

ჯანდაცვის პოლიტიკა, ეკონომიკა და სოციოლოგია Health Policy, Economics & Sociology PRINT ISSN 2960-9992 ONLINE ISSN 2960-9984

## Environmental Risk Management of Pharmaceuticals: Comparative Global Practices

ფარმაცევტული პროდუქტის გარემოზე ზემოქმედების რისკების მართვა: საერთაშორისო პრაქტიკების შედარებითი მიმოხილვა https://doi.org/10.52340/healthecosoc.2025.09.01.06

# ნანა შაშიაშვილი<sup>1a</sup>

## Nana Shashiashvili<sup>1a</sup>

<sup>1</sup>საქართველოს ტექნიკური უნივერსიტეტი, თბილისი, საქართველო <sup>1</sup>Georgian Technical University, Tbilisi, Georgia

### Abstract

Introduction: Pharmaceutical waste significantly contributes to environmental pollution. Improper disposal practices result in the release of active pharmaceutical ingredients into water and soil, threatening biodiversity, promoting antimicrobial resistance, and posing public health risks. Addressing these complex and growing challenges requires a coordinated, multi-stakeholder, and systemic approach supported by evidence-based policies and sustainable practices. Methodology: This study conducts a comparative analysis of pharmaceutical waste management practices and legislative frameworks in selected European countries. The research focuses on systems for collecting and disposing of expired and unused medications, examining the roles of pharmacies, governmental bodies, and the pharmaceutical industry across different institutional and socioeconomic contexts. Results: The comparative analysis of pharmaceutical waste management systems in European countries reveals significant differences in organization, government involvement, and funding mechanisms. Centralized models, such as in France and Spain, are well-regulated and heavily rely on public-private collaboration. In contrast, decentralized systems, like Finland, emphasize local government participation. Countries like Hungary and Romania are still transitioning, facing challenges in public engagement and regulatory enforcement. Conclusion: To enhance sustainability in pharmaceutical waste management, the study recommends improving public education, investing in infrastructure, promoting professional training, and establishing unified legal frameworks that engage all stakeholders. These measures are essential for protecting environmental and public health and promoting more responsible pharmaceutical practices worldwide.

Keywords: Pharmaceutical waste, Environmental pollution, Waste management

Quote: Shashiashvili N. Environmental Risk Management of Pharmaceuticals: Comparative Global Practices. Health Policy, **Economics** Sociology, 2025; 9 and (1).https://doi.org/10.52340/healthecosoc.2025.09.01.06

## აბსტრაქტი

 $\odot$ 

შესავალი: ნარჩენები მნიშვნელოვანი ფარმაცევტული წყაროა გარემოს დაბინძურებისათვის. განადგურების არასწორი წამლის პრაქტიკა იწვევს აქტიური ფარმაცევტული ნივთიერებების გამოყოფას წყალში და ნიადაგში, რაც საფრთხეს უქმნის

<sup>&</sup>lt;sup>a</sup> n.shashiashvili@tsmu.edu

https://orcid.org/0009-0003-5239-5905

CC This is an open access article distributed under the terms of the Creative Commons attribution-noncommercialsharealike 4.0 international (cc BY-nc-sa 4.0). License (http://creativecommons.org/licenses/by-nc-sa/4.0/)

ბიომრავალფეროვნებას, ხელს უწყობს ანტიმიკრობული რეზისტენტობას და წარმოადგენს სერიოზულ რისკს საზოგადოების ჯანმრთელობისთვის. ამ რთული და მზარდი გამოწვევების მოსაგვარებლად საჭიროა კოორდინირებული, მრავალმხრივი და სისტემური მიდგომა, რომელიც ემყარება მტკიცებულებაზე დაფუძნებულ პოლიტიკას და მდგრად პრაქტიკას. მეთოდოლოგია: კვლევა უკავშირდება შერჩეულ ევროპულ ქვეყნებში ფარმაცევტული ნარჩენების მართვის პრაქტიკებისა და საკანონმდებლო ჩარჩოების შედარებით ანალიზს, ვადაგასული და გამოუყენებელი მედიკამენტების შეგროვებისა და განადგურების სისტემების ეფექტურობის შეფასებას, აგრეთვე აფთიაქების, სახელმწიფო უწყებებისა და ფარმაცევტული ინდუსტრიის როლების განსაზღვრას სხვადასხვა ინსტიტუციურ და სოციალურ-ეკონომიკურ კონტექსტში. **შედეგები:** ევროპულ ქვეყნებში ფარმაცევტული ნარჩენების მართვის სისტემების შედარებითი ანალიზი აჩვენებს ორგანიზაციის, მთავრობის ჩართულობისა და დაფინანსების მექანიზმების მნიშვნელოვან განსხვავებებს. ცენტრალიზებული მოდელები, როგორიცაა საფრანგეთი და ესპანეთი, საჯარო-კორპორატიული თანამშრომლობის მხარდაჭერით, კარგად რეგულირდება. დეცენტრალიზებული სისტემები, ფინეთის მაგალითზე, ხაზს უსვამს ადგილობრივ მთავრობათა მონაწილეობას. ქვეყნები, როგორიცაა უნგრეთი და რუმინეთი, ჯერ კიდევ გარდამავალ ფაზაში არიან, მხარეთა ჩართულობისა და რეგულაციის აღსრულების გამოწვევებით. **დასკვნა:** ფარმაცევტული ნარჩენების მართვის პრაქტიკის გასაუმჯობესებლად რეკომენდაციას იძლევა საზოგადოებრივი განათლების გაძლიერეზის, კვლევა ინფრასტრუქტურაში ინვესტიციების განხორციელების, პროფესიული გადამზადების ხელშეწყობის ასპექტებზე და წარმოაჩენს ყველა დაინტერესებული მხარის ჩართულობის აუცილებლობას ერთიანი სამართლებრივი ჩარჩოს შემუშავებისთვის. აღნიშნული ნაბიჯები აუცილებელია როგორც გარემოს, ისე საზოგადოების ჯანმრთელობის დაცვისა მიზნებისთვის და გლობალურ დონეზე, ფარმაცევტულ სფეროში უფრო პასუხისმგებლიანი პრაქტიკის ხელშესაწყობად

საკვანმო სიტყვები: ფარმაცევტული ნარჩენები, გარემოს დაბინმურება, ნარჩენების მართვა.

**ციტატა:** შაშიაშვილი ნ. ფარმაცევტული პროდუქტის გარემოზე ზემოქმედების რისკების მართვა: საერთაშორისო პრაქტიკების შედარებითი მიმოხილვა. ჯანდაცვის პოლიტიკა, ეკონომიკა და სოციოლოგია. ჯანდაცვის პოლიტიკა, ეკონომიკა და სოციოლოგია, 2025; 9 (1). https://doi.org/10.52340/healthecosoc.2025.09.01.06.

### Introduction

Pharmaceutical waste has become a significant and escalating contributor to environmental pollution. Improper disposal of medications—often leading them into surface waters, soils, and occasionally the food chain—is associated with the degradation of water quality, the proliferation of antimicrobial resistance, and threats to biodiversity (Wilkinson et al., 2022).

Addressing this multifaceted issue necessitates a coordinated and systemic approach. The pharmaceutical industry must adopt environmentally sustainable production practices, aligning with the "Green Pharmacy" concept. Healthcare professionals should consider the ecological footprint of treatment choices during therapy individualization, while pharmacists play a critical role in educating patients on the safe return of expired or unused medications. Pharmacists are uniquely positioned to educate the public on the safe use and disposal of medicines. As accessible community-based actors, pharmacies are critical in pharmaceutical take-back programs—one of the most effective strategies to minimize pharmaceutical residues in the environment (Shashiashvili, 2025).

However, professional engagement alone is not sufficient. A sustainable, integrated system must be developed—one that protects both environmental and public health and is supported by clear policy, adequate infrastructure, and intersectoral collaboration (Cyclamed, 2021). Community pharmacies and local authorities must collaborate on structured collection programs supported by public awareness campaigns and technical

ჯანდაცვის პოლიტიკა, ეკონომიკა და სოციოლოგია 2025; 9 (1) Health Policy, Economics & Sociology

infrastructure. Evidence suggests that standardized dosing in hospitals and supply models based on actual demand can substantially reduce pharmaceutical waste. Pharmaceutical residues remain a serious source of environmental contamination, posing critical challenges in both high-income and low- and middle-income countries. Uncontrolled disposal methods—such as flushing medicines down the toilet or dumping them in landfills—lead to the release of active pharmaceutical ingredients into water and soil systems, endangering ecosystems and public health (Johnson & Bell, 2022). Widespread public education campaigns are urgently needed to raise awareness about the importance of proper pharmaceutical waste sorting and disposal (Environmental Protection Agency [EPA], 2023).

#### **Research** Aim

The aim of this study is to examine and compare the practices and legislative frameworks of selected European countries regarding the collection and disposal of expired and unused medicines. It seeks to identify the key stakeholders involved in these processes and assess the effectiveness of current mechanisms in mitigating environmental risks. The findings may serve as a foundation for the development of environmentally responsible policy models.

#### Methodology

This research is based on document analysis of legal regulations, official guidelines, and relevant government programs in various European countries related to the collection, transportation, and destruction of pharmaceutical waste. The data were obtained from official government sources, international agency reports, and peer-reviewed academic literature.

#### Results

Every year, over 100,000 tonnes of pharmaceutical products are consumed globally, with 24% of this consumption occurring in Europe. Throughout their production, usage, and disposal, Active Pharmaceutical Ingredients (APIs) and other chemical components are released into the environment, contributing to significant pollution. A large share of pharmaceutical manufacturing now takes place overseas, with China producing 80-90% of antibiotic APIs, and India being the leader in the production of finished dose medicines. This shift has resulted in pollution scandals, particularly in China and India, where antibiotic production has been linked to the spread of drug-resistant bacteria. Additionally, environmental pollution from these manufacturing plants has been observed in the European Union and other regions.

Pharmaceuticals are also released into the environment through human and veterinary consumption, as between 30-90% of an oral drug dose is excreted unchanged in urine. Over 600 different APIs have been detected in the environment, often at levels posing a significant environmental risk. These APIs have been found in various media, including drinking water, wastewater, sewage sludge, and soils. In the European Union alone, over 3,000 APIs are marketed as human or veterinary drugs. While the environmental impact of most of these substances is not fully understood, certain APIs are known to persist and accumulate in the environment, with documented ecotoxicological effects. These include reproductive impairment in fish populations, the harmful impact of antibiotics on bacteria and algae, and the decline of vulture populations due to poisoning by diclofenac in carcasses of treated animals.

The presence of antibiotics in the environment contributes to the rise of antimicrobial resistance (AMR), which is one of the most pressing global health threats. The burden of AMR, in terms of lives lost, increased morbidity, and healthcare costs, is much greater than current estimates suggest. For instance, 25,000 deaths were attributed to AMR in 2007, and projections indicate a 15-fold increase in AMR-related morbidity in Europe by 2050, with an estimated 390,000 deaths.

Despite growing concerns about the environmental risks of pharmaceuticals, the regulation of their environmental release remains nearly nonexistent. Key issues include a lack of public and governmental access to information on the environmental impact of APIs, insufficient monitoring requirements, and the absence of specific emission limits for pharmaceutical releases from manufacturing plants. There are no established limits for pharmaceuticals in drinking water, surface water, wastewater, or hospital effluents. Furthermore, the management of pharmaceutical waste is not adequately regulated, and there is no obligation to monitor pharmaceuticals present in sewage sludge or manure used in agriculture. Given these gaps in regulation, there is an urgent need for the emission of pharmaceuticals into the environment to be better controlled to ensure proper monitoring and the prevention of environmental contamination throughout their lifecycle (European Environmental Bureau, n.d.).

### Country Case Studies:

**Belgium.** A collaborative model between regional authorities, community pharmacies, and the pharmaceutical industry enables the systematic collection of expired and unused medicines. Under regulations enacted on January 21, 2009, all pharmacies in Belgium are legally required to accept returned medications from patients at no cost. These returns must be stored separately and then transferred to licensed distributors for safe disposal. Additionally, public education efforts are actively pursued, including informational brochures and guidelines that clarify which types of medicines are eligible for return and which are not (Health Care Without Harm Europe, 2013).

**France.** Since 2007, France has operated a mandatory national system for the safe collection and disposal of unused medicines known as Cyclamed. This scheme involves community pharmacies accepting unused or expired medicines from the public, storing them in designated containers, and passing them on to authorized pharmaceutical wholesalers for final disposal. The disposal process utilizes incineration, with the resulting steam and energy being repurposed for secondary use, contributing to energy efficiency. The system is funded through a compulsory fee paid by pharmaceutical manufacturers, making it cost-free for both patients and pharmacies. Cyclamed is also active in public engagement and awareness-raising. Pharmacies are provided with promotional materials such as posters, and advertisements are featured in public transport. Pharmacists receive customized prescription stamps to remind patients of their option to return unused medications. In addition, cardboard packaging from returned medicines is collected separately to be processed through the general recycling system. France also has a specialized scheme for sharp medical waste, which is collected free of charge by pharmacies (Cyclamed, 2020).

**Greece**. In Greece, a comprehensive pharmaceutical waste management framework has been established under the coordination of the Institute of Pharmaceutical Research and Technology (IFET), operating under the supervision of the National Organization for Medicines (EOF). This initiative is supported by the national pharmaceutical association and other relevant stakeholders. Specialized containers have been installed in all pharmacies, where citizens can deposit expired or unused medicines. Once a container is full, pharmacists notify the local pharmaceutical cooperative. Certified personnel then collect the waste using secure bags and transport them to IFET's central facility for deactivation. The process is regulated through a monitoring system that ensures traceability and oversight from the point of collection to final destruction. Upon completion, authorized agents issue formal documentation confirming the safe disposal of the materials. In 2019 alone, the program collected around 120 tons of pharmaceutical association, in collaboration with the Ministry of Education, has launched initiatives aimed at informing young people. Pharmacists also play a key role in raising awareness and encouraging appropriate disposal behaviors among the general public. A recent initiative focuses on managing sharp waste generated from influenza vaccination campaigns (IFET, n.d.).

**Spain.** Spain's national system for the collection and disposal of unused and expired medicines, known as SIGRE (Integrated System for the Management and Collection of Packaging), has been operational since 2001. This program was initiated by the pharmaceutical industry in partnership with the Ministry of Health and the General Council of Pharmacists. Participation in SIGRE is nearly universal, with over 99% of community pharmacies involved. Special containers are installed in pharmacies where patients can deposit unused medications and their packaging. Pharmacies are responsible for the secure storage of these containers. Once full, licensed waste management companies are notified and arrange for the transport of the materials to SIGRE's central sorting facility. At the sorting center, the waste is categorized to determine its final destination — whether for recycling, incineration, or energy recovery. SIGRE also implements wide-reaching public awareness campaigns using television, radio, print media, and social networks. Furthermore, it works directly with the pharmaceutical industry to improve eco-design in drug packaging. This initiative has resulted in over 500 packaging modifications aimed at reducing material use and enhancing recyclability (SIGRE, n.d.).

**Czech Republic.** Pharmacies are mandated to accept unused or expired pharmaceuticals, which are stored in secure, designated containers. Licensed waste transporters are then responsible for transferring the collected waste to authorized incineration facilities, where destruction occurs through environmentally safe methods (Act on Pharmaceuticals, 2020).

**Denmark.** In Denmark, public pharmacies are obligated to collect medical waste from the public. Municipalities are responsible for the logistics and costs associated with transportation and disposal, ensuring that pharmacies are not financially burdened. In the spring of 2021, Danish pharmacists launched a national awareness campaign aimed at educating the public about the environmental consequences of improper pharmaceutical waste disposal and encouraging the return of unused medicines. Furthermore, a six-month pilot project was initiated in three municipalities to collect and recycle empty insulin pens from diabetic patients. The materials used in the pens — such as plastic, metal, and glass — are sorted and reused. This initiative is the result of a cross-sector partnership involving community pharmacies, patient organizations, pharmaceutical wholesalers, municipal governments, the Danish Environmental Protection Agency, and the pharmaceutical company Novo Nordisk (European Journal of Health Law, 2021).

Italy. Since the 1980s, Italy has implemented a pharmaceutical waste collection system through the efforts of several organizations, aiming to ensure proper management of expired medicines and reduce environmental harm. One of the primary actors in this system is Assinde, a consortium composed of shareholders from the pharmaceutical manufacturing sector, wholesale distributors, and both private and municipal pharmacies. This initiative serves a dual purpose: optimizing inventory management within pharmacies and minimizing the ecological footprint of pharmaceutical waste. The program covers the collection, transportation, and destruction of all expired medicines—including veterinary pharmaceuticals—in full compliance with legal regulations. In January 2016, Assinde signed an agreement with Italy's Ministry for the Environment, enhancing regulatory oversight for both hazardous and non-hazardous medical waste. Additionally, many municipalities operate their own expired medicine disposal schemes. Specially designated containers, located both inside and outside pharmacies, facilitate public access and participation. This network is active in nearly every urban area across the country (Assinde, 2016).

**Slovak Republic.** In Slovakia, pharmacists play an active role in educating the public on the environmentally safe disposal of unused medicines, both in pharmacies and through online platforms. In 2016, the Slovak Chamber of Pharmacists launched an awareness campaign focused on promoting rational drug use and proper waste disposal. As part of the campaign, educational materials were distributed to inform patients about the correct handling of expired or unwanted medicines. Pharmacies across the country collect such medicines and ensure their safe disposal through Blue Planet, a specialized company that handles pharmaceutical waste incineration (European Journal of Health Law, 2021).

**Finland.** Finland has a long-standing tradition of involving pharmacies in environmental protection efforts. Nearly all pharmacies nationwide accept expired or unused medicines returned by consumers. The Finnish Medicines Agency (Fimea) is working on the development of an environmental classification system that will provide pharmacists and patients with information regarding the environmental impact and usage patterns of medicinal products. Currently, only aquatic environmental impact data are publicly available. However, the Finnish Medicines Information Centre is developing a more comprehensive assessment framework that will consider the entire life cycle impact of pharmaceuticals—from production to disposal (Fimea, 2024).

**Sweden**. Pharmaceutical waste management in Sweden is tightly regulated by national legislation. Since 2009, pharmacies have been assigned extended producer responsibility for medicines unused after home treatment. They are legally obliged to accept pharmaceutical waste from the public free of charge and to provide guidance on appropriate return procedures. These operational costs are covered by the trade margin set by the Swedish Dental and Pharmaceutical Benefits Agency (TLV) (PGEU, 2019). Pharmacies engage in public education campaigns and organize initiatives such as the "Big Collection Day," which aims to increase citizen participation in pharmaceutical waste return. A classification system based on the PBT index—persistence, bioaccumulation, and toxicity—supports professionals in making informed decisions regarding the environmental risk of medicinal products (One of Sweden's largest pharmacy chains, Apotek Hjärtat, has introduced a project to help consumers identify environmentally preferable pharmaceuticals. A specific eco-label is awarded to products whose manufacturers PGEU, 2019):

- Publish environmental sustainability reports following the GRI standards;
- Participate in the Pharmaceutical Supply Chain Initiative (PSCI);
- Avoid excipients banned under Swedish legislation.

Pharmacy staff receive specialized training to communicate the significance of this label and the environmental implications of medicines to patients.

**Portugal.** Portugal has implemented a national awareness initiative titled "Use Medicines Responsibly – We Are All Accountable," which targets the general population, healthcare providers, and policymakers. This campaign leverages multiple communication platforms to raise awareness about the responsible use and proper disposal of pharmaceuticals. The VALORMED program, established in 1999, oversees the collection and recycling of expired medicines and theirs packaging. As of 2019, approximately 98% of Portuguese pharmacies were participating in this scheme. Pharmaceuticals are collected in specialized containers, then sent for recycling or energy recovery. Since 2008, the program has expanded to include the collection of used syringes and X-ray films. VALORMED has also initiated the collection and processing of veterinary pharmaceutical waste, reflecting a broadened scope in addressing pharmaceutical-related environmental risks (VALORMED, n.d.).

**Netherlands.** The Royal Dutch Pharmacists Association (KNMP) is a signatory of the national "Green Deal," a policy initiative that aims to align economic development with environmental protection. Dutch pharmacists not only collect expired medications but also advise patients on appropriate and necessary medicine use, thereby reducing overall waste. They work closely with general practitioners through regular pharmacotherapy meetings to reinforce sustainable prescribing practices. Complementary initiatives include:

• "Green Pharmacy" projects under the Ministry of Health's Waste in Healthcare program;

• A sustainable packaging roadmap (2019–2022) developed collaboratively by various pharmaceutical associations (EAHP, n.d.).

Of particular note is the Pharmaswap initiative, a platform enabling the exchange of unopened, properly stored medicines between pharmacies to avoid unnecessary disposal. During the pilot phase, this program prevented the destruction of medications valued at over  $\in$ 54,000. Moreover, some pharmacies now deliver medicines to patients via environmentally friendly couriers such as bicycle messengers.

ჯანდაცვის პოლიტიკა, ეკონომიკა და სოციოლოგია 2025; 9 (1) Health Policy, Economics & Sociology

Pharmaceutical companies are also committing to carbon-neutral logistics and aim to operate entirely on renewable energy by 2030 (EAHP, n.d.).

**Pan-European Initiative: MedsDisposal Campaign**. The Pharmaceutical Group of the European Union (PGEU) plays a leading role in the MedsDisposal campaign, which aims to increase public awareness about the proper disposal of unused or expired medications. The campaign brings together a diverse range of stakeholders — including healthcare professionals, industry representatives, and student organizations — to support its multidisciplinary approach. One notable feature is the interactive map, which provides country-specific disposal guidelines in users' native languages. Social media is actively employed as a tool for outreach, helping expand the campaign's reach and effectiveness across a broad demographic spectrum (MedsDisposal, n.d.).

The case studies reviewed reveal that pharmacists globally play a proactive role in managing and mitigating environmental risks associated with pharmaceuticals. Despite variations in national regulatory frameworks, several core trends can be identified:

• **Pharmaceutical collection through pharmacies** is a cornerstone of environmental strategy in nearly all countries examined.

• **Public awareness campaigns** are widespread, with pharmacists providing educational resources through direct communication and digital platforms.

• **Extended Producer Responsibility (EPR)** is particularly emphasized in countries like Sweden and Spain, where industry stakeholders are required to fund collection and disposal systems.

• **Eco-labeling and transparency** regarding the environmental impact of pharmaceutical products are increasingly used to promote sustainable consumer choices.

• **Innovative technological solutions,** such as the Netherlands' *Pharmaswap* and carbon-neutral delivery systems, highlight the role of digital tools and logistics in sustainable pharmaceutical practices.

Below is a comparative table (N1) summarizing key characteristics of pharmaceutical waste management in the case study countries:

Country	System and Organizations Involved	State/Govern ment Involvement	Collection Methods	Funding and Financial Mechanisms	Processing and Disposal	Public Campaigns and Awareness Initiatives
France	Cyclamed (non-profit organization)	Supported by government, special return points in rural areas	Collection via pharmacies and public drop-off bins	Funded by the pharmaceutic al industry	Transport and disposal strictly follow national regulations	Educational campaigns and widespread placement of collection bins
Spain	SIGRE (non- profit organization)	Local government cooperation	Pharmacy- based containers and roadside collection sites	Funded by pharmaceutic al manufacturer s	Specialized recycling centers process the collected waste	Environmen tal education and awareness actions
Hungary	Recyclomed (non-profit initiative)	State- supported; local	Collection via pharmacies	Industry- financed	Destruction compliant	Campaigns on safe disposal of

Table 1. Key Characteristics of Pharmaceutical Waste Management Based on Country Case Studies

		authorities involved	and designated bins for expired		with national regulations	expired pharmaceuti cals
Finland	Local municipalities	Public and socio-	medicines Mobile collection	Publicly funded,	Project-based transportatio	Public awareness
	coordinate the system	economic involvement through municipalities	units; operational across all regions	minor contributions from local governments	n and environment ally safe disposal	campaigns adapted to regional needs
Romania	Pharmacies bear full responsibility	A legal framework exists, but limited enforcement for producers	Only through pharmacies ; no broader public collection infrastruct ure	Financed by individual pharmacies	Limited oversight of disposal effectiveness	Emphasis on developing a national system for expired medicine management
Italy	Assinde <sup>24</sup> and pharmaceutical associations	Formal agreements with the Ministry of Environment	Container- based systems in pharmacies , public drop-off services	Industry- funded; supported by local governments	Includes intermediate storage facilities and regulated destruction	Official campaigns and local initiatives by municipalitie s
Netherla nds	KNMP (Royal Dutch Pharmacists Association), local authorities	Government policies on post-consumer pharmaceutica l waste	Collection points in pharmacies and public areas	Joint funding from national and local governments	Waste is processed in compliance with environment al regulations	Educational campaigns in pharmacies; awareness through KNMP platforms
Portugal	VALORMED (pharmaceutica l sector initiative)	Government and pharmaceutica l supply chain cooperation	Collection in pharmacies via designated containers	VALORMED 's operational budget covers the system	Medicines are gathered and transported to licensed treatment facilities	National media campaigns and public education strategies
Bulgaria	EKO-Pharma (infrastructure- based system)	State and municipal engagement	Collection containers are placed in pharmacies	Local government funding	Controlled disposal and supervised transportatio n	Public awareness efforts and subsidization of the pharmacy network
United Kingdom	Eco-Pharm (project-based systems)	National-level government involvement	Public and pharmacy- based	Primarily financed through the	NHS- managed recycling and	Global environment al awareness

			collection	public health	safe disposal	campaigns;
			points	sector (NHS)	schemes	thematic
			-			initiatives
Latvia	PhS (Latvian	Government	Municipal	Funded by	Specialized	Participation
	Pharmaceutical	regulation and	and	pharmacies	collection	in
	Scheme)	oversight	pharmacy-	-	centers	nationwide
	,	0	based		manage waste	environment
			collection		disposal	al protection
			centers		1	campaigns
Sweden	Svenska	Sector-specific	Special	Financed by	Waste is	Environmen
	Apoteksförenin	regulations at	pharmacy	local	recycled or	tal education
	gen (Swedish	the local level	containers	administratio	destroyed in	through
	Pharmacy		and	ns	regulated	varied
	Association)		publicly		facilities	outreach
			promoted			activities
			programs			
Slovakia	FPDK (Slovak	Government	Sub-	Industry-	Disposal	Campaigns
	Pharmaceutical	oversight and	containers	funded	aligns with	via
	Distributors	municipal	in		national	publications
	Association)	participation	pharmacies		legislation	and video
			; collection		and protocols	content for
			through			the general
			local			public
			transport			
			programs			
Greece	Pharmacy	State-	Public	Financed by	Controlled	Eco-
	Association of	supported	collection	pharmacies	disposal	awareness
	Greece		containers		through	campaigns
			for unused		designated	and public
			medicines		collection	information
					points	services
Denmark	Danske	Governed by	Investigati	Municipal	Environment	"Destroy
	Apoteker	local	on-based	budget	ally safe	Medicine
	(Danish	pharmaceutica	container	allocations	disposal and	Waste"
	Pharmacy	l policies	systems in		recycling	public
	Association)		pharmacies			campaign
Czech	Česka	Government	Pharmacy	Government-	Branded as	Information
Republic	lékárnická	involvement	and	financed with	"Medicine	al programs
	komora (Czech	and regulatory	roadside	partial	Waste	targeted at
	Pharmacy	oversight	collection	industry	Collection"	raising public
	Chamber)		points	support	with clear	awareness
					disposal	
					processes	

Source: Author's analysis

Based on the comparative table of pharmaceutical waste management systems across various European countries, several key patterns and differences can be identified in terms of organization, government involvement, collection mechanisms, funding, disposal practices, and public awareness efforts. In many countries, such as France, Spain, and Hungary, pharmaceutical waste collection systems are operated by non-profit organizations with support from the state. These initiatives are well-structured and rely heavily on pharmacy-based collection points, often supplemented by public drop-off bins. In contrast, countries like Finland and the Czech Republic operate under the coordination of municipalities or national public health agencies, highlighting a more direct role of government in managing the system. Some systems, like those in Italy and Portugal, exemplify strong public-private collaboration, involving both pharmaceutical associations and government authorities. Pharmacy-based collection remains the universal method across all countries, with most offering secure containers in pharmacies for the disposal of expired or unused medicines. A few countries, such as Finland, also use mobile collection units to improve access, particularly in remote regions. Funding mechanisms vary widely. In countries such as France, Spain, and Hungary, the pharmaceutical industry is primarily responsible for financing the system. Others, like Finland and the UK, rely more on public funding through municipalities or national health systems. Some nations apply a hybrid model, combining public and private financial contributions to ensure sustainability. Waste processing and disposal in these countries follow strict national regulations. Medicines collected through these systems are transported and destroyed or recycled under controlled conditions to prevent environmental contamination. However, enforcement levels and infrastructure vary, as seen in Romania, where there is a legal framework but limited regulatory oversight and a lack of broader collection infrastructure. Public education and awareness campaigns are a crucial component of these systems. Countries such as France, Spain, and the UK invest heavily in national campaigns, educational materials, and pharmacy-based outreach to inform citizens about proper medicine disposal. Other countries, like Sweden and Slovakia, tailor their initiatives to local contexts through targeted communication strategies. Nonetheless, some regions still face challenges in integrating public engagement into their pharmaceutical waste strategies, which can limit overall effectiveness

A comprehensive comparative analysis reveals that pharmaceutical waste management systems across European countries exhibit significant diversity, particularly in organizational models, government involvement, collection mechanisms, funding sources, and public awareness efforts. A common trend is the use of pharmacies as primary collection points, ensuring accessibility. Non-profit organizations often play a key role in system coordination, frequently supported by governmental structures. However, the effectiveness of these systems largely depends on financial sustainability, public engagement, and the strength of regulatory frameworks.

Overall, pharmaceutical waste management models can be broadly categorized into three types:

- Centralized and well-regulated models (e.g., France and Spain),
- Decentralized systems coordinated by municipalities (e.g., Finland),
- Transitional and underdeveloped systems are still in need of improvement (e.g., Hungary and Romania).

Based on this classification, five countries have been selected to represent different approaches to pharmaceutical waste management:

1. *France – Centralized and Legally Structured Model.* In France, pharmaceutical waste management operates under a centralized and strictly regulated system coordinated by Cyclamed, a non-profit organization established by the French Public Health Code. This legal framework mandates the participation of all entities involved in the pharmaceutical supply chain, including marketing authorization holders, manufacturers, importers, and distributors. Pharmacies are legally obligated to accept unused or expired medicines from the public, while wholesale distributors are responsible for transporting sealed waste containers to authorized treatment facilities. The entire system is funded by the pharmaceutical industry, with financial contributions calculated based on the volume of medicinal products released onto the French market. The effectiveness of this model is further reinforced by nationwide public awareness campaigns and community outreach efforts, which promote responsible disposal behavior among citizens.

2. Spain – Effective Public-Private Collaboration. Spain's pharmaceutical waste management system is coordinated by SIGRE, a non-profit organization financed by pharmaceutical manufacturers in compliance with national legislation. Spanish law places a strong emphasis on environmental protection, requiring clear eco-labeling on pharmaceutical packaging to inform consumers about proper disposal. Marketing authorization holders are legally obligated to participate in all stages of the waste management process, including collection and treatment. Pharmacies serve as the primary public interface—functioning both as collection points for unused or expired medicines and as platforms for public education. They actively conduct awareness campaigns aimed at encouraging responsible consumer behavior. Wholesale distributors also play a key operational role by collecting, storing, and transporting pharmaceutical waste to authorized destruction facilities. The entire process is funded through SIGRE's mechanisms, ensuring financial sustainability and environmental compliance.

*3. Finland – Decentralized, Environmentally Oriented System.* In Finland, pharmaceutical waste is classified as hazardous under both the Finnish Medicines Act and the Waste Management Act, and is therefore subject to strict regulatory control. Responsibility for managing such waste is shared between municipalities and pharmacies. Municipalities are legally obligated to handle hazardous household waste, while pharmacies are mandated to accept unused or expired medicines returned by the public. The Finnish Medicines Agency (FIMEA) advises citizens on safe disposal practices and designates appropriate return points. To improve accessibility, especially in remote areas, the system incorporates mobile collection units alongside pharmacy-based infrastructure. The Pharmaceutical Industry Federation (PIF) actively supports the system by promoting environmental responsibility through national awareness campaigns, including initiatives like "A Baltic Sea Free from Pharmaceutical." In the downstream supply chain, wholesale distributors are responsible for collecting pharmaceutical waste and ensuring its safe destruction, often using incineration methods that contribute to energy recovery. The entire system is primarily publicly funded, with additional contributions from local governments. Overall, Finland's decentralized yet tightly regulated model places strong emphasis on sustainability and citizen engagement, reflecting a national commitment to environmental protection.

4. Hungary – Developing but Regulated System. Hungary operates a coordinated pharmaceutical waste management system led by Recyclomed, a non-profit organization responsible for overseeing collection and disposal activities. Hungarian pharmaceutical legislation mandates that producers not only finance the system but also take an active role in its operational aspects. Recent regulatory reforms have introduced further obligations, including the submission of environmental data and direct involvement in the collection, transport, and disposal of expired medicines. Pharmacies are equipped with designated containers for public use, while wholesale distributors manage the logistics of waste transportation to authorized facilities. The costs associated with disposal are shared proportionally among pharmaceutical companies based on their market share in Hungary. Although the system benefits from a clear legal framework and growing industry participation, public awareness and citizen engagement remain limited, posing challenges to the system's overall effectiveness and long-term sustainability.

**5.** Romania – Formal Structure with Practical Limitations. In Romania, pharmacies bear full responsibility for pharmaceutical waste collection. Although legislation assigns oversight duties to NAMMDR, the system remains poorly implemented in practice. Public engagement is extremely low—fewer than 1% of citizens return expired medicines to pharmacies, while most dispose of them in regular household waste. This poses significant environmental and public health risks due to the lack of enforcement and infrastructure.

The low return rate in Romania is attributed to several factors:



The analysis of five selected countries demonstrates that effective pharmaceutical waste management depends on coordinated efforts between governments, the pharmaceutical sector, and the public. France and Spain exemplify mature systems with clear regulatory mandates and financial stability. Finland stands out for its focus on environmental sustainability and geographic accessibility. Hungary represents a system in transition, gradually improving its regulatory framework, while Romania highlights the risks associated with weak enforcement and limited public involvement despite formal legal structures.

#### Conclusion

This comparative analysis of pharmaceutical waste management systems across European countries underscores both the diversity of organizational models and the emergence of shared priorities in addressing pharmaceutical-related environmental risks. Despite variations in regulatory frameworks, financing mechanisms, and public engagement levels, several common trends suggest the convergence of best practices across Europe.

One key unifying feature is the central role of pharmacies as primary collection points for expired or unused medicines. These institutions serve not only as physical collection hubs but also as publicfacing platforms for education and awareness, thereby amplifying their impact on responsible disposal behavior. In countries like France and Spain, centralized systems led by non-profit organizations (Cyclamed and SIGRE) demonstrate how legal mandates, industry funding, and coordinated stakeholder engagement can produce robust, sustainable models. Pharmacists in these systems are empowered to fulfill their dual function as health professionals and environmental stewards.

However, professional involvement alone does not guarantee success. A sustainable pharmaceutical waste management system requires integration across all sectors—governmental, professional, industrial, and public. Finland's decentralized but environmentally driven approach exemplifies how municipalities and pharmacies can share responsibilities effectively, even in rural or underserved areas. By contrast, Hungary illustrates a system in transition, where regulatory improvements and increased industry obligations coexist with weak public participation. Romania highlights the risks of poor enforcement and minimal stakeholder collaboration, where legal structures exist but lack practical support and public trust.

These cases collectively point to the core attributes of an effective system: clear regulatory frameworks, reliable and diversified funding, accessible infrastructure, environmentally sound disposal methods, and ongoing public education. Despite the progress made, significant challenges persist across many countries, particularly regarding:

- Divergent and often unstable financing structures,
- Low public awareness of proper disposal practices,
- Absence of detailed regulations on pharmaceutical waste recycling,
- Weak monitoring and reporting systems for returned medicines.

To address these issues, a harmonized and intersectoral approach is essential. Policy recommendations include:



While some countries offer exemplary models, others still face barriers related to infrastructure, enforcement, and community engagement. Overcoming these barriers requires political will, cross-sector collaboration, and the active participation of both professionals and the public.

Ultimately, achieving a sustainable pharmaceutical waste management system—one that safeguards both public health and the environment—depends on integrated governance, professional accountability, and societal commitment. The experience of countries like France, Spain, and Finland demonstrates that when legal clarity, financial responsibility, and educational outreach align, pharmaceutical waste management can become a cornerstone of environmental stewardship and public health protection across Europe and beyond.

## **References:**

- Act on Pharmaceuticals. (2020). Czech Republic: No. 378/2007 Coll., as amended in 2020. Retrieved from <u>https://www.zakonyprolidi.cz</u>
- Assinde. (2016). Agreement with the Ministry for the Environment on the management of pharmaceutical waste. Retrieved from <a href="https://www.assinde.it">https://www.assinde.it</a>
- Cyclamed. (2020). French Drug Take Back System. Retrieved from <u>https://circabc.europa.eu/d//workspace/SpacesStore/50e71cdb-4cd1-40b1-b342-</u> 0d0799087c7c/Day%202 EPR%20for%20solid%20pharma%20waste Cyclamed.pdf
- Cyclamed. (2021). Pharmaceutical Waste Management in France.
- EAHP. (n.d.). PharmaSwap: A pioneering healthcare initiative reducing medication waste. European Association of Hospital Pharmacists. Retrieved from <u>https://www.eahp.eu/gpis/pharmaswap-pioneering-healthcare-initiative-reducing-medication-waste-and-promoting</u>
- Environmental Protection Agency (EPA). (2023). The impact of pharmaceuticals released to the environment. <u>https://www.epa.gov/household-medication-disposal/impact-pharmaceuticals-released-environment</u>
- European Environmental Bureau. (n.d.). The problem of pharmaceutical pollution. Retrieved May 3, 2025, from <a href="https://eeb.org/the-problem-of-pharmaceutical-pollution/">https://eeb.org/the-problem-of-pharmaceutical-pollution/</a>
- European Journal of Health Law. (2021). Innovative public health initiatives in pharmaceutical waste management: A review of EU country practices, 28(3), 215–230. <u>https://doi.org/10.1163/15718093-28030001</u>

- Fimea Finnish Medicines Agency. (2024). Environmental classification system for pharmaceuticals. Retrieved from <a href="https://www.fimea.fi/web/en/environmental-impact">https://www.fimea.fi/web/en/environmental-impact</a>
- Health Care Without Harm Europe. (2013). Unused Pharmaceuticals: Where Do They End Up? Retrieved from <a href="https://europe.noharm.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf">https://europe.noharm.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf</a>
- IFET (Institute of Pharmaceutical Research and Technology). (n.d.). About Us. Retrieved from <u>https://www.ifet.gr/167/en/About-Us/</u>
- Johnson, C., & Bell, S. J. (2022). Linking emerging contaminants to production and consumption practices. WIREs Water, 9(1), e1615. <u>https://doi.org/10.1002/wat2.1615</u>
- MedsDisposal. (n.d.). About Us. Retrieved from <u>https://medsdisposal.eu/about-us/</u>
- NAMMDR. (2020). Pharmaceutical Waste Management in Romania.
- PGEU. (2019). Best Practice Paper on Green and Sustainable Pharmacy in Europe. Pharmaceutical Group of the European Union. Retrieved from <u>https://www.pgeu.eu/wp-content/uploads/2019/11/PGEU-Best-Practice-Paper-on-Green-and-Sustainable-Pharmacy-in-Europe.pdf</u>
- PGEU. (2019). MedsDisposal Campaign: Raising Public Awareness on Pharmaceutical Waste.
- Recyclomed. (2021). Pharmaceutical Waste Management in Hungary.
- Shashiashvili, N. (2025). The strategic role of the pharmacist in environmental risk management. Georgian Scientists, 7(2), 184–195. <u>https://doi.org/10.52340/gs.2025.07.02.17</u>
- SIGRE. (2021). Pharmaceutical Waste Management in Spain.
- SIGRE. (n.d.). How the System Works. Retrieved from <u>https://www.sigre.es/en/how-it-works/</u>
- Slovak Chamber of Pharmacists. (2016). National awareness campaign on pharmaceutical waste disposal. Retrieved from <u>https://www.sleks.sk</u>
- VALORMED. (n.d.). Quem Somos. Retrieved from <u>https://valormed.pt/quem-somos/overview/</u>
- Wilkinson, J. L., Boxall, A. B. A., & Kolpin, D. W. (2022). Pharmaceutical pollution of the world's rivers. Proceedings of the National Academy of Sciences, 119(8), e2113947119. https://doi.org/10.1073/pnas.2113947119