

Safe disposal of unused medicines

A One Health approach for national systems



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ISBN: 978-92-807-4274-9

Job number: DTI/2756/NA

DOI: <https://doi.org/10.59117/20.500.11822/49324>

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Suggested citation

United Nations Environment Programme (2026). *Safe Disposal of Unused Medicines — A One Health Approach for National Systems*. Nairobi. <https://wedocs.unep.org/handle/20.500.11822/49324>

Production: Nairobi

URL: <https://wedocs.unep.org/handle/20.500.11822/49324>

Cover design: Beverley McDonald

Acknowledgements

The United Nations Environment Programme (UNEP) gratefully acknowledges the invaluable contributions of the experts named below.

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UNEP gratefully acknowledges the financial support provided by the Global Environment Facility.

Acronyms and abbreviations

AMR	Antimicrobial resistance	UNICEF	United Nations Children's Fund
APIs	Active pharmaceutical ingredients	USA	United States of America
BSI	British Standards Institution	WHO	World Health Organization
COP	Conference of the Parties	WOAH	World Organization for Animal Health
EPPPs	Environmentally Persistent Pharmaceutical Pollutants	WASH	Water, Sanitation and Hygiene
ERA	Environmental Risk Assessment		
EPR	Extended producer responsibility		
EU	European Union		
EDI	Expired Drug Initiative		
FAO	Food and Agriculture Organization of the United Nations		
LMICs	Lower- and middle-income countries		
NatRUM	National Return and Disposal of Unwanted Medicines		
OECD	Organisation for Economic Co-operation and Development		
PPP	Polluter pays principle		
R&D	Research and development		
SAICM	Strategic Approach to International Chemicals Management		
SDGs	Sustainable Development Goals		
SF	Substandard and Falsified Medicines		
UNEP	United Nations Environment Programme		

Terms and Definitions

For the purposes of this report, the terms listed below are used as follows:

An active pharmaceutical ingredient: is a chemical substance contained in a pharmaceutical that gives the pharmaceutical its therapeutic effect.

Engineered landfills: are landfills that combine natural protection with engineered systems to ensure the long-term confinement and control of hazardous and other waste. Engineered landfills should be designed based on the type of waste that they will take in, the risk that that type of waste presents and the site where the facility will operate. They are off limits to unauthorized persons.

Encapsulation: is a disposal operation based on solidification, a clean-up method that entraps hazardous waste in a monolithic mass of high structural integrity to prevent it from encountering potential leaching agents.

A hazard: is an intrinsic, potentially harmful property or the ability (of any substance) to cause harm. Harm is an injury or damage to the health of people and/or to the environment.

Healthcare waste: is waste generated by healthcare activities, ranging from used needles and syringes to soiled dressings, body parts, diagnostic samples, blood, chemicals, pharmaceuticals, medical devices and radioactive materials.

Immobilization: is the prevention of the free movement of contaminants from waste or byproducts into the environment. Immobilization options include encapsulation and the inertization of unused medicines.

Incineration: is the destruction of waste by combustion, typically in facilities designed to achieve high-temperature oxidation of hazardous wastes, often converting them into less harmful residues such as ash, gases and heat.

Leakage: refers to materials that stray from an intended pathway and 'escape' or are otherwise lost to the system. Litter is an example of system leakage.

Substandard and falsified medicine: is any medicinal product which contains a misrepresentation of its identity, including its packaging and labelling, name or composition; its origin, including its manufacturer, country of manufacture, country of origin and marketing authorization holder; or its history, including records and documents relating to the distribution channels used.

A pharmaceutical: is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Reverse logistics: is the process of planning, implementing and controlling the efficient, cost-effective flow of raw materials, in-process inventory, finished goods and related information from the point of consumption to the point of origin for the purpose of value recapture or proper disposal.

Treatment: refers to any method, technique or process for altering the biological, chemical or physical characteristics of waste to reduce the hazards it presents and facilitate, or reduce the costs of, disposal. The basic treatment objectives include volume reduction, disinfection, neutralization and other changes in composition to reduce hazards.

Unused medicines: are human and/or veterinary medicines that were meant for use and have expired, become unusable or are not needed for other purposes. They are generated in key sectors including healthcare facilities, agricultural production and households/municipal sources.

Waste: refers to substances or objects that are disposed of, intended for disposal, or destined for disposal as required by provisions of national law.

Sources of definitions relevant to the safe disposal of unused medicines: (Basel Convention 2003; European Union (EU) 2011; UNEP 2021a 2021b; UNEP 2024a; WHO 2025).



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Executive Summary

Pharmaceuticals are essential for human and animal health; however, their release into the environment, particularly through sources such as the improper disposal of unused medicines, poses serious risks, including antimicrobial resistance (AMR), endocrine disruption and toxicity. Unused medicines often result from changes in treatment, misdiagnosis, over-prescription, non-adherence or the inappropriate management of medicine supplies during emergencies. Reports from many countries have underscored the need to improve the management of unused medicines, and so have the countries' National Action Plans (NAPs) on AMR. However, lack of a holistic approach often hinders the effective implementation of safe disposal practices, exacerbating environmental pollution by pharmaceuticals and heightening global health concerns.

This report addresses such challenges by proposing a comprehensive, systematic and multisectoral framework with a stepwise approach to strengthening national systems for the safe disposal of unused human and veterinary medicines within a One Health approach. For illustration, it calls attention to experiences from different countries worldwide. It focuses on three key sectors: healthcare, agriculture and households. Informed by surveys, stakeholder consultations and national reports, it proposes an integrated approach structured around four foundational pillars: waste prevention, comprehensive take-back schemes, legal and policy frameworks, and awareness-raising within and across sectors.

Preventing the generation of waste from unused medicines at source is the first critical measure to avoiding the challenges and costs associated with disposal in the first place. Measures that can be taken to that effect range from improved access to safe water, sanitation, hygiene, biosecurity, vaccination programmes and the appropriate use of medicines to the effective management of substandard and falsified medicines, emergencies and medicine donations.

Comprehensive take-back schemes that encompass all stages—from planning to final treatment and monitoring—make it possible to return and appropriately manage unused medicines from households, healthcare facilities, veterinary clinics and farms. A systematic, stepwise approach, tailored to national contexts, contributes to the schemes' success. The report describes key steps, which involve planning, collection, segregation, registration and storage, transportation, final disposal and treatment, as well as monitoring and evaluation. It also highlights some of the important enabling conditions that will help make such schemes successful; they should have broad coverage and be well-structured, user-friendly, standardized and accessible through widespread collection points. Their effectiveness depends on coordination, robust monitoring, clear policies and active stakeholder engagement. Integrating often-overlooked veterinary medicines into national systems ensures a cohesive and effective approach. It is of utmost importance to classify hazardous waste appropriately in order to effectively prevent risks, and thereby avoid cross-contamination and reduce costs.

Legal and policy frameworks play a central role in defining responsibilities, regulating disposal practices and addressing environmental risks. Legislation that outlines disposal methods for different hazardous waste types and aligns with global agreements provides an enabling environment for safe disposal practices. Integrated planning, coordination and accountability mechanisms can support national policies that clearly outline the roles of the relevant actors — including the authorities, regulators, pharmaceutical producers, healthcare providers, farmers and waste handlers. The report explores financing models, such as voluntary take-back schemes, Extended Producer Responsibility (EPR), government-funded programmes and fee-based or taxation approaches, that have been implemented in different contexts. Further support to the overall system includes sustainable public procurement, environmental risk assessment, transparency, surveillance and

monitoring systems, as well as eco-labelling and packaging standards.

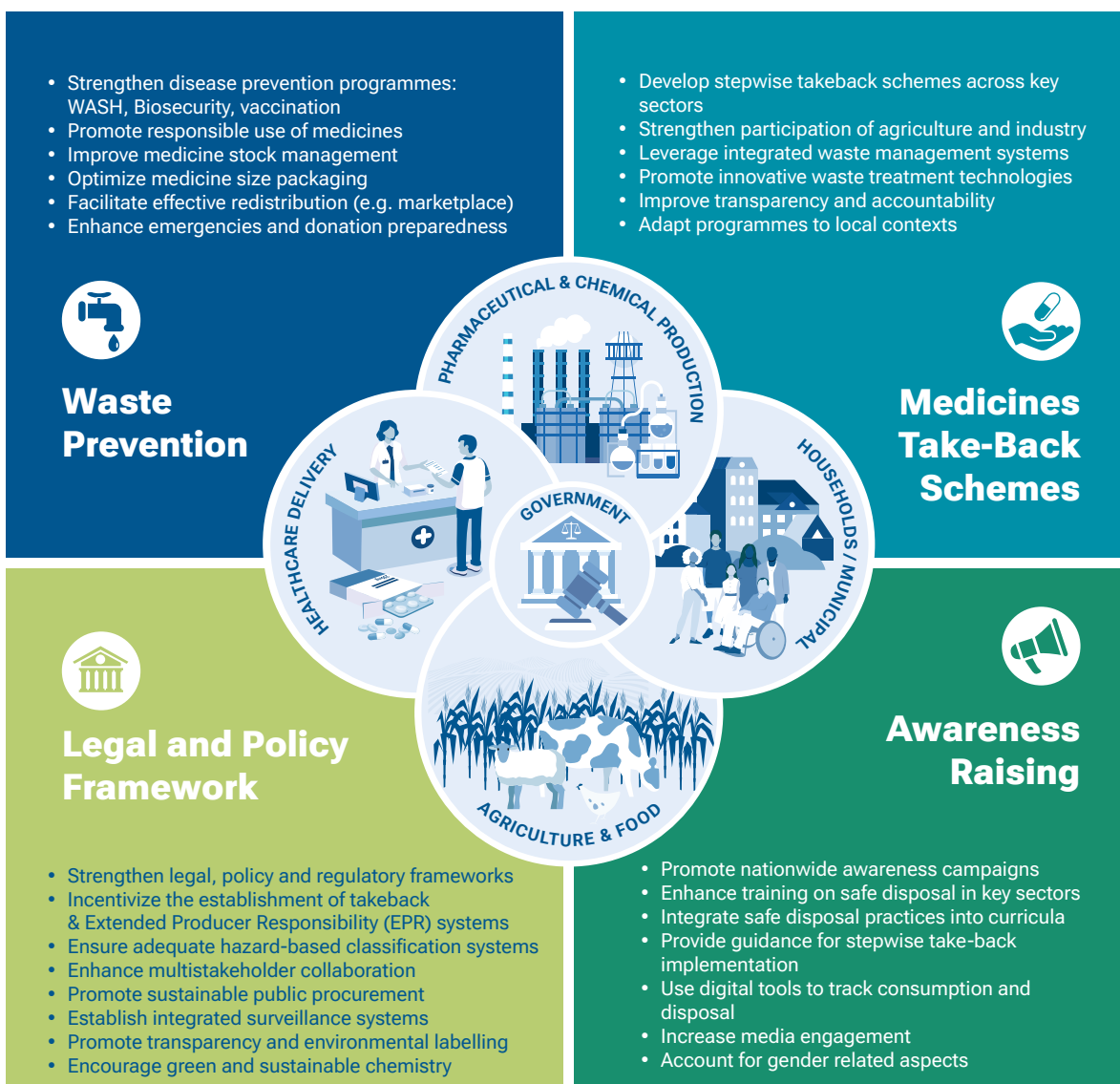
Targeted and regular national awareness campaigns help promote waste prevention and encourage participation in take-back schemes. Tailored messaging for healthcare professionals, veterinarians, farmers and consumers strengthens engagement and understanding of proper disposal practices. Campaigns are more likely to be effective if they are designed around stakeholder needs and supported by digital tools, school curricula, professional education and media outreach. Inclusive, cultural and gender-responsive approaches enhance participation and strengthen outreach efforts.

Continuous assessment and innovation remain essential for improving disposal systems. Successful pilot projects can be adapted to local needs and scaled effectively. Investments in advanced waste-treatment technologies, digital traceability tools and research on pharmaceutical pollution help improve efficiency and policy development. It is crucial to enhance technical capacity and increase funding in order to ensure long-term sustainability and the resilience of national systems for the safe disposal of unused medicines.



Safe Disposal of Unused Medicines from Key Sectors

Four Pillars



01

Introduction

While pharmaceuticals are essential for human and animal health, their release into the environment is an increasing concern, posing potential risks to human and animal health, ecosystems and economies. Human and veterinary unused medicines comprises expired or no-longer-needed pharmaceuticals, as well as items contaminated by, or containing, pharmaceuticals. Such waste is often collected and processed alongside other healthcare and municipal waste. However, unused medicines might require specific handling for control purposes (for instance in the case of narcotics) and owing to its unique chemical composition, hazardous properties and potential environmental persistence. Effective unused medicines management calls for regulations, guidelines and practices that separate unused medicines from general healthcare and municipal wastes, with special consideration for hazardous waste, which requires specific management and oversight (WHO 2025). This document focuses exclusively on human and veterinary medicines intended for use that have expired, become unusable, or lost their value for other purposes. The unused medicines (expired or unexpired) are generated in key sectors, including healthcare facilities, agricultural production as well as households and municipal sources.

1.1 Rationale and purpose

Improper disposal of unused medicines poses significant environmental and health risks, yet substantial gaps remain in the management of unused medicines within and across households, healthcare facilities and agricultural production. Lack of a comprehensive, systematic and multisectoral approach has hindered the effective implementation of safe disposal practices, heightening concerns about environmental pollution from pharmaceuticals and about global health.

Addressing this issue has been recognized as a national priority in a number of countries. In addition,

key international forums have underscored the importance of national-level safe disposal systems:

- NAPs on AMR in many countries highlight the need for the improved management of unused medicines. The AMR Quadripartite Joint Secretariat (FAO, UNEP, WHO and WOA) has reinforced this priority by carrying out capacity-building initiatives and integrating environmental considerations into AMR NAPs. In 2023, Multi-Partner Trust Fund projects in some countries identified the need to strengthen national systems for the safe disposal of medicines (Quadripartite Joint Secretariat n.d.; WHO n.d.).
- The safe disposal of unused medicines has emerged as a critical measure for addressing pharmaceutical pollutants throughout their life cycles, as highlighted in UNEP's "Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment" (UNEP 2020a).

This document aims to strengthen the implementation of national systems for the safe disposal of unused medicines within a One Health approach. It proposes an integrated approach structured around four key pillars within and across critical sectors, along with a stepwise approach for implementing effective comprehensive take-back schemes. By providing a comprehensive foundation for policy development, it equips policymakers and the relevant stakeholders with actionable, evidence-based insights to implement effective, context-specific strategies for the prevention, reduction and environmentally sound management of unused medicines and its associated impacts.

1.2 Causes of accumulations of unused medicines

Unused medicines may accumulate for various reasons, including expiration, changes in treatment needs, over-prescription, misdiagnosis, adverse

reactions to medicine, patient non-adherence, death of patients, stockpiling and errors in prescription or purchase. During emergencies, quantities of unused medicines can grow due to mismatched donations, short expiry dates of supplied medicines, inappropriate storage and excess donations beyond local needs, leading to expiry. Additionally, bulk purchasing incentives and inefficient distribution contribute to medicine waste. Addressing such issues is critical to minimizing the environmental impact and protecting global health (Brechtelsbauer and Shah 2020; United States Environmental Protection Agency 2020; UNEP 2022; WHO 2025).

1.3 Unused medicines-management market

The unused medicines-management market industry is projected to grow from US\$1.21 billion in 2024 to US\$2.54 billion by 2032, showing a compound annual growth rate of over 6 per cent. Key drivers include advancements in waste-treatment technologies, the expanding pharmaceutical industry and increases in: the amount of expired medications; healthcare expenditures; and medicine use (Market Research Future n.d.). Global medicine use has risen by 14 per cent over the past five years and is projected to grow by another 12 per cent by 2028, substantially contributing to unused medicines, including unused medicines. Countries across North America, Europe, Latin America, Africa and the Middle East are expected to see growth exceeding 30 per cent in pharmaceutical spending, driven by population growth and a shift to higher-cost medicines. Pharmaceutical spending by the People's Republic of China is expected to rise by 21 per cent over the next five years, with a 20-per-cent increase in volume, reflecting a continued focus on expanding access to novel drugs through the National Reimbursement Drug List (Institute for Human Data Science [IQVIA] 2024). In Germany for example, the use of medicines intended for humans is forecast to grow by up to 40–70 per cent by 2045 compared to 2017 (civity Management Consultants 2017). Additionally, estimates for the global trajectory of antimicrobial use suggest an increase in antimicrobial use in animals in the coming years (Acosta *et al.* 2025). The rise at the global level is driven by advancements in healthcare, population growth, aging populations and medical technology, highlighting the considerable environmental and financial challenges of unused medicines.

Globally, estimates put the proportion of household medications that become waste at up to 50 per cent. Such disparities vary across countries and pharmaceutical types, driven by factors such as differences in available resources, regulations, access to medicines, healthcare systems and levels of awareness (OECD 2019; WHO 2011). Hazardous waste constitutes about 10–15 per cent of all healthcare waste, with unused medicines accounting for approximately three per cent of hazardous healthcare waste globally (Agamuthu and Barasarathi 2021; Mohammed *et al.* 2021). Estimates put treatment and disposal costs of medical waste at over US\$630/ton in the United Kingdom of Great Britain and Northern Ireland and US\$790/ton in the United States of America (USA) (Giakoumakis *et al.* 2021). Additionally, society incurs an economic loss when pharmaceuticals go to waste. The Netherlands and Italy, discarded medicines worth US\$105 million and US\$211.42 million annually, respectively. While comprehensive data are scarce, medicine wastage in lower and middle-income countries (LMICs) leads to notable financial losses.

1.4 Sources of pharmaceuticals in the environment

The key sectors contributing to the releases of pharmaceuticals in the environment include: the pharmaceutical industry; healthcare facilities, such as hospitals and clinics; laboratories, research and teaching facilities; pharmacies; veterinary practices; veterinary pharmacies and veterinary drug shops for both companion animals and food-producing animals; agriculture production (e.g. terrestrial and aquatic animals and plants) and households/municipalities (UNEP 2023).

Improper disposal of unused medicines—such as discarding them with municipal waste without proper treatment, flushing them down toilets or sinks, or burning them at unauthorized sites—significantly contributes to pharmaceutical pollution in the environment. For example, when unused medications are discarded in municipal waste destined for landfills, pharmaceutical residues may leach into the environment through poorly engineered landfill sites, inadequately treated leachate or runoff. Furthermore, the burning of unused medicines through inappropriate low-temperature incineration or open burning can lead to the release of hazardous air emissions. Additionally,

flushing unused medicines into wastewater systems introduces pharmaceuticals into wastewater treatment plants, which are generally ineffective at fully removing these pollutants. The extent of removal varies significantly depending on the type of treatment and the nature of pharmaceuticals. Moreover, some settings may lack such treatment plants (OECD 2022).

As a result, pharmaceutical compounds are often detected in various environmental compartments, including wastewater, drinking water, surface water, groundwater and soil, either in their original forms or as metabolites (Beek *et al.* 2016; German Environment Agency, n.d; Hanna *et al.* 2018; Hanna *et al.* 2020; Hanna *et al.* 2023).



Caption: Up to 50 per cent of household medications become waste, posing risks to human and animal health and the environment. Photo: Pixabay

1.5 Environmental and public health impacts

Improper disposal of unused medicines may lead to the presence of pharmaceuticals in the environment, which pose significant risks to the environment, and to human and animal health. The risks include AMR, endocrine disruption and toxicity. Pharmaceutical residues can accumulate in soil and water, impacting plants, animals and ecosystems, with potential health and ecological consequences. Furthermore, pharmaceuticals can enter the food chain through

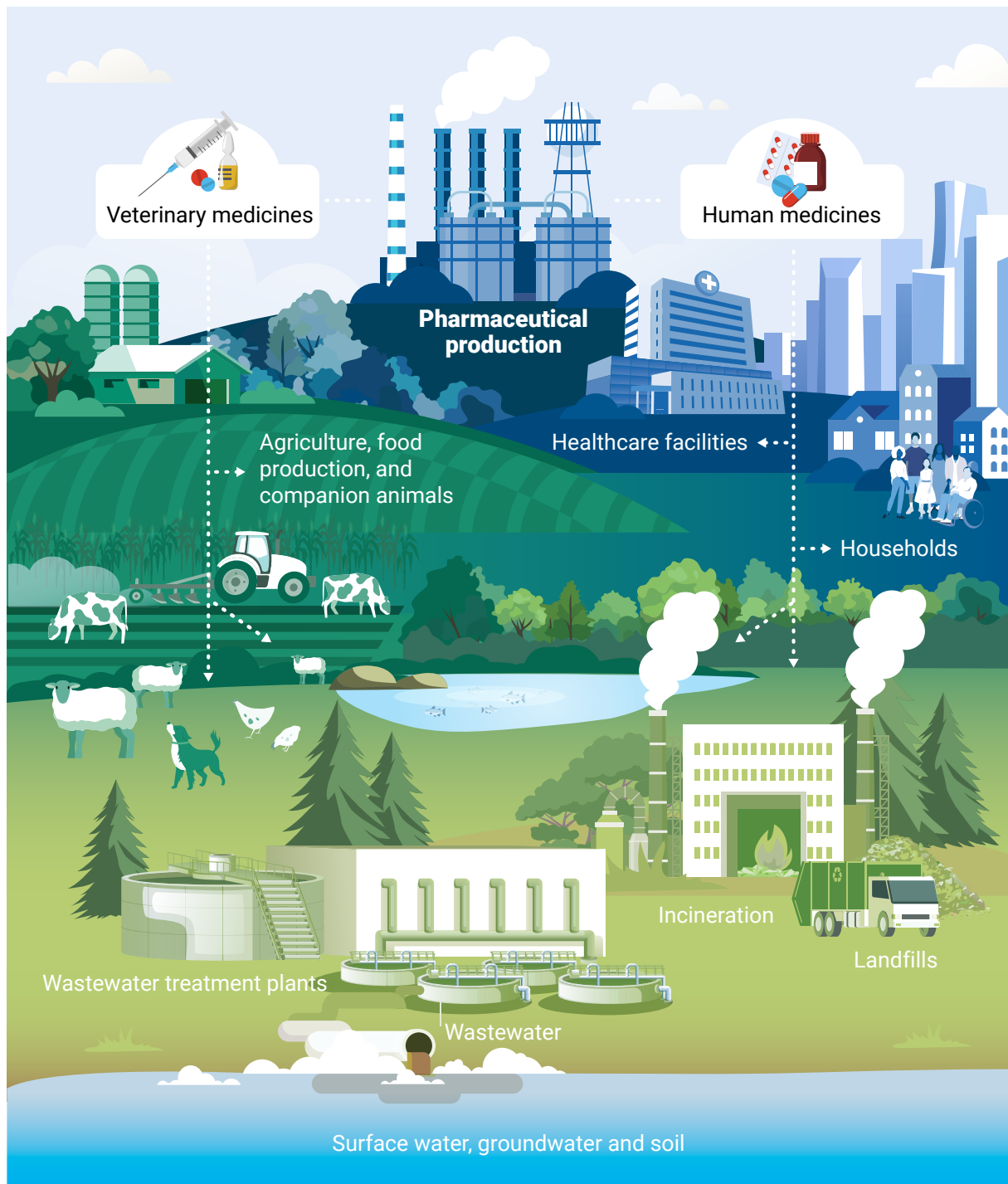
animal feed and plants, raising concerns about food safety. What is more, pharmaceutical mixtures and the interaction of different medicines can trigger additional, unforeseen and potentially harmful effects on the environmental and / or human and animal health. For example, human exposure to antibiotic residues or direct contact with antibiotic-resistant bacteria through contaminated drinking water or food can increase the risk of infections caused by such bacteria, posing significant health risks to individuals and the general population (Shen *et al.* 2018).

WHO recognizes AMR as “one of the top global public health and development threats.” It is estimated that bacterial AMR was directly responsible for 1.27 million deaths globally in 2019 and contributed to 4.95 million deaths. Additionally, new estimates predict 39 million human deaths directly attributable to bacterial AMR between 2025 and 2050 (which equates to three deaths every minute) and 169 million deaths

associated with bacterial AMR. If not adequately addressed, AMR would have serious consequences, among them escalating healthcare expenditures, productivity losses and devastating impacts on livestock production, food security and environmental sustainability (Naghavi *et al.* 2024; WHO n.d.). AMR is closely linked to the triple planetary crisis of climate change, biodiversity and nature loss, and pollution



Sources and Pathways of Unused Medicines



and waste, driven by human activity along with unsustainable consumption and production patterns.

While the causes of AMR are multifaceted, safe disposal of unused antimicrobial human and veterinary medicinal products, such as antibiotics (e.g. ciprofloxacin, penicillin) and antifungal medicines (e.g. triazoles) is important in helping reduce the AMR risk (UNEP 2023). Improper disposal of unused medicines can also lead to increased risks of poisoning and to air, water and soil pollution. For example, open burning and low-temperature incineration of unused medicines can, in certain conditions, release dioxins and furans—human carcinogens linked to various adverse health effects. Improper disposal may also promote black market sales and the wrongful consumption of expired or substandard and falsified (SF) medications, resulting in significant human health risk, financial losses and resource wastage (Richmond *et al.* 2018; Wilkinson *et al.* 2022; Adamie *et al.* 2024; McDonnell *et al.* 2024).

Under the Strategic Approach to International Chemicals Management (SAICM), the fourth meeting of the International Conference on Chemicals Management (ICCM), held in 2015, recognized environmentally persistent pharmaceutical pollutants (EPPPs) as an issue of concern. In 2023, the ICCM adopted the Global Framework on Chemicals, replacing SAICM, and issues were transitioned on an interim basis to “issues of concern” as part of the Global Framework on Chemicals until the next session of the Conference, at which time the Conference will determine their path (SAICM/ICCM.4 2015; UNEP 2024).

1.6 A One Health response

A One Health approach is key to addressing the disposal of unused medicines. The approach recognizes the close link between, and interdependence of the health of humans, domestic animals, wildlife, plants and the environment (Figure 1). Given the steady rise in the global production and use of pharmaceuticals, there is a critical need to implement effective strategies to minimize their presence in the environment and curb their associated impacts. This should involve waste-prevention measures and comprehensive programmes to take back unused medicines, supported by the promotion of preventive actions, strengthened legislation and regulations, efficient awareness raising and outreach,

along with coordinated, cross-sectoral efforts among the relevant stakeholders (WHO 2021; OECD 2022; Allerton *et al.* 2023).

1.7 Economic benefits of the safe disposal of unused medicines

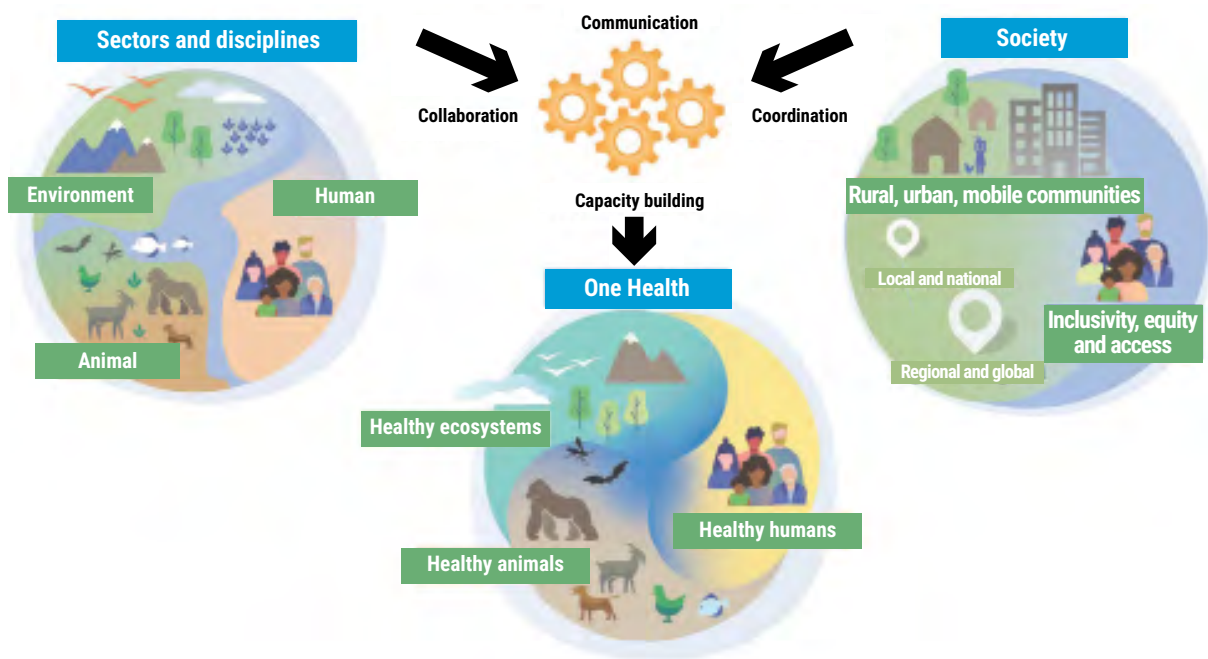
Effective systems for the safe and environmentally responsible disposal of unused medicines provide not only environmental and health benefits but also economic advantages for all stakeholders, including the public and industry. It potentially reduces costs, creates jobs and drives market growth while enhancing operational efficiency and boosting a facility’s reputation, competitiveness and long-term sustainability.

There is evidence that EPR systems have reduced financial burdens on public budgets and taxpayers by shifting the costs of waste management from local authorities to producers and consumers (OECD 2016). EPR systems also contribute to green growth through the waste-management sector, with substantial market value (European Environment Agency 2011). EPR systems for unused medicines generate both economic and environmental benefits. The systems promote technological and organizational innovation and enhance supply-chain management (OECD 2016).

1.8 Gender aspects

Accounting for gender specificities related to the disposal of unused medicines is critical, given the diverse societal roles that shape decision-making, access to resources and exposure to hazards. Women, children and vulnerable populations face heightened risks of chemical exposure, influenced by factors such as geography, behaviour, age, nutrition and cumulative exposure to multiple chemicals. Women, particularly those working in the healthcare and agriculture sectors, are disproportionately exposed to hazardous pharmaceuticals, which is often compounded by inadequate personal protective equipment—especially in LMICs—and entrenched gender roles in pharmaceutical management. Addressing such disparities through targeted interventions, informed by the collection of gender-specific data, specific training initiatives and inclusive decision-making processes can markedly enhance safety. This is in line with the Sustainable Development Goals (SDGs), particularly SDG 5, which focuses on promoting gender equality

Figure 1: One Health definition developed by the One Health High-Level Expert Panel (WHO 2021).



and ensuring safer and more inclusive working environments for all. In addition gender-responsive approaches in unused medicines management can help promote safer practices, equitable participation and more effective public awareness campaigns (UNEP 2022).

1.9 Methodology

This document investigates initiatives related to the safe disposal of unused medicines from households, healthcare facilities and agricultural production, focusing on current practices, associated challenges and the legal and policy frameworks at the global and national levels.

Data and information were collected through the activities indicated below.

- A desk review of national reports was carried out along with studies and surveys.
- A survey questionnaire was distributed to assess medicine use, waste generation, management practices, challenges and key stakeholders for the safe disposal of unused medicines in selected countries. The survey consists of 14 sections containing 40 questions altogether.

- Interviews with the relevant stakeholders from countries including Albania, Indonesia, Germany, Morocco, Peru and Togo were conducted to gather insights and collect data.

The selection of countries for this document on the safe disposal of unused medicines, centred on two key factors: the need for improved disposal practices; and existing frameworks or initiatives in place. The selection sought to ensure a balanced representation of challenges, solutions and regions, allowing for meaningful insights. Countries with significant gaps in disposal systems were included to highlight urgent needs, while those with established practices were chosen to showcase effective models and potential best practices. The disseminated survey questionnaire received responses from the public authorities of Colombia, Indonesia and Peru.

Findings from case studies, based on survey questionnaires in selected countries, were validated as part of the review process.

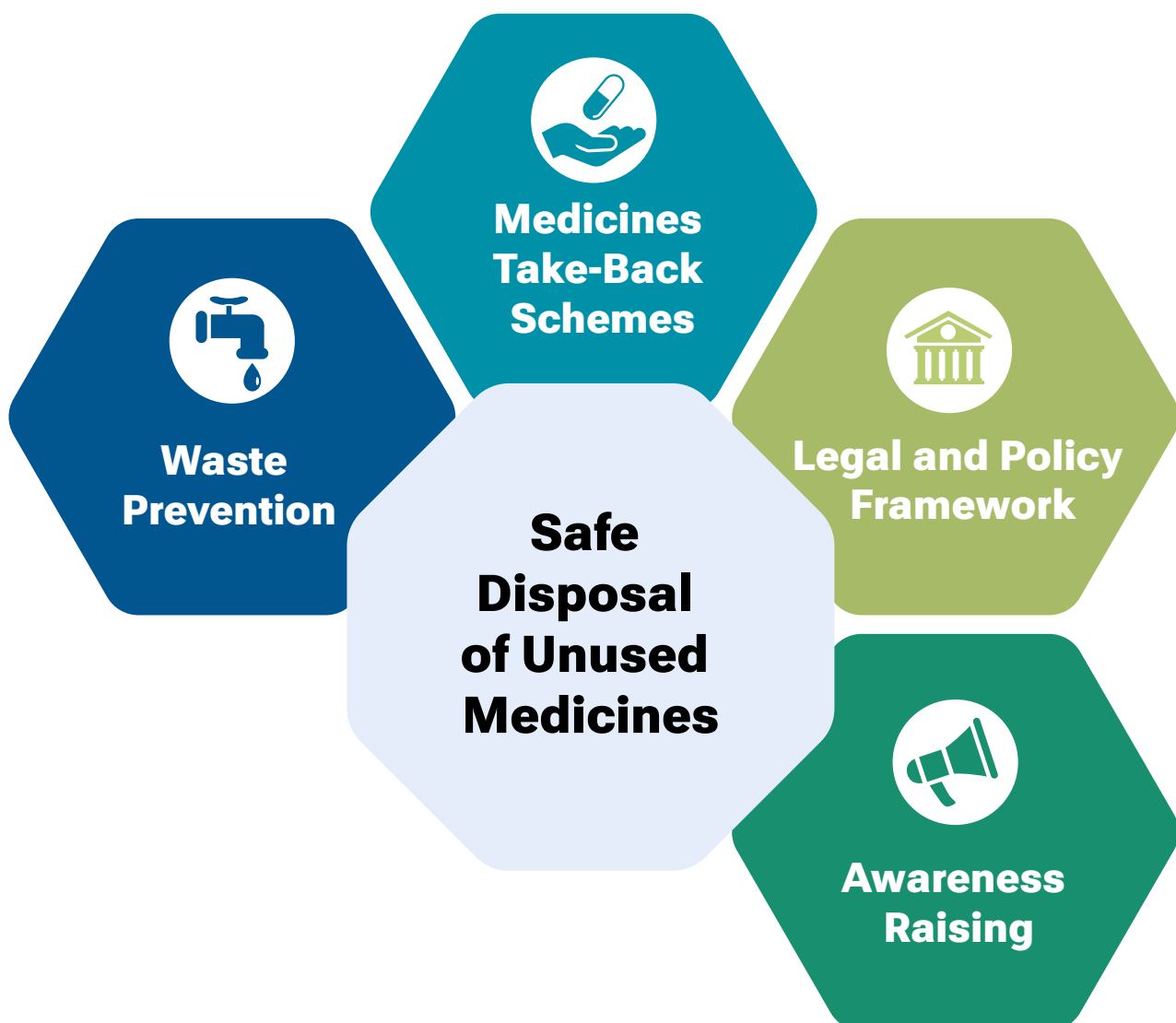
02

Measures for the safe disposal of unused medicines

Ensuring the safe disposal of unused medicines in key sectors, such as households, healthcare facilities and agriculture production requires a systematic and comprehensive approach throughout the entire lifecycle of pharmaceutical products.

This chapter proposes an integrated approach structured around four key pillars (Figure 2), among them waste prevention and comprehensive take-back schemes, supported by legal and policy framework along with awareness raising within and across critical sectors. Additionally, it proposes a stepwise approach for implementing effective take-back schemes.

Figure 2: Key pillars of safe disposal of unused medicines





2.1 Waste prevention

Preventing waste at the source is one of the most effective strategies for reducing human and veterinary medicine waste. It was estimated that the generation of around 40 per cent of unused medicines in the Netherlands could be averted through improved waste-prevention measures (Bekker *et al.* 2018). This section outlines key preventive measures relevant to unused medicines. They include disease prevention, the appropriate use of medicines, marketplaces for unused medicines and the effective management of SF medicines, emergencies and medicine donations.

2.1.1 Disease prevention

In order to reduce reliance on medicines, it is crucial to prevent disease in households, healthcare facilities and agricultural settings. For human health, this includes implementing optimal infection prevention and control measures, enhancing access to clean Water, Sanitation, and Hygiene (WASH) and promoting public health initiatives (for instance healthy diets and regular exercise). In 2023, a total of 743 million people had no water service at their healthcare facilities globally (WHO and United Nations Children's Fund [UNICEF] 2024).

In agricultural settings, effective animal husbandry practices play a key role. They include avoiding overcrowding, adhering to robust biosecurity protocols, maintaining stringent hygiene standards and ensuring comprehensive vaccination programmes. Providing incentives for farmers to adopt improved management practices can remarkably lower the need for antibiotics, which subsequently reduces waste. This dual approach benefits humans and animals alike by reducing dependence on medicines, fostering a more sustainable agricultural system, minimizing waste and mitigating environmental pollution (FAO, WOAHA and WHO 2020).

In Norway, the development of a vaccine to prevent salmon furunculosis, a highly infectious disease, has led to a significant reduction in antimicrobial use in aquaculture. The achievement is attributable to the safety and effectiveness of the vaccine itself as well as to robust public-private partnerships, which facilitated its rapid adoption. The vaccination strategy was further enhanced by participatory legislation that introduced zoning measures and improved coordination among

production units to disrupt the transmission of infections¹ (WOAHA n.d.). Such collaborative strategies have also been successfully implemented in the Faroe Islands, Scotland and Chile, where a neighbourhood system has been developed (Midtlyng *et al.* 2011).

2.1.2 Appropriate use of medicines

The appropriate use of medicines is crucial for minimizing overuse, misuse and waste in the human and animal sectors. WHO estimates that over half of all medicines worldwide are prescribed, dispensed or sold inappropriately, and that half of patients fail to use them correctly.

Actions that are key to promoting the appropriate use of medicines include establishing a national body to coordinate policies, improving diagnostics and implementing medication stewardship programmes. The actions are complemented by using clinical guidelines, developing a national essential medicine list and strengthening the surveillance of the use of medicines in humans and animals. It is equally important to ensure equitable access to medicines and include pharmacotherapy in medical curricula. There is a crucial need for additional measures, such as restricting over-the-counter sales, avoiding unnecessary prescriptions and instituting bans on the use of antimicrobials as growth promoters in livestock and aquaculture (Rutta *et al.* 2015; WHO 2018 n.d.; Browne *et al.* 2021; Ferreira *et al.* 2022; FAO and WOAHA 2023).

It is also important to strengthen pharmacists' capacities to manage the dispensing of medication effectively and promote the return of unused medications. Additionally, there is a need to ensure an adequate number and strategic allocation of trained healthcare and animal health professionals to prevent suboptimal healthcare delivery (Parente and Morton 2018). Such initiatives primarily target antimicrobial end users, who include patients, animal owners (e.g. farmers as well as pet owners), physicians, animal health professionals and pharmacists.

¹ For purposes of international trade or disease prevention or control, "zone" refers to a part of a country, defined by the veterinary authority as containing an animal population or subpopulation with a specific animal health status with respect to an infection or infestation.



Caption: WASH is essential for preventing infectious diseases and reducing waste of unused medicines. Photo: Safari Consoler

The FAO initiative, “Reduce the Need for Antimicrobials on Farms for Sustainable Agrifood System Transformation”, is a ten-year programme supporting the transformation of the agrifood system by reducing the need for antimicrobials through appropriate use and good practices. Aligned with NAPs on AMR and FAO’s One Health approach, it fosters partnerships and integrates regional and global efforts to combat AMR (FAO n.d.)

Targeted medications tailored to the specific needs of individual patients or animals can also lead to fewer, more effective treatments, thereby reducing the likelihood of waste. This highlights the importance of access to diagnostic tests, which play a crucial role in guiding therapy selection. To reduce the quantity of unused medicines, facilities could consider limiting the amount of medicine dispensed to a patient at one go through unit-dose packaging. They could use trial prescriptions or samples to assess the effectiveness of medication before issuing a full prescription, and opt for smaller containers of medicines at the pharmacy.

For example, the Walter Reed Army Medical Center, in the USA, dispenses 99 per cent of pharmaceuticals as unit doses to reduce wastage. Most are blister packs from the manufacturer, while some, including liquid medications in 5-, 15- and 30-millilitre (ml) doses, are packaged on-site. The Marshfield Clinic in Wisconsin switched to purchasing 15-ml or smaller vials of lidocaine instead of 50-ml bottles, reducing both medication waste and purchasing costs (United States Environmental Protection Agency 2010).

However, several challenges hinder the appropriate use of medicines. In some countries, residents in urban and rural areas, particularly those in remote rural locations, frequently seek direct access to medicines over the counter owing to limited healthcare availability or for financial reasons. Cultural practices and past experiences reinforce the tendency to obtain medications without the guidance of healthcare and veterinary professionals, which further complicates efforts to promote the appropriate use of medicines. The misuse of medicines is another challenge, where incomplete diagnostics and patient demand for quick cures may for instance lead doctors to prescribe antibiotics unnecessarily. Lack of awareness and poor regulation and enforcement further amplify excessive dispensing and use, including via online sales (Bach *et*

al. 2016; Davies and Wales 2019; Al-Omari *et al.* 2020).

2.1.3 Marketplace and redistribution

Marketplaces for unused medicines can facilitate their safe and effective redistribution from households, healthcare facilities and agricultural settings, potentially preventing and reducing medicine waste. Additionally, they can improve the matching of supply and demand while boosting economic savings. This is possible only if the returned medicines meet strict quality criteria, including authenticity, unopened packages, the remaining shelf life and proper storage conditions. Regulations and government oversight are essential to ensuring safety and compliance. It is estimated that approximately 19 per cent of unused medicines in the Netherlands qualify for redispersing and redistribution (Bekker *et al.* 2018). A study conducted in the Netherlands showed a link between the redispersing of unused oral anticancer medicines with waste reduction and cost savings, which can improve the affordability and sustainability of cancer treatment (Smale *et al.* 2023). In most countries, the redistribution of unused medicines is uncommon owing to concerns about quality assurance, counterfeit risks and legal restrictions.

Case study from the Netherlands: PharmaSwap

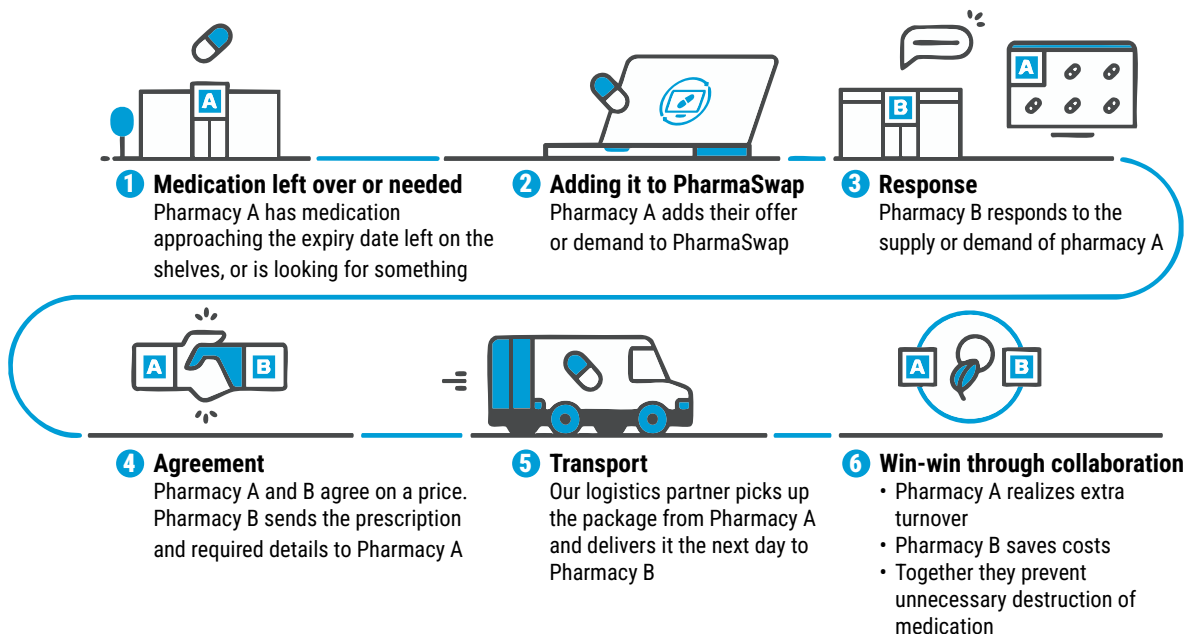
This innovative online platform helps pharmacists and wholesalers exchange medication supplies to curb the waste of medicines nearing their expiration date. This unique marketplace allows pharmacies and wholesale organizations to advertise and exchange medicines, effectively cutting costs and waste. Certified pharmacists can sell unused or undamaged medicines to other pharmacies in need, often at discounted prices, all while adhering to strict regulations. In the Netherlands, PharmaSwap (launched in 2022) allows certified pharmacists to sell unused, unexpired medicines to other pharmacies in need (PharmaSwap 2022).

PharmaSwap facilitates two primary types of exchanges

Wholesale to pharmacy: Wholesale organizations offer medicines with limited expiry dates to pharmacies, helping minimize unnecessary waste. **Pharmacy to pharmacy:** Pharmacies can trade medications under regulated conditions. Once they agree on a transaction, the selling pharmacy assumes the role of the treating pharmacy, and both parties adhere to instructions provided by PharmaSwap.

Currently, PharmaSwap connects eight hospital pharmacies, 1,265 community pharmacies and eight wholesalers. Through more efficient stock management it has successfully redistributed over 13,816 packages and saved more than €2,008,610 in procurement costs.

PharmaSwap: how it works between pharmacists



2.1.4 Effective management of substandard and falsified medicines

The prevalence of SF medicines is a critical health, socioeconomic and environmental challenge that deprives individuals of access to quality, affordable treatments and contributes significantly to mortality. Ineffective or harmful SF medicines drive up medication use and waste since they necessitate additional treatments, prolonging illnesses and straining healthcare resources. According to WHO, at least one in ten medicines in LMICs is SF. Countries spend an estimated US\$30.5 billion per year on SF medical products. Challenges and emerging threats include the rise in online sales of medical products, advances in technology, the global movement of goods, the use of artificial intelligence to design easily falsified products and the impact of social media in promoting certain products (WHO 2024a).

Estimates link 122,350 annual deaths of children under five in sub-Saharan Africa to poor-quality antimalarials. Sub-Saharan Africa is particularly vulnerable, with 70–90 per cent of medicines being imported and 42 per cent of global SF trafficking cases originating in the region. This illegal US\$200 billion global market undermines economies and has potential links to organized crime and terrorism. Recognizing the urgency of the issue, six African nations signed a political declaration, the Medicines and Falsified Quality Initiative, at the Lomé Summit on 18 January 2020. The initiative commits the Democratic Republic of the Congo, Ghana, Niger, Senegal, Togo and Uganda to ratifying international agreements, introducing stricter criminal sanctions against traffickers and raising public awareness of the dangers of SF. Supported by international organizations, this joint effort aims to address: the multidimensional threat to public health; safety economic stability; and environmental sustainability (Fight against medicines that kill n.d.; Ministry of Health, Public Hygiene and Universal Access to Care 2022).

2.1.5 Effective management of emergencies and medicine donations

Building a resilient health system is crucial for reducing unused medicines through effective management of emergencies and medicine donations. In Colombia, the Fundación Banco de Medicamentos is a leading

organization with over 20 years of experience in managing and distributing medicine donations and healthcare supplies to vulnerable communities across the country. In 2023, the programme delivered 8,651,028 units of medicines and health supplies, reaching 28 departments, 225 beneficiary institutions and 118 municipalities and cities. The programme efficiently links private pharmaceutical companies with national and international public and private entities to fill gaps in the health system by supplying essential health products. Maintaining strict oversight of product quality, safety and expiration dates to prevent potential health risks is a critical challenge in the donation of medicine. Such initiatives must be conducted exclusively by authorized and trustworthy entities, within the relevant legal framework, to ensure the integrity of medicines at every stage—reception, storage and distribution. This robust approach minimizes the risks of counterfeiting, adulteration or illegal trade, thereby protecting public health and the environment in Colombia (survey questionnaire 2024; Banco de Medicamentos 2024).



Caption: Managing and distributing donated medicines: a sustainable solution in efforts to reduce the accumulation of unused medicines. Photo: Banco de Medicamentos (BDM)

Case study from Peru: System for the safe disposal of unused medicines

In Peru, unused medicines management is regulated by various legislative frameworks. Management is governed by laws ensuring proper handling, destruction and disposal. The Regulation for Pharmaceutical Establishments (Decree N° 014-2011-SA) mandates the destruction of expired, damaged or contaminated products at least annually, following approved procedures to prevent waste accumulation. The Good Manufacturing Practices Manual (D.S N° 021-2018-SA) requires manufacturers to implement waste-management policies to address risks and prevent accumulation, ensuring the treatment of waste to prevent health and environmental hazards. The Technical Health Standard (NTS N° 144-MINSA-2018-DIGESA) classifies unused medicines as “Special Waste, Type B.2,” requiring the decommissioning of expired medications.

Unused medicines is categorized under the Legislative Decree on Comprehensive Solid Waste Management (DL N°1278) as hazardous or non-hazardous, depending on its risk level. Hazardous waste requires special handling, while non-hazardous waste poses minimal risk. The Technical Health Standard further divides waste into three classes. Class A refers to bio-contaminated waste. Class B concerns special waste: hazardous chemical waste, unused medicines and radioactive waste. Class C relates to common waste.

Unused medicines management in Peru involves multiple stakeholders, including the ministries of health, the environment, production and agrarian development, as well as academia, professional associations and civil society, working together to ensure proper waste management in line with national regulations.

Peru has strived for many years to combat illegal trade and collect expired medicines. According to recent data, the country saw the destruction of 7.5 tons in 2019; 8.4 tons in 2020; 6 tons in 2021; 11 tons in 2022; and 9 tons in 2023. As part of the national campaign to collect expired and unusable medications from households, containers are placed in collection centres across Metropolitan Area of Lima, including in hospitals, health centres and pharmacies. The campaign began in 2017 with seven mobile points and 75 kg collected. It expanded over the years: 2018 (15 points, 102 kg); 2019 (58 points, 1,437 kg); 2020 (64 points, 724 kg); 2021 (81 points, 1,764 kg); 2022 (101 points, 2,984 kg); and 2023 (144 points, 3,500 kg). As of 2024, there were 164 points with approximately 2,500 kg collected.

Despite progress, challenges persist. Delays in approving the Administrative Directive which governs waste destruction, have obstructed standardized procedures. It is crucial to expand the collection point network, especially in institutions like EsSalud, (Social Health Insurance of Peru), and raise public awareness in order to improve participation and compliance (survey questionnaire 2024).



2.2 Comprehensive take-back schemes for unused medicine

Take-back schemes are programmes designed for the return of unused medicines—both human and veterinary—and require a systematic and comprehensive approach to ensure the safe and environmentally sound management of unused medicines. The schemes can facilitate the return of unused human medicines from households and healthcare facilities, as well as veterinary medicines from veterinary practices, farms and households with companion animals. They are guided by local or national regulations and policies and supported by stakeholder collaboration. Existing take-back schemes often focus solely on collection, without a comprehensive and systematic approach to proper disposal. This section proposes a stepwise approach to ensure the environmentally sound disposal of unused medicines.

The implementation of the approach takes into account the national context, local infrastructure and regulations, as well as the approach's technical and economic feasibility. This is vital to ensuring that it is adapted and well suited to local needs. When well designed and properly implemented, such programmes minimize the environmental and economic impacts of unused medicines while promoting public health and safety. Effective coordination among stakeholders, such as pharmacies, governments, regulatory authorities, pharmaceutical producers, healthcare facilities, agricultural sectors and consumers is essential for the success of such initiatives. By establishing clear regulations, ensuring transparent monitoring, providing incentives, promoting public-private partnerships and adopting tailored approaches, take-back schemes can significantly improve the management of unused medicines across all sectors.

In addition, integrating take-back schemes into existing municipal solid waste-management systems can considerably improve efficiency, accessibility and resource optimization, particularly in resource-limited settings. By consolidating unused medicine-waste collection with established municipal waste infrastructures, the schemes reduce redundancy, lower operational costs and enhance accessibility for diverse populations. The Global Waste Management Outlook 2024 emphasizes the benefits of integrated

waste-management systems in creating synergies by streamlining collection and treatment infrastructure. Leveraging such systems for the management of unused medicines is especially advantageous in LMICs, where resource constraints often limit the feasibility of standalone programmes. This approach not only aligns with efficient resource use but also strengthens the overall waste-management framework (UNEP 2024a).

The stepwise approach for comprehensive unused medicine take-back schemes includes planning; collection; segregation; registration and storage; transportation; final disposal and treatment; and monitoring and evaluation.



2.2.1 Planning

There is a need to develop comprehensive unused medicine-waste-management plans that cover the full lifecycle of

pharmaceuticals and that take into account the relevant stakeholders from key sectors, among them the local authorities. This includes mapping and documenting consumption patterns, manufacturing sites, waste-treatment capacities and waste types and volumes. Effective planning also necessitates waste assessment, training and awareness programmes, health and safety protocols for workers, the scheduling of waste-management activities, tracking strategies for unused medicines, emergency-response planning, resource allocation and monitoring and evaluation (Mehtonen *et al.* 2020). It is vital to take into account the security of unused medicines, particularly controlled substances, and to address the risk of diversion of collected unused medicines (United States Environmental Protection Agency 2023).



2.2.2 Collection

Take-back schemes facilitate safe disposal, allowing consumers to return unused medicines to designated



collection points for appropriate disposal. The points are typically provided by pharmacies, local government waste facilities, pharmaceutical industries, veterinary practices or agencies equipped to manage unused medicines and ensure proper disposal.

Participation in take-back schemes varies significantly across countries. For instance, in the Baltic Sea region of Europe (nine countries), the percentage of surveyed citizens returning unused medicines to designated collection points ranges from about 10 per cent to 70 per cent. Several factors influence the variation in returned medicines in the region, for instance responsibility (municipalities or pharmacies handling collection), legislation (clarity and the enforcement of laws), public participation (awareness and convenience) and incentives (rewards or free services) (Mehtonen *et al.* 2020).

Enhancing the effectiveness of take-back programmes requires addressing implementation gaps through targeted strategies. Broad participation calls for well-structured, user-friendly, standardized and widely publicized programmes. It is also essential to provide information in multiple languages to ensure accessibility (Umweltbundesamt 2025). Additionally, there is a need to establish accessible collection points across urban and rural locations, alike, to maximize reach and impact. Establishing clear programme ownership is essential, alongside legislation that defines financial responsibilities for the stakeholders involved. Public awareness, strong coordination and regular monitoring are key to the effective disposal of medication, and to creating an enabling environment for community engagement and continuous programme improvement (OECD 2022).



2.2.3 Segregation

The objective of pharmaceutical segregation is to categorize pharmaceuticals for proper management based on their hazardousness and dosage form. Proper segregation at the facility (e.g. hospitals, pharmacies, veterinary clinics or other operators) clears the way for qualitative and

quantitative prevention, halting pollution by other waste streams and saving costs. WHO guidance categorizes unused medicines as: non-hazardous waste (that does not pose a significant risk to health or the environment) such as minerals, electrolytes and metals; hazardous waste (that is chemically dangerous or toxic) such as antimicrobials and anti-inflammatory medicines; and hazardous controlled waste (pharmaceuticals that are regulated owing to their potential for abuse or misuse) such as opioid analgesics, benzodiazepines and amphetamines.

The segregation process also considers dosage forms (solids, liquids or gases) and must be maintained until the final disposal. All inadequately labelled medicine should be considered hazardous. It is important to have teams, supervised by pharmacists, carry out large-scale segregation following emergencies. This ensures proper labelling and the use of protective equipment (Basel Convention 2003; Mehtonen *et al.* 2020; Sapkota and Pariatamby 2023; WHO 2025).



2.2.4 Registration and storage

Following segregation, the relevant stakeholders (e.g. hospitals, pharmacies, veterinary clinics or other operators)

should register unused medicines and maintain records for tracking and reporting. The storage of such waste must follow strict safety protocols that include appropriate containers and storage in designated areas before final disposal and treatment. This involves secured and ventilated storage facilities, to prevent pollution, and compliance with national regulations on storage times and conditions. Operators need to maintain well-documented storage units that track waste types and quantities.

Storage areas must be secure, accessible only to authorized personnel, well-lit and easy to clean. Waste should be stored on shelves with separate compartments for hazardous and non-hazardous materials, with hazardous liquids placed on leak-proof trays. It is important to lock away controlled substances for added security. There is a need to

plan additional storage capacity for emergencies and assess long-term storage sites for pollution risks, such as fire, explosion and biological hazards. Leaks and spills must be managed appropriately (Mehtonen *et al.* 2020; Basel Convention 2003; Sapkota and Pariatamby 2023; WHO 2025).



2.2.5 Transport

Transport approaches vary based on the waste category. Hazardous unused medicines should be collected, labelled and transported to treatment facilities

in appropriate containers that prevent leakage and comply with regulations or policies. The transport of hazardous waste must follow national regulations or, where inexistent, the United Nations guidelines for transporting dangerous goods. Hazardous controlled substances require additional monitoring by the relevant authorities and police during transport and disposal. The Basel Convention regulates unused medicines destined for transboundary transport, which involves a prior informed consent procedure before crossing borders, ensuring compliance with safety and environmental standards (Basel Convention 2003; Sapkota and Pariatamby 2023; WHO 2025). More details about the control procedure are available on the UNEP website (UNEP 1998).

regulatory and safety factors, as well as resources. All methods demand proper training for waste handlers and adherence to environmental standards and safety. Treatment options can be considered for hazardous waste and hazardous controlled waste.

- Optimal treatment options include high-temperature incineration with flue gas cleaning, coprocessing in a high-temperature process (cement kiln) and waste immobilization, followed by disposal in an engineered landfill.
- Interim options with incremental improvement include high-temperature incineration with no or limited flue gas treatment, a medium-temperature dual-chamber incinerator with auxiliary burners, burial in an engineered landfill and immobilization and disposal in controlled a landfill.
- Immediate short-term response in emergency situations include encapsulation and disposal in an uncontrolled landfill.

Low- and medium-temperature incineration without auxiliary burners, burial in an uncontrolled or controlled landfill without prior treatment or immobilization and dilution of hazardous pharmaceuticals are discouraged. They pose a high risk to health and the environment and should be avoided. Further details can be found in guidelines of WHO, 2025, and the Basel Convention (Basel Convention 2003; Basel Convention 2022a; Basel Convention 2022b; WHO 2025).

The recycling of pharmaceutical packaging that has not had direct contact with the product (not primary packaging) is also relevant. It is important to remove or obscure all sensitive information, such as patient details, company names and medicines' names. The Global Waste Management Outlook 2024 emphasizes the importance of recycling close resource loops, reducing reliance on virgin material and aligning with the principles of the circular economy, to minimize the waste footprint.

Wastewater

Flushing unused medicines down the drain is an inappropriate disposal method and typically is not recommended, as it leads to pharmaceuticals entering wastewater systems. It is vital to implement proper measures to prevent and control pharmaceutical



2.2.6 Final disposal and treatment

Unused medicines

Unused medicines and final disposal methods vary by country context. Non-hazardous waste can be treated like

other waste if secure infrastructure prevents reuse or resale; otherwise, it needs to be handled as hazardous. Mixing hazardous and non-hazardous waste makes it necessary to classify all waste as hazardous and to dispose of it as such, and should be avoided to prevent increased disposal costs. Selecting and implementing treatment options depends on waste characteristics,

pollution in wastewater in order to minimize environmental risks. For example, the untreated discharge of antimicrobial effluent can promote resistant microorganisms in the environment (WHO 2024b). Globally, only 52 per cent of wastewater is adequately treated, a proportion that drops to 26 per

cent in LMICs. Weak regulations and poor enforcement aggravate the issue (United Nations University [UNU] and INWEH 2024).



Caption: Diverse treatment methods and hybrid technologies for the efficient management of unused medicines water. Photo: abdo alshre

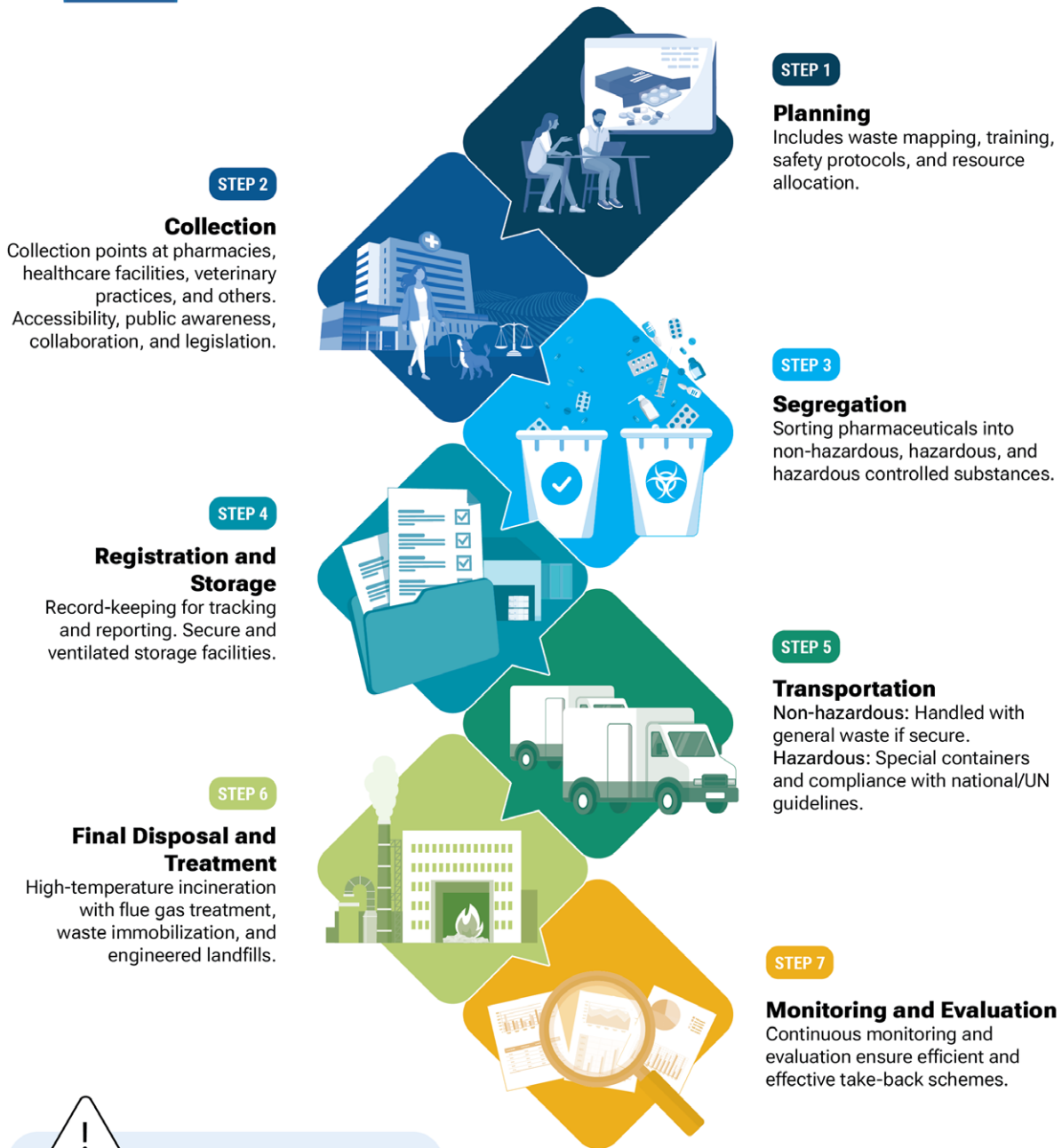
The efficiency of pharmaceutical removal in wastewater treatment plants varies widely, depending on the physio-chemical properties of the Active Pharmaceutical Ingredients (APIs), the effluent and treatment methods employed. While advanced treatment methods, such as advanced oxidation processes and activated carbon filtration can efficiently remove pharma pollutants from effluents, there is a need for more environmentally responsible options. Although newer technologies, such as advanced catalysts that generate oxidants, show promise in

neutralizing APIs at potentially lower energy costs, current solutions remain expensive. Treatment options have limitations; biological treatments in use, like activated sludge, are inadequate to eliminate pharmaceuticals in effluent (Langbehn *et al.* 2021). There is a need to integrate the use of diverse treatment methods and hybrid technologies into solutions in key sectors to minimize the release of pharmaceuticals in the effluent. It is also crucial to apply the best, available, cost- and energy-efficient technologies to the management of effluent. This includes setting



Comprehensive Take-Back Schemes of Unused Medicines

Take-back schemes are a key pillar in the safe disposal of unused human and veterinary medicines and require a systematic, stepwise approach.



discharge targets to promote sustainable, locally appropriate wastewater-management technologies (Rizzo *et al.* 2013; Khasawneh and Palaniandy 2021; UNEP 2023; Singh and Shankar 2024). For instance, under Switzerland's 2016 water protection law, about 100 sewage treatment plants must be upgraded by 2040 to meet national water quality standards. A sewage tax paid by residents will fund the upgrades, including an additional purification stage (Wepf 2016).



2.2.7 Monitoring and evaluation

It is vital to continuously monitor and evaluate the efficiency and effectiveness of implementing a

comprehensive take-back scheme. This responsibility rests both with operators managing processes and external authorities conducting independent inspections. Key activities include regular audits, updates to plans and the implementation of corrective actions. Robust systems for data collection, reporting and monitoring support evidence-based policymaking and the tracking of progress. Key indicators include take-back programme performance, the quantities of unused medicines collected and disposed of safely as well as the levels of public engagement. It is possible to integrate implementation progress into the Tracking AMR Country Self-assessment Survey (TrACSS), which enhances accountability and alignment with broader AMR strategies (Basel Convention 2003; Mehtonen *et al.* 2020; Quadripartite on AMR n.d. a; Quadripartite on AMR n.d. b; Sapkota and Pariatamby 2023; WHO 2025).

Case study from Indonesia: System for the safe disposal of unused medicines

In Indonesia, unused medicines is defined as hazardous waste and includes expired, unused or contaminated medications and their packaging, that pose environmental and health risks. In 2023, the country recorded the production of about 47 tons of waste from pharmaceutical industries and 785 tons from healthcare facilities.

The responsibility for unused medicines management spans the Ministry of Environment and Forestry, the Ministry of Health, local governments, healthcare facilities, the pharmaceutical industry, waste management companies, waste transporters and the National Agency for Disaster Countermeasure.

Unused medicines management is regulated under Government Regulation No. 22/2021 on Environmental Protection, Ministerial Regulation No. 6/2021 on Hazardous Waste Management, and Ministerial Regulation No. P.56/2015 for Health Service Waste. The Ministry of Health and the Ministry of Environment and Forestry work together on compliance initiatives, addressing issues and promoting safe practices. However, they face challenges such as lack of awareness and training in proper unused medicines-management practices, sectoral coordination gaps, inadequate infrastructure and financial constraints.

Unused medicines from households (or the equivalent) is classified as specific waste and regulated under the Ministry of Environment and Forestry's Regulation No. 9/2024. The regulation stipulates that specific waste be collected in the temporary landfill, transported to a specific waste treatment facility and handed over to the Waste and Hazardous Waste Management Services.

While public health promotion and improved sanitation practices are in place to prevent waste generation, they are hampered by limited resources. The country implemented the extended producer responsibility principle to manage unused medicines. This requires healthcare facilities to manage waste storage, treatment and disposal, and to report through the Digital Reporting and Evaluation System. However, limited infrastructure and resources make compliance difficult.

Unused medicines must be stored in designated facilities and treated by methods, such as incineration, autoclaving and irradiation. While incineration remains the most common method, rural areas lack adequate facilities, which makes compliance challenging.

The Reporting and Evaluation System records and audits waste management but faces challenges due to inadequate training and staffing. The Government also provides incinerator grants to regional hospitals, although access remains limited in rural regions. Awareness campaigns and capacity-building programmes aim to improve compliance. However, some businesses resist changing established practices, and operator turnover presents training challenges.

Although emergency situations call for competency-certified waste managers and an emergency-response system, infrastructure gaps hamper preparedness. While plans are underway to establish collection depots for temporary healthcare waste storage, they face logistical and capacity challenges (survey questionnaire 2024).



2.3 Legal and policy framework, roles and financing mechanisms

Legal and policy frameworks are key to providing the foundations for the safe disposal of unused medicines. As a general rule, waste should be prevented whenever possible. Whenever waste is generated, it should be treated to prevent its releases in the environment. Different types of waste require specific disposal methods, and legislation often outlines measures to reduce or eliminate the various waste streams.

Integrated planning and robust accountability mechanisms are key to ensuring efficient resource use and the effective management of complex waste streams, such as medicines. National policies and guidelines should embrace relevant aspects of global policies and treaties that countries have adopted. There is a need for national guidelines and plans to: clarify the roles and responsibilities of the relevant stakeholders from the various sectors involved in preventing the generation of, and reducing, unused medicines; and to tailor a plan to meet the requirements of each context. Such clarification concerns the authorities, pharmaceutical producers, distributors, healthcare facilities, agricultural settings and pharmacists. Establishing clear roles promotes effective collaboration and accountability among all parties, which enhances the overall efficiency of the management of unused medicines. Efficient and safe waste management calls for clearly communicated instructions on the practices (OECD 2022). Principles such as “polluter pays,” “precautionary,” “duty of care,” and “prior informed consent” underpin effective waste management (WHO 2017). Increasingly, policy frameworks embed unused medicines management within circular-economy approaches. In this context, unused medicines management is shifting towards a circular model structured around six steps: reduction, reclamation, reuse, recycling, recovery and rethinking (OECD 2022).

2.3.1 Roles of the relevant stakeholders

Numerous stakeholders at the national, regional and global levels have roles in advancing actions to ensure the safe disposal of unused medicines. The stakeholders include, but are not limited to:

- the relevant public and regulatory authorities across health, agriculture, the environment and industry;
- healthcare facilities, agricultural productions, the pharmaceutical industry and municipalities;
- private sector entities and associations, including pharmaceutical manufacturers, animal producers, healthcare providers, pollution-control companies and waste management firms;
- civil society organizations, including community groups, youth organizations, consumer associations and professional bodies representing doctors, pharmacists, veterinarians and farmers;
- international organizations;
- academic and research institutions, networks and media outlets;
- procurement teams or agencies dealing in pharmaceuticals for human, animal and plant use; and
- waste and wastewater management services that handle unused medicines.

The government plays a pivotal role in ensuring the proper disposal of unused medicines by aligning solutions with local infrastructure, implementing tailored practices to reduce pharmaceutical pollution, providing incentives, supporting public education to raise awareness and minimize waste and securing funding, while enforcing environmental regulations for the safe disposal of unused medicines. The authorities often collaborate with organizations, such as pharmacies, to manage and maintain designated drop-off locations for unused medicines. The collection systems implemented vary by country, typically involving pharmacy take-back programmes or drop-off points specifically designated for unused medicines. Governments can support such efforts by introducing regulatory measures, inter alia, EPR schemes, which require producers to manage unused medicines responsibly. Regulatory frameworks should also permit take-back programmes (Tong *et al.* 2011; Rogowska and Zimmermann 2022; Gwenzi *et al.* 2023; Wang *et al.* 2024).

Regulatory authorities are key players in developing effective regulations for the safe disposal of unused medicines. While some countries have specific legislation for unused medicines management, many still lack dedicated systems and instead handle

unused medicines within broader healthcare waste management (Amaral and Fop 2013; Mehtonen *et al.* 2020).

In the USA: Under the Secure and Responsible Drug Disposal Act (2010), the Drug Enforcement Administration permits pharmacies and organizations to collect unwanted medications. By 2022, 63 per cent of states had enacted related laws. The Drug Enforcement Administration organizes a National Prescription Drug Take-Back Day twice a year. During this event, various collection sites are set up nationwide to collect and properly dispose of unused medications (Barenie *et al.* 2022). There are some industry-funded take-back schemes, such as the medication, education and disposal (MED)-Project, for unused medicines from county households. Med-Project now runs 23 such programmes in the USA, including three state programmes in California, Washington and Massachusetts. Local regulations, requiring the counties to pass laws that determine the funding and administration of the take-back schemes, mandated the programmes (MED-Project n.d.).

Pharmaceutical production encompasses the processing of raw material, the manufacture of APIs, drug formulation, packaging and distribution as well as the management of expired or end-of-life

products. Where preventive and control measures are inexistent or inadequate, this process can release pharmaceuticals into the environment, posing risks to the latter and to human health. A case in point is the emergence and spread of AMR. Such releases primarily occur through manufacturing operations and the discharge of effluent and waste.

The global pharmaceutical manufacturing supply chain is highly complex, involving multiple entities that supply APIs and finished products. Given the complexity, responsible manufacturing practices are essential for protecting the environment. The practices include the management of medicine waste, preserving access to clinically important medicines, safeguarding public health and the environment, maintaining regulatory compliance, upholding corporate social responsibility and preserving industry reputation (Access to Medicine Foundation 2023; WHO 2024b). Pharmaceutical companies have a vital role in ensuring the safe disposal of their own medications and of unused medicines generated from various sources. The companies may partner with local organizations to help implement take-back schemes. They may also support awareness campaigns, including by working alongside healthcare providers and agricultural professionals to convey messages about the proper disposal of medications (OECD 2019).

Caption: Responsible manufacturing practices can effectively manage unused medicines. Photo: Jess Loiterton



In the People's Republic of China: In August 2023, over 2,800 pharmacies in Kunming joined the city's expired medicine take-back programme. Consumers return expired medications to designated pharmacies for inspection and disposal under regulatory supervision. As a pilot city, Kunming aims to expand the programme across Yunnan Province, establishing a long-term recovery system (Kunming Administration for Market Regulation 2023).

At the World Pharmaceutical Retail Industry Conference in 2021, the People's Republic of China launched a programme to manage expired household medicines. Using artificial intelligence, GPS and over 100,000 retail pharmacies, the programme makes it possible to carry out full lifecycle monitoring for safe, traceable disposal and prevents re-entry into the market (ChinaNews 2021).

Healthcare facilities, such as pharmacies, play an important role in managing unused medicines, with pharmacies serving as effective collection points for unused medicines in many countries. Their responsibilities arise at different key steps of the pharmaceutical lifecycle, including prudent medicine selection, the promotion of appropriate prescribing and dispensing, patient adherence and proper storage practices. Effective stock management by pharmacists is essential for building resilience to medicine shortages, enhancing risk management during crises and wars, and minimizing the risk of medicine expiring. Pharmacists can also advise patients and the public on safe disposal methods for unused medications and train healthcare staff on appropriate waste management protocols. Initiatives such as those at Hennepin County Medical Center and Falls Memorial Hospital, in Minnesota, in the USA, have shown that waste and inventory reduction strategies can bring about significant cost savings, with the two institutions achieving reductions of US\$80,000 and US\$123,000, respectively. The initiatives succeeded in minimizing unused medicines by reducing excess stock, preventing the expiration of medicine and providing detailed usage reports (Smith *et al.* 2008; Ehrhart *et al.* 2020). Incentives can further enhance disposal practices. For example, in Sweden, pharmacies offer bonus credit points to consumers who return unused medicines, demonstrating how financial rewards can motivate safe disposal behaviours (Swedish Pharmacy Association 2024).

Agriculture authorities may assume responsibility for ensuring accessible disposal systems and providing information on collection points for farmers, animal keepers and veterinarians. Local veterinary clinics and pharmacies may accept unused veterinary medicines from farmers and animal keepers for safe disposal. However, some are reluctant to implement take-back programmes owing to the associated costs and the time and resources needed for the process. Financial support or incentives from government or industry stakeholders could help mitigate these challenges and make take-back programmes more feasible particularly for smaller veterinary clinics. Additionally, streamlined procedures can improve the overall efficiency of such programmes. Agricultural production may also establish dedicated collection points for veterinary medicines, with specific responsibilities assigned to pharmaceutical producers, distributors and agricultural operators for safe waste management. By assigning clear responsibilities, the agricultural sector can ensure that waste is properly managed at every step of the process. Collaboration between agricultural operators, pharmaceutical companies and healthcare facilities is key to creating a sustainable system that reduces the environmental impact of unused veterinary medicines (Cyclavet n.d.; European Platform for the Responsible Use of Medicines in Animals [EPRUMA] n.d.; Sander and Zack 2023).

In 2014, the Canadian Animal Health Institute partnered with CleanFarms to launch a national programme for Canadian livestock and horse owners to safely dispose of unused or expired animal medications. Building on the successful programme for the collection of obsolete pesticides, started in 1998, this initiative provides farmers with an environmentally responsible, free disposal option. Every three years, each province hosts a collection event where farmers can drop off obsolete products at designated sites. Until the collection periods, farmers are advised to store medications securely. Collected items are then safely transported to high-temperature incineration facilities for disposal. The programme covers unused agricultural pesticides (labelled with a pest-control product number), including used miticide strips, commercial pesticides for golf courses and pest control products in industrial and commercial settings (also labelled with a pest-control product number), livestock and equine medications used in agricultural contexts (labelled with a Drug Identification Number, serial, notification, or pest-control product number). CleanFarms operates this programme in partnership

with CropLife Canada and Canadian Animal Health Institute (Canadian Animal Health Institute n.d.).

2.3.2 Financing mechanisms and take-back scheme models

Voluntary take-back schemes

In some countries, pharmacies voluntarily act as collection points for unused medicines, with municipalities managing their safe disposal. For example, in the Netherlands, pharmacies collaborate with municipalities to ensure proper waste treatment. Over half of the population (54 per cent) is reported to use the return scheme and dispose of unused medication via this channel (KNMP 2020).

Extended producer responsibility

EPR is an essential component of the polluter pays principle (PPP), shifting the responsibility for waste management from governments to producers. In the pharmaceutical sector, this involves implementing take-back systems, organizing awareness campaigns, facilitating the return of unused medicines and ensuring their proper disposal. By transferring economic and organizational responsibility to the producer, EPR offers the potential to create a financially sustainable system for the take-back schemes. An effective EPR programme covers a broader product lifecycle through a combination of mandatory and voluntary measures. When properly implemented, it enhances transparency, mobilizes significant financial resources and increases collection rates. Fee modulation can provide further incentive for design improvements, potentially reducing reliance on primary materials.

Core principles linked to successful EPR schemes include clearly defining the producers and their responsibilities, setting collection targets and fostering stakeholder coordination. Working with governments helps ensure a level playing field and fair competition. Transparency remains essential for monitoring and evaluation, while embracing the role of the informal sector can enhance overall effectiveness (OECD 2024).

A 2014 European Commission study identified significant variations in producer fees across product categories under EPR schemes, reflecting differences

in scope, cost coverage and implementation approaches. No single EPR model emerged as the most cost-effective. A 2015 OECD review placed deposit-refund systems and advance disposal fees among the more efficient instruments for waste reduction. However, research on the cost-effectiveness of other EPR mechanisms, including take-back programmes—particularly in the pharmaceutical sector—remains limited (European Commission 2014; OECD 2015). In its 2021 report on modulated fees in EPR schemes the OECD states that while fee differentiation based on environmental performance can improve outcomes, no universally optimal model exists owing to differences in national contexts and product characteristics. Such findings underscore the growing relevance of EPR in unused medicines management and the need for further empirical analysis and impact assessment to provide an evidential basis for effective EPR policy design (OECD 2021).

The EU took steps to this purpose in 2024 by recasting the Urban Wastewater Treatment Directive, introducing EPR obligations for manufacturers of medicines. Under the new rules, pharmaceutical producers will be required to cover at least 80 per cent of full costs. These include investment and operational expenses for the quaternary treatment of urban wastewater to remove micropollutants resulting from the products that manufacturers place on the market and from the residues of those products, as well as costs related to monitoring (EU 2024).



OECD Guiding Principles for EPRs

The OECD Guidance Manual (OECD 2016) includes six checklists for policy makers as well as the following set of guiding principles for the design and development of EPR policies and programmes:

- EPR policies and programmes should be designed to provide producers with incentives to incorporate changes upstream at the design phase in order to be more environmentally sound.
- Policies should stimulate innovation by focusing more on results than on the means of achieving them, thus allowing producers flexibility with regard to implementation.
- Policies should take into consideration a lifecycle approach so that environmental impacts are not increased or transferred somewhere else in the product chain.
- Responsibilities should be well defined and not be diluted by the existence of multiple actors across the product chain.
- The unique characteristics and properties of a product, product category or waste stream should be factored into policy design. Given the diversity of products and their different characteristics, one type of programme or measure is not applicable to all products, product categories or waste streams.
- The policy instrument(s) selected should be flexible and chosen on a case-by-case basis, rather than setting one policy for all products and waste streams.
- The extension of producer responsibilities for the product's life cycle should be done in a way to increase communication between actors across the product chain.
- A communication strategy should be devised to inform all the actors in the product chain, including consumers, about the programme and to enlist their support and cooperation.
- To enhance a programme's acceptability and effectiveness, a consultation of stakeholders should be conducted to discuss goals, objectives, costs and benefits.
- Local governments should be consulted in order to clarify their role and to obtain their advice concerning the programme's operation.
- Both voluntary and mandatory approaches should be considered with a view on how to best meet national environmental priorities, goals and objectives.

The OECD countries with the highest ratios for the collection of unused medicines—France, Portugal, Spain and Sweden—have EPR programmes with comprehensive national coverage and established pharmacy collection points (OECD 2022). While most EPR policies are found in high-income countries, several LMICs and upper middle-income countries have begun to introduce EPR schemes in the past decade (Slunge and Alpizar 2019). For instance, the pharmaceutical industry funds the national collection system and take-back schemes in Mexico through an EPR (Amaral and Fop 2013; Singrem 2018). In 2009, Colombia also introduced an EPR system for unused medicines, assigning responsibility and implementation costs to pharmaceutical manufacturers and importers (survey questionnaire 2024; Future Policy 2022).

Case study from Colombia: Take-back system and EPR

In 2009, as part of a national policy for regulating the management of waste from hazardous products, the Colombian Ministry of the Environment and Sustainable Development (MESD) introduced Resolution 371 that makes it compulsory to regulate the collection and disposal of such products. The post-consumer return systems established by Resolution 371 focus on the household sector. The Resolution requires producers (importers and manufacturers) to implement plans or take-back systems for end-users to return unused medicines (human and veterinary) through collection points, campaigns and other mechanisms, which the National Environmental Licensing Authority (ANLA) then evaluates, supervises and monitors. Pharmacies and healthcare institutions are also required to participate in the plans, which include collection campaigns, in coordination with the local environmental authorities, public awareness efforts and agreements with licensed waste managers to ensure proper disposal of expired medicines.

Based on the data from the Post-consumption Plan for Expired Pharmaceuticals or Medicines provided by ANLA, in compliance with Resolution 371 of 2009, over 2,090 tons of post-consumption waste comprising household medicines were safely managed in Colombia between 2010 and 2023. This involved the 2,837 collection points scattered across 30 departments and more than 181 cities or municipalities. In addition to gathering unused medicines through collection points, and working on behalf of 97 per cent of the pharmaceutical industry (the largest programme), the Punto Azul Corporation carried out a strategy to receive managed unused medicines through direct returns from pharmaceutical laboratories. Overall, 2,116 tons of post-consumer unused medicines was managed, adequately treated and disposed of as hazardous waste between 2016 and 2022, thereby preventing environmental pollution and risks to public health.

Working alongside the local and national authorities, territorial environmental authorities conduct annual education and awareness campaigns on expired pharmaceuticals, informing waste producers about collection points and proper waste-management strategies. In addition, various environmental education initiatives promote proper unused medicines management. Such collaboration involves environmental and health authorities, the pharmaceutical industry, academia, trade associations and large retailers. Since 2023, Punto Azul has provided training and certification for 2,573 medicine stores across Colombia to encourage consumer awareness and responsible actions for the environment.

Collected unused medicines is treated through controlled incineration, a high-temperature process (800–1200°C) that manages gases and ashes in compliance with Resolution 909 of 2008, which sets maximum emission limits for hazardous waste treatment facilities. Only licensed hazardous waste handlers are permitted to carry out this treatment. The relevant environmental authority oversees compliance through continuous monitoring and gas studies, while Punto Azul audits contracted waste handlers.

Resolution 371 received the Future Policy Special Award 2021 in the EPPP category, awarded by the World Future Council.

However, a number of challenges have been identified and require a remedy. In particular, the collection points for post-consumer medicines covered only 75 per cent of the national territory as of 2022. Public awareness of proper disposal methods remains limited. Additionally, current regulations do not clearly define responsibilities for producers and local authorities; for their part, producers provide insufficient standardized data reporting. There is a need to update existing collection mechanisms (survey questionnaire 2024).



Government-funded schemes

Several countries carry out government-funded schemes to ensure the safe and environmentally responsible disposal of unused medicines. The National Return and Disposal of Unwanted Medicines Program (NatRUM), launched in 1999, is an Australian Government-funded initiative aimed at the safe and environmentally sound disposal of expired or unused medicines. The programme provides a national service, allowing individuals to return unused medicines to participating pharmacies at no cost. The final disposal is primarily conducted through high-temperature incineration, ensuring compliance with environmental and safety standards. Since 2001, the initiative has helped collect over 13,000 tons of unused medicines (Australian Government Department of Health, Disability and Ageing 2023).

In the United Kingdom: Pharmacies are obliged to take back and sort unused medicines brought by patients under National Health Service (NHS) regulations, while care home medicines require a Waste Management License. The system, funded by the local authorities without pharmaceutical industry involvement, aims to ensure safe disposal while reducing environmental risks. In addition to pharmacy collections, the NHS occasionally organizes local events. In 2004, the system helped dispose of 600 tons of medicines, costing over £1 million annually (Amaral and Fop 2013).

Fee-based and taxation models

Minor fees for community participants in take-back programmes align with the “polluter pays” and “pay-as-you-throw” principles, supporting the economic sustainability of initiatives for the safe disposal of unused medicine. For example, Switzerland has implemented a tax system to fund upgrades to wastewater treatment plants, aiming to eliminate over 80 per cent of micropollutants, including pharmaceuticals, at 120 facilities. Residents will continue contributing nine Swiss francs annually to a fund until 2034, covering up to 75 per cent of upgrade costs. Once a plant launches a new treatment stage, residents connected to it will be exempt from the fee. Meanwhile, Switzerland will impose taxes in order to upgrade wastewater treatment facilities with advanced technologies, and thereby reduce pharmaceutical

pollutants in water. In Uganda, the National Drug Authority charges fees for the supervision and destruction of unused medicines based on the destruction method and type of unused medicines (Alshemari *et al.* 2020; Iosue 2020).

In Europe: The EU List of Waste (2000/532/EC) only categorizes cytotoxic and cytostatic medicines as hazardous. Other unused medicines are not categorized as hazardous. The EU requires Member States to establish collection systems for unused medicines, where directive 2004/27/EC stipulates that “Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired”. Individual Member States are responsible for determining the necessity of separate collection through take-back systems to ensure appropriate disposal. While most EU countries have adopted separate collection mechanisms, others, such as Germany, do not have a nationally mandated scheme. In Germany, medicine-return schemes exist at the local level, where pharmacies voluntarily collect unused medicines, or municipalities provide hazardous waste-collection or recycling points. At the national level, unused medicines are disposed of in solid household waste, with waste incinerated for energy recovery. Public awareness campaigns inform citizens on safe disposal practices and discourage flushing unused medicines (Deutscher Ärzteverlag GmbH, Redaktion Deutsches 2021). The lack of detailed guidelines has led to varied medicine take-back systems, with most EU countries using pharmacies as collection points but differing in financing and waste handover processes. This inconsistency results in uneven citizen participation: while France, the Netherlands and Sweden report high return rates, Cyprus and Poland have much lower rates, and 95 per cent of citizens in Romania dispose of unused medication in solid household waste. Consequently, there is growing pressure to harmonize these systems across the EU (EU 2004; EU 2008; Amaral and Fop 2013; Cyclamed n.d.; Mitkidis *et al.* 2021).

In Canada: The Government proposes several initiatives for the return of unused medicines, with varying approaches depending on funding and legal requirements. The responsibility for covering 100 per cent of the costs for take-back programmes falls on the manufacturer, brand owner or first importer/seller of a pharmaceutical product (Public Safety Canada n.d.). The Health Products Stewardship Association operates

free take-back programmes for the safe disposal of unused medications and used medical sharps in British Columbia, Manitoba, New Brunswick, Ontario, Prince Edward Island and Quebec. The programmes not only assist producers in meeting their stewardship obligations but also support collection locations in implementing effective disposal solutions. Additionally, the Health Products Stewardship Association educates consumers on safe disposal practices, fostering stronger connections within communities and the industry while promoting a safer environment and healthier communities. As of December 2023, the Health Products Stewardship Association has collected 5,120 tons of medications since its inception and has established 6,389 participating collection locations (the Health Products Stewardship Association (HPSA) 2025).

In Albania: The Chemicals and Waste Management Programme supported a 20-month project to strengthen Albania's waste and chemical management framework. Key goals included improving legislation, creating a unused medicines unit within the National Agency for Medicines and Medical Devices and building institutional capacity. The project also raised awareness among stakeholders and focus on reducing unused medicines in open fields. Additionally, gender considerations were integrated into the initiative, with special attention to women's exposure to unused medicines. These efforts helped Albania strengthen its commitment to global environmental agreements (UNEP 2019).

Case study from Germany: The Friedrich-Alexander-Universität Expired Drug Initiative (FAU EDI)

The FAU EDI in Germany—the recovery of APIs from expired drugs and their use as reference compounds or research chemicals:

The two major aims of FAU EDI are to; develop reliable and optimized processes for the recovery of APIs from expired drugs; and provide broad support to research, teaching and environmental monitoring through the subsequent distribution of the recovered compounds.

Inspired by an earlier research project for which naltrexone was required as a comparably expensive starting material, the Heinrich research group at FAU Erlangen-Nürnberg began assessing whether such demand for research chemicals could also be met by the recovery of APIs from expired drugs.

Some regions of Germany recommend the disposal of expired drugs as part of household waste. While this is safe owing to subsequent waste incineration (waste-to-energy), it also inevitably destroys many highly valuable APIs that had previously produced large amounts of waste during their synthesis.

Starting with four selected pharmacies in 2017, the collection network currently comprises: a local branch, including the city of Erlangen and the adjacent districts of Forchheim and Erlangen-Höchstadt; a national branch consisting of around 25 large clinical pharmacies; three wholesalers throughout Germany; and SuperDrecksKëscht, in Luxemburg, as the first European partner.

Through this collection network, around 500 different APIs are retrievable in reasonable amounts—measurable in kilogrammes. Some 230 APIs have so far been investigated to determine the potential to recover them from the relevant drugs. As a result of increasingly optimized processes and a steadily growing number of recovered APIs, FAU EDI began supporting research and teaching not only at FAU, but also at universities and research institutes throughout Germany in 2021. Beside continuously expanding the existing national distribution network, Germany also expects other European partners to shortly join the initiative.

Legislation designed to ensure patient safety prevents the use of the APIs recovered at FAU to produce human or veterinary medicine (Friedrich-Alexander University n.d.).

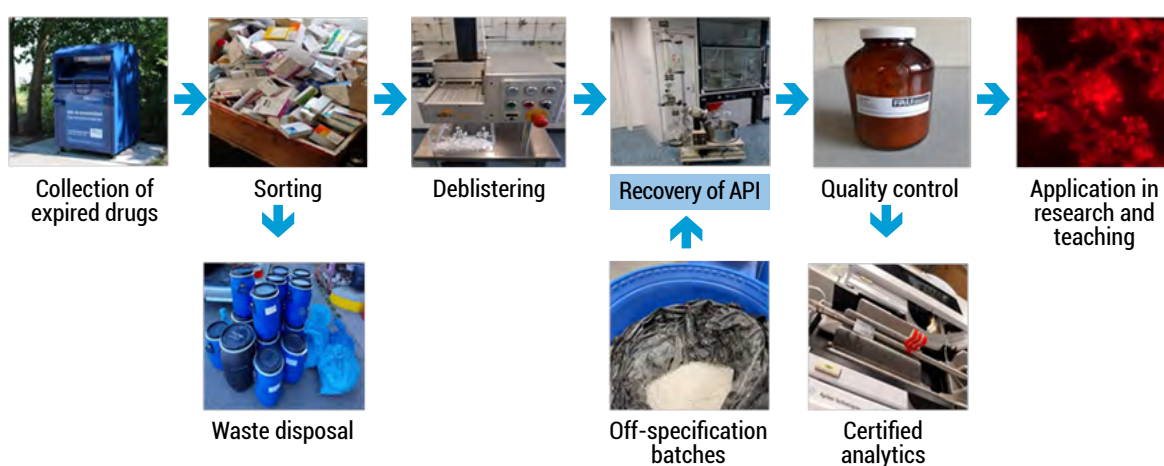


Figure 6: Workflow at FAU EDI: from expired drugs to a broad range of research chemicals.

2.3.3 Sustainable public procurement

Sustainable public procurement is a powerful tool for achieving environmental and economic benefits, fostering innovation and promoting sustainable practices. Recently, there has been a marked increase in policy support for sustainable public procurement at the national and international levels, establishing it as a critical avenue for advancing sustainable production and consumption patterns, particularly in the global health sector (UNEP 2020b). By integrating sustainability criteria into procurement processes, governments can effectively influence supply chains and encourage more responsible practices across various industries and other sectors.

Procurement initiatives with clear criteria improve efficiency, prevent fraud and enhance outcomes. Harmonized regulations simplify compliance and create a fair market, while a tiered procurement approach provides incentives to manufacturers to exceed minimum standards, driving sustainability and innovation.

UN organizations worked together on the task team for Sustainable Procurement in the Health Sector to launch the Sustainable Procurement Index for Health. The index includes environmental criteria for pharmaceuticals to assess the management of wastewater and monitoring of water quality (UNDP 2021). Sustainable Procurement in the Health Sector supports manufacturers, suppliers, procurers and healthcare facilities, providing information and a procurement questionnaire, as well as offering incentives to enhance their environmental and social sustainability (UNEP 2020b; UNEP2021).

Experiences from the vaccine market highlight ways in which global pooled procurement can shape markets. While UNICEF and the Pan American Health Organization have used global pooled procurement to lower pharmaceutical prices for LMICs, focusing solely on price can lead to reliance on a single manufacturer, risking price hikes. To address this, UNICEF adopted split tendering to encourage competition. These lessons can inform global strategies for the procurement of medicines, providing incentives to manufacturers to adopt environmentally responsible practices, with differential pricing to support the higher costs of sustainable production (Bare and Laura 2015).

In the United Kingdom, pharmaceutical companies bidding for the NHS's newly launched Antimicrobial Product subscription model are—as of August 2024—required to obtain certification from the British Standards Institution (BSI) Kitemark for Minimized Risk of AMR, which ensures responsible manufacturing and emission control to reduce AMR. Through this procurement requirement, the NHS aims to promote global best practices and scale efforts to address the AMR threat (NHS 2024).

In 2019, Norway launched a pilot programme focused on sustainable procurement, where antibiotic manufacturers receive rewards for demonstrating good environmental practices. The criteria for the rewards include the company's environmental policy, strategy and systems for managing environmental issues. In the antibiotic procurement process, 30 per cent of the decision weight depends on environmentally friendly production. If successful, the criteria will extend to other procurement processes (WHO 2018).

In June 2018, Sweden initiated a pilot study with four pharmaceutical companies and five patented antibiotics to test a new reimbursement model. Suppliers ensure the availability of specific antibiotic products through designated warehousing and receive a guaranteed annual income per product. If sales do not meet expectations, the Government compensates the suppliers. Additionally, manufacturers of non-patented antibiotics can request price increases to avoid market shortages. This model may also include environmental requirements, such as discharge limits, ensuring both supply chain stability and environmental protection (Gotham *et al.* 2021).

While some of these examples are not directly related to the safe disposal of unused medicines but rather focus more broadly on unused medicines, they serve as examples of possible implementation measures and could be expanded to include criteria or ideas connected to the disposal of unused medicines

2.3.4 Environmental risk assessment

The safe disposal of unused medicines needs to be part of a regulatory environmental risk assessment (ERA), as improper disposal constitutes one of the major pathways for medicines to enter the environment. The outcome of an ERA informs measures to minimize

pharmaceutical emissions and manage risks, including targeted risk-reduction actions and product labelling to guide proper disposal by patients, healthcare providers and other stakeholders (UNEP2020a; Oldenkamp *et al.* 2024).

ERA is crucial for evaluating the risks of substances like pharmaceuticals on health and the environment, guiding informed decision-making and policy formulation. However, many of the over 4,000 APIs used worldwide lack ERAs, making post-marketing assessments for identifying and mitigating potential hazards inadequate. There is a need to update the assessments regularly to include new data and technological advancements. Key improvements in ERA include assessing risks at the active ingredient level, evaluating the environmental impact of existing pharmaceuticals, considering total ingredient discharge and developing effective risk-mitigation strategies. Effective policy requires clear guidelines, while audits, inspections and incentives ensure compliance (Swartjes *et al.* 2012).

Globally, veterinary pharmaceuticals are evaluated for environmental safety before marketing according to guidelines from the Veterinary International Conference on Harmonization. Meanwhile, only a few countries, such as Canada, the USA and certain European nations, assess human pharmaceuticals for environmental impact. In Europe, a draft revision of guidelines from the European Medicines Agency was proposed in 2018. However, most other countries lack specific regulations, and manufacturers are required to follow general chemical safety standards. Japan introduced guidance on ERA for new pharmaceuticals in 2016, but it lacks detailed calculation and testing instructions, relying on EU and US guidelines for further details (Lee and Choi 2019; Whomsley *et al.* 2019).

2.3.5 Transparency and accountability

It is possible to achieve transparency through government requirements or voluntary actions, which obliges key sectors to disclose data on medicine usage and waste management practices, using a centralized, publicly accessible database. Disclosures would concern the disposal of unused medicines, environmental impacts, emission levels, compliance with discharge limits and disposal outcomes. Blockchain technology can further

support this by making real-time tracking possible, improving communication, reducing shortages and minimizing reliance on fragmented systems. Greater transparency in pharmaceutical production, sales, use and disposal is essential for bridging knowledge gaps and tracking environmental impacts. Monitoring and disclosing data across these sectors makes it easier to identify pharmaceutical use patterns and associated risks. Public disclosure of audit results fosters accountability and drives improvements throughout the sector. Additionally, understanding governance structures and key actors is vital for implementing targeted interventions, aligning incentives and forming partnerships to address the environmental and societal impact of pharmaceuticals. Access to such data remains limited across the globe, preventing prescribers and consumers from making environmentally conscious choices. While regulatory changes take time, consumer pressure has historically driven improvements in social and environmental standards (Larsson and Fick 2009; Årdal *et al.* 2021; Access to Medicine Foundation 2023).

The initiative by New Zealand's Medicines Regulatory Agency, Medsafe, directs all approved drugs to disclose the manufacturers of APIs, drug products, finished dosage forms and the local site of product release. Such transparency helps the Government identify and address supply-chain bottlenecks. By making such information public, the initiative also aims to identify potential pollution sources and encourage sustainable sourcing practices. To be effective, these data should be updated regularly or delivered in real-time (United States Pharmacopeia 2020). While this initiative is not directly linked to safe disposal, data on the amount and type of medicines manufactured, along with usage data, can help estimate the volume of medicines in the market and potential waste. Additionally, it can serve as an example for other key sectors to implement similar measures and disclose data on the disposal of unused medicines.

2.3.6 Surveillance and monitoring

Effective surveillance of pharmaceuticals in the environment is critical to identifying areas at high risk of pollution, particularly those affecting water sources, ecosystems, and human and animal health. Surveillance data also provide a reflection of the use of pharmaceuticals at the national level. For



example, wastewater-based surveillance, particularly for antimicrobials and AMR, is an emerging tool with remarkable value. In hospital settings, it can detect AMR trends to guide infection control, facilitate early intervention and assess containment efforts. When integrated with municipal wastewater data, this approach also supports tracing sources of infection, which helps bind clinical and environmental health monitoring (Conforti *et al.* 2025; Penney *et al.* 2025).

A One Health approach to surveillance is essential, especially where it concerns the disposal of unused medicines. Integrated systems are needed to generate data that inform the targeting of policies on pharmaceutical use, environmental residues and their impacts across all sectors. Current efforts remain fragmented, limiting their effectiveness.

Surveillance systems must generate representative, harmonized and actionable data to support evidence-based policymaking. It is essential to standardize methods for sampling, analysis and reporting to ensure comparability across regions and countries. Transparency in data publication fosters accountability and public trust, while coordination with regulatory bodies ensures compliance and supports policy enforcement.

Sustainable financing, political commitment and international cooperation are critical to strengthening surveillance infrastructure and technical capacity. Despite international recommendations, achieving cross-sectoral integration remains a challenge due to divergent priorities and limited coordination. There is an urgent need for global standards and guidance to pave the way for coherent, multisectoral monitoring and response systems (University of York n.d.).

Some initiatives focus on the global monitoring of pharmaceuticals, including:

The Pharmaceuticals in the Environment database, compiled by the German Environment Agency, reviewed and analysed 2,062 publications up until 2020. The database focuses on worldwide Maximum Environmental Concentrations published in peer-reviewed journals. Residues of human and veterinary pharmaceuticals in the environment have been

measured in 89 countries in all UN regions. For Germany, 414 active substances or their transformation products were reported, while 749 were reported for the EU and 992 were recorded worldwide. Most of the substances were found in the effluents of wastewater treatment plants (liquid emissions—(i) globally: 771(ii)EU: 591 (III)Germany: 339). In surface water, groundwater and drinking water 703 substances were detected globally and 198 in Germany (liquid emissions). Additionally, 37 substances were detected in surface water, groundwater or drinking water in all five UN regions (German Environment Agency n.d.).

The University of York, in the United Kingdom, launched the Global Monitoring of Pharmaceuticals Project in 2019 to gain a comprehensive understanding of the extent and causes of pharmaceutical pollution in freshwater worldwide. The largest and first truly global study of its kind, the project brought together over 120 collaborators from 104 countries, monitoring 61 pharmaceuticals at 1,052 sampling sites along 258 rivers. The study, covering a population of 471.4 million people, found that pharmaceutical pollution in surface water poses a threat to environmental and human health in more than a quarter of the locations examined (University of York n.d.).

2.3.7 Eco-labelling and packaging

The primary purpose of labelling medicine is to comply with the relevant health agency requirements and approvals. There are strict regulations governing what may be included on a label and in a package insert to ensure consumer safety and provide essential information. In addition to meeting these critical health and safety standards, there is growing interest in introducing eco-labelling for pharmaceuticals. Eco-labelling, based on recognized environmental standards, offers a way to communicate the environmental impact of products, including production methods and waste management practices. So far, no broadly recognized international standard-setting body—especially for production methods—has adopted a single, science-based international standard specifically for the eco-labelling of medicines. Although not yet implemented for pharmaceuticals, such labelling could help promote responsible manufacturing and informed consumer choices, while enabling healthcare professionals to make more environmentally responsible prescribing decisions.

Clear disposal instructions on medicine packaging, in patient information leaflets or directly on medication labels, can increase consumer awareness and encourage responsible behaviour. Reducing packaging sizes can decrease the risk of accumulation and improper disposal of unused medicines. Promoting recyclable or biodegradable materials for pharmaceutical packaging can further reduce environmental impacts. Packaging design that improves the conservation of pharmaceuticals is also crucial. The EU made it mandatory in 2004 to include disposal instructions in the labelling of medicines, specifically in the patient leaflet (Directive 2004/27/EC). This requirement aims to minimize environmental harm by guiding consumers on how to properly dispose of unused medicines. It is noteworthy that the labelling refers to safe disposal guidance (EU 2004).

Pharmaceutical packaging today integrates smart technologies that enhance its informational capacity beyond traditional labels and leaflets. Smart packaging solutions use Radio Frequency Identification tags, Near Field Communication and QR codes to connect with smartphones, tablets and personal computers, providing instant access to websites, PDFs, videos and apps. This cross-media approach improves communication, offers multilingual support and extends access to critical information. Additionally, intelligent packaging systems, such as conductive ink printing and embedded screens with sensors, assist patients in therapy monitoring and adherence, transforming packaging into an interactive and dynamic healthcare tool. While promising, there is a need to consider adding multiple QR codes to prevent complications in pharmacy dispensing and issues with falsified medicines by (Penati 2025).



2.4 Awareness raising and communication

It is essential to carry out effective regular awareness campaigns nationally for key stakeholders—such as healthcare professionals, veterinarians, consumers and farmers—to promote waste prevention and facilitate adherence to take-back schemes for unused medicines. By offering clear guidelines and tailored messaging, such initiatives not only enhance participation but also raise awareness about the critical importance of proper disposal methods. Tailoring campaigns to the specific needs of

each stakeholder helps keep the messaging relevant and effective, ultimately fostering greater engagement across all audiences. It is equally important to integrate the management of unused medicines into broader Integrated Solid Waste Management campaigns and provide targeted training for diverse stakeholders.

Lack of knowledge about the environmental and health risks associated with improper disposal of medicines is widespread, and calls for significant efforts to raise awareness and educate the public. In South India, a survey found that 83 per cent of respondents were unaware of the environmental impact of the disposal of unused medicine. A similar result was observed in Selangor, Malaysia. In South Africa, 65 per cent of people surveyed didn't know how to properly dispose of medications, and 95 per cent had never received information about it from healthcare professionals (Gwenzi *et al.* 2023). A study in Indonesia revealed that 53.1 per cent (72 per cent female, 28 per cent male) of respondents were not aware that improper disposal of medication could harm the environment and health. Most respondents (79.5 per cent) had never received information about proper practices for the disposal of medication (Alfian *et al.* 2021).

National authorities and other relevant stakeholders can support these efforts with broader communication campaigns to promote responsible disposal practices. Additionally, training journalists and involving communication experts boosts media coverage and creates impactful messages on the disposal of medication. Gender balance among communicators and experts helps ensure diverse perspectives and better representation of women and other underrepresented groups. Information should be transparent and accessible in order to foster consumer engagement and accountability. Chances are that it will be delivered in multiple languages, based on the local demographics, to ensure broader understanding and participation.

There is also a need for science communication to help share scientific findings on unused medicines and its impacts on health and the environment. Involving health insurers in such discussions adds another layer of support, promoting environmentally friendly alternatives, including health and environmental education. It is vital to approach the issue of unused medicines through a cultural perspective that takes into

account social, economic and political factors. Cultural beliefs and values significantly influence ways in which medications are prescribed, consumed and disposed of, which in turn affects behaviours related to pollution monitoring and reporting. Recognizing such cultural dimensions can inform strategies that resonate more deeply with communities and encourage sustainable practices (Thomas 2017).

Pharmacists, veterinarians and other healthcare professionals play a central role in guiding clients on the proper storage and disposal of medicines, including by informing them about local disposal options during routine visits. It is necessary for training programmes to concentrate on educating healthcare professionals, veterinarians, farmers and stakeholders in the animal health industry on the need and ways to minimize unused medicines. Additionally, initiatives to further integrate safe medicine-disposal practices and the subject of pharmaceutical pollution into school curricula and professional education will help foster a culture of appropriate medicine use and waste management. It is also essential to use targeted communication and outreach efforts to promote behaviour change and raise awareness on gender-specific issues related to the disposal of medicine (Allerton *et al.* 2023; Ercolani *et al.* 2023; United Kingdom Health Security Agency 2025).

Environmental classification schemes help healthcare professionals and veterinarians make informed prescribing decisions based on the environmental impact of medicines. The schemes encourage prescribers to consider the environmental risks of pharmaceuticals and aim to reduce the release of harmful substances into the environment. For example, the Swedish Association of the Pharmaceutical Industry has developed a voluntary environmental classification scheme that covers approximately 200 APIs. Pharmaceutical companies submit data, which are then made available online for prescribers and consumers to access. This initiative provides transparency and enables healthcare professionals to consider the impact on the environment when prescribing medications (Farmaceutiska Specialiteter i Sverige (FASS) 2024). Region Stockholm places priority on reducing pharmaceuticals in water given that they are an environmental concern. To this purpose, the regional Drug and Therapeutics Committee introduced the “Wise List” of recommended medications for common diseases, which takes into

account both cost-effectiveness and environmental impact. Pharmaceuticals on the Wise List are evaluated for their environmental risk based on persistence, bioaccumulation and toxicity, which helps doctors make informed prescribing decisions. Overall, 77 per cent of Stockholm’s doctors were following these guidelines by 2009. In 2014–2015, a leaflet was distributed to prescribers, providing information on environmental risks, the Wise List’s classification system, the precautionary principle and guidance for reducing environmental impacts.

The MedsDisposal Campaign, a collaboration between European healthcare, industry and pharmacy associations, promotes the proper disposal of unused medicines across the EU. This underscores the power of cross-sector partnerships in raising awareness and encouraging responsible disposal practices (MedsDisposal 2024). Community initiatives, such as Medicine Disposal Days, organized with pharmacies and hospitals, seek to promote responsible disposal practices by raising awareness and providing safe collection points for unused medications. Evidence from Palestine and countries such as Nepal and Serbia highlights the positive impact of enhanced knowledge and training on safe disposal practices (Jovanović *et al.* 2016; Tabash *et al.* 2016; Paudel *et al.* 2019). In the USA, pharmacists who benefited from educational interventions were reportedly more likely to recommend proper medication disposal methods during patient counselling (Jarvis *et al.* 2009). In 2019, the United States Food and Drug Administration launched its Remove the Risk campaign to raise awareness about the risks of unused opioids and promote their safe disposal. The campaign leverages social media, radio and television to enhance public understanding of proper disposal methods for unused opioids (Food and Drug Administration n.d.). The World AMR Awareness Week, held annually in November, is a global campaign to raise awareness of AMR and promote best practices among key groups, including the public, healthcare workers, animal health professionals, environmental advocates, farmers, policymakers and the youth. The week features events such as high-level meetings, youth summits, webinars and panel discussions worldwide, all aimed at curbing the spread of AMR pathogens (Quadripartite Joint Secretariat on AMR n.d.). Governments and other stakeholders could leverage World AMR Awareness Week to convey the message on the need for the safe disposal of unused antibiotics.

In the United Kingdom, the Keep Antibiotics Working media campaign conducted in England, from 2017 to 2019, was a multi-channel social marketing and communications initiative aimed at raising public awareness and supporting general practitioners in responsible antibiotic prescribing. Initially developed in England, the campaign was later adopted by Scotland, Wales and Northern Ireland. The primary goals of the campaign were to reduce patient expectations for antibiotic prescriptions and bolster general practitioners' confidence in prescribing antibiotics appropriately. Evaluations of Keep Antibiotics Working showed a significant increase in campaign recognition, outperforming previous national antibiotic awareness efforts. Additionally, participants' knowledge, awareness and understanding of AMR improved considerably after the campaign. The campaign also had a positive impact on general practitioners, with those who were aware of Keep Antibiotics Working reporting greater confidence in refusing antibiotics when unnecessary. The general practitioners were also more likely to explain to patients why antibiotics were ineffective for viral infections.

In 2023, Scotland used the Keep Antibiotics Working branding for an 'antibiotic amnesty' campaign, encouraging the public to return unused antibiotics to pharmacies instead of keeping or sharing them. This demonstrates the brand's adaptability to future campaigns, depending on public health needs (Gilham *et al.* 2023).

In the veterinary sector, the United Kingdom has actively promoted behaviour change for several years, which has played a key role in substantially reducing antimicrobial use in animals over the past decade, and thereby helped lower the volumes of unused medicines that require disposal. The country has achieved a remarkable 59-per-cent decrease in antibiotic use in food-producing animals. A voluntary, sector-led approach that has transformed attitudes and practices around antimicrobial use was the engine behind this success. The United Kingdom has now embraced antimicrobial stewardship as a core principle of its agriculture. The Responsible Use of Medicines in Agriculture Alliance spearheaded the industry's ownership of the issue, which, along with strong collaboration between the industry and Government, was central to this achievement. This approach contrasts with the more regulatory and enforcement-driven strategies seen in other countries.

Core principles of behaviour change that have helped achieve such success include: avoiding blame and guilt; making the issue relevant and salient; using regulation by reputation; working with the right messengers; and aligning actions with incentives. These strategies have fostered a more sustainable and responsible approach to antimicrobial use in agriculture in the United Kingdom (FAO and Medicines Directorate 2022). The companion animal sector has used stewardship guidelines (PROTECT ME), non-prescription forms and owner education to actively promote appropriate use of antimicrobials (Allerton *et al.* 2021; Wright *et al.* 2024).



Caption: Raising awareness to reduce antimicrobial use in agriculture. Photo: Italo Melo

in April 2024, the campaign collected 335 tons of prescription drugs and related materials through 4,607 collection sites across multiple states. The United States Drug Enforcement Administration's website provides comprehensive resources, allowing users to easily find nearby collection sites. Additionally, the site displays statistics from each Take Back Day, enabling the public to track participation and the volume of materials safely collected at each event nationwide (Drug Enforcement Administration n.d.).

In Germany, the noPILLS programme in Dülmen, was a two-year training and educational campaign focused on promoting sustainable consumption and the responsible disposal of pharmaceuticals. The initiative involved 13 schools, all local pharmacists, numerous doctors, sports clubs and various community stakeholders, successfully raising environmental awareness among 77 per cent of the population. Additionally, the campaign achieved a 20-per-cent increase in the proper disposal of unused medications and a 10-per-cent decline in the use of painkillers between medical treatments. Key communication channels that proved effective included doctors' waiting rooms and an annual unused medicines-collection calendar (noPILLS 2015).

Through its Healthy Cities Office, Kuwait's Ministry of Health launched the take-back campaign, Medication without Harm: A Multisectoral Initiative, to coincide with the 2022 World Patient Safety Day. The initiative emphasized coordinated planning, communication and collaboration among stakeholders, encouraging residents in participating "Healthy cities" to return unwanted medications to designated collection centres. Involving 405 households, the campaign collected 7,648 items, which were categorized according to the British National Formulary and analysed. The campaign gathered consultations at collection sites, for use in enhancing patient confidence in medication compliance and safety. Once sorted, the medications were disposed of safely. In the six-day event, 57 per cent of the returned items originated in the Ministry of Health and 43 per cent in the private sector; 52 per cent were expired and 59 per cent were in solid form, with painkillers making up the bulk at 18 per cent (Abahussain *et al.* 2024).

03

Conclusion and recommendations



Safe Disposal of Unused Medicines from Key Sectors Four Pillars



This final chapter presents a concise set of recommendations derived from the key pillars outlined in this document, to be considered as part of efforts to strengthen and implement national systems for the safe disposal of unused medicines in critical sectors.

3.1 Waste prevention

- strengthening disease-prevention programmes by improving sanitation, hygiene, biosecurity and vaccination;
- promoting appropriate medicine use through diagnostics, stewardship, guidelines and targeted therapies;
- ensuring the effective management of SF medicines, emergencies and medicine donations; and
- improving the management of medicine inventories for greater supply-chain efficiency

3.2 Medicine take-back schemes

- expanding accessible take-back schemes with a comprehensive stepwise approach in key sectors;
- adapting programmes to national and local contexts;
- strengthening agricultural sector participation in the safe disposal of unused veterinary medicines;
- encouraging industry involvement for enhanced engagement and shared responsibility in the management of unused medicines;
- promoting innovative technologies for waste and wastewater treatment;
- improving data-collection and traceability systems; and
- promoting robust monitoring and reporting mechanisms for greater transparency and accountability.

3.3 Legal and policy frameworks and multi-sectoral collaboration

- classifying pharmaceuticals by hazard for proper disposal;
- strengthening legal frameworks with sustainable financing and regular updates;
- developing national guidelines, clear roadmaps and roles for the management of unused medicines;

- promoting EPR and financial incentives for safe disposal;
- ensuring compliance through environmental permits, audits and reporting mechanisms;
- exploring circular economy solutions and public sustainable procurement;
- boosting multi-sector collaboration within a One Health approach, and stakeholder engagement at the national and global levels;
- establishing global databases for best practices and streamlining institutional responsibilities;
- developing integrated surveillance systems with standardized methods;
- promoting eco-labelling and smart packaging for medicines; and
- consolidating research on practices, pharmaceutical impacts and sustainable technologies, in line with national policies and regulatory standards.

3.4 Awareness raising

- strengthening nationwide awareness campaigns through regular monitoring;
- enhancing gender responsive training on safe disposal practices in key sectors;
- providing clear instructions and guidance on ways to implement a comprehensive stepwise approach to the proper management of unused medicines;
- using digital tools like apps and websites to track the consumption and disposal of medicine;
- incorporating safe disposal practices into the curricula of primary and secondary schools and professional education;
- increasing media engagement to promote proper disposal methods; and
- promoting gender inclusivity in education and decision-making to support equitable waste-management strategies.

3.5 Continuous evaluation and innovation

- regularly assessing the practices and adapting successful pilot projects for local scalability;
- investing in innovative waste-treatment technologies, leveraging artificial intelligence, machine learning and advanced materials; and
- increasing funding, the number of skilled

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Special thanks to UNEP's funding partners. For more than 50 years, UNEP has served as the leading global authority on the environment, mobilizing action through scientific evidence, raising awareness, building capacity and convening stakeholders. UNEP's core programme of work is made possible by flexible contributions from Member States and other partners to the Environment Fund and UNEP Planetary Funds. These funds enable agile, innovative solutions for climate change, nature and biodiversity loss, and pollution and waste.

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