

## PHARMACEUTICAL POLLUTION AND THE ROLE OF INDUSTRY: ALIGNING GEORGIA'S ENVIRONMENTAL REGULATIONS WITH EU STANDARDS

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### ABSTRACT

Environmental risks associated with pharmaceuticals are increasingly recognized as a global public health and ecological concern. This paper provides a comparative overview of Georgia's pharmaceutical regulatory framework in relation to international standards, particularly those of the European Union and Sweden. The analysis draws upon official policy documents, legislation, and published academic literature, focusing on environmental risk assessment (ERA), extended producer responsibility (EPR), medicine take-back systems, and industry engagement in environmental initiatives. The review identifies several regulatory and institutional gaps in Georgia, including the absence of mandatory ERA, a national return mechanism for unused medicines, and clearly defined producer obligations and oversight mechanisms. The discussion underscores the importance of policy alignment with EU practices and the role of the private sector in promoting sustainable pharmaceutical waste management. The paper

concludes by advocating for the implementation of green pharmacy principles and the development of legislative and economic incentives to support environmentally responsible practices in the pharmaceutical sector and strengthen environmental governance in Georgia.

**KEYWORDS:** *Environmental risk, Green pharmacy, Pharmaceuticals, Pollution.*

### INTRODUCTION

The environmental risks posed by pharmaceutical substances have become an increasingly pressing issue on the global health and ecological agenda. Pharmaceuticals, once released

into the environment through production, use, or disposal, can contaminate water sources, soil, and ecosystems, contributing to antimicrobial resistance and ecological imbalances.<sup>[1]</sup> In response, numerous countries and regional bodies such as the European Union have developed strategic frameworks and regulatory mechanisms to manage these risks. However, the level of regulatory maturity and enforcement varies significantly across countries. Georgia, a country in transition with aspirations of EU alignment, faces the challenge of strengthening its pharmaceutical environmental governance. This article explores how Georgia's regulatory framework aligns with and diverges from international best practices and EU standards in managing the environmental impact of medicinal products.

### **Aim of the study**

#### **The primary objective of this study is threefold**

- To review and compare how pharmaceutical businesses are regulated in terms of environmental risk in countries with both advanced and underdeveloped regulatory systems.
- To identify and describe key elements of effective international models that ensure environmental accountability in the pharmaceutical industry.
- To assess the current state of Georgia's pharmaceutical industry-related environmental regulations by comparing them with best practices from a selected high-performing country and the European Union framework.

Through this comparative perspective, the study seeks to uncover the strengths and gaps in Georgia's approach to managing pharmaceutical pollution from an industry standpoint and to offer practical recommendations for aligning business practices and regulations with EU standards.

### **METHODOLOGY**

This research adopts a qualitative comparative analysis based on a document review method. No experimental procedures were conducted. Instead, the study focuses on analyzing legal and policy documents from Georgia, the European Union, and a reference country (e.g., Sweden or France). Sources reviewed include: National legislation and regulatory frameworks; Strategic policy documents and governmental reports; Academic publications and international guidelines.

The comparative framework is structured around four key thematic areas relevant to industry-related environmental regulation: Environmental risk assessment (ERA) requirements for pharmaceutical companies; Implementation of extended producer responsibility (EPR) mechanisms; National or regional pharmaceutical take-back systems; Industry involvement in public environmental awareness and sustainability initiatives.

This non-interventional, document-based methodology allows for in-depth exploration of policy gaps and alignment opportunities without requiring human or animal subjects.

## RESULTS

Pharmaceutical-related environmental risks are particularly severe in countries with high levels of prescription drug usage, inadequate waste management systems, and weak or poorly enforced sustainability policies. In such contexts, the environmental impact of medicines is intensified due to the absence of effective regulatory frameworks and operational oversight. The following countries are often cited as examples where the management of these risks remains significantly underdeveloped.

India faces considerable challenges in controlling pharmaceutical environmental risks. Despite being a global pharmaceutical hub, the country struggles with insufficient regulation and enforcement. Waste generated by the pharmaceutical industry often enters water bodies and soil due to a lack of structured waste treatment and disposal systems. In addition, the country's enormous consumption of prescription drugs contributes to high levels of unused medicines and environmental contamination. As a result, large volumes of pharmaceutical residues remain unprocessed, increasing the risk of pollution and long-term ecological harm.<sup>[2]</sup>

China's pharmaceutical sector is one of the most extensive in the world. However, the rapid industrial growth has outpaced the development of effective environmental protections. In many cases, pharmaceutical waste is improperly disposed of during production processes, contributing to soil and water pollution. Although there is growing attention toward ecological sustainability, enforcement gaps and limited public awareness—especially in rural and industrial regions—continue to hinder proper pharmaceutical waste management.<sup>[3]</sup>

As a rapidly developing nation, Brazil has established environmental legislation addressing pollution risks. Nonetheless, oversight remains weak, and enforcement mechanisms are limited. The scale of pharmaceutical consumption within both the industrial and healthcare

sectors is high, yet adherence to environmental safety standards among manufacturers and end-users is inconsistent. Consequently, medicines are frequently disposed of without sufficient control, leading to contamination of water and soil.

In many African countries, particularly Nigeria, weak infrastructure and fragmented waste management systems present a critical challenge. Pharmaceutical waste is often handled without standardized protocols, and disposal into open water sources or uncontrolled landfills is common. Although environmental laws may exist, enforcement is sporadic. Furthermore, public awareness around sustainable pharmaceutical practices remain low, exacerbating the environmental burden.

Mexico illustrates the intersection of high pharmaceutical usage with systemic regulatory shortcomings. The legal framework for pharmaceutical waste management is underdeveloped, leading to gaps in control and accountability. As a major exporter and consumer of pharmaceuticals, Mexico faces elevated environmental risks due to poor coordination between stakeholders and insufficient investment in sustainable waste disposal systems.

Countries such as China, Brazil, Nigeria, and Mexico face considerable obstacles in managing the environmental impact of pharmaceuticals. Despite the presence of robust pharmaceutical industries, these nations often lack comprehensive ecological regulations or struggle with weak enforcement. Addressing these challenges requires urgent policy reform, infrastructure investment, and capacity building to protect both environmental and public health.

Pharmaceuticals in the environment (PiE) represent an emerging and complex challenge for environmental and public health policy across Europe. Various countries have adopted different regulatory approaches and practical solutions to reduce the ecological risks caused by pharmaceutical residues in water, soil, and ecosystems. Among these, countries such as Sweden, Germany, the Netherlands, France, and Norway stand out for their efforts to regulate, monitor, and mitigate these environmental impacts.<sup>[4,5,6]</sup>

The table (N1) below provides a comparative overview of key regulatory and practical elements related to pharmaceutical environmental risk management across these five European countries.

## Environmental Regulations on Pharmaceuticals in Europe

Table N1

Regulation/ Practice	Germany	Sweden	Netherlands	France	Norway
Environmental Risk Assessment (ERA)	Mandatory for new medicines (EMA standard)	Requires additional ecotoxicological data	Covers the <i>use phase</i>	Based on EMA; no extra requirements	Follows EEA guidelines
Medicine Return Systems	Operates in all pharmacies	Legally mandated	Standardized system	Cyclamed program covers all pharmacies	Government-funded national system
Monitoring of Water Contamination	Conducted at municipal level	Comprehensive national monitoring	Publicly accessible database	Selective monitoring	Systematic and regular
Extended Producer Responsibility (EPR)	Exists, but limited in scope for pharma	Under consideration for pharma	Covers pharmaceuticals	Mandatory; producers fund return programs	Partially implemented
Public Awareness / Education	Campaigns exist	Online resources and brochures	Integrated into pharmacy services	National awareness campaigns	Integrated into schools and healthcare
Unused Medicine Disposal Guidelines	Pharmacies collect; state handles disposal	Special containers are mandatory	Subsidized disposal for pharmacies	Cyclamed ensures safe disposal	Managed by public authorities
Support for Eco-Pharmaceutical Innovation	Research grants available	Strong focus on “green pharmacy”	Innovation by producers is incentivized	Public funding for green R&D	National initiatives embedded in strategy

Source: Created by the author based on contextual analysis

Among the countries compared, Sweden is widely recognized as a leader in addressing pharmaceutical pollution and integrating environmental sustainability into health policy. Sweden's holistic approach—characterized by regulatory foresight, proactive public engagement, and innovation incentives—serves as a benchmark for effective pharmaceutical environmental governance (Table N2).

#### Sweden's Key Policy Factors in Green Pharmacy Implementation

**Table N2**

Key Factor	Explanation
Proactive ERA Policies	Requires environmental risk data for both new and existing pharmaceuticals.
Comprehensive Water Monitoring	Operates a national database with high-resolution data on pharma residues.
Use Phase Consideration	Uniquely considers post-consumption impacts in environmental assessments.
Public Education Campaigns	Engages the public and healthcare professionals in green pharmacy initiatives.
Innovation Incentives	State-run programs reward greener pharmaceuticals during procurement processes.

*Source: Created by the author based on contextual analysis*

Sweden, Denmark, and Norway demonstrate that it is possible to combine healthcare innovation with strong environmental stewardship. Their policies offer valuable lessons for other European countries aiming to improve pharmaceutical risk governance. Clear environmental assessments, effective waste disposal systems, and public participation are crucial pillars of a sustainable and eco-conscious pharmaceutical sector.<sup>[7,8]</sup>

As the European Union continues to revise environmental and pharmaceutical regulations, these countries provide a blueprint for integrating environmental safety with public health and industrial innovation.

#### Comparative insights

While Sweden stands out, Denmark and Norway also demonstrate strong ecological leadership and commitment to reducing PiE-related risks.

#### Denmark's Strengths

- **Renewable energy leadership:** Among the top countries in wind and solar energy integration.
- **Cross-border collaboration:** Active in EU-wide eco-policy development and pharmaceutical waste reduction.
- **Sustainable urban development:** Emphasizes green architecture and transport systems.

#### Norway's Strengths

- **Strong environmental budget:** Significant public funding for ecological protection and pharmaceutical waste systems.
- **Organic agriculture:** High rates of organic farming reduce chemical runoff into natural systems.
- **High public awareness:** Citizens actively participate in sustainable practices and eco-education.

#### Shared strengths

- All three countries have robust environmental legal frameworks and national values aligned with sustainable development.
- Each country combines education, research, and enforcement to improve pharmaceutical lifecycle management.<sup>[9,10,11]</sup>

The comparative analysis reveals significant disparities in pharmaceutical environmental risk governance between high-performing countries and those with underdeveloped regulatory systems. While nations like Sweden and Norway demonstrate integrated, transparent, and innovative frameworks, countries such as India, Nigeria, and Mexico struggle with enforcement, infrastructure, and public awareness. Georgia, similarly, lacks comprehensive mechanisms such as mandatory environmental risk assessments and producer responsibility policies. These findings highlight the urgent need for legislative reform, institutional coordination, and strategic investment to ensure sustainable pharmaceutical management in Georgia.

#### DISCUSSION

*Comparative Analysis: Sweden and Georgia in Managing Environmental Risks from Pharmaceuticals.*

Sweden is frequently recognized as a benchmark for best practices within the European Union in managing the environmental risks associated with pharmaceuticals. The Swedish



model embodies a comprehensive, multi-layered approach that integrates stringent regulatory frameworks, institutional oversight, environmental monitoring, and public engagement. This approach serves as a valuable template for countries like Georgia, where pharmaceutical environmental protections are still under development and regulatory frameworks remain fragmented.

The following analysis compares Sweden and Georgia across several critical domains, highlighting key differences and identifying policy options for adapting Sweden's model to the Georgian context (see Table N3).

#### Comparative Analysis – Sweden vs. Georgia

**Table N3**

Category	Sweden	Georgia
Regulatory Framework	Robust, clearly defined legislation with binding environmental standards.	Underdeveloped; lacking specific legislation and standards addressing pharmaceutical pollutants.
Institutional Oversight	Dedicated agencies with clear mandates for pharmaceutical waste and risk management.	Absence of specialized institutions responsible for pharmaceutical environmental risks.
Monitoring & Documentation Systems	Advanced, systematic monitoring of pharmaceutical residues in environmental matrices (water, soil, air).	Fragmented, sporadic monitoring; limited data availability and accessibility.
Public Awareness & Education	Extensive awareness campaigns, education programs targeting professionals and the public.	Low public awareness; minimal educational outreach on pharmaceutical environmental impacts.
Stakeholder Engagement	Active involvement of pharmacists, healthcare providers, industry, and citizens.	Limited engagement of relevant stakeholders in environmental pharmaceutical management.

**Source:** Created by the author based on contextual analysis

*Policy recommendations: Adapting the swedish model in georgia*

In light of the growing environmental concerns linked to pharmaceutical contamination, Georgia faces an urgent need to strengthen its national framework for pharmaceutical environmental governance. Drawing on international best practices—particularly the Swedish model, which emphasizes transparency, intersectoral coordination, and environmental



responsibility—Georgia can develop a more sustainable and effective system for managing pharmaceutical waste and mitigating ecological risks. The following recommendations outline key steps Georgia can take to align its practices with successful elements of the Swedish approach, adapted to the country's institutional, legal, and socio-economic context.

1. **Strengthen the Legal and Regulatory Framework.** Georgia must develop and implement clear, enforceable legislation that comprehensively addresses the environmental impact of pharmaceuticals. This includes legally binding requirements for proper disposal procedures, mandatory environmental risk assessments (ERAs) for pharmaceutical products, and compliance mechanisms for manufacturers, distributors, and healthcare providers.
2. **Establish a National Environmental Oversight Agency.** Creation of an independent, authoritative agency responsible for pharmaceutical environmental risk management is critical. This agency should have the mandate to set environmental safety standards, coordinate national monitoring efforts, enforce regulations, and facilitate collaboration among healthcare institutions, industry stakeholders, and environmental authorities.
3. **Develop Robust Monitoring and Reporting Systems.** Nationwide implementation of systematic environmental monitoring for pharmaceutical residues in water bodies, soil, and air is essential. Utilization of modern digital tools and data analytics should be prioritized to efficiently collect, process, and disseminate information, ensuring transparency and enabling evidence-based policymaking and public access to data.
4. **Promote Public Education and Community Engagement.** Educational initiatives targeting healthcare professionals, pharmacists, and the general public must be intensified. Awareness campaigns should emphasize responsible medication use and disposal practices, highlighting the environmental and public health risks posed by improper pharmaceutical waste management.
5. **Foster International Collaboration.** Engagement with European Union institutions and global organizations is vital for Georgia to adopt proven best practices, access technical assistance and funding, and build institutional capacity. Sweden's experience offers an excellent model for collaborative twinning projects, joint research initiatives, and capacity-building programs designed to strengthen Georgia's environmental pharmaceutical governance.

By adopting lessons from Sweden's comprehensive approach, Georgia can build a sustainable, resilient model for managing the environmental risks posed by pharmaceuticals. Such reforms would contribute significantly to ecological protection, improve public health

outcomes, and facilitate closer alignment with European integration frameworks. The implementation of structured regulations, investments in sophisticated monitoring systems, and inclusive education strategies will represent critical steps toward a forward-looking environmental health policy.

### *Comparative analysis: EU and Georgia in Managing Pharmaceutical-Related Environmental Risks*

The increasing awareness of pharmaceutical pollutants in the environment has compelled the European Union (EU) to develop and implement comprehensive, multi-level strategies aimed at mitigating ecological risks throughout the entire life cycle of medicinal products. In contrast, Georgia remains in the nascent stages of integrating environmental considerations into pharmaceutical regulation, characterized by fragmented yet evolving policies. This section examines the existing gap between the EU and Georgia and outlines potential pathways for regulatory harmonization and policy advancement.

The European Union has adopted a robust framework of regulations and policies specifically designed to prevent and reduce the environmental impact of pharmaceuticals. Central to this framework are the European Green Deal and the Zero Pollution Action Plan, which collectively aim to minimize environmental pollutants, including pharmaceutical residues, by applying a preventive, life-cycle-based approach.<sup>[12]</sup> One of the cornerstone initiatives is the Strategic Approach to Pharmaceuticals in the Environment (PiE), introduced by the European Commission in 2019. This strategy comprehensively addresses all phases of the pharmaceutical supply chain—from production through consumption to final disposal—and focuses on several critical actions:

- Ecotoxicological assessment prior to market authorization, ensuring new medicinal products undergo rigorous environmental impact evaluation before entering the market.
- Promotion and development of environmentally-friendly pharmaceuticals under the concept of "Green Pharmacy," which encourages innovation to minimize ecological footprints.
- Efforts to reduce the volume of improperly disposed medicines, thus limiting pharmaceutical residues entering the environment.<sup>[13]</sup>

In addition, the EU mandates Environmental Risk Assessment (ERA) for all new medicinal products seeking market approval through the European Medicines Agency (EMA). This requirement facilitates early identification and mitigation of potential environmental harms.

The principle of Extended Producer Responsibility (EPR) has been adopted in several member states, legally obligating pharmaceutical manufacturers and distributors to manage the post-consumer waste lifecycle of medicines, including unused and expired drugs.<sup>[14]</sup>

Moreover, public awareness initiatives and national medicine take-back programs—such as France’s Cyclamed, Portugal’s Valormed, and Sweden’s pharmacy-based return schemes—play a crucial role in reducing pharmaceutical waste. These initiatives are supported by the Water Framework Directive (2000/60/EC), which mandates member states to monitor, report, and mitigate pharmaceutical contaminants in aquatic environments, thereby protecting water quality and biodiversity.<sup>[15]</sup>

#### Georgia’s Environmental Commitments: Emerging Frameworks

Georgia has initiated significant foundational steps to integrate environmental protection within its legislative framework. The adoption of the Law on Environmental Liability represents an important move toward aligning national practices with European Union directives concerning environmental damage prevention and remediation. Furthermore, the introduction of Extended Producer Responsibility (EPR) principles within the general waste management sector signals an increasing commitment to sustainability and environmental stewardship.

However, despite these positive developments, Georgia currently lacks a dedicated environmental strategy specifically addressing pharmaceuticals. There is no mandatory requirement for Environmental Risk Assessments (ERA) during drug registration processes, nor are there established national programs for the safe return or disposal of unused medicines. Public education campaigns focused on pharmaceutical pollution remain minimal or absent. Although Georgia’s general environmental policies cover broad issues, they have yet to be explicitly tailored to mitigate pharmaceutical contaminants in water, soil, or waste streams (see Table N4).

#### EU vs Georgia – Pharmaceutical Environmental Risk Management

**Table N4**

Regulatory Area	European Union (EU)	Georgia
Green Policy / Strategy	European Green Deal and	No specific strategy; existing

	Zero Pollution Action Plan incorporate pharmaceutical environmental concerns.	policies are general environmental frameworks.
Pharmaceuticals in the Environment (PiE)	Strategic EU approach adopted in 2019 to comprehensively manage pharmaceutical pollutants.	No formal or documented strategy targeting pharmaceutical pollution.
Environmental Risk Assessment (ERA)	Mandatory under the European Medicines Agency (EMA) for all new medicines prior to registration.	Not required; registration procedures focus on quality, safety, and efficacy, excluding ERA.
Extended Producer Responsibility (EPR)	Enforced in multiple member states, including obligations for pharmaceutical waste collection and disposal.	Implemented in general waste management but excludes pharmaceutical-specific mandates.
Medicine Return Systems	Established and active national programs (e.g., Cyclamed in France, Valormed in Portugal, pharmacy returns in Sweden).	No official or accessible medicine take-back systems available to consumers.
Public Awareness Programs	Extensive campaigns addressing pharmaceutical pollution and proper disposal practices.	Public education on pharmaceutical environmental risks is very limited or non-existent.
Water Pollution Control	Water Framework Directive mandates monitoring and mitigation of pharmaceutical residues in aquatic environments.	Water quality monitoring exists but does not specifically address pharmaceutical residues.

**Source:** *Created by the author based on contextual analysis*

The European Union demonstrates a comprehensive and dynamic framework to address the environmental risks posed by pharmaceuticals, integrating precautionary principles, producer accountability, and public participation at regulatory and practical levels. These initiatives contribute to the overarching objectives of sustainable pharmaceutical management and environmental preservation.

In contrast, Georgia remains at an initial stage of development in this domain. Despite partial alignment through certain legislative instruments, the absence of a targeted pharmaceutical environmental strategy, insufficient enforcement mechanisms, and lack of awareness and education programs represent critical gaps.

*Strategic Priorities for Strengthening Pharmaceutical Environmental Management in Georgia.*

To effectively address current gaps and promote sustainable management of pharmaceuticals in the environment, Georgia should prioritize the following strategic actions:

- Develop a focused national strategy that explicitly addresses pharmaceuticals as environmental contaminants.

This strategy should define clear goals, roles, and responsibilities for managing pharmaceutical pollutants throughout their life cycle—from production and distribution to consumption and disposal. It must integrate environmental and public health perspectives, align with international best practices, and serve as a roadmap for legislative and operational reforms.

- Introduce mandatory Environmental Risk Assessments (ERAs) as a prerequisite for all new medicinal product registrations. Incorporating ERA requirements will ensure that potential ecological impacts of pharmaceuticals are systematically evaluated before market approval. This preventive approach enables early identification and mitigation of environmental risks, promoting safer pharmaceutical innovation and use.
- Implement pilot programs for medicine take-back schemes through pharmacies to ensure safe disposal of unused or expired medications. Pilot initiatives will help establish effective and accessible collection points, encouraging consumers to return unwanted medicines instead of improper disposal. These programs should be designed with stakeholder input and supported by clear guidelines, logistical frameworks, and public incentives.
- Launch targeted public awareness campaigns to educate healthcare professionals and the public on the environmental impact of pharmaceuticals and promote responsible disposal practices.

Educational efforts should highlight the risks posed by pharmaceutical contaminants to ecosystems and human health, fostering a culture of environmental responsibility. Campaigns can leverage multiple media platforms and collaborate with professional associations to maximize reach and impact.

- Facilitate enhanced intersectoral coordination among health authorities, environmental agencies, and pharmaceutical stakeholders to ensure cohesive policy implementation.

Effective management requires continuous communication and joint action between sectors involved in pharmaceutical regulation, waste management, environmental monitoring, and

public health. Establishing formal coordination mechanisms will improve policy coherence, resource sharing, and enforcement capabilities.

Adopting these strategic priorities in alignment with EU standards will significantly improve Georgia's capacity to manage pharmaceutical environmental risks, enhance public health, and advance the country's European integration ambitions.

## CONCLUSION

Pharmaceutical pollution represents a complex regulatory and ethical challenge that necessitates active involvement from both policymakers and the pharmaceutical industry. This study demonstrates that, while the European Union provides a comprehensive and integrated regulatory framework grounded in sustainability principles, environmental risk mitigation, and producer responsibility, Georgia's current system remains fragmented and insufficiently enforced.

Key gaps identified in Georgia include the lack of mandatory Environmental Risk Assessments (ERAs) for new medicinal products, underdeveloped medicine take-back and disposal schemes, and limited awareness initiatives driven by the pharmaceutical industry. These deficiencies not only hinder effective management of pharmaceutical contaminants but also pose risks to environmental and public health.

The findings highlight the urgent need for Georgia to enhance regulatory coherence and build institutional capacity by learning from EU best practices. In particular, fostering proactive environmental stewardship within the pharmaceutical sector is essential. This entails adoption of green manufacturing processes, compliance with rigorous environmental assessments, and active participation in safe medicine disposal programs.

Strengthening collaboration among government agencies, industry stakeholders, and the public emerges as a critical success factor for establishing a sustainable pharmaceutical sector in Georgia. By addressing these challenges, Georgia can improve environmental protection, safeguard public health, and advance its European integration objectives.

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