharmaceutical waste and 1,800 liters annually.

The volume indicated only provides a glimpse of the approximate amount and therefore may not be taken as the actual amounts. Nevertheless, the volumes point to substantial amount of pharmaceutical waste being disposed of by chemists and pharmacies in the EAC region.

3.5.2 Disposal methods

Chemists and pharmacies dispose of most of the solid waste they generated themselves. Various methods of disposal for solid pharmaceutical waste are employed by the outlets, these include:

- Burning.
- Landfill.
- Incineration.
- Handing over to garbage collectors.

For incineration, however, the respondents hand over the waste to facilities with the capacity for incineration. Even so, a high number of the respondents did not indicate using any waste disposal method for their pharmaceutical waste. Burning is the most frequently used method for solid pharmaceutical waste disposal for those outlets recorded to have a waste disposal method. Landfill is also used by the respondents. Direct disposal of solid pharmaceuticals in the sewer is notable by those outlets that are connected to the sewer lines while a pit / pit latrine is reported to be used by a small group of the respondents.

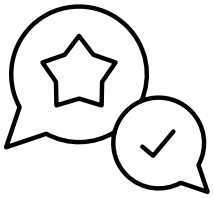
For liquid pharmaceutical waste, dilution is commonly used disposal method in chemists and pharmacies. Unused/ expired medicines are directly emptied into the sink /toilet / sewer / environment for respondents that indicated using dilution as a disposal method. Landfill for liquid pharmaceutical waste is pouring out expired/unused pharmaceutical liquids into the environment (land/ground).

Even though not carried out in large quantities, it is a common practice for chemists and retail pharmacies to hand over waste that they are unable to dispose of themselves to garbage collectors, their suppliers and in a few cases, the regulatory bodies.

3.5.3 Challenges

Different challenges were highlighted by respondents regarding the disposal of pharmaceutical waste in retail pharmacies and they are compiled below. These challenges cut across the entire EAC region.

- The disposal cost is too expensive.
- The disposal process is too cumbersome and bureaucratic as it involves too many institutions and officers' drug regulatory agencies, environmental agencies, Police, and municipal Council etc.
- Inadequacy of storage containers and space for pharmacies to keep pharmaceutical waste for a relatively long period awaiting appropriate disposal.
- Insufficient companies for hazardous waste collection and disposal.
- Lack of training and knowledge of guidelines and disposal procedures at retail level.
- No areas for disposal at retail pharmacy level for small quantities of pharmaceutical waste. It is difficult to dispose of a small quantity of waste, as some costs for approvals are constant regardless of size of waste, which results in keeping waste for long time.
- Lack of knowledge and understanding of pharmaceutical waste management especially for the public.
- No clear policies in handling expired pharmaceutical products.
- Few companies provide pharmaceutical waste disposal services, but also difficult to access the incinerators.
- Long process to obtain authorization for the disposal of pharmaceutical waste.
- Lack of appropriate premises to keep the pharmaceutical waste from the pharmacies before disposal, obliging the pharmacists to dispose of them with general garbage.
- Inadequate personal protective equipment for pharmaceutical waste.



3.5.4 Recommendations

In consideration of the role that chemists and pharmacies play within the pharmaceutical waste generation and disposal web, the study sought to understand the support the respondent deemed necessary for them to be able to play a more active role in collecting pharmaceutical waste from households. Among the noted inclusions were:

- Community education and sensitization on safe disposal of pharmaceutical waste, to include returning them to the chemists and pharmacies for proper disposal.
- Offer training to the chemist staff on proper pharmaceutical waste management. Chemists / pharmaceutical to be given financial support to aid in the disposal of expired drugs.

- Provision of the right waste storage containers and bags for expired drugs and pharmaceutical waste.
- Training of households on pharmaceutical waste disposal. The government should offer this as a free service along with the establishment of local pharmaceutical waste collection centers.
- Prepare, enforce, and implement regulations and guidelines for pharmaceutical waste management.
- Empowering health professions and pharmaceutical companies in pharmaceutical waste management.
- If possible, distributors can take back pharmaceutical products to be disposed of and be refunded for the service.
- A multi-sector collaboration between public institutions and stakeholders is needed to create appropriate management of pharmaceutical waste.
- There is a need to establish a known governmental company responsible for the disposal of pharmaceutical wastes.
- Make affordable and consistent prices for the dispoal of pharmaceutical waste.
- Ensure the process of getting approval for pharmaceutical waste disposal is straightforward.
- Establish collection points and distribute specific collection bags for proper disposal of pharmaceutical wastes.
- To increase the number of incinerators and pharmaceutical waste disposal sites in the Partner States.

3.6 Garbage Collectors

The presence of pharmaceutical waste in household garbage has been reported in many studies in different parts of the world. There are various reasons that result in pharmaceutical products finding their way into the household garbage. The main reasons why a pharmaceutical product remains unused by the patient at the household level and becomes waste are:

- Changing in dosages or changing the medicinal product for the patient.
- The death of the patient.
- The non-completion of the therapy or inappropriate use of the drug by the patient.
- The discontinuation of the therapy due to side effects or when the patient feels better.
- Bad storage conditions.

One of the pathways of disposal of pharmaceutical waste from households is disposal as garbage. In the EAC region, segregation of waste at household level is not practiced and in rural setups, garbage is disposed of at source, through burning, composting, burying and for containers, recycling.

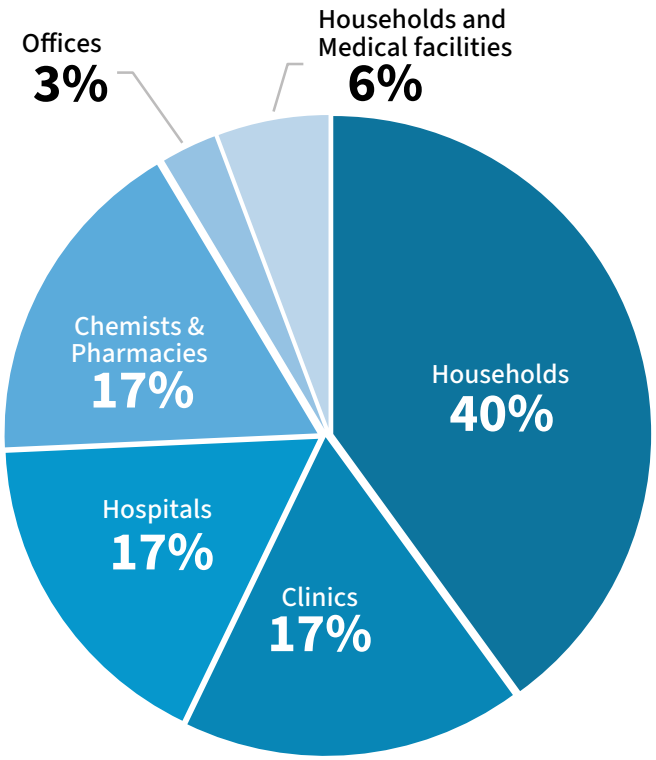
Table 19:
Treatment and Disposal Methods of Pharmaceutical Waste by Garbage Collectors in the EAC

Waste	Disposal Method
Solid waste (tablets, capsules)	Disposed with other organic waste, composting waste, burying and open burning
Liquid waste	Disposed on sewage system and pits
Plastic containers of medicines	Separated for recycling and open burning
All drugs and medicine	Dispose with other general waste
All drugs and medicine	Separate and dispose in the municipal waste area

Garbage collection is practiced only in the urban centers. A snapshot on the presence and types of pharmaceutical waste in domestic garbage can be seen from the analysis of waste collected by garbage collectors. This will give an indication of the need to dispose the waste at household level and further on how pharmaceutical waste from households is disposed of after collection.

The pharmaceutical waste is present in the household garbage bins in significant quantities, which are difficult to assess. The collections done by garbage collectors are a means of disposal of pharmaceutical waste from the households. After collection, the waste is taken to dumping sites. During this scoping study, a total of 24 garbage collectors were sampled in the Partner States, whereby no respondent was sampled from South Sudan.

Figure 8:
Sources of Pharmaceutical Waste for Garbage Collectors in the EAC



Only garbage collectors who collect waste from hospitals and clinics are aware of guidelines and regulations on pharmaceutical waste management in the different Partner States and will have undergone some level of training of handling of pharmaceutical waste. Garbage collectors handling household waste alone do not offer training on handling of pharmaceutical waste to their personnel. However, all of the garbage collectors' firms handling the whole or part of the waste spectrum, report to offer training of pharmaceutical waste handling, except two firms who handle pharmaceutical waste did not have trained staff.

Over 50% of garbage collectors attempt to separate the waste to sort out what can be useful, and what can be recycled, while 25% of the respondents separate the pharmaceuticals from other waste. Only one out of the six who separate the pharmaceutical waste send it to an authorized entity for proper disposal, the others use open burning as a method of disposal. Various reasons are given for not separating.

The reasons for disposal of the pharmaceutical waste with domestic garbage are varied and include:

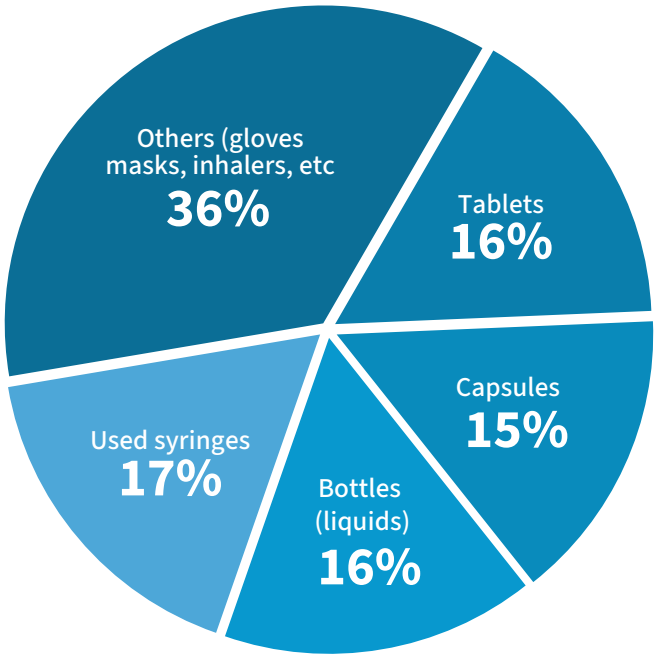
- Protection of domestic animals, since if improperly disposed of within the household, there is a possibility of the animals feeding on the pharmaceutical waste.
- Not having this kind of obligation.
- Lack of information and knowledge on best disposal method.
- No guidance given by authorities.
- Lack of awareness on disposal methods of pharmaceuticals.
- It is a difficult and requires additional costly for entities handling domestic garbage

Garbage collectors also indicated that since there are no guidelines in this regard, they continue to mix all types of garbage from households, including the pharmaceutical waste, to be transported to the dumping sites.

However, the aspect of mixing of waste was also interpreted by garbage collectors in household and chemists /pharmacies domain to refer to the mixing of waste from both sources, and disposal as domestic waste. This is done to reduce disposal costs and even noted that there are no punishments or fines by government if found to do so.

All the garbage collectors (100%) declared finding different types of pharmaceutical dosage forms and devices used to dispense medication from household garbage. All types of medicine/ pharmaceutical waste are found in the household garbage bin. This waste includes tablets and capsules (expired and unused medicines), liquid bottles, as well as used syringes and needles.

Figure 9:
Types of waste reported in the household garbage by the garbage collectors

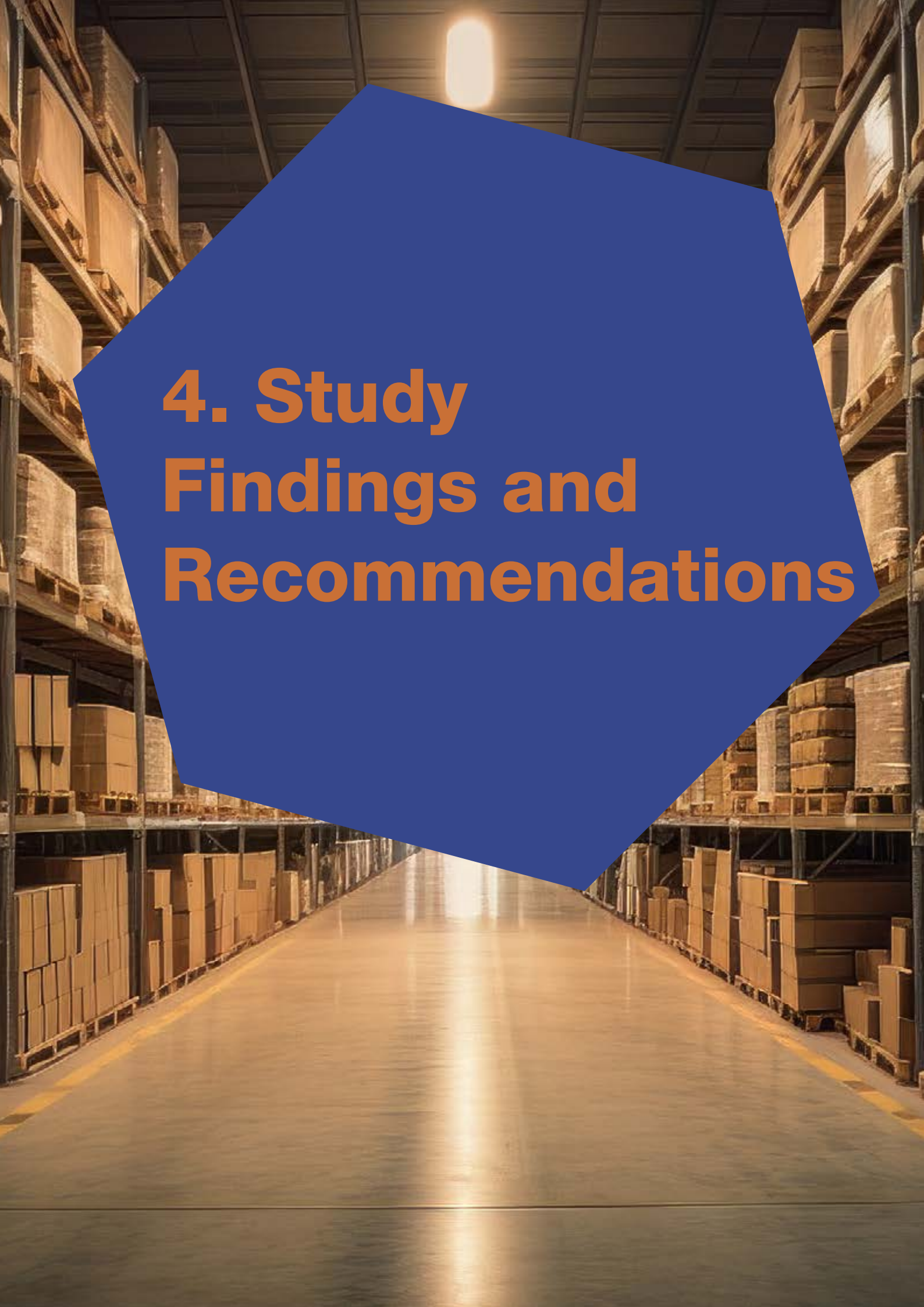


Apart from medicines, other pharmaceutical and medical waste have been reported in household garbage, these include, disposable masks, used bandages or other dressings. After collection, the garbage collectors take the waste to the dumping sites, usually without any further treatment and packages of medicines, strips of tablets and capsules, bottles of syrups are visible at the garbage dumping sites in the outskirts of municipalities.

The respondents placed the responsibility of pharmaceutical waste with the respective ministry, government, local authorities, national medicines authorities, suggesting that the separated waste is delivered to dedicated warehouses with the government taking over the disposal costs.

Challenges were similar in all Partner States as:

- Personnel protective equipment for staff.
- Lack / limited knowledge.
- Information / sensitization at household level and garbage collection firm level.
- Waste separation into colored bag at household level.
- Cost of treatment of pharmaceutical waste.



4. Study Findings and Recommendations

4.1 Summary Findings

A sample size of 312 facilities, across the six Partner States were sampled. The type of pharmaceutical waste disposed of by respondents included the full range of pharmaceuticals and related devices. These included among others, tablets, capsules, liquid bottles, used syringes and needles.

Approximate cumulative annual waste volumes disposed of were established, as shown in Table 20. It is important to note that the waste volumes recorded only represent a shapshot of the actual volumes.

Table 20:
Estimated Cumulative Annual Pharmaceutical Waste Quantities in Six EAC Partner States

Facility	Pharmaceutical Waste (kg)
National Regulators	31,208,750
National Medical Stores	1,842,473
Manufacturers	123,411
Pharmaceutical Warehouses and Stores	90,433
Hospitals and Health Facilities	127,937
Retail Pharmacies and Chemists	6,800
Garbage Collectors	--
Cumulative	**33,399,804**

-- no data available

Waste segregation, though practiced by many facilities such as manufacturers and hospitals, is not highly practiced at the tail end of the chain by the retail chemist and garbage collectors, who directly interact with the households.

The most prevalent mode of solid waste disposal by the manufacturers, regulators, health facilities and pharmaceutical stores is incineration. Hospitals and Warehouses, however, employ more than one disposal method which includes burning, landfill, and handing over to garbage collectors. For retail chemists and pharmacies, burning, landfill and handing over to the garbage collectors are the most common waste disposal methods used. Liquid waste is diluted and poured into the sinks, sewers, or the environment.

A very small percentage, almost negligible (less than 1%), of households return unused or expired medicines to the chemists, hospitals, stores, or the relevant authorities. Almost all pharmaceutical waste from the households is taken over by the garbage collectors, Garbage collectors do not segregate pharmaceutical waste from the other household waste for purposes of safe disposal. All waste from garbage collectors is mixed and disposed of as household garbage.

The cost of disposal varies from Partner State to Partner State, and within the individual states, it varies from facility to facility. There is no harmonized costing for disposal within the individual Partner States and across the entire region.

The study also established that:

- Unsafe disposal of expired/unwanted pharmaceuticals and pharmaceutical waste, presents a challenge to the safety of the environment and a serious health risk to both humans and animals.
- There are huge quantities and volumes of pharmaceutical waste being generated across the region and a high percentage of these volumes are not disposed properly.
- All stakeholders, from manufacturers, regulators, distributors, hospitals, chemists, garbage collectors and households have a role to play in achieving sustainable pharmaceutical waste management in the region.
- There are currently existing guidelines and regulations for pharmaceutical waste management in each Partner State. However, there are no harmonized guidelines for the EAC.
- There is a need to have harmonized regulations and guidelines on pharmaceutical waste management under the guardianship of the EAC secretariat, to complement the already available guidelines and regulations in each Partner State.
- The Pharmaceutical waste disposal methods being used are inadequate and there should be concern of continuing environmental pollution, which is taking place in the EAC Partner States.
- The number of incinerators that have the right specifications and capacity to handle the volumes of pharmaceutical waste being generated within the EAC is inadequate.
- The cost of pharmaceutical waste disposal across the region is high and there is a need for harmonization to achieve proper waste disposal.
- There is minimal engagement between the authorities and households on disposal of pharmaceutical waste.
- There are no records whatsoever, either qualitative or quantitative, on the pharmaceutical waste generated from households and improperly disposed of into the environment.
- There is na eed to establish guidelines that directly target the disposal of pharmaceuticals from households.
- There is a knowledge gap in pharmaceutical waste management across all sectors and therefore a need to train and retool players and stakeholders on pharmaceutical waste management.
- There is need to establish training and community empowerment programs, targeting households on pharmaceutical waste management.
- There is need to establish collective and deterrent policies for deliberate improper disposal of pharmaceutical waste within the EAC region.

4.2 Recommendations

- Fast track or shorten processes for approval to dispose of pharmaceutical waste and related used devices from health facilities, to prevent accumulation of pharmaceutical waste for many years.
- Harmonize regulations and guidelines on pharmaceutical waste under the guardianship of the EAC secretariat to complement the already available guidelines and regulations in each Partner State.
- Each player along the pharmaceutical products and related devices distribution chain, should keep formal records on the quantities of pharmaceutical waste being generated and such records should be available for audits by the Authorities.
- Install enough incinerators with the correct specifications and capacity to handle the volumes of pharmaceutical waste being generated within the EAC.
- Harmonize the cost of pharmaceutical waste disposal to achieve sustainable pharmaceutical waste management.
- Invest in knowledge disseminating programs in pharmaceutical waste management across all sectors involved. Train and retrain players and stakeholders on pharmaceutical waste management. Inclusion of pharmaceutical waste management in the school curricula to induce a culture change for upcoming generations in sustainable pharmaceutical waste management.
- Increase engagement between the authorities and households on disposal of pharmaceutical waste.
- Establish harmonized collective and deterrent policies for deliberate improper disposal of pharmaceutical waste within the EAC region.
- The EAC secretariat to establish mechanisms for monitoring and evaluation of the status of pharmaceutical waste management in the Partner States.
- Government to consider provision of incentives for the population returning pharmaceutical waste to designated collection centers.

5. Conclusion

5.1 International Best Practices

In all waste management considerations, waste generation minimization is always most preferable, as it manages the overall waste that will require disposal[4]. The consequences of improper disposal may lead to contamination of water sources (ground and surface waters) and may also lead to the drugs being collected by scavengers and landfill/dumpsite workers. The best practice involves:

- Follow the laws, regulations, and guidelines on PW management. In this way, all the PW in the State is accounted for, and no PW will be disposed improperly into the environment and protecting public health.
- Do not pour or flush PW down drains or toilets, nor burn PW. There are WHO guidelines[5] on safe disposal of unwanted pharmaceutical, in which the methods and how the expired and unwanted pharmaceuticals can be disposed. To safely dispose of the PW, expertise and equipment for medium temperature and high temperature incineration, engineered landfills, immobilization and inertilization facilities and dilution are required.
- Waste segregation is crucial in the identification of the proper disposal method to apply. This requires expertise.
- The employees in all health facilities should be trained in the proper disposal of the PW.
- The citizenry should be educated on proper PW disposal.

5.2 Conclusion

The study was based on secondary sources, such as existing literature, studies, policies, etc. as well as primary data/information from in-depth interviews with key stakeholders. The study and data collection was conducted across the EAC Partner States (excl. DRC). Data and information collection and gathering was facilitated by the Partner States institutions and stakeholders, that include National Medicines Regulatory Agencies, National Medical Stores, Pharmaceutical Products Manufacturers, not for profit medical stores, importers and distributors of pharmaceutical products, dispensing pharmacies, and big hospitals across the Partner States.

This study has presented qualitative and quantitative information on the handling and amounts of pharmaceutical waste generated in the region. Data was collected using validated tools. A total of 312 facilities distributed over the six Partner States of EAC at various levels of the value chain of pharmaceutical products were sampled and provided the data used in this report.

4 Republic of Kenya, Guidelines for safe management of pharmaceutical waste, 2019

5 WHO Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies, March 1999

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