

Evaluating household pharmaceutical waste systems in Albania and the European Union: A comparative study

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ABSTRACT

The amount of waste pharmaceuticals generated in households has increased steadily, due to societal and production changes. Therefore, managing household pharmaceutical waste (HPW) is an important challenge for our society. The study presents a comparative assessment of HPW management in Albania and practices in European countries, followed by recommendations on building a functional management system for HPW in Albania. Public and pharmacist perception on this issue is a key element in achieving sustainable waste management goals. The amount of waste pharmaceuticals stored remains low, with 86% respondents storing several tablets, primarily antipyretics (53). Regarding pharmacists, 86% responded that they don't accept expired/unused products from patients, even though the demand from the latter is almost absent; 88% of the pharmacists refuse to cover the cost of waste generated by family members. The Albanian legislative and regulatory framework remains fragmented and incomplete, creating uncertainty regarding the responsibilities, competencies, and administrative regulatory roles of various actors.

Keywords: pharmaceutical waste, expired drugs, unused drugs, pharmaceutical disposal, household hazardous waste

INTRODUCTION

The use of drugs has reached industrial expansion. They are widely found in each of our homes in large and unnecessary quantities. We can encounter them in workplaces, public spaces, and other settings, without considering the institutions that have an inevitable and necessary need for their use, ranging from pharmaceutical operators to large hospital centers. Household pharmaceutical waste is part of the group of household hazardous waste, which includes a wide range of materials that exhibit various hazardous properties. The definition of waste is included in Article 3 of the Waste Framework Directive (WFD) Directive 2008/98/EC, as modified by Directive (EU) 2018/851, as part of the Circular Economy Waste Package. These are based on provisions set for in the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal, 1999.

The study was conducted in the Municipality of Tirana, the most populous area in Albania, accounting for ~32% of the national population (2023 census). Tirana also generates the highest share of hospital waste (60% of the total) (NEA, 2024). As hazardous waste, it must be treated exclusively by operators

licensed by the National Environmental Agency, following uniform standards nationwide.

The study aims to identify the existing mechanisms for the collection, processing, and disposal of household pharmaceutical waste in Tirana, as well as the gaps in legislation and regulation, by comparing them with standardized practices in European Union countries.

The methodology is based on the collection of qualitative and quantitative data, the analysis of the legislative documents, and interviews with the citizens and the pharmacists in the municipality of Tirana, where preliminary findings show considerable disparity with the European standards. According to the US Environmental Protection Agency (EEA, 2015), 100 kg of waste is generated for every 1 kg of herbs produced, considering the entire production chain, from the raw materials acquisition and the manufacturing process to the end user consumption. It is worth noting that most of this waste can be collected and managed through conventional solid waste treatment methods, except 20% of the total waste may be classified as hazardous, depending on regulatory definitions across different jurisdictions.

In Albania, there is no district system for managing the pharmaceutical waste generated by household, for consequence, the throwing of such waste is often disposed of

improperly, including being flushed down toilets, discarded in kitchen bins, or mixed with general household waste. In contrast, pharmacies are required to follow a regulated disposal system for hazardous waste. The established one-year contract with a licensed company for hazardous waste management companies, as specified in Chapter III, Articles 8, of the Decision of the Council of Ministers No. 798, dated 29/09/2010, on the Administration of the Hospital Waste. These contracts generally cover an annual waste quantity of up to 20 kg, with additional fees incurred if this threshold is exceeded. However, these provisions are implemented in a truncated manner in most municipalities in the country.

Thus, the release of pharmaceutical waste in the environment has become a growing concern due to the significant risk it poses to humans, animals, and ecosystems (Aliko et al., 2021). Molecules and chemicals from unused drugs and pharmaceutical products are reported by Albania's research institutions in groundwater, surface water, or living aquatic plants, presenting a growing concern within the national research community.

According to the World Health Organization (WHO), pharmaceutical waste requires strict control and management due to its significant risks to human health and the environment. Environmentally, improper handling of pharmaceutical waste, particularly untreated antibiotics and medicines containing cytotoxic agents, can lead to contamination of surface and groundwater, including potable water sources, thereby entering food chains and posing risks to ecosystems and human health. Although incineration is widely used as a final treatment option, unsafe practices such as open burning or poorly controlled combustion can result in the emission of hazardous air pollutants and the deposition of contaminated ash into surrounding soil and infrastructure.

Despite the recognition of these risks at the international level, a critical gap persists in Albania with regard to the systematic management of household pharmaceutical waste. While environmental and health hazards associated with pharmaceutical waste are well documented, Albania lacks comprehensive, standardized, and accessible mechanisms for the separate collection and safe treatment of pharmaceuticals generated at the household level. In practice, unused or expired medicines are frequently disposed of through municipal waste streams or wastewater systems, increasing the likelihood of environmental contamination.

This gap reflects limitations in regulatory implementation, public awareness, and infrastructure, as well as the absence of clearly defined responsibilities across the pharmaceutical supply chain. Addressing this gap is essential for aligning Albania's waste management practices with WHO recommendations and EU environmental standards, and for mitigating long-term risks to public health and environmental integrity.

The determination of antibiotic concentrations in the water samples represents a critical analysis, given the extensive use of various antibiotics in medical treatment. The problem of antibiotic-resistant bacteria has been recognized for more than a decade (WHO, 2020). As bacteria exposed to antibiotics in sludge or water environments possess the capacity to develop resistance mechanisms. Hospital and

healthcare centers serve as continuous sources of various pharmaceutical compounds, including antibiotics, sedatives, antipyretics, and anti-inflammatories, and chemotherapeutic chemicals, which, along with medicaments administered to Humans and domestic animals, such as antibiotics, hormones, and analgesics, have been detected in tap water supplies (Kümmerer, 2009). A large quantity of drugs that are excreted by humans and animals are spread into the environment through toilet leaching and organic fertilizers distribution, as well as through sewage discharge, wastewater sludge, and both surface and subsurface pathways. Uncontrolled disposal of hospital waste into rivers, streams, or landfills contributes significantly to the presence of various pharmaceuticals in groundwater and surface water (Dudhabhate & Kokare, 2023). While several studies in Albania have investigated the occurrence of specific pharmaceutical groups such as antibiotics, antipyretics, and beta blockers in river systems (Nuro et al., 2024) and their subsequent impacts on biota (Aliko et al., 2019). The study conducted during the COVID pandemic, when drug usage significantly increased, evaluated the concentration of pharmaceutical elements in the examined water systems and algae populations (Tahiri et al., 2023). Various investigations have assessed the effects of antidepressants and anti-inflammatories on species such as frogs, revealing that these two classes of pharmaceuticals negatively impacted growth and development by delaying the metamorphosis timing and reducing body mass. Additional research examining pharmaceutical effects on fish in a lotic aquatic environment documented alterations in nervous system function and swimming behaviour (Aliko et al., 2021). Establishing these species as potential bio-indicators of pharmaceutical contamination in aquatic systems.

BACKGROUND

Legal and Regulatory Framework for Pharmaceutical Waste Management

The Republic of Albania currently lacks specific legal or sub-legal instruments directly addressing pharmaceutical waste as an independent regulatory category. Nevertheless, pharmaceutical waste is categorized as a specialized subset of hospital waste, incorporated within the broader legislative framework governing hospital waste and pharmaceutical products. The existing regulatory instruments include: Decisions of the Council of Ministers (DCM).

DCM No. 798 (29.09.2010)

This regulatory instrument approved the regulation on the approval of the regulation "On the management of hospital waste, which provides the following definition of pharmaceutical waste:

- 1) Pharmaceutical waste encompasses expired or unused pharmaceutical products expired or unused, contaminated pharmaceutical products from spillage or contamination, excess medications, vaccines or serums, and ancillary materials used during pharmaceutical handling, including containers, personal protective equipment (gloves, masks), and primary packaging (tubes, bottles).

- 2) Hazardous waste includes infected waste, pathological, drilling waste, sharps, pharmaceutical waste, toxic substances, chemical and radioactive materials, contaminated water, and infected solvent.

DCM No. 402 (30.06.2021)

This legislative instrument, entitled “On the approval of the waste catalogue”, established a comprehensive taxonomic classification system for waste management in alignment with European Union standards.

Within this regulatory framework, pharmaceutical waste is categorized under chapter 18 (“Wastes from Human or Animal Health Care and/or Related Research”), specifically:

- 18.01.08* - Cytostatic and cytotoxic pharmaceutical products (classified as hazardous waste, denoted by asterisk)
- 18.01.09 - Pharmaceutical products not classified under 18.01.08

- National Guide for the Safe Management of Hospital Waste, formally adopted through Ministerial Order No. 17 (12.01.2012), provides additional procedural and implementation guidance for healthcare facilities and waste management entities.

The European Context of Household Pharmaceutical Waste Management

Household pharmaceutical waste is classified as household hazardous waste, which encompasses a wide range of materials exhibiting various hazardous properties, as defined in Article 3 of the Waste Framework Directive (WFD) 2008/98/EC, as amended by Directive (EU) 2018/851, which forms part of the Circular Economy Waste Package.

The criteria for the classification of hazardous waste are outlined in the revised Annex III of the WFD, while the criteria related to the origin and type of waste are described in the European List of Waste (LoW). According to Article 20 of Directive (EU) 2018/851, by 1 January 2025, Member States have established separate collection systems for hazardous waste fractions produced by households to ensure that such waste is treated in accordance with Article 4 (which establishes the waste hierarchy) and Article 13 (which protects human health and the environment), and to prevent contamination of other municipal waste streams. Further ascertainment for the above is provided in the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee (COM/2019/128 final), as well as in the Commission Notice (2020/C 375/01).

Article 127b of Directive 2004/27/EC requires EU Member States “to ensure the existence of appropriate collection systems for unused or expired pharmaceutical products.” Furthermore, Article 54(j) requires the adoption of specific precautionary measures regarding the disposal of unused pharmaceutical products or waste derived from such products, as appropriate, as well as references to any suitable national collection systems.

Comparative Assessment of Implemented Practices in Different European Countries

Most citizens of EU Member States can dispose of their expired medicines at pharmacies or designated collection points. In the United Kingdom, unused pharmaceutical waste must be returned to a pharmacy, and collection at designated disposal points is not permitted (Legislation, 1990, 2005a; Department for Environment, Food and Rural Affairs, 2018). Other approved collection locations within the EU include nursing homes and retirement communities. Collection periods vary from one-day events to continuous or periodic collection schemes. To finance collection and cover associated costs, EU Member States have implemented several practices based on the Extended Producer Responsibility (EPR) principle for expired medicines.

France

The collection of pharmaceutical waste is managed by the organization Cyclamed, which is financed by pharmaceutical producers to coordinate the separate collection of unused medicines (Agence de la transition écologique, 2015, 2017). Cyclamed conducts awareness campaigns for patients and all actors in the pharmaceutical supply chain, including more than

21,000 pharmacies, 200 distributors, and 190 laboratories that are part of the Cyclamed system (2019). Cyclamed manages to collect 62% of unused medicines. In 2019, the total volume collected was 10,500 tons, equivalent to 162 g per inhabitant. The total cost amounts to approximately €10 million, funded through a producer contribution of €0.0032 per medicine box (excluding VAT). Around 50% of the total cost is associated with waste disposal (€250 per ton), which includes incineration costs (€120 per ton), as well as storage and transport. The procurement of collection bins provided to pharmacies represents about 25% of the cost, communication expenses account for 10%, and overall management accounts for 5%. The remaining portion covers various studies and research activities.

Denmark

Pharmacies in Denmark are required by law to take back household pharmaceutical waste (Mitkidis et al., 2021). This service is provided free of charge, meaning that consumers returning pharmaceutical waste cannot be charged by the pharmacy, and pharmacies themselves cannot be charged by local authorities for the treatment of hazardous waste. The procedure involves pharmacies entering into agreements with municipalities, which hold regulatory authority over waste management, to ensure the collection and disposal of household pharmaceutical waste. Pharmacies in this municipality are required to collect, classify, and store household pharmaceutical waste in the provided containers and to request collection when necessary.

Czech Republic

Article 88(1) of the Medicines Act stipulates that expired or unused pharmaceutical products must be disposed of in a manner that prevents any risk to human or animal life and health, as well as to the environment. Article 89(2) of the same Act obliges pharmacies to accept pharmaceutical waste from

households. After receiving pharmaceutical waste from individuals, pharmacies are required to handle it according to the procedures applicable to hazardous waste within the framework of the Waste Act.

The new Waste Act of 2020, in Part 11 (Title VI), sets out further obligations for pharmacies in this regard. According to Article 91, pharmacies must separate pharmaceutical waste originating from citizens and households from the waste they generate themselves and must also maintain a specific and continuous register for it. These disposers collect the household pharmaceutical waste from pharmacies free of charge and may subsequently apply to regional authorities for cost reimbursement. According to research conducted by the Czech State Institute for Drug Control (SÚKL), Czech citizens returned unused medicines to pharmacies worth approximately €128 million in 2018, a figure four times higher than in 2008 (SUKL, 2020).

Greece

As a result of non-compliance with EU law due to the failure to implement Directive 2004/27/EC, Greece established a temporary pharmaceutical take-back system through a Ministerial Decision in 2012. According to Article 1 of this decision, household pharmaceutical waste must be collected and temporarily stored in special containers placed in selected, highly visible, and easily accessible locations within all pharmacies across the country. These containers are provided free of charge to pharmacies by the Institute of Pharmaceutical Research and Technology (IFET). The decision stipulates that the collected waste is to be transported from pharmacies via existing distribution networks to a central collection and disposal point, with the final disposal taking place outside Greece (Aliberton, 2019). The responsibility for the final disposal of household pharmaceutical waste lies with IFET, which also bears overall responsibility for the implementation of the ministerial decision, under the supervision of the National Organization for Medicines (EOF). Interestingly, Article 7 of the Ministerial Decision introduces the obligation for the involved public authorities to inform and educate the public on how to use the collection system properly, rather than disposing of pharmaceutical waste as ordinary household waste. Finally, Article 9 provides for the imposition of administrative sanctions on pharmacies that fail to comply with the specified conditions.

United Kingdom

In the United Kingdom, household pharmaceutical waste must be returned to pharmacies, which are legally obliged to accept and arrange the disposal of unwanted medicines (Legislation, 2013). Among the jurisdictions studied, the UK has the largest number of legislative acts governing the operation of the pharmacy takeback system.

According to Schedule 4, paragraphs 14(3) and 15 of the 2013 Regulations, pharmacies are required to:

- Classify received pharmaceutical waste into solids (including ampoules and vials), liquids, and aerosols.
- Store medicines in containers supplied by or on behalf of the NHS Commissioning Board (NHSCB).

- Comply with any other legal requirements concerning the storage or disposal of such medicines (e.g., as hazardous waste).
- Cooperate with any relevant agreements established by the authority responsible for the collection of pharmaceutical waste from pharmacies.
- Ensure that pharmacy staff are aware of the risks associated with handling pharmaceutical waste and follow appropriate procedures.

Furthermore, pharmacies have additional obligations related to the handling, storage, and transport of pharmaceutical waste. However, if no formal agreements are in place with the relevant authorities, pharmacies are not obliged to accept medicines returned by citizens or households.

METHODOLOGY OF THE STUDY

The Public Questionnaire

A survey assessing citizens' opinions on the management of expired and unused medications was conducted during the first trimester of 2024. The study was conducted in the framework of the "Tirana Ime 2.0 - PharmaWipe" Project, implemented by the Resource Environmental Center Albania (REC Albania), funded through the program "Capitals Cooperating for Common Challenges in Hazardous Waste Management – Yerevan, Warsaw, Tirana," as supported by the European Union (EU). The semi-structured questionnaire was distributed via Google Forms through the social media channels of Resource Environmental Center Albania (RE Albania) and reached over 150 citizens in the Municipality of Tirana.

The research used a quantitative approach, using a non-probability, simple sampling methodology. The development of the questionnaire was informed by prior applied research conducted in other countries, where validated public surveys on pharmaceutical waste management had already been developed and implemented. This was done to ensure methodological validity and facilitate standardization in measurement.

Furthermore, the questionnaire was reviewed and adapted by experts in the field, with the support of the Albanian Pharmaceutical Order, to reflect the specific characteristics of Albania's pharmaceutical system and the consumption behaviour trends of residents in the Municipality of Tirana.

The Pharmacist's Questionnaire

The survey was conducted between February and March 2024, targeting pharmacists operating within the municipality of Tirana. A total of 50 pharmacists were interviewed to gather their perspectives on the collection of household-generated pharmaceutical waste and their willingness to participate in or support the establishment of a structured pharmaceutical waste management system for the public.

A quantitative research approach was adopted for both pharmaceutical professionals and public opinion. With the assistance of the Albanian Pharmaceutical Order, a semi-structured questionnaire was developed, consisting of 12

questions grouped into two thematic categories. The sampling technique used was non-random and non-probability-based, focusing on a targeted group of respondents.

The first group of questions aimed to assess pharmacists' perceptions of the current pharmaceutical waste management practices, as well as their views on what they consider to be the optimal management model. The second group of questions explored the pharmacists' knowledge and attitudes regarding the existing legal framework on pharmaceutical waste management in Albania, including their professional stance on the current situation.

Pilot Point Methodology

The methodology consisted of an initial six-month preparatory phase, which included analysis of the existing legal framework, surveys assessing public and pharmacists' perceptions, expert consultations, and coordination meetings with local and national institutions.

A pilot scheme was subsequently implemented in five public health centers in Tirana (Health Centers No. 1, 4, 6, 7, and 10), selected in collaboration with the Ministry of Health and Social Protection. In each center, a dedicated 1 m² area in the main hall was allocated for the installation of controlled and publicly accessible pharmaceutical waste collection points.

A licensed hazardous waste management company was contracted to ensure the collection, transport, storage, and final disposal of the collected pharmaceutical waste. The pilot points were installed in May 2024 following coordination meetings and staff training. Each collection point consisted of a legally compliant healthcare waste container, an awareness-raising poster, and clear signage indicating that the bins were exclusively for unused or expired household medicines.

RESULTS AND DISCUSSION

Results of Public's Opinions

Among the 175 respondents, 73% were women. Although the questionnaire did not include gender as a variable for analysing levels of awareness or engagement, a preliminary observation of the gender distribution suggests that women may exhibit a higher sensitivity toward the issue of pharmaceutical waste management. The majority of respondents were between 20 and 40 years old, with a smaller proportion aged over 40. This age distribution likely reflects the method of data collection, as the questionnaire was disseminated via social media platforms, which are more commonly used by younger demographics. This approach limits the participation of older age groups, who generally have lower access to or engagement with digital survey tools. In contrast, older populations are more effectively reached through traditional information channels, such as mass media and healthcare centers, including pharmacies and primary healthcare facilities. As expected, the majority of respondents (97%) held a university degree, while the remaining 3% reported having a higher education qualification.

Regarding pharmaceutical waste disposal methods, 92% of respondents reported disposing of medications with regular household waste (as in **Figure 1**), considering this the simplest disposal method. A small percentage of respondents disposed of pharmaceutical waste via toilet systems, perceiving this as a more secure disposal method within a dedicated management framework. A negligible percentage reported using alternative disposal methods such as combustion or disposal in dedicated pharmaceutical waste bins, which are largely unavailable in public areas in Albania, except in very limited cases.

Regarding the quantity of expired/unused medications, 86% of respondents reported generating "some tablets," followed by 12% who indicated they generate "a dozen," and 2% who reported generating more than "a dozen" tablets.

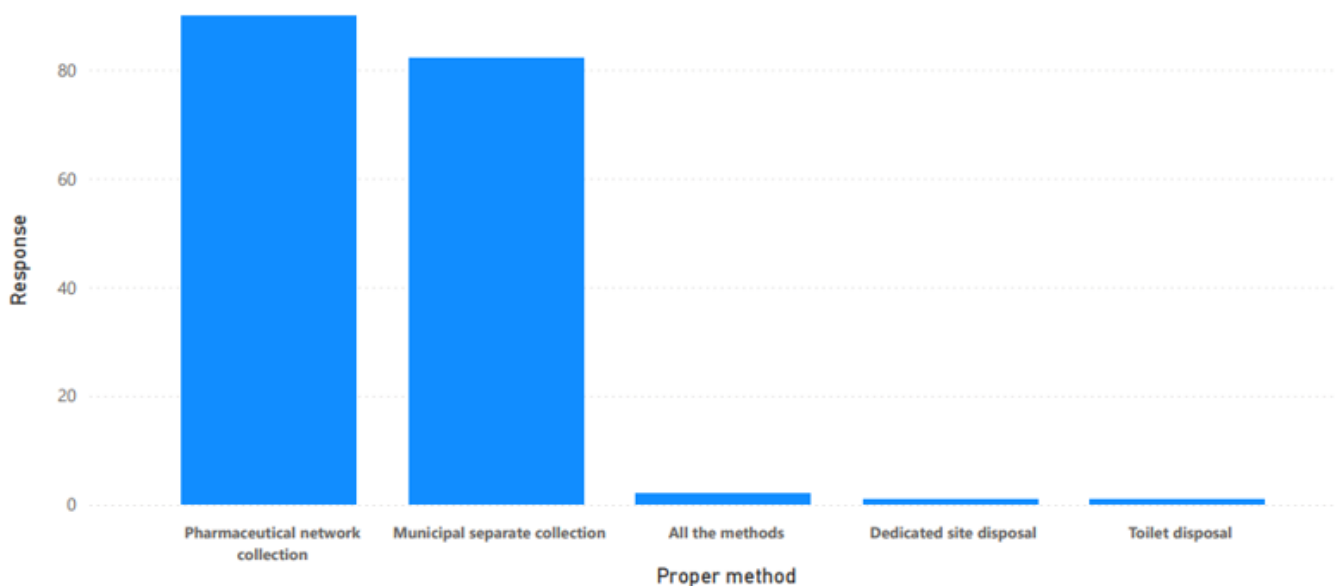


Figure 1. Disposal methods of expired/unused pharmaceutical products by citizens of Tirana (Source: Authors' own elaboration)

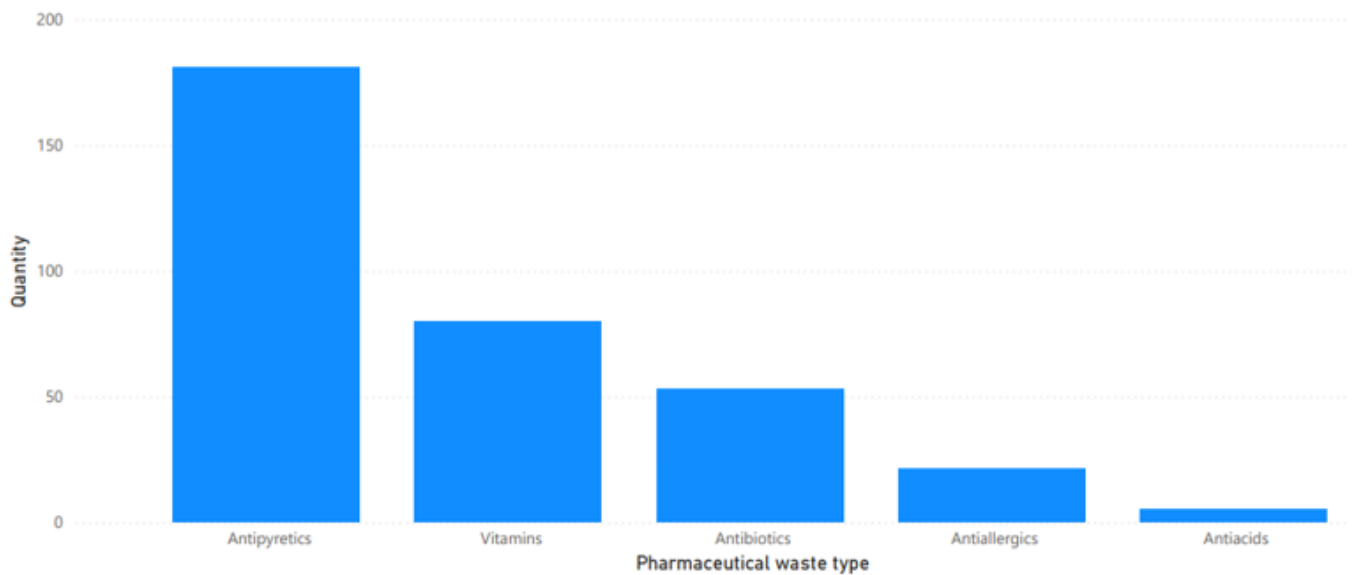


Figure 2. Types of household pharmaceutical waste generated by interviewed citizens (Source: Authors' own elaboration)

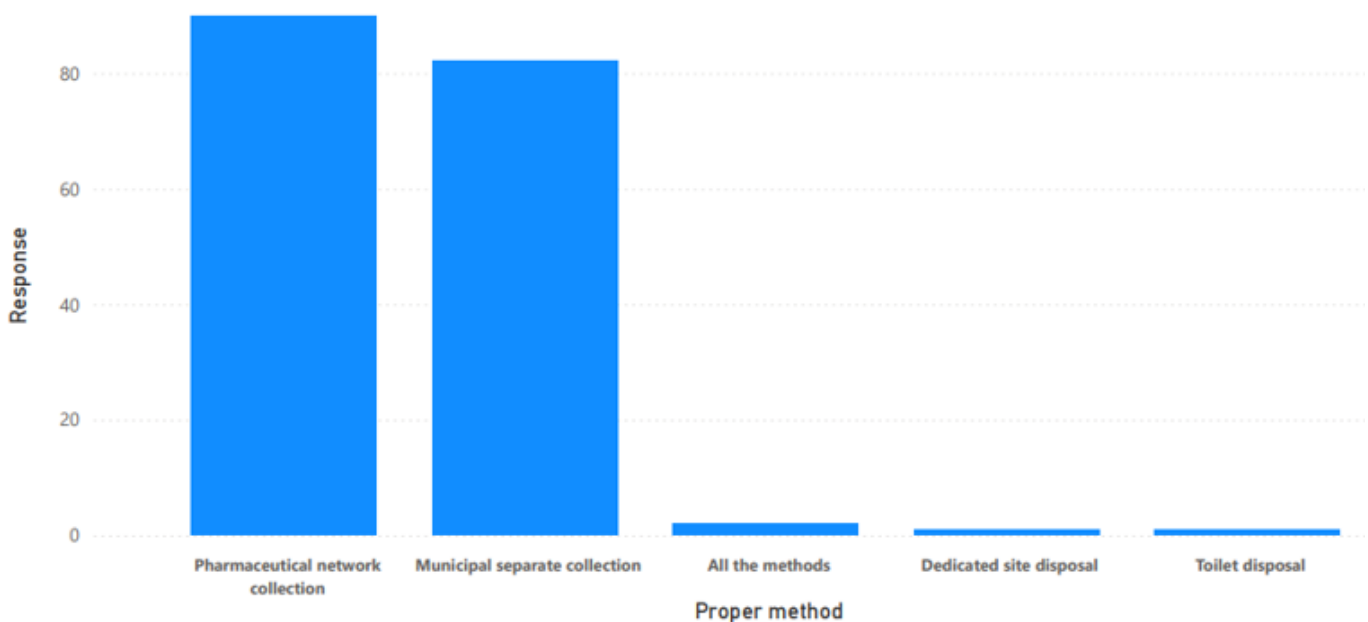


Figure 3. The opinion of citizens about the best method for pharmaceutical waste disposal (Source: Authors' own elaboration)

These results (Figure 2) align with expected pharmaceutical waste quantities generated at the household level.

Concerning the therapeutic categories of unused or expired medications, antipyretics and analgesics represented the most frequently discarded category, accounting for 53% of responses, followed by vitamins at 24%. Antibiotics comprised 16% of reported pharmaceutical waste. Other therapeutic categories were less prevalent, with anti-allergic representing 6% and antacids 1% of responses, respectively (Figure 2).

Regarding respondents' awareness of the environmental and health consequences associated with improper pharmaceutical waste disposal, 51% indicated they were partially informed about these issues, while 49% reported not knowing the potential environmental and health impacts resulting from inappropriate disposal practices.

Given the absence of a dedicated management system for household pharmaceutical waste disposal in Albania, citizens demonstrated limited knowledge regarding appropriate disposal methods. When asked about proper disposal practices, 51% of respondents identified pharmacies as the appropriate disposal location, while 47% indicated that differentiated collection by municipal enterprises represents the correct approach. A notable minority of 3% reported toilet disposal as an acceptable method (Figure 3).

The lack of awareness regarding the risks of improper pharmaceutical waste disposal represents a significant challenge, comparable to the disposal problem itself. Addressing public knowledge gaps about collection, disposal methods, and hazardous waste management is crucial. When asked about preferred awareness-raising strategies, 64% of respondents identified mass media approaches (newspapers,

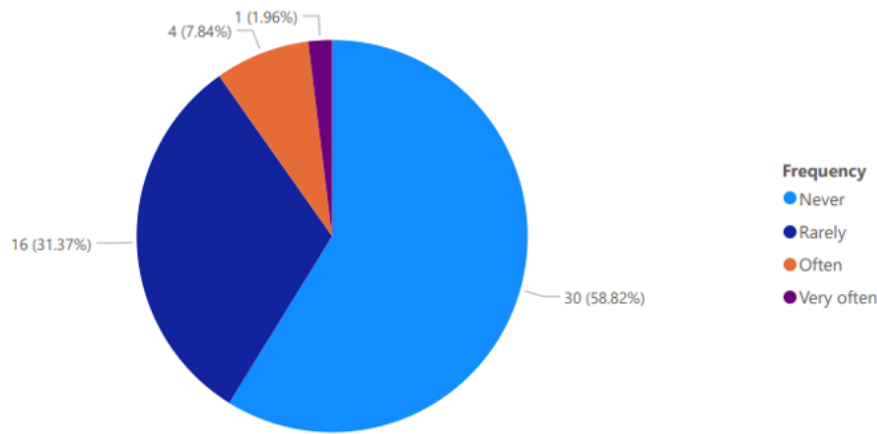


Figure 4. The frequency with which pharmacies are asked to accept pharmaceutical products (Source: Authors' own elaboration)

internet, and leaflets) as the most effective method, while 55% favoured direct education from healthcare professionals, specifically doctors or pharmacists.

When respondents were asked about their willingness to participate in a dedicated pharmaceutical waste management system, 77% expressed readiness to cooperate, while 21% remained neutral. Only 2% of the sample indicated reluctance to participate. Furthermore, nearly all respondents (99%) affirmed their support for initiatives establishing pharmaceutical waste collection points, provided such facilities are located conveniently near their residences.

Results of Pharmacists' Opinions

A total of 51 pharmacies participated in this survey, representing approximately 18% of the 281 pharmacies registered in the Municipality of Tirana by the Compulsory Health Care Insurance Fund. When asked whether their pharmacies accept expired or unused pharmaceutical waste from households, the majority of respondents (86%) stated that they do not accept such waste from patients. Only a small proportion (14%) reported that they accept the return of pharmaceutical products for disposal purposes.

Those who do accept waste explained that they do so despite the financial burden associated with disposal, which they must cover themselves.

Regarding the frequency with which patients request to return pharmaceutical waste, 59% of pharmacists responded with "seldom," while 31% described such requests as "rare." Only 10% of respondents indicated that patients "often" or "very often" request to return expired or unused medications to the pharmacy for disposal (Figure 4).

Several questions addressed the quantity and type of pharmaceutical waste generated. The majority of pharmacies (75%) do not exceed the 20 kg waste threshold included in their annual contracts with recycling companies. Furthermore, 88% of pharmacies refuse to accept the disposal of household pharmaceutical waste, while only 12% are willing to do so.

Regarding the financial responsibility for pharmaceutical waste disposal, most pharmacists (69%) believe that the costs should be covered by state institutions. Another 23% think that pharmaceutical warehouses or distributors should bear this responsibility. A smaller proportion believes the costs

should fall on recycling companies (5.5%) or citizens (2.5%). Notably, if pharmacies themselves were required to bear these costs, 88% would oppose such a measure, citing the absence of a legal obligation (Figure 5).

Public awareness among patients regarding the risks of improper disposal of pharmaceutical waste by households remains low. Pharmacies, as institutions closely connected with the public, often receive questions from patients about this issue.

Approximately 82% of pharmacists stated that raising patient awareness is very important, as it is a critical step toward implementing an effective pharmaceutical waste management system. Another 8% considered it somewhat important, while 10% did not see it as important.

When asked about their knowledge of the legal framework for pharmaceutical waste management in Albania, 69% of pharmacists reported being informed, while 31% considered themselves uninformed. Only 41% of those surveyed viewed the current legal framework as "clear". However, within this group, 33% said it was "clear but difficult to implement," and only 8% described it as "clear and easy to implement." The remaining pharmacists had various concerns: 23% found the framework "incomplete," 10% deemed it "unclear," another 10% considered it "inappropriate," and 16% had no information or were unsure.

Results of the Piloting Process on Four Pilot Points

During the four months of pharmaceutical waste monitoring, collection levels were low, ranging from 0.8 kg to 1.2 kg across centers (Table 1). Despite modest quantities, these results establish a baseline for evaluating program effectiveness. Public awareness of proper pharmaceutical waste disposal was found to be low, underscoring the need for stronger education and communication efforts. All monitored health centers reported mixed waste, revealing inadequate separation and storage practices. Implementation challenges included staff resistance to new disposal bins, due to concerns about suitability and safety, as well as the need for clearer waste management procedures and staff training. Overall, the findings indicate limited system efficiency and emphasize the necessity for continuous monitoring, improved awareness, and stronger institutional collaboration to enhance the program's effectiveness and ensure its sustainability.

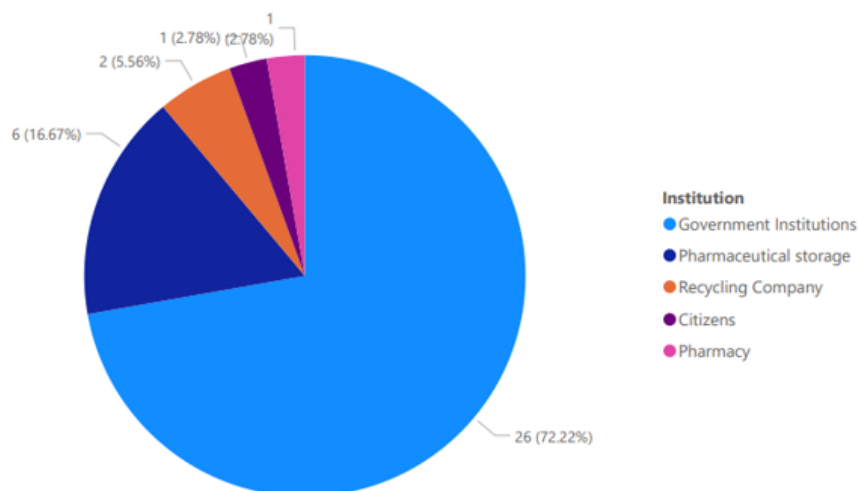


Figure 5. The opinion of pharmacists on which institution should bear the cost of disposing household pharmaceutical waste (Source: Authors' own elaboration)

Table 1. First-month results of pharmaceutical waste monitoring from Tirana citizens at four pilot sites

Healthcare centers	Quantity of pharmaceutical waste (kg)	Public awareness	Variety of pharmaceutical waste	Challenges faced
HC-1	1.1 kg	Low	Mix	Other waste
HC-4	0.8 kg	Low	Mix	Other waste
HC-4	0.9 kg	Low	Mix	Other waste
HC-4	1.2 kg	Low	Mix	Other waste

CONCLUSION

This study highlights a contrast between the pharmaceutical waste disposal system in Albania and the systems currently implemented in several European countries. Significant steps remain to be taken, as a comprehensive and functional system is largely absent. In many countries, the management of expired or unused pharmaceutical products includes their return to community pharmacies. Subsequently, the pharmaceutical operator is responsible for coordinating further stages, including engagement with licensed recycling or disposal companies and arranging transportation. The costs incurred throughout this process are reimbursed by the competent authorities.

There is a significant lack of clarity regarding the responsibilities, competencies, and administrative-regulatory roles of the various institutional actors involved in pharmaceutical waste management. The classification of expired and unused medicines as hazardous healthcare waste under national legislation (Legislation, 2005b) establishes a clear regulatory obligation for safe management. However, applying the same requirements to household-generated pharmaceutical waste as to waste produced by hospitals and large healthcare institutions reveals a significant implementation gap. This gap stems from unequal infrastructural capacity, financial resources, and institutional support across actors involved in pharmaceutical distribution and waste management.

Pharmacies occupy a strategically critical position in this policy landscape. They represent the most accessible interface between the public and pharmaceutical products and are therefore well-positioned to serve as collection points for unused or expired medicines. At the same time, pharmacies,

particularly small private ones, demonstrate resistance to assuming financial and operational responsibility for household pharmaceutical waste. This resistance is not only behavioural but structural, reflecting the absence of supportive policy instruments and clear cost-sharing mechanisms.

Current practice shows that pharmacies already manage expired or unsold stock through contracts with licensed waste operators. However, these arrangements are designed for commercially generated waste and do not account for additional volumes returned by citizens. As a result, pharmacies face increased costs, liability concerns, and operational uncertainty, which discourages participation in take-back schemes and leads to inconsistent acceptance of household pharmaceutical waste.

From a policy perspective, this tension highlights the limitations of a regulatory approach that relies primarily on classification and compliance without addressing economic feasibility. The proximity of pharmacies to the public creates an implicit expectation of responsibility, yet this expectation is not matched by regulatory clarity, financial compensation, or institutional support. Consequently, the burden of managing household pharmaceutical waste is fragmented, often shifting to municipal waste streams or informal disposal practices.

To address this imbalance, policy design should prioritize mechanisms that redistribute responsibility across the pharmaceutical supply chain. Extended Producer Responsibility (EPR) schemes, public-private cost-sharing models, or dedicated national funds for pharmaceutical waste collection could enable pharmacies to function as accessible collection points without bearing disproportionate costs. Simplified infrastructure standards and clear liability

frameworks would further reduce operational barriers and increase participation.

In conclusion, effective management of household pharmaceutical waste requires policy alignment between accessibility, responsibility, and capacity. Without such alignment, pharmacies remain underutilized as collection nodes, regulatory objectives remain unsatisfied, and environmental and public health risks persist. A shift toward integrated, incentive-based governance instruments is therefore essential to bridge the gap between regulatory intent and on-the-ground implementation.

In Albania, household pharmaceutical waste remains unregulated, with no institutional responsibility assigned to the Albanian Order of Pharmacists or the National Agency for Medicines and Medical Devices, despite its classification as hazardous. In contrast to EU directives, which mandate organized collection systems and extended producer responsibility (EPR), Albania lacks a structured management scheme, adequate public awareness, and dedicated legislation. This regulatory gap highlights a clear divergence from EU standards on pharmaceutical waste governance.

Therefore, the revision of the new draft law on waste management is crucial and should be aligned with the European Union's legal framework, in accordance with the principles of the circular economy and the protection of public health and the environment.

The findings indicate that the majority of citizens currently dispose of pharmaceutical waste together with general urban waste. This practice is primarily driven by the absence of a dedicated system for the safe collection and disposal of pharmaceutical waste, along with a lack of supporting infrastructure. Additionally, there is a notable gap in public awareness regarding the environmental and health hazards associated with the improper disposal of such waste.

Furthermore, pharmacies are generally unwilling to engage in the establishment of collection infrastructure or assume the associated costs, due to the absence of a clear legal mandate and a lack of financial support or incentives.

The piloting of a test system for pharmaceutical waste management at selected health centers resulted in minimal waste collection. This outcome suggests that access to these collection points is limited for the public. Consequently, the study proposes that pharmacies may represent a more effective and accessible alternative for waste collection, given their proximity to end users and routine interaction with patients.

Author contributions: MQ: methodology, supervision; NM: investigation, resources; MQ & NM: conceptualization, writing – original draft, data curation, formal analysis. Both authors agreed with the results and conclusions.

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Ethical statement: The authors stated that ethical approval was not applicable for this study. All subjects interviewed consented to the anonymity provided during questionnaire administration, and

no data subject to Law No. 10/2023, “On Information Classification,” were accessed, disclosed, or otherwise breached.

AI statement: The authors stated that ChatGPT 5.0 was used solely for the purpose of enhancing the text and improving the quality of English; the authors remain fully responsible for the content, interpretation, and final wording of the manuscript.

Declaration of interest: No conflict of interest is declared by the authors.

Data sharing statement: Data supporting the findings and conclusions are available upon request from the corresponding author.

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