



Pharmaceutical Waste Disposal: Current Practices in Tirana, Albania

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Current Practices in Tirana, Albania

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This report represents the work of four WPI undergraduate students submitted to the faculty as evidence of completion of a degree requirement. WPI routinely publishes these reports on its website without editorial or peer review. For more information about the projects, please see http://www.wpi.edu/Academics/Projec

Authorship

The members of this team contributed equally to the report and the project. All members wrote parts of the draft for each section, and then edited the report as needed. The questionnaire used in the interviews was developed by the whole team.

Chapters were divided up into multiple sections and then distributed equally to all the members of the team. When a member finished writing their section, he/she then read over and edited the sections written by other members of the group. This writing and editing process was followed throughout the duration of this report. Before any documents were submitted, the group read the chapter out loud together. One member would read, two members would make suggestions, and the fourth member would write them down. Roles were changed after every subsection.

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Abstract

Managing pharmaceutical waste effectively can reduce risks to the environment and public health. In collaboration with the EDEN Center, an Albanian environmental NGO, our study assessed and analyzed the current pharmaceutical waste management system in Tirana. We interviewed ten percent of the over 730 pharmacies in Tirana as well as other stakeholders to identify the current practices, challenges, and opportunities for improvement. Our study concluded that pharmacists would benefit from more information regarding laws, treatment companies, and their environmental impact. We also recommend additional incentives and regulations be implemented by the government, and a further study be conducted to expand upon our findings.

Executive Summary

Background

Environmental Impact

While pharmaceutical drugs have had profoundly positive effects, they have caused major environmental issues. Through improper disposal, medicines are found in water supplies in varying concentrations and pose risks to the environment and to human health. Antibiotics are among the most common and most harmful drugs found in the water supply. Though present in just trace levels, they allow bacteria to develop and spread antibiotic resistance, which makes bacterial infections more challenging to treat (Neu, 1992). Endocrine disruptors, like hormonal birth control, are also dangerous when leaked into the environment, especially for wildlife. The major dangers include developmental malformations, interference with reproduction, increased cancer risk, and disturbances in the immune and nervous system function (Norris, 2005; Gilbert, 2011).

Pharmaceutical Waste Management

To reduce these risks, pharmaceutical waste must be sorted and specially treated in one of several ways. Popular methods include the use of lined landfills, incineration, return to the manufacturer for chemical recycling, or encapsulation in cement (World Health, 1999). Pharmacies often do not have the resources or expertise to achieve this independently, and thus contract with a treatment company (Smith, 2002). This treatment

company is usually paid to remove and manage the waste properly.

Pharmaceutical Waste Management in Albania

As pharmaceutical waste management reform has been increasing globally, many organizations have undertaken the task of assessing and improving disposal practices in their own countries. This can be seen in Albania as well, with the research and initiatives developed by the Environmental Center for Development Education and Networking (EDEN Center, 2014). In 2015, the EDEN Center completed a research document on the disposal of all medical waste across the country. In this study they found a significant lack of information concerning the disposal of pharmaceuticals (EDEN Center, 2016). After the report on medical waste was completed, the EDEN Center reached out to us for assistance in examining pharmaceutical waste management in the capital city of Tirana.

Institutions for Pharmaceutical Distribution, Regulation, and Disposal

The city of Tirana has 730 pharmacies, most of which are privately owned and very small, distributed amongst the 11 administrative units. The districts that we focused on were Ish-Blloku, the Center, and Ali Demi. These pharmacies are presided over by the Order of the Pharmacists, the Ministry of Health, the Ministry of Environment, and many smaller governmental bodies. The Council of Ministers is the primary legislative body

that established the required disposal practices of pharmacies. These laws state that pharmaceutical waste must be destroyed by an organization with the proper environmental license (For Hazardous Waste Management, Chapter 4 Articles 12-13, 2006). Therefore the pharmacies must contract with a treatment company to dispose of their waste.

There are a few private treatment companies that have the certification from the government to handle the treatment of pharmaceutical wastes. Unfortunately there have been some scandals involving these waste removal companies, where some have been implicated in dumping waste into the environment rather than treating it correctly (Fraud, 2015). These actions have weakened the credibility of treatment companies and discouraged pharmacies from working with them. Alternatively, pharmacies can give their waste to the National Center for Drug Control, which then contracts with a treatment company to handle the waste from various pharmacies.

There was limited information in the literature regarding reasons why pharmacies may not obtain contracts to manage their waste. Possibilities we considered included: avoiding disposal costs; lack of training or knowledge; and distrust in the treatment companies. However, no relationship has been established between any of these factors and the practices of pharmaceutical waste disposal in Tirana. Our research attempted to fill the gaps in the current understanding of these causes.

Objectives

- + Assess the current practices and policies for pharmaceutical waste management in Tirana;
- + Uncover the challenges that are preventing effective pharmaceutical waste management;
- + Identify stakeholders' roles and perspectives in the pharmaceutical waste management system;
- + Demonstrate the need for more information on the subject of pharmaceutical waste management;

Methods

We examined the practices of approximately 10% of the pharmacies in Tirana using a structured questionnaire with both closed and open ended questions. Pharmacies were interviewed in three of the eleven administrative units of Tirana, whose different locations and demographics were analyzed for their effects on the practices of the pharmacies. These respondents were fully informed that all of their answers would be kept completely confidential and that the information gathered was only intended to improve the waste management system. We used a multi-method approach consisting of interviews with the assistance of volunteer translators, direct subject observations, and the analysis of government and private records. The most important interview questions asked were:

- + Does this pharmacy produce pharmaceutical waste, and if so, how much?
- + Does this pharmacy have a contract with a treatment company?
- + How often does the Ministry of Health Inspector visit this pharmacy?
- + What challenges do you face with pharmaceutical waste disposal, and what recommendations do you have to improve the system in place?

We used inductive thematic analysis in order to come up with trends from the data that we found (Berg, 2004). Additionally, we analyzed the associations between the responses and factors such as location, traffic level, and inspection frequency.

Similar interviews were conducted with other stakeholders in the pharmaceutical waste management system, including distributors, Ministry officials, and treatment company representatives, to provide a more complete picture.

The responses from the pharmacists and the stakeholders together demonstrated the current practices and challenges in the pharmaceutical waste management system, as well as revealing the feasible opportunities for improvement.

Results

Current pharmaceutical waste disposal practices and their causes

Our study approached 74 pharmacies, approximately 10% of those in Tirana, of which almost 20% of pharmacies declined to participate in our study. There were a variety of explanations for their refusals. Responses we received include: pharmacists feeling they were successful and felt our study was not necessary, pharmacies having opened in the last few days, pharmacists telling us that they were too busy, and responding with anger. Of the pharmacies that were interviewed, about 70% acknowledged that they produce pharmaceutical waste, but most claimed to only produce small amounts of waste. While their interpretations of "small" varied, most pharmacists used this as a justification for not having a contract. The remaining pharmacists that claimed they did not produce pharmaceutical waste occasionally explained that they buy in very small quantities or reduce prices as medications approach their expiration.

Over half of the pharmacies interviewed admitted to not having a contract with a treatment company. This was attributed to several different factors. Obtaining contact information for the treatment companies was a significant barrier, as was a lack of trust in their disposal practices. Our study also concluded that the cost of a contract with a treatment can be prohibitive for a small pharmacy. The small size of the pharmacies makes them less likely to comply with the law. These pharmacies perceived their amount of waste as being inconsequential, and may have

had difficulty appreciating the impact of waste from all the pharmacies combined.

Interviewed pharmacists were also asked how often they are visited by an inspector from the Ministry of Health. We found that answers varied greatly, though the median number of visits was once annually. A correlation can be observed that pharmacies which receive more frequent inspection visits are more likely to have a contract and comply with the law. It is difficult for the pharmacists to rely on an enforcement system that is not consistent. This can be viewed in Figure 1 below.

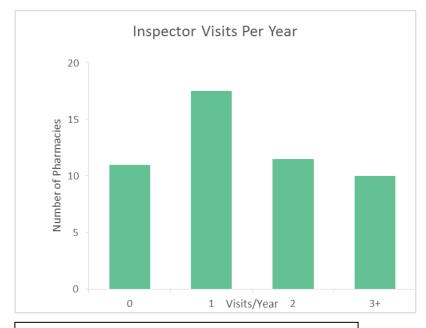


Figure 1: Frequency of Inspection Visits

Challenges expressed by pharmacists

Pharmacists were especially varied in their willingness to express their difficulties and offer recommendations. Some were dismissive, expressing that they did not need any help, while others were willing to explain their struggles at length.

Many pharmacists felt that the cost of disposing of pharmaceutical waste properly was a significant disincentive. Pharmacists expressed that they could not pay for the waste removal, since the expired medication already represented a loss of income. Many did not want to pay annual fees due to their small waste production levels. The pharmacies in our study were small and over 90% were independently owned, rather than being a part of a chain, which reduces their capital resources. Further, the control of the wholesale price by the Ministry limits flexibility in pharmacy budgets. Therefore, many pharmacists seemed justified in saying that they did not have a contract due to its price.

We found that pharmacists were lacking information about the laws and regulations that they must be following, which makes it very hard for them to comply. We received many different answers from the pharmacists about the laws. Over a third of all pharmacists that were interviewed claimed that they were confused or lacked knowledge about the laws and regulations regarding pharmaceutical waste. Other pharmacists claimed they knew and followed the law. In both cases, we found that not all of pharmacists were following the laws. It seemed that they were not all provided with the same information and the information they did have was not always clear to them. Therefore, many pharmacists would appreciate more guidance, information, and assistance from their government.

Recommendations

Access to Information

The most pervasive issue observed was the sparse and inconsistent information pharmacists had been provided about the laws they are expected to adhere to, the treatment companies they can contact, and the impact of improper disposal on the environment. Pharmacists would benefit from information in a simple and clear format, with updates as information changes. It would be important to include the current laws regarding pharmaceutical waste disposal, contact information for available treatment companies, and an explanation of the environmental impact of improper disposal, even in small quantities.

Ministry of Health Controls

Our research study found that frequent and regular visits from a Ministry of Health inspector are associated with a greater percentage of pharmacies having contracts and following the law. Increasing oversight may make pharmacists more aware of the consequences for not complying. In addition, it could provide an opportunity for the pharmacists to ask any questions they may have regarding the laws or treatment companies.

Incentives for Proper Waste Disposal

Many pharmacists expressed that they would be motivated by various incentives the government could offer. These could include financial reimbursements, tax cuts, or even the opportunity to advertise to customers that their pharmacy is environmentally friendly.

Further Investigation

The data that we collected was highly variable, and our results generated many additional questions about the current system. A study with greater resources will be better able to investigate all of the stakeholders involved, including the perspective of the government, and extend the study to pharmacies across Albania.

Contents

Authorship	
Acknowledgements	i
Abstract	ii
Abstract	ii
Executive Summary	i
Background	i
Results	V
Recommendations	vi
List of figures	
List of Tables	
Chapter 1: Introduction	
Chapter 2: Background	
2.1 Environmental Effects of Pharmaceuticals	
2.2 Global Pharmaceutical Waste Management	2
2.3 Pharmaceutical Waste Management Practices in Pharmacies	
2.4 Environmental Center for Development Education and Networking	8
2.5 Pharmaceutical Use in Albania	8
2.6 Institutions for Pharmaceutical Distribution, Regulation and Disposal	12
2.7 Pharmaceutical Waste Management Challenges in Albania	16
Chapter 3: Methodology	18

3.1 Assessing the Current Practices in Albania		
3.2 Obstructions to Proper Waste Management	20	
3.3 Interviewing Additional Stakeholders	20	
3.4 Data Management	21	
Chapter 4: Results	22	
4.1 Would you be willing to participate in our study?	26	
4.2 Do you produce any pharmaceutical waste? How much?	26	
4.3 Do you have a contract with a treatment company?	27	
4.4 How often does the inspector come?	30	
4.5 Do you understand the laws?	31	
4.6 What do you find challenging?	32	
4.7 Challenges Expressed by Additional Stakeholders	33	
Chapter 5: Recommendations	35	
Appendix A	36	
List of Treatment Companies	36	
Appendix B	37	
Interview Protocol	37	
Interview with Pharmacists	38	
Questionnaire:	38	
Appendix C	39	
Interview with Distributor	39	
Questionnaire:	39	
Interview with Treatment Company	40	
Questionnaire:	40	

Pharmacy Contract	42
Appendix D	. 43
Detailed table of responses broken down by location and other factors	43
Chart of Responses by Neighborhood	46
Appendix E	. 47
Busyness ranking	47
Works Cited	48

List of Figures

FIGURE 1: THE PROGRESSION OF ANTIBIOTIC RESISTANCE (BIOLEGEND, 2015)	3			
FIGURE 2: A DEFORMED LEOPARD FROG METAMORPH FOUND NEAR LAKE CHAMPLAIN IN VERMONT (ZIMMER, 2011)	4			
Figure 3: Correct Pharmaceutical Waste Pathway				
FIGURE 4: RECOMMENDED PHARMACEUTICAL WASTE STREAMS (SMITH, 2002)	7			
FIGURE 5: EDEN CENTER LOGO (2016)	8			
FIGURE 6: ABSOLUTE ALBANIAN PHARMACEUTICAL EXPENDITURE COMPILED FROM DATA FROM THE WORLD BANK (2016), THE MINI	STRY OF HEALTH (2016), AND MOSSIALOS, ET AL (2004)			
FIGURE 7: RESULTS OF HOXHA ET AL 2015 SURVEY				
FIGURE 8: REFUGEES FROM KOSOVO COMING INTO ALBANIA (FILMAID INTERNATIONAL, 2015)				
FIGURE 9: MAP OF ADMINISTRATIVE UNITS (2016)	12			
FIGURE 10: MINISTRY OF ENVIRONMENT	13			
FIGURE 11: MEDI-TEL TREATMENT FACILITY	14			
FIGURE 12: INSTITUTIONS INVOLVED IN REGULATING PHARMACEUTICAL WASTE (EDEN CENTER, 2015, TRANSLATED FOR THIS REPORT)15			
FIGURE 13: WASTE PRODUCED BY REGION OF ALBANIA (BEQIRI, 2015, TRANSLATED FOR THIS REPORT)	16			
FIGURE 14: SAMPLE ALI DEMI STREET	23			
FIGURE 15: RESPONSES IN ALI DEMI	23			
FIGURE 16: ALI DEMI PHARMACY LOCATIONS AND TRAFFIC LEVELS	23			
FIGURE 17: ISH-BLLOKU PHARMACY LOCATIONS AND TRAFFIC LEVEL	24			
FIGURE 18: SAMPLE ISH-BLLOKU STREET	24			
FIGURE 19: RESPONSES IN ISH-BLLOKU	24			
FIGURE 20: SAMPLE CENTER STREET	25			
FIGURE 21: RESPONSES IN CENTER	25			
FIGURE 22: CENTER PHARMACY LOCATIONS AND TRAFFIC LEVELS	25			
FIGURE 23: RESPONSES BY TRAFFIC LEVEL	27			
FIGURE 24: FREQUENCY OF INSPECTOR VISITS	30			
List of Tables				
Table 1: Pharmaceutical Waste Management Methods	5			
TABLE 2: HEAT MAP OF RESPONSES BY FREQUENCY OF INSPECTORS	30			

Chapter 1: Introduction

Steep growth in the pharmaceutical industry over the last several decades has led not only to more medications on the market but also to a significant environmental and public health hazard when these drugs are not disposed of properly. Pharmaceutical drugs are classified as any "natural or chemical substances used for treating, curing and preventing different types of diseases" (Pharmaceutical Drugs, 2009). If not handled and disposed of properly, pharmaceutical waste can ultimately enter water bodies, including drinking water sources, through sewer lines and as effluent from landfills. This can lead to public health and ecological risks, such as antibiotic resistance in bacteria (Neu, 1992).

There has been a significant global effort to prevent pharmaceutical waste from polluting the environment. Though the types of waste are varied, when they are properly collected and sorted, there are several safe ways to discard of pharmaceutical waste (World Health, 1999). Pharmacies in the United States and elsewhere often contract with treatment companies to manage their

pharmaceutical waste, as the pharmacists themselves are not always given training about the disposal regulations (Smith, 2002). However, current research suggests that Albanian pharmacies are not utilizing treatment companies, and may not be disposing of their waste properly (EDEN, 2016). Though regulations are in place in Albania regarding pharmaceutical waste disposal practices (For Pharmaceutical Drugs and Service, 2014), research suggests that many pharmacies do not consistently follow regulations (Hoxha, Malaj, Tako, & Malaj, 2015). The first step in developing effective policies for the treatment of pharmaceutical waste is gaining a better understanding of the reasons why pharmacies are not complying with the regulations (Tong, Peake & Braund, 2011).

Our sponsor, The Environmental Center for Development Education and Networking (EDEN Center) wants to assess and improve pharmaceutical waste disposal practices in Albania. From 2014 to 2015, the EDEN Center performed a study in five cities in Albania that was aimed at providing information regarding the gaps in the chain of health care waste management in Albania. By interviewing manufacturing and treatment operators as well as healthcare waste inspectors, this study highlighted a lack of information on the disposal practices of pharmacies. They have therefore asked us to conduct a study to learn how and why pharmacies dispose of their pharmaceutical waste. This study will demonstrate the need for a larger study of pharmaceutical waste management practices in pharmacies across Albania.

While in Tirana we examined the drug disposal practices of pharmacies in several different neighborhoods of the city. We interviewed pharmacy owners and pharmacists, as well as pharmaceutical suppliers, treatment companies, and public health officials. This illuminated the varied perspectives about the challenges and opportunities for safer disposal of out of date and unused medicines. Understanding these challenges will be critical to developing solutions for safer pharmaceutical waste disposal practices in Albania.





The purpose of this chapter is to examine the current literature regarding pharmaceutical waste, global management efforts, the challenges they face, and the applications to Tirana, Albania. In section 2.1, we discuss the various effects that pharmaceuticals have on the environment. When antibiotics get into the water, they can cause antibiotic-resistant bacteria, and steroids can affect the messenger hormones in animals exposed to the water. Section 2.2 focuses around the methods that can be implemented in order to properly dispose of the pharmaceutical wastes. Section 2.3 will center around the impacts of medications that are discarded into public waste streams. In section 2.4, we discuss the EDEN Center and its mission to promote awareness of environmental issues. The use of pharmaceuticals as well as the issue of self-medication in Albania is explained in section 2.5. In section 2.6, the laws and regulations on the distribution and disposal of pharmaceutical drugs are evaluated. Finally in section 2.7, we discuss the regulations and challenges that Albania faces when it comes to the disposal of pharmaceutical waste.

2.1 Environmental Effects of Pharmaceuticals

While pharmaceutical drugs have had profoundly positive effects, they have caused major environmental problems. Through improper disposal the drugs have found their way into the water supply, and this has many negative side effects, not all of which are fully understood. In most water supplies, pharmaceutical residues are detected at trace levels, but even low concentration levels, between 1 part per trillion and 1 part per billion, can have toxic effects. Antibiotics are among the most common drugs found in the water supply. These drugs are particularly dangerous; they cannot kill bacteria in such low

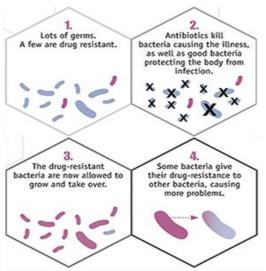


Figure 1: The progression of antibiotic resistance (BioLegend, 2015)

concentrations, but create more resistant bacteria. Any individual bacterium that has this resistance can transmit it to other bacteria. Antibiotic resistant bacteria have to be treated with less commonly used antibiotics, which can be impossible in areas where full medical care is not available. There have even been documented cases of "superbugs" that have become resistant to all of the regularly used antibiotic medicines (Neu, 1992). According to the Center for Disease Control, 2 million Americans were infected by bacteria with antibiotic resistance in 2013. Of those infected, twenty-three thousand died from the infection (Centres for Disease Control and Prevention, 2013). Without the ability to quickly and effectively treat bacterial infections those patients who are most vulnerable will be in serious danger. These patients include those undergoing chemotherapy for cancer and dialysis for renal failure, children, the elderly, and those recovering from surgery, especially organ transplantation. These types of infections are even more dangerous for those countries that do not have sophisticated

medical treatment centers where sterile protocol is not followed as often.

The other major group of drugs that is having profoundly negative effects on the environment is steroids. Steroids are a group of medications that contain a particular carbon ring backbone made of three cyclohexane rings and one cyclopentane ring (Tyler, 1998). The hormones naturally found in every animal share this same base structure. Steroids can enter animals without being acutely toxic; however, they can mimic or inhibit the actions of the internal messenger hormones, especially those that compose the endocrine system. The endocrine system is the collection of glands that produce hormones that regulate metabolism, growth and development, tissue function, sexual function, reproduction, sleep, and mood, among other things, making endocrine disruption extremely dangerous (Norris, 2005). The major dangers include developmental malformations, interference with reproduction, increased cancer risk, and disturbances in the immune and nervous system function. Amphibians have been shown to be particularly affected by these



Figure 2: A deformed leopard frog metamorph found near Lake Champlain in Vermont (Zimmer, 2011)

drugs. Birth defects have become common in many species of frogs (Norris, 2005).

One example of extreme endocrine disruption was documented in a French study of fish near a pharmaceutical production plant. The levels of endocrine disrupting molecules, specifically those found in birth control pills, reached a level high enough to affect the physiology of the Gudgeon fish being studied. "Downstream from the factory, the researchers found that on average 60% of the fish had both male and female sexual characteristics" (Gilbert, 2011, pg. 1), as compared to only 5% upstream of the factory. This clearly shows that the drugs being allowed to enter the river were seriously affecting the fish through endocrine disruption. The scientists recorded the concentration of dexamethasone at the extremely high level of over 10 micrograms per liter. Both of these environmental problems are consequences of improper disposal of pharmaceuticals. These environmental dangers can be prevented with a proper disposal system.

2.2 Global Pharmaceutical Waste Management

Though there are many dangers associated with pharmaceutical waste, it can be properly and safely treated. The simplest method is to dispose of the waste in a landfill, though it has the potential to be very dangerous. Using a landfill for pharmaceutical waste management should

always be the last resort because of its likelihood to allow pharmaceuticals to enter waterways through runoff and thus impact the environment. Using landfills for medical waste is only safe when they are located far away from bodies of water, or are specially lined to contain hazardous waste. Most landfills used today are designed to contain household waste, not to prevent pharmaceutical waste from leaching out into the water supply.

It can often be safer to return the pharmaceutical waste to the original manufacturer. If they are properly separated and not yet expired, these drugs even have the potential to be reused by the manufacturer with proper chemical purification. The problem arises when the pharmaceuticals are expired, because they are then classified as hazardous waste. Most pharmaceuticals that would be returned to the manufacturer or donor are expired and therefore cannot be resold without extensive chemical treatment. Specific procedures must be followed whenever hazardous waste is transported internationally. These procedures require significant investments of time and money (World Health, 1999). The manufacturers or donors that take back their

pharmaceuticals would dispose of them using the other described methods.

A less complex method for pharmaceutical waste management is incineration. Incineration is the process of burning the pharmaceuticals at temperatures upwards of 1,200°C. This method's major benefit is that the pharmaceutical is prevented from entering the water supply. However, incineration can be a costly disposal method. In 1999 the World Health Organization estimated the cost of incineration in the

Northwestern Balkans to range from US \$2.2/kg to US \$4.1/kg. Though inflation has certainly increased this value since 1999, incinerating the entire stockpile of pharmaceuticals in Croatia, for example, would have cost between US \$4.4 million and US \$8.2 million (World Health, 1999). Another point of concern when burning pharmaceuticals is the possibility that toxic gases are produced and released into the environment. These toxic fumes can be absorbed into substances like activated carbon or cement clinker product to

Table 1: Pharmaceutical Waste Management Methods

Method	Safety	Ease	Cost
Landfill	High possibility to leak into waterways	Easiest method	N/A
Returning to Original Source	Depends on the source and how they dispose of the pharmaceuticals	Can be difficult if pharmaceuticals are expired and travel internationally	N/A
Incineration	Possibility for toxic gaseous by products	Access to able facilities is difficult	>US \$2.2/kg - US \$4.1/kg
Encapsulation	Can handle all types of pharmaceuticals in both solid and liquid states	Can send to an encapsulating company or use a machine	Machines can be purchased to complete this task

Information that inspired this table was compiled from World Health, 1999

prevent them from damaging the atmosphere (World Health, 1999). Another method of disposal is encapsulation. Encapsulation is the practice of partially filling a plastic or steel drum with pharmaceuticals and then completely filling it with concrete or other similar substances in order to prevent the chemicals from leaching out into the environment (World Health, 1999). Table 1 to the left summarizes the pharmaceutical waste management methods as described above.

2.3 Pharmaceutical Waste Management Practices in Pharmacies

Pharmacies play a large role in the disposal of pharmaceutical waste by properly collecting and sending waste to appropriate disposal facilities. Pharmacies are a crucial location for proper collection and disposal because in addition to producing their own expired medicines when overstocked, some even buy back expired medications from consumers (Seehusen & Edwards, 2006). There is a significant amount of legislation surrounding pharmaceutical waste disposal by pharmacies in the United States, including the Resource Conservation and

Recovery Act, enforced by the EPA (Smith, 2002), as well as various other rules from the U.S. Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and many more (Stericycle Environmental Solutions, 2016). While pharmacies could manage some of these regulations on their own by sorting their waste and disposing of it accordingly, "pharmacists do not routinely receive instruction in environmental regulations," making this process more difficult (Smith, 2002, pg 17). However, Figure 4 on the following page from Smith (2002) shows a suggested system for pharmacies to use.

To simplify this process, some countries have developed alternative systems. In the city of Novi Sad, Serbia, pharmacies can dispose of their waste at transfer stations; these transfer stations are also open to the public. The Serbian Prime Minister is trying to convince the rest of the country to adopt these transfer stations and mimic Novi Sad. The pharmaceutical waste is collected and then disposed of it in a safe manner, most commonly incineration (Milutinovic, V., & Trumbulovic, L, 2014).



Figure 3: Correct Pharmaceutical Waste Pathway

As an alternative, many pharmacies utilize a pharmaceutical waste disposal company like Stericycle Environmental Solutions. This is only one of many companies in the US, yet they dispose of over 336 thousand tons of pharmaceutical waste annually (Stericycle Environmental Solutions, 2016). This practice is common in many nations across the globe, as one survey in New Zealand published that "80.4% and 61.1% [of pharmacies] respectively reported that solid and semi-solid medications were removed by contractors," which was regarded as an "appropriate and viable method" (Tong et al, 2011, pg 197, 201). The use of these programs is therefore encouraged as the simplest and most effective method, especially when the pharmacists have limited access to training regarding proper pharmaceutical waste disposal (Smith, 2002). However, this method is expensive for the pharmacy because they must pay a yearly fee to use the treatment company, and some additionally charge by weight. Whichever method is chosen, however, pharmacies and their disposal practices play a crucial role in the pharmaceutical waste management system.

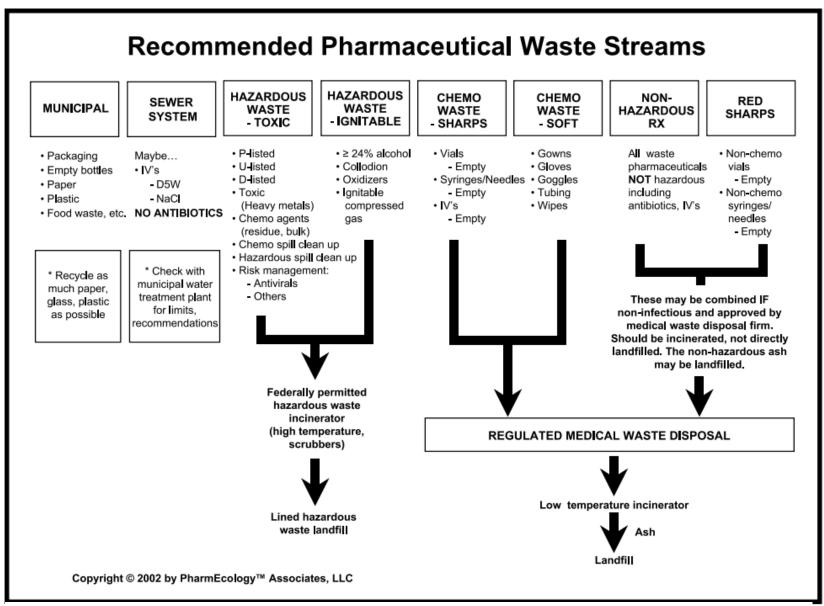


Figure 4: Recommended Pharmaceutical Waste Streams (Smith, 2002)

2.4 Environmental Center for Development Education and Networking

As pharmaceutical waste management reform has been increasing globally, many organizations have undertaken the task of assessing and improving disposal practices in their own countries. This can be seen in Albania as well, with the research and initiatives developed by the Environmental Center for Development Education and Networking (EDEN Center, 2014). The EDEN Center has become one of the most active non-profit and non-politically oriented organizations in Albania since its establishment in 2004 (EDEN Center, 2014). The mission of the EDEN Center is to promote sustainable environmental practices through education of the public and collaboration with other organizations. The EDEN Center's major funding comes from its donors, including the EU Commission, the Global Environment Fund, UNICEF, the World Health Organization, the CEE Bankwatch Network, and the American Embassy. From 2014 to 2015, the EDEN Center completed a research document on the disposal of all medical waste across the country. In this report they found a significant lack of information concerning the disposal of

pharmaceuticals (EDEN Center, 2016). After the report on medical waste was completed, the EDEN Center reached out to the WPI Albanian Project Center to recruit assistance to examine pharmaceutical waste management in the capital city of Tirana.



Figure 5: EDEN Center Logo (2016)

2.5 Pharmaceutical Use in Albania

Pharmaceutical waste management is an issue of particular importance in Albania, as many factors have contributed to a large accumulation of expired pharmaceutical waste. One factor for this

continuously growing stockpile is the recent expansion of the pharmaceutical industry in Albania. Compared to other countries in Europe, including Serbia, Slovakia, and Poland, Albania has spent a higher percentage of its total healthcare expenditure on pharmaceuticals over the last two decades, recorded at 25% in 1999 (Mossialos, Walley, & Mrazek, 2004). In recent years this percentage has risen considerably, to 35% and 55% in 2013 and 2015 respectively (Ministry of Health, 2016). These percentages only represent an increase in the purchases of pharmaceuticals as opposed to other curative measures. The Ministry of Health has not released the growth in the pharmaceutical industry in any absolute values. However, an absolute increase can be proven as there has been data published for the growth of the GDP in Albania. The percentage of the healthcare expenditure that contributes to the pharmaceutical industry is increasing; the percentage of the GDP allocated to healthcare has been generally increasing (World Bank, 2016; Memaj & Duka, 2008); the GDP has been relatively steady (World Bank, 2016). A graphic of the increase in the absolute pharmaceutical expenditure can be found on the following page.

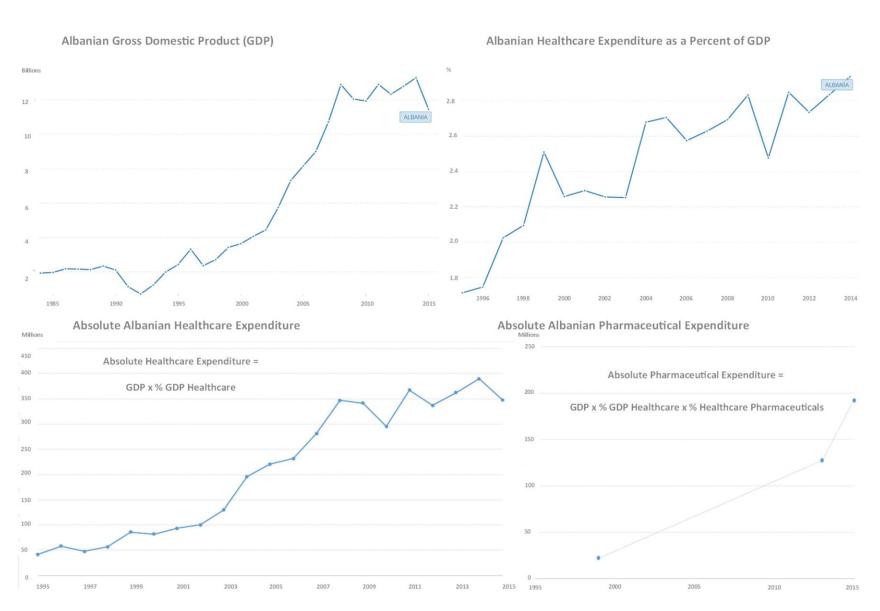


Figure 6: Absolute Albanian Pharmaceutical Expenditure Compiled from Data from the World Bank (2016), the Ministry of Health (2016), and Mossialos, et al (2004)

This collectively suggests a massive expansion of the pharmaceutical industry in Albania. In the past two years, 671 new drugs have been registered with the Ministry of Health, which is approximately one for every working day. These drugs are becoming cheaper as well, making them even more popular with consumers. In September 2016, the Minister of Health, Ilir Beqaj, claimed in a media outlet that the previous year (2015) had seen 48.2 million pharmaceutical purchases, which represented a 17.5% increase from the 41 million in 2012 (Ministry of Health, 2016). 48.2 million purchases would suggest a rate of 16.6 prescriptions (or what should have been prescriptions) per person per year, compared to 12.7 in the US (The Henry J Kaiser Family Foundation, 2016). This suggests a greater number of pharmaceuticals that must be produced in or imported into Albania. It could be reasonably assumed that the increase in pharmaceutical medications sold and used will cause a corresponding increase in the amount of pharmaceutical waste.

There is reason to believe that many of these pharmaceuticals will be allowed to expire as many Albanian consumers are purchasing unnecessary antibiotics. As previously noted, antibiotics can pose risks to the environment when overused and especially when improperly discarded. In many countries, this is addressed with regulations to reduce the number of prescriptions for antibiotics written by practitioners (Slomski, 2016; McIsaac, 1998; Ranji, 2008). Such regulations may be needed in Albania, as rates of prescribing are quite high, with 66% of urban and 74% of rural visits to a general practitioner resulting in a prescription, according to a 2006 survey (Fournier, Tourigny, Ylli, Nuri, & Haddad).

However, it is common for Albanians to self-medicate using antibiotics, weakening the efficacy of regulating antibiotics with prescriptions. Selfmedication is the act of using medication to treat common illnesses or health problems, and many people will selfmedicate in order to avoid a costly medical bill or because they believe that they know how to make themselves better. A questionnaire was given out in 2014 (Jorgji, Bebeci, Apostoli, & Apostoli) to 350 young people who visited 10 different pharmacies in Tirana. The results of this survey showed that nearly 80% of those surveyed selfmedicated with antibiotics, which was correlated with responses that reported low and medium levels of education. Jorgji

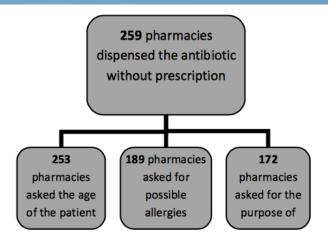


Figure 7: Results of Hoxha et al 2015 Survey

et. al. specifically found that people most commonly used amoxicillin as an antibiotic when they were self-medicating. This practice of self-medication is enabled by the pharmacies, of which reportedly 80% are willing to give out amoxicillin without a prescription, according to a 2015 survey (Hoxha et al). Amoxicillin is not considered an over the counter medication by the Albanian Ministry of Health (Cikuli, 2007), suggesting that this is a cultural issue rather than a legislative one. Both the consumers and the pharmacists currently seem willing to utilize and distribute antibiotics without definite cause, likely due to a lack of knowledge about the dangers associated. Without the consultation of a physician, patients are more likely to be unaware that antibiotic

courses should be completed and may stop taking the drugs once they feel better. These excessive antibiotics may then be left to expire, or disposed of improperly within the home.

Finally, pharmaceuticals that were donated to Albania to support Kosovo refugees in 1999 currently represent a

large source of expired waste. At the time, The Health Insurance Scheme covered an estimated 70% of the population, and further the tate covered only 20% of required drugs and medical supplies in hospitals. The influx of Kosovo refugees put even further strain on the healthcare sector. As a result, the international



Figure 8: Refugees from Kosovo Coming into Albania (FilmAid International, 2015)

community made every effort to assist during this crisis and donated several tons of pharmaceutical drugs to Albania. These donations were audited by the World Health Organization, and it was found that easily 50% would be useless and eventually require disposal (Watson, 1999). Over 40% had no mention of an expiry date, another 40% reportedly had less than a year before their expiration date, and as much as 80% of the medications that were donated were not requested by Albania. Many of the companies that donated were trying to get rid of old and expired medications. They also had the incentive of getting tax writeoffs by "donating" the medicines to a country in need ("Drug Donations," 1999). This led to an enormous stockpile of unused and expired drugs, with Albania bearing the financial burden of disposal. Currently there is no evidence to suggest that these extensive stockpiles have been properly disposed of over the last two decades, and Albania currently lacks the infrastructure to do so. Combined, these factors suggest that Albania would benefit greatly from a system to properly dispose of expired and unused pharmaceuticals.

2.6 Institutions for Pharmaceutical Distribution, Regulation and Disposal

The city of Tirana has 730 pharmacies, most of which are privately owned and very small, distributed amongst the 11 administrative units. There is a constant flux in the location and number of pharmacies in Tirana. The districts that we focused on were Ish-Blloku, Qendra, and Ali Demi, located respectively in the southcentral, central, and eastern sections of Tirana. We used "Ish-Blloku" to refer to a section of Administrative Unit 5, which contains the neighborhoods Ish-Blloku and Tirana e Re. Ish-Blloku was once the home to many political leaders during the communist era of Albania. Since communism ended, this area has become a wealthier part of Tirana (Williams, 2014). This has allowed the pharmaceutical market to thrive in this neighborhood because people can afford to pay for the medications. We used "Qendra," the Albanian word for center, to refer to parts of Administrative Units 10 and 7, including the neighborhoods 21 Dhjetori, Rruga Bouojës, Rruga Durrësit, and Rruga Myslym Shyr. Qendra is the busiest part of Tirana, and it was expected to therefore be

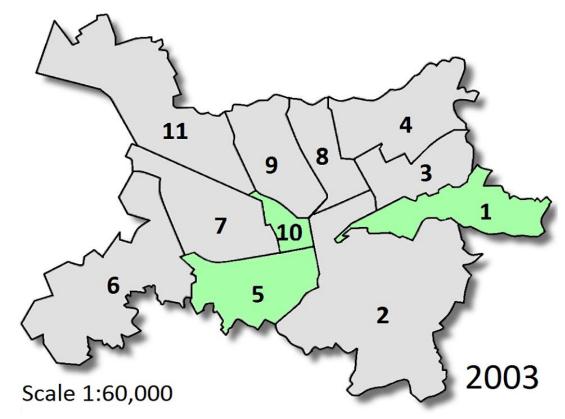


Figure 9: Map of Administrative Units (2016)

more controlled than other areas. By comparison, Ali Demi, which is a part of Administrative Unit 1, is less central to the city of Tirana, and has somewhat less prosperous customers frequenting their pharmacies.



Figure 10: Ministry of Environment

All pharmacies in Tirana are subject to regulations set by the Ministry of Health, the Ministry of the Environment, and several other institutions. One of these institutions is the Order of Pharmacists (UFSH)¹, which is a professional

organization that presides over the pharmacies to assist in regulations. The UFSH is a public entity that is composed of pharmacists that "represents their professional interests at the level of institutional partnership" (On the Order of Pharmacists in the Republic of Albania, 2003, page 36). This organization was created to unite the pharmacists and to protect them, by ensuring that they are

properly trained and enforcing the norms of medical ethics. The UFSH sets an ethical and professional standard, which the pharmacist must uphold, as well as the standards for their education. This organization keeps a record of all the pharmacists in Albania, partially due to the pharmacists' mandatory membership within the group. This attempts to ensure consistent and appropriate practices in pharmacies across Albania.

The Ministry of Health is another institution that exercises control over the pharmaceutical industry, both by setting regulations for and by directly monitoring the industry. The Ministry wants to "build a comprehensive system of traceability (track and trace) of drugs in the country" (Ministry, 2016). In order to improve the traceability, control stamps were implemented in 2011 for all drugs imported and produced in Albania. In accordance with Chapter IV, Article 20 of Law no. 9323, these stamps must include the name and dosage of the medication, the retail price, the ID number of the manufacturer or importer, the serial number of the reference, and the barcode. The Ministry controls the information on these stamps, including the prices and dosages, which the pharmacies must then follow.

¹ In Albanian, Urdhri i Farmacisteve te Shqiperise

Inspectors are required to visit the pharmacies to make sure they are following the regulations and laws, but there is very little information about how frequently the inspections must occur. Several laws work together to ensure, at least in theory, that pharmaceutical waste is disposed of properly. These laws were designed to match those of the European Union to aid Albania in gaining entrance into the EU (Johnson, 2001). The law For Hazardous Waste Management (Chapter 1 Article 4, 2006) states that hazardous waste management must be carried out by the entity that produced the waste. However, the law requires that any who dispose of pharmaceutical waste procure a license to do so (For Hazardous Waste Management, Chapter 4 Articles 12-13, 2006), and the application process is sufficiently demanding that it would not realistically be performed by the pharmacies themselves. Therefore the pharmacies must contract with a treatment company that does have the proper licenses to dispose of the waste. Pharmacies are required to verify the license of any third party they contract with, keep detailed records of their waste and its disposal, and submit documentation of the transfer of this waste



Figure 11: Medi-Tel Treatment Facility

to their regional environmental agency (For Hazardous Waste Management, Chapter 3 Article 8, 2006). The Ministry of Health established a regulatory organization, the National Center for Drug Control² (QKKB), which accepts expired pharmaceutical drugs from some pharmacies, as well as performing other regulatory functions in the market. It monitors distributions, negotiates with manufacturers to lower the prices of name brand medications, and seeks to prevent

shortages of medications (For Medicines and Pharmaceutical Services, 2004). The QKKB is managed and regulated by the Council of Ministers (For Medicines and Pharmaceutical Services, 2004, Chapter 3 Article 12). Manufacturers, importers, and distributors of pharmaceuticals are then required to give periodical updates of their activity to the QKKB (For Medicines and Pharmaceutical Services, 2004, Chapter 6 Article 28). There are a few private treatment companies that have the certification from the government to handle the treatment of medical wastes. The list of these companies that we have identified can be found in Appendix A. The

² In Albanian, Qendra Kombëtare e Kontrollit të Barnave

three major companies are Medi-Tel, Ilirjan & Kadeli and EuroTeam. Medi-Tel is the largest of the three, making over 93 million lek (740,000 USD) in government subsidies during 2015 while Ilirjan & Kadeli and EuroTeam made 24 million (190,000 USD) and 21 million (166,000 USD) respectively (Treasury, 2016). This money is given by the government to help hospitals pay for the disposal of their hazardous medical waste. The treatment companies are supposed to take the hazardous waste from their contracted suppliers and, following the regulations from the Ministry of the Environment, properly dispose of it. Unfortunately there have been some scandals involving these waste removal companies. In 2015, one treatment company was found to be throwing waste from the Berat hospital into the Osumi River (Fraud, 2015). In addition to the obvious environmental destruction this causes, this has the serious consequence of weakening the credibility of these companies and discouraging pharmacies from contracting them.

To summarize the many institutions and their connections, Figure 12 to the right shows the transition of pharmaceuticals from production

through disposal, as well as the different enforcement agencies charged with regulating the pharmaceuticals.

As the graphic below shows there are often multiple ministries that control a both single issue. In the case of

pharmaceutical waste, the Ministries of Health and of the Environment have oversight. To complicate the situation further both ministries have organizations with overlapping responsibilities and the ability to make regulations. This leads to

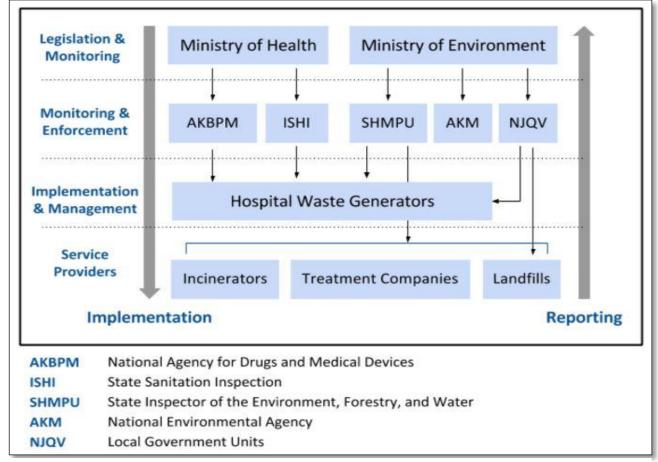


Figure 12: Institutions involved in regulating pharmaceutical waste (EDEN Center, 2015, Translated for this report)

over complication of the legislation, leaving the pharmacy owners unsure of the current regulations. The national government is interested in collaborating with "local government bodies, people who produce and manage hazardous waste, with nonprofit organizations, as well as business and professional organizations" (For Hazardous Waste Management, Chapter 2 Article 6, 2006). This collaboration is necessary to create an effective regulatory system, but requires a careful balance to prevent confusion surrounding each jurisdiction and to prevent these organizations from overlooking improper disposal practices.

2.7 Pharmaceutical Waste Management Challenges in Albania

While there is legislation in place that should ensure that Albania meets the global standard of pharmaceutical waste disposal, there is very little evidence that it is being carried out effectively. Though the QKKB should receive reports of all pharmaceutical waste being created and disposed of, there is no public record of this waste (National Agency for Medication

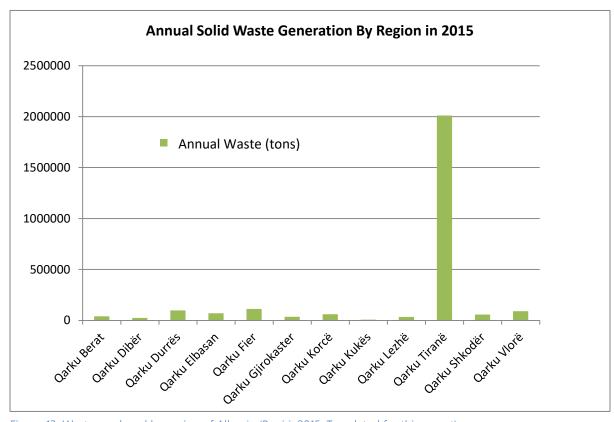


Figure 13: Waste produced by region of Albania (Begiri, 2015, Translated for this report)

and Medical Devices). Further, the National Environmental Agency³ (AKM) did not mention the state of pharmaceutical waste management in any of their State of the Environment Reports over the last half decade (AKM, 2011-2015). In the Solid

Urban Waste section of the 2015 State of the Environment Report, the AKM stated that the provision of sites for medical and hazardous waste was a top priority, implying that more work was needed (Beqiri, 2015). As the figure above clearly shows, Tirana is a crucial location for solid waste management. Further, a preliminary study conducted by the EDEN Center

³ In Albanian, Agjencia Kombëtare e Mjedisit

suggested that very few of the pharmacies they contacted had contracts with treatment companies. Our study seeks to illuminate this issue and provide data on the current disposal practices in Tirana.

Current literature has limited information on the potential causes for this possible lack of compliance with regulations. One potential factor may be the cost of disposal. As noted above, the Albanian legislature puts the financial burden on the "person who produces hazardous waste," which has been taken to mean the pharmacies as the medications were not waste when the pharmacies received them (For Hazardous Waste Management, Chapter 1 Article 4, 2006). Such a financial burden can be a major disincentive for pharmacies, especially smaller pharmacies like those commonly found in Albania. Globally, small scale pharmacies have compensated for this financial strain by charging for returned medicines, or through government assistance (Jonjic, 2014). Pharmacies may also be failing to comply due to a lack of training for the pharmacists, especially regarding proper disposal methods. Although students participate in one semester of professional experience (Department, 2010), Albanian pharmacy

students feel that they could benefit from more practical work experience before they complete their studies. This lack of training can lead to improper prescriptions and other potentially dangerous mistakes (Hwang, 2014). It could also cause mistakes that involve dispensing incorrect types or amounts of medications, which would increase the amount of pharmaceuticals in need of disposal, and pharmacists may be less likely to follow disposal regulations that they do not fully understand. Finally, there have been some allegations, as noted above, that the treatment companies are not trustworthy and may be improperly disposing of the medications after they receive them from the pharmacies (Fraud, 2015). A pharmacy may be discouraged from paying money to contract with one of these companies if it believes that the company is not honest. However, none of these factors has been directly correlated with the practices of pharmaceutical waste disposal in Tirana. Our research will attempt to fill the gaps in the current understanding of these causes.





The goal of our project was to assess how pharmacies in several neighborhoods of

The goal of our project was to assess how pharmacies in several neighborhoods of Tirana dispose of expired or unused medications to determine possible causes of improper pharmaceutical waste management, and to identify opportunities to improve pharmaceutical waste disposal practices and therefore reducing ecological and public health risks due to antibiotic resistant bacteria and endocrine system disruptors. Our objectives were as follows:

- Assess the current practices and policies for pharmaceutical waste management in Tirana;
- Uncover the challenges that are preventing effective pharmaceutical waste management;
- Identify stakeholders' roles and perspectives in the pharmaceutical waste management system;
- Demonstrate the need for more information on the subject of pharmaceutical waste management;

Chapter 3: Methodology

3.1 Assessing the Current Practices in Albania

We examined the practices of approximately 10% of the pharmacies in Tirana using a structured questionnaire with both closed and open ended questions. This 10% is not representative of the city as a whole, but is rather selected from three neighborhoods. These different neighborhoods, as outlined in section 2.6, had been selected to vary in their demographics and expected levels of regulation from the Ministry of Health. The expectation was that the neighborhoods located closer to the center would be regularly visited by the Ministry Inspector and would likely be in greater compliance with regulations, while more suburban neighborhoods would have less oversight. It was also expected that neighborhoods that were wealthier would be more compliant than less affluent areas because the pharmacies may be in a better financial position to pay for a contract, and their wealthier clientele might be more concerned with the standards of the pharmacy. This research design gave us a basis to compare the effect of location and affluence on waste disposal practices in pharmacies.

To gather information from these pharmacies, we conducted interviews with pharmacists and owners of pharmacies with the help of volunteers from the EDEN Center as translators. We used a multimethod approach consisting of interviews, direct subject observations, and the analysis of government and private records. These respondents were fully informed that all of their answers would be kept completely confidential and that the information gathered was only intended to improve the waste management system. This helped to gain the trust of our interviewees and increased their willingness to share their views. In each neighborhood analyzed, we approached every pharmacy about participating in our study. The questionnaire used for these interviews can be found in Appendix B. These interviews consisted of questions including:

- + Are any medications disposed of by this pharmacy?
- + How much medication does this pharmacy dispose of?
- + How are these medications disposed of?

+ Does this pharmacy have a contract with a treatment company?

This data was compiled and used to establish the current state of the pharmaceutical waste management in Tirana. For narrow questions, like those that simply required yes or no answers we used a quantitative analysis. For example, a binary question like "Does a treatment company handle these disposals?" could produce a statistic such as "xx% of pharmacies have a contract with a treatment company." For the open ended questions we conducted a thematic analysis (Berg, 2004). Thematic analysis is a commonly used qualitative data analysis method, and the purpose was to identify patterns across a set of data. In order to identify these themes and patterns, the process consisted of familiarization with the data, data coding, and searching for themes (About, 2016). We used inductive thematic analysis in order to come up with trends from the data that we found. After each interview, we reviewed and summarized the data, and then added keywords and tags like "contract," for pharmacies that had contracts, and "no companies," for pharmacies that claimed

Chapter 3: Methodology

there were no treatment companies in Tirana. The entire list of keywords and tags used to find trends in the data can be found in the appendices. This helped us to analyze our data by showing us the connections and patterns between the pharmacies.

During interviews we also asked the pharmacists questions about how often the Ministry Inspectors came to the pharmacies. This data helped us to see how much control the Ministry had over the waste management system in Tirana demonstrating the relationship between the enforcement of and the adherence to the law.

3.2 Obstructions to Proper Waste Management

In our interviews, we identified the challenges that were preventing proper pharmaceutical waste management in Albania. The challenges we investigated were cultural, educational, and fiscal in nature. We also researched the current disincentives that prevent proper waste disposal practices. We asked the following questions:

+ What do you find most challenging about following the regulations?

- + What would help to make it easier for you to follow the proper disposal regulations?
- + What incentives would make the pharmacies want to conform to the regulations?
- + What recommendations do you have to improve the system?

These questions and the relevant interview protocol can be viewed in Appendix B. The responses were analyzed both quantitatively and qualitatively. As the interviews progressed, we noted the themes that arose more often and their frequency. Open ended questions like "What do you find most challenging about following the regulations?" could produce figures such as "xx% of pharmacies felt the regulations were too costly to follow." This allowed us to see the varied perspectives of different pharmacists. Further, it showed which solutions would be effective for the greatest quantity of pharmacies.

Though we have mentioned that we took steps to gain the trust of those we interviewed, there were some pharmacists that were uncomfortable giving us a complete picture of their practices. However, their reluctance was still used as data, as it is likely that a pharmacist that is unwilling to talk to us about their contract

with a treatment company does not have a contract. The responses from these interviews provided us data about the current practices and sentiments of pharmacists in Tirana through which to further investigate the causes of these practices.

3.3 Interviewing Additional Stakeholders

We conducted interviews with our stakeholders in order to expand our understanding of the issues surrounding the pharmaceutical waste management system in Tirana. We interviewed a treatment company representative and a distributor. Interviewing the stakeholders was important to our study because we received information about the system from the whole chain of command, not just the pharmacies. These organizations may further illustrate the current practices for pharmaceutical waste management and their causes. Additionally, they will give us more information about their potential to influence these practices for the better.

We interviewed distributors as well, which are intermediary companies that buy from manufacturers and sell to pharmacies, often additionally acting as

Chapter 3: Methodology

warehouses for unwanted medications. Our interviews included the following questions:

- + Does your company currently manage expired pharmaceutical waste?
- + If so, how much? What happens to this waste?
- + What is your interpretation of the law regarding this disposal?
- + Who do you feel should be responsible for paying for the waste disposal?

The additional questions can be found in Appendix C. Their responses to these questions demonstrated the perspectives of a commercial organization that is responsible for managing expired pharmaceutical waste in a similar way to the pharmacies.

A letter was sent to the AKM, requesting information on any treatment companies they had provided licenses to. A list of the treatment companies can be found in Appendix D. We interviewed the treatment companies that are licensed in Tirana, to understand their current practices and any challenges they may face. We asked questions including:

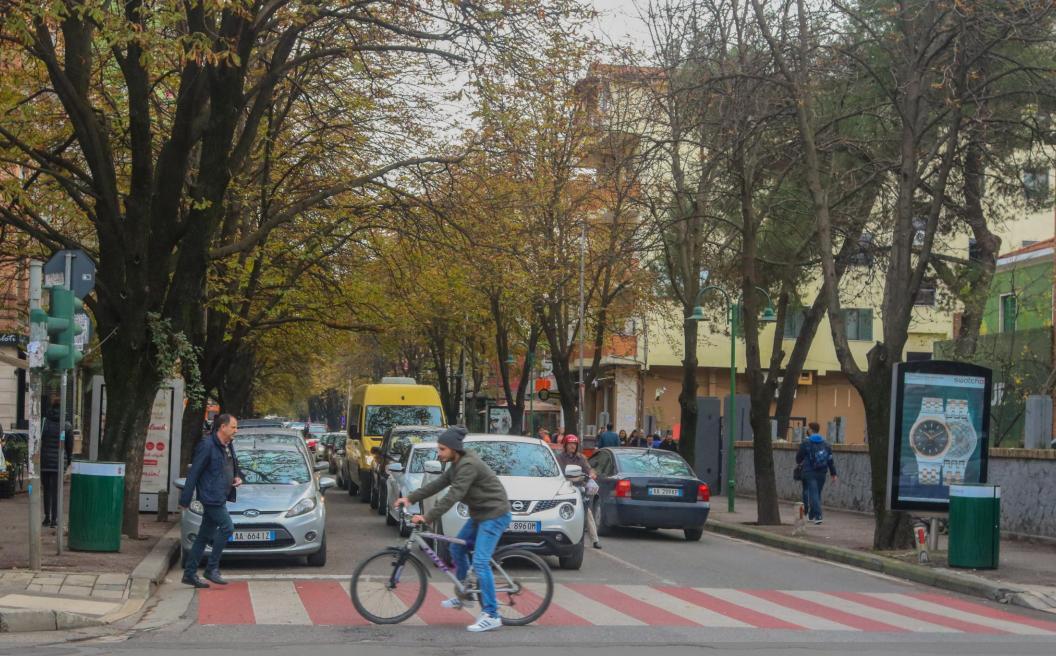
- + How many contracts do you have with pharmacies in Tirana?
- + How much waste do you dispose of?
- + How do you dispose of this waste?
- + How do you charge for this service?
- + How do you market your company to gain additional contracts?

The response from the treatment company about the number of contracts and their costs were compared with the information provided to us by pharmacists. We also used their information about marketing, cost, and disposal methods to understand the reasons pharmacists might not use these companies. Through these interviews we expanded our understanding of the web of influences surrounding this issue.

3.4 Data Management

The information collected in our study was sensitive, and thus we established a protocol to manage the data collected. We maintained confidentiality for the pharmacy and anonymity for the pharmacist during all interviews. We never collected personal information about the pharmacist we interviewed. We transcribed all interviews, and these transcriptions were given a code based on the pharmacy. A separate corresponding code was used to plot the locations of pharmacies on maps of the city. To reference between the maps and transcripts, we used a grid of the code's correspondences, which was deleted at the conclusion of this study. This allowed us to track a pharmacy's location without providing specific information about responses of that pharmacy. All of these separate files were password protected. Our transcripts and analyses were shared with EDEN through data exchange with Jonida Mamaj-Hafizi.





Chapter 4: Results

In this chapter of the report we will discuss the major findings that were a result of the 74 interviews that we performed in Qendra, Ish-Blloku, and Ali Demi. In addition to interviews with pharmacies, we interviewed with some of the stakeholders of this project. An interview was conducted with a pharmaceutical distributor. We also interviewed a representative of Medi-Tel, a treatment company that works in the Tirana area. The transcripts from these interviews can be found in Appendix C. The findings helped to provide insight on the issues in the pharmaceutical waste management system in place in Tirana. The results are organized into different sections based off of our original interview questions. Quotations are paraphrased from the translators; the pharmacist originally spoke in Albanian

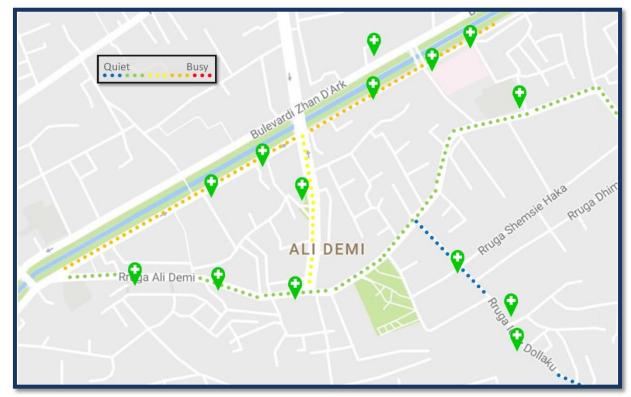


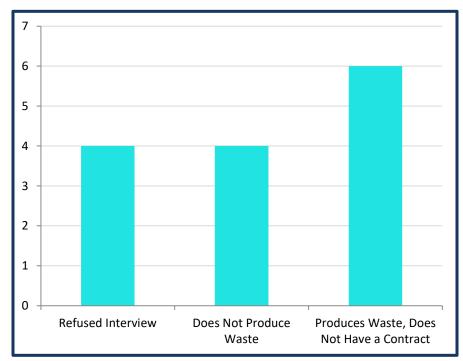
Figure 16: Ali Demi Pharmacy Locations and Traffic Levels

Figure 14: Sample Ali Demi Street



Figure 15 to the left shows the 14 pharmacies that we interviewed in Ali Demi. Ali Demi is the least populated district we examined, with the least traffic. Figure 16 demonstrates the quiet nature of this area. Our study did not uncover any pharmacies with contracts in Ali Demi, as can be seen in Figure 14 below, and the highest percentage of pharmacies that refused to participate in the study were located here.

Figure 15: Responses in Ali Demi



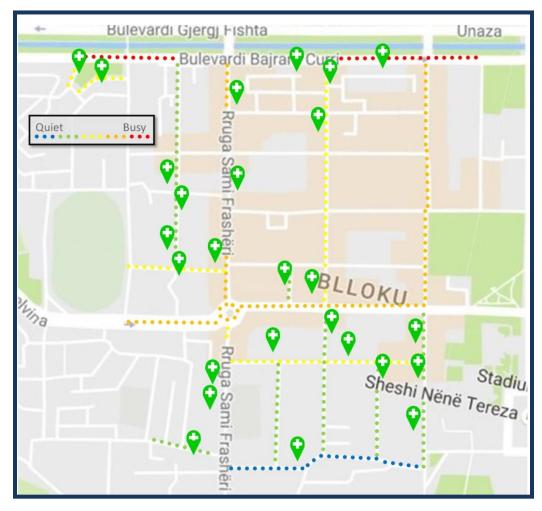


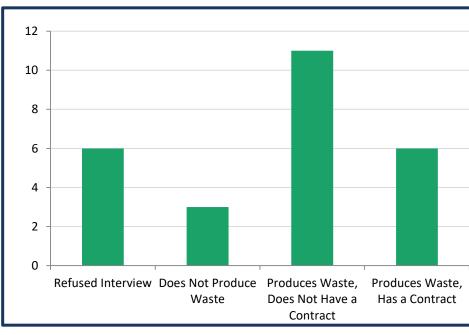
Figure 17: Ish-Blloku Pharmacy Locations and Traffic Level

As you can see in Figure 17 above, Ish-Blloku has 26 pharmacies that are spread out with some small clusters. Ish-Blloku is one of the wealthier areas within Tirana, with very busy streets. An average street in Ish-Blloku is shown in Figure 18. The responses received in Ish-Blloku were varied, as can be seen in Figure 19, but most pharmacists did not have a contract despite producing pharmaceutical waste.



Figure 18: Sample Ish-Blloku Street





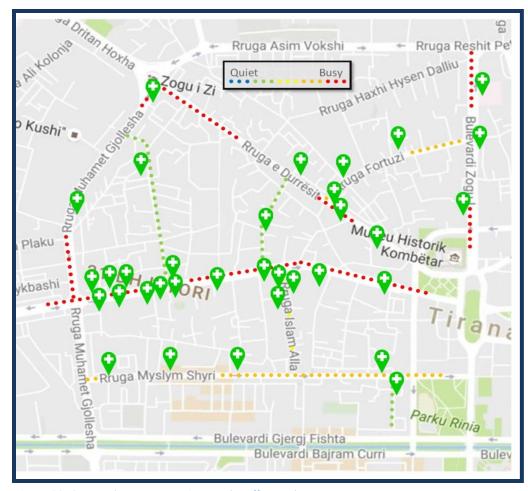
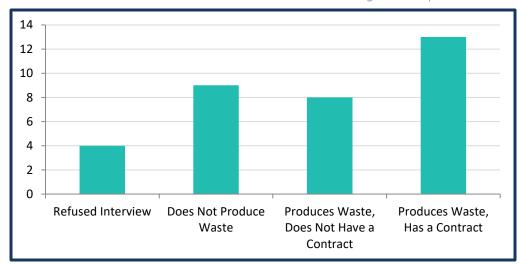


Figure 22: Center Pharmacy Locations and Traffic Levels

Figure 21: Responses in Center



The 34 pharmacies in Qendra, shown in Figure 22, were located very close together. Qendra is very popular with extremely busy streets. Figure 20 exemplifies the populated streets common in Qendra. This area had the highest percentage of pharmacies with a contract, and the overall high level of compliance is visible in Figure 21.

Figure 20: Sample Center Street



4.1 Would you be willing to participate in our study?Almost 20% of pharmacies approached to be interviewed declined to participate in our study.

When we approached pharmacies, we first introduced ourselves and described the objectives of our project. The pharmacists were given the choice as to whether or not they wanted to speak with us. Some refused to be a part of our study for various reasons. Ali Demi had the highest concentration of pharmacists that did not want to speak with us, where 29% of pharmacists refused. There were a variety of explanations for their refusal in all of the districts we studied. Some pharmacists, primarily located in Qendra, felt that they knew the law well enough and failed to see the justification of our study. Some pharmacists were openly hostile towards us; one pharmacist, in particular, yelled at us until we left her store. Other negative responses we received include: pharmacists telling us that they did not have time, pharmacists telling us that they were too busy, and pharmacists acting generally dismissive about our questions and our study. Another response we received was that the pharmacy was new and had opened in the past few days, and therefore they would not have any information to give us. Many times we viewed this information with some skepticism, as in previous weeks we had seen the same pharmacies running while we were mapping out pharmacy locations.

4.2 Do you produce any pharmaceutical waste? How much?

About 70% of pharmacies interviewed acknowledged that they produce pharmaceutical waste, but most claimed they produced small amounts of waste.

The vast majority of the pharmacists we approached, over 80%, were willing to participate in our study. The first question asked to the pharmacists was if they produced any pharmaceutical waste. A significant portion of these pharmacies, about 30% of those interviewed, responded that they did not. According to a pharmacist in Ish-Blloku, it is impossible to not produce any waste and "anyone who says otherwise is not being honest," which led us to inquire at pharmacies that claimed to avoid producing waste how

they achieved this. One pharmacist said that she reduced the price of the drugs as their expiration dates approached in order to sell them faster. It should be noted however, from our interview with Medi-Tel. that medications are often imported into the country within three months of their expiration date. This leaves pharmacists very little time to sell the medications, causing them to be very careful with the amount that they order to make sure that waste is not produced. 58% of the pharmacies that were interviewed acknowledged that they did produce pharmaceutical waste. Of those pharmacies, many said that they only had a small amount of waste. Throughout all of the interviews, we found the word "small" to mean anything from two to four boxes of waste, two to three products, 30 tabs of expired medicine per month, or two small boxes. Individually these pharmacies produce an amount of waste they perceive as inconsequential, but may not recognize that together the waste adds up to significant amounts.

4.3 Do you have a contract with a treatment company?

Over half of the pharmacies that we spoke with admitted to not having a contract with a treatment company.

Of the 60 pharmacies that were willing to answer our questions, 18 of them said that they did have a contract with a treatment company. Our study found a number of factors that affected the percentage of pharmacies with a contract. The location had a large impact on the likelihood of the pharmacy having a contract. Qendra was the busiest, most central area that we analyzed. While answers were varied, Qendra had the highest percentage, 38%, of pharmacies with contracts. In contrast, Ali Demi, the least central and least busy district, did not have any pharmacies with a contract. From this data, the reasonable conclusion can be drawn that a pharmacy is more likely to have a contract when located in a wealthier, more visited part of the city. To clarify this, we assigned each street a rank based on how busy it was and its relative size and traffic. The ranks were determined through observations of the foot and motor traffic. As the streets get busier the

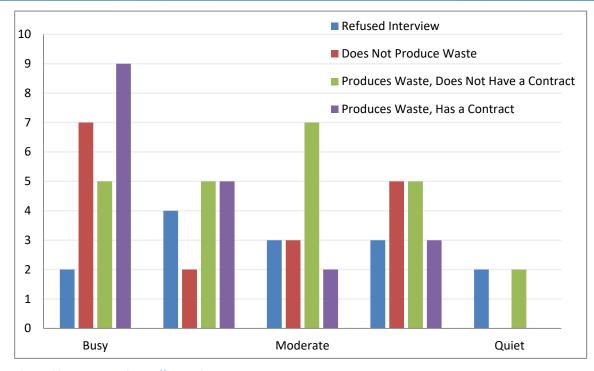


Figure 23: Responses by Traffic Level

percentage of the pharmacies that are complying with the laws increases.

We received a wide range of responses as to why the pharmacists had decided to get a contract with a treatment company. Many explained that they

wanted to protect the environment. Others simply did not want to be breaking the law. While the reasoning behind why some pharmacists have a contract is important, our study focused primarily on the responses of those without one.

Over half of the pharmacies in our study admitted to not having a contract with a treatment company. This 56% can

be divided into two major categories; 23% claimed to have no waste at all and therefore had no need for a contract and 33% who have waste but did not have a contract. Many of the

"It is the law and so we must have a contract."

-Pharmacist

pharmacies that claimed to produce no waste were dismissive, and less interested in discussing the challenges of proper disposal. The group that did have waste, but did not have a contract, provided insightful responses and reasons for not using a treatment company and from these we have been able to identify the flaws in the waste management system.

The small size of the pharmacies makes them less likely to comply with the law.

Half of the pharmacists we spoke with mentioned that they had very small amounts of waste. The majority of the time this was used to demonstrate that they did not need to have a contract because they believed they could just throw away or otherwise dispose of the small amount of waste that they had without making a large environmental impact. The pharmacies may not be able to see the impact that their relatively small amounts of waste has on the environment or the cumulative damage caused by many pharmacies all behaving this way.

The cost of treatment can be prohibitive.

Cost was another pervasive influence on pharmacy owners. The two most

common prices mentioned to us for treatment were annual fees of either 6000 or 12000 lek (46.99 or 93.98 USD). Some pharmacies also mentioned a security deposit of 6000 lek. Finally pharmacists mentioned being charged by quantity of

"I already lost money from not being able to sell the medicine so I cannot afford to pay for their disposal as well."

waste to be removed. One mentioned paying 400 lek/kg (1.42 USD/lb), while another mentioned paying the value added tax (V.A.T.) of 2% of the price of the expired medications. The treatment company we interviewed, Medi-Tel, showed us contracts where they charged 20 Euros (22.60 USD) annually, 500 lek/kg (1.76 USD/lb), and the 2% V.A.T. Concerns about cost may be a legitimate expression of pharmacies' inability to pay, rather than a complaint. Most of these pharmacies are individually owned, as opposed to large chain companies or those with many investors, which limits their capital

resources. This lack of capital means they may not be able to front the yearly cost of disposal. Further, the control of the wholesale price by the Ministry limits the profit margins and therefor the flexibility of pharmacy budgets. Therefore many pharmacies seemed justified when they said that they did not have a contract due to its price.

Obtaining contact information for the treatment companies is a barrier for pharmacies.

A quarter of the pharmacists interviewed either could not find a treatment company or believed that none existed. This meant that they were unable to follow the regulations, assuming they wanted to. Additionally, during our own extensive research we could not find contact information for a majority of the treatment companies. After receiving the response from the Environmental Agency, we were given a list of 10 different treatment companies that have environmental licenses. We then tried to find any form of contact information for these companies but our successes were limited. This supported the pharmacists that claimed they could not locate information about treatment companies.

However, when we interviewed a representative from Medi-Tel, he believed his information was easy to find, especially when looking on the website for the National Center of Business. He implied that pharmacies were likely to claim that they did not know of any companies to justify avoiding contracts. However,

pharmacies that did have contracts also claimed that they had experienced difficulty contacting a company. Further, our own experiences suggest

"To get a contract I would have to call multiple ministries."

-Pharmacist

that even with the National Center of Business, some companies remain difficult to find. If the treatment companies marketed themselves better, they could drastically increase their own business and reduce the amount of improperly disposed of waste. Alternatively, Medi-Tel believes that more Ministry control and oversight would encourage more contracts with pharmacies. Whether it comes from the treatment companies or the Ministry, pharmacists would benefit from more information about the available treatment companies.

A lack of trust in the treatment companies is a significant barrier.

Many pharmacists responded that they do not trust treatment companies to properly dispose of the waste. A quarter of the pharmacies interviewed in Ish-Blloku mentioned that they do not believe the

> treatment companies are properly disposing of the medicines, but instead are simply throwing them away. This idea has very important

implications. Pharmacists who distrust the companies have no motivation, other than blind compliance with the law, to contract with a treatment company. A lack of trust is a significant barrier that will have to be overcome to establish an effective waste disposal system.

Some believe pharmacists may not need contracts, as they can return their waste to a distributor.

A few pharmacists mentioned that they did not have a contract because they could simply send their waste to a depot. This was confirmed by the Medi-Tel representative when he said that the law states that all pharmacies should be able to return their expired medication. It was also mentioned by the distributor we interviewed, who stated that a pharmacy should never have a contract, as they can always return waste to the distributor free of charge. He stated this with complete assurance, but among 60 interviews we only found two pharmacies that said that they returned their waste to a depot. Pharmacists have no reason to lie about this, if this option is as easy and legal as implied. This seems to support the assertion that there is inconsistent and limited information available to pharmacists and other stakeholders in the pharmaceutical waste management system.

4.4 How often does the inspector come?

Pharmacists have trouble relying on the inspection system.

During our interviews, we asked the pharmacists how frequently the inspectors came to the pharmacies each year. Figure 25 below shows the frequency of inspector visits per year for 48 different pharmacies varied.

The number of visits ranged between 0-12 times per year, and responses were very inconsistent, with many pharmacists

Table 2: Heat Map of Responses by Frequency of Inspectors

20	0	1	2	3+
Has Contract	27%	17%	29%	60%
Produced Waste	36%	63%	67%	20%
No Waste	36%	20%	14%	20%

giving us a range of possible frequencies. One pharmacist mentioned that the inspectors were very unscheduled and would come "maybe once a year, maybe three times a week." Pharmacists have trouble relying on the inspection system. Through our interviews, we found that

there was a relationship between the number of inspector visits per year and whether or not the pharmacy had a contract or waste. Table 2 is a heat map that shows the relationship between the number of inspector visits to a pharmacy per year

(ranked between 0 and 3+)⁴ and if the pharmacy has a contract and/or waste. This figure shows the correlation between the frequencies with which the inspectors visit and the responses they provided about their disposal practices in the pharmacies that responded to this question. Pharmacies that told us about their inspector visits either had a contract (Has Contract), did not have a contract but did admit to producing waste (Produced Waste), or claimed they did not produce waste, and therefore did not have or need to have a contract (No Waste).

Inspector Visits Per Year

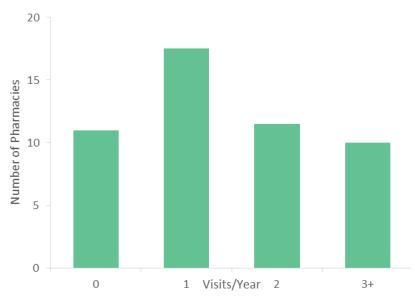


Figure 24: Frequency of inspector visits

⁴ If we receive an answer with a range of values, it went with the lower of the two values.

"There is no one enforcing the laws so we have no need to follow them."

-Pharmacist

The color code in the heat map is used to show the different percentages of pharmacies that fit into the category based on the number of inspector visits they had per year. The darker the green in each box, the higher the percentage. For example, of all the pharmacies that said they saw the inspector annually, 63% did not have a contract with a treatment company but had waste. Since the 63% is a higher number compared to the other numbers,

the box is a darker green color.
Percentages are displayed to normalize the different sample sizes. This heat map was created with the

"No one provides information about the laws and regulations."

percentages of the pharmacies that were inspected a certain number of times. Each

column therefore totals 100%. This was selected because not all pharmacies responded about their inspection frequency and 100% would not have been reached. This heat map helps to show that the number of inspector visits did seem to contribute to a higher percentage of pharmacies that had a contract with a treatment company.

4.5 Do you understand the laws?

Pharmacists were lacking information about the laws and regulations that they must be following.

According to Law No. 9323 "On Medicines and Pharmaceutical Services" Article 4, producers of hazardous waste must have an environmental license in order to dispose of the waste. This is why

pharmacies use treatment companies. We found that pharmacists lacked information about the laws and regulations that they must be following, which makes it very hard for them to comply. We received many different answers from the

pharmacists about the laws. Some pharmacists claimed they knew and followed the law, while others claimed that they had not been given enough information. In both cases, we found that not all of pharmacists were following the laws, even if they knew the provisions. 21 out of the 74 pharmacists that were interviewed claimed that they were

confused or lacked knowledge about the laws and regulations regarding

"We feel very uninformed about the laws" -Pharmacist

pharmaceutical waste.

While some pharmacists were aware that they did not know the laws, some claimed to know the laws. About one in three of these did not seem to be acting in accordance with the law. One pharmacist said that she dug a hole in the ground and then deposited the expired drugs in that hole. She then mentioned that she knew the law, even though she said that she did not need a treatment company to take care of the expired drugs. A few pharmacies said they are following the law but they do not have a contract for the waste they acknowledged producing. Therefore, we can infer that they do not completely understand the laws or they do not want to follow them.

4.6 What do you find challenging?

Pharmacists varied in their willingness to participate in this section of the interview.

Pharmacists in Ali Demi were very willing to discuss their challenges and recommendations with us. While fewer pharmacists were interested in participating in the interview than those in other neighborhoods, those we did speak with were much more receptive. They were frustrated by the lack of help and information they received, and appreciated our attention and interest in improving their businesses. Their concerns will be discussed in greater detail below, as will those of each district.

In contrast, many of the pharmacists we spoke with in Qendra were less interested in discussing the challenges they faced. Many did not feel the need to make any recommendations they had. Several claimed to be well informed, well behaved, and thus did

not need to speak to us further. In general, they seemed unreceptive to the idea that

someone like us would be coming around to help them, and about one in five of those we talked to seemed hostile, rude, or dismissive.

Many pharmacists felt that the cost of disposing of pharmaceutical waste properly was a significant disincentive.

Depending on the company, pharmacists can get charged annually and per weight of the waste treated, often with an additional security deposit. It was comparatively more likely for Ish-Blloku pharmacists

"Pharmacists do not

but are forced to by

the cost of

complying."

to worry about the cost of the contracts,

but it was a recurring sentiment in all areas. Pharmacists expressed that they could not pay for the waste removal, since the expired medication already represented a loss of income. Many felt that, given the small

amount of waste they produce, it was not in their best interest to pay annual fees for a contract. Pharmacists reported crushing some of their waste to reduce the cost of disposal. The pharmacies in our study were small and over 90% were independently owned, rather than being a part of a chain, which makes the costs of obeying the law more onerous and unappealing. One pharmacist suggested that the government should offer tax cuts for disposing of

> pharmaceutical waste, and many expressed that they would appreciate more financial assistance. For pharmacists to comply with the

laws they must have adequate financial resources.

However the increased cost of environmental protection is something that the pharmacies may need to foot despite their initial discomfort. The environment is a shared resource that all must work to protect. There is a long precedent of regulation to protect the environment hurting business at first but benefiting society in the long run (Matheus, 2015). So while pharmacists may have expressed concerns with the costs,

"We feel like we're losing lots of money because we follow the law."

-Pharmacist

want to break the law, -Pharmacist

these complaints may just be an unavoidable part of environmental regulation.

Many pharmacists would appreciate more guidance and assistance from their government.

The Ministry of Health is in place to set regulations for and monitor the pharmaceutical industry, but many pharmacists feel that they are not getting enough help from the Ministry. Some pharmacists even said that they felt the Ministry was not motivated to make the process easier. A few of the pharmacies that had been open for less than a year said that they were waiting for the Ministry to come tell them what to do with their waste. They assumed that eventually

someone would come and help them, but had not seen

"The government is not here to help us."

-Pharmacist

anyone yet. One pharmacist chose not to participate in our recommendations portion of the interview because she felt it would be pointless. She said that she had brought her recommendations to the Ministry of Health and to the Order of the

Pharmacists and no one had taken her seriously. "Nothing is going to be done," she told us. Interactions like these left her and some of the other

pharmacists with the impression that they could not use these institutions for support.

4.7 Challenges Expressed by Additional Stakeholders

Distributor

The distributor we interviewed also experienced difficulties with the pharmaceutical waste management

system. Our contact explained that his distribution company would take the expired medicines back free of charge from the pharmacies, but that this happened very rarely because he would accept and fill orders daily. He

informed us that after years his company had accumulated a large stockpile of pharmaceutical waste, and that he was waiting for a cheaper way to dispose of it. This practice of stockpiling medications may not be isolated; in our interview with a

"[The Ministry] doesn't distribute the rules and regulations well, the companies must keep up with what they do."

-Distributor

Medi-Tel representative he suggested that hospitals within the city could be accumulating as much as 20 tons of expired pharmaceutical waste without any clear intentions to dispose of it properly. The distributor we interviewed chose to

stockpile his waste because he believed there was only one company that was currently treating such waste and felt that meeting the price they charged would significantly impact his business. He lamented that he had to take such financial risks when purchasing inventory and incur heavy disposal costs if they did not pay off.

This distributor expressed the challenges he had encountered with the Ministry of Health and other government institutions. He felt as though the process to declare waste to the government and report its transfer to a treatment company was time consuming and demanding. He also felt as though the various Ministries had the responsibility to enforce the laws, and suggested that the Ministry should take a more active role in this enforcement.

Treatment Company

The treatment company representative we interviewed saw various opportunities to manage pharmaceutical wastes more effectively. He claimed that

many of the other treatment companies were dishonest, and publicity surrounding this tarnished the reputations of other

"[The QKKB] has their own waste, they cannot take care of other waste."

treatment companies, including his company Medi-Tel. He was very eager to be transparent with their practices, as he felt that pharmacies would not be likely to get contracts with treatment companies they found suspicious.

He also said that from his perspective the government did not adequately enforce the laws concerning pharmacies. In our interview, he asked where the pharmacies we had spoken to send their waste, and we mentioned that, among other institutions, some pharmacies send their waste to the QKKB. The Medi-Tel representative claimed that the QKKB, as a national organization, was not the proper

institution to be taking care of the waste. Rather, in his opinion, it should focus on enforcement of regulations. He believes that even this government institution is not working correctly because there is limited information concerning the business

practices at the QKKB. Medi-Tel only has 4 contracts with pharmacies, but he stated that "the government is not pushing pharmacies to follow the regulations, and with more enforcement the system would work." Although he is not out actively seeking contracts with

pharmacies, he believes that the pharmacies will begin searching for his company when there is more enforcement.



Chapter 5: Recommendations

Improving Access to Information

The most prevalent issue that we found was the lack and inconsistency of information provided to pharmacists. We believe that pharmacists would benefit tremendously from knowing specifically which laws they are expected to adhere to. It would also be helpful to inform pharmacists how they can get in contact with treatment companies, so that the process can be as simple as possible. Finally, it would be important to include information about why it is important to follow these laws, as well as the environmental impact of even a small amount of pharmaceutical waste, which could be distributed to pharmacists and pharmaceutical students. A possible way to distribute this information would be to create a fact sheet or pamphlet to distribute to pharmacies. This would give pharmacists the information they need to effectively contract with a treatment company.

Frequent and Consistent Regulations

Additional steps that may help improve pharmaceutical waste management include increased oversight from the ministry. This increased oversight, e.g. more frequent and consistent visits from a Ministry of Health and Environment inspector, may make pharmacies feel that there are greater consequences for not complying with the regulations. In addition, it could provide an opportunity for the pharmacists to ask any questions they may have regarding the laws or treatment companies.

Incentives for Proper Waste Disposal

Another method to positively impact the current waste management system would be to establish incentives for complying with the law. Incentives that could improve the disposal practices of pharmacies include financial subsidies, tax cuts, or even the opportunity to advertise to customers that their pharmacy is environmentally friendly. Previous attempts at regulating this industry have shown that incentives have been an effective way to increase compliance, because pharmacies must have adequate resources to comply.

Further Investigation

The data that we collected was highly variable, and revealed many questions about the current system. Our study was limited in its scope, and the pharmacies we interviewed were not representative of the city, not to mention the country as a whole. We have also seen some inconsistencies in the responses we received. Examples include varied opinions about returning waste to the distributors, the regulatory role of the government, and the availability of information to the pharmacists. Additionally, it would be beneficial to analyze the practices and perspectives of the relevant government bodies.

While we have been able to outline major recommendations that could improve the system as it currently stands, more options could be identified and analyzed. A study with greater resources and authority will be better able to investigate all of the stakeholders involved. Our final recommendation is that these issues be studied further.



Appendix A

List of Treatment Companies

EuroTeam
EcoTeam
Hygeia Hospital
Iridiani
V.A.L.E. Recycling
Medi-Tel
3 P Life Logistic
SaniService
Kneo Transport Kompani
Elkiri & Company

Appendix B

Interview Protocol

Considerations:

- + When requesting the interview we asked the pharmacist if they were willing to have an interview with us. This was done by the translator, and the interview proceeded in Albanian if the pharmacist was willing.
- + Interviews took place in the pharmacy.
- + We interviewed pharmacy owners and pharmacists.

Biases

- + We remained neutral in our questions, so the respondents did not feel pressured to give us the answer we want.
- + We asked mostly open ended questions, instead of pointed questions that lead to one particular answer.

Lying

- + We told them that this interview is completely anonymous.
- + We told them that we are trying to help improve the country and environment.

Validity

- + We interviewed all pharmacies in each neighborhood.
- + Quasi Statistics were used to turn qualitative data into quantitative data.

Interview with Pharmacists

Date: Time:

Location: Pharmacy

Attendees: Introduction:

We are American students doing research on the question of how pharmaceuticals are disposed. We are assisting the Eden Center, which studies environmental issues in Albania in the hopes of resolving them. We just wanted to let you know that what you tell us in the interview will be confidential, can be anonymous, and we are simply trying to collect data for our report. We will not identify you by name in any of the reports using any of the information obtained from this interview, and your confidentiality in this study will remain secure. This study is intended to understand what is currently happening in the city as a whole so that we can help, and we would be thankful for as much accurate information as you can provide.

If there are any questions that you do not want to answer, just let us know and we will move on to a different question.

Before we begin the interview, do you have any questions for us?

Questionnaire:

- + Do you have pharmaceutical waste? How much waste do you produce per week?
- + Do you have a contract with a treatment company? Which company do you have a contract with? How long have you had this contract? How much does it cost you to manage your waste? Where does your waste go? (Incineration, storage, throw away)
- + How often does the inspector come to the pharmacy?
- + What do you find most challenging about following the regulations? What would help to make it easier for you to follow the proper disposal regulations? What incentives would make the pharmacies want to conform to the regulations? What recommendations do you have to improve the system?
- + Is there anything else you would like to talk about, or is there any information we can provide?
- + At the end of the interview, we thanked the pharmacist for their time.

Appendix C

Interview with Distributor

Location: Apartment Date: 12/12/2016 Time: 9:00 PM

Attendees: Distributor, Students

Introduction:

We are American students doing research on the question of how pharmaceuticals are disposed. We are assisting the Eden Center, which studies environmental issues in Albania in the hopes of resolving them. This study is intended to understand what is currently happening in the city as a whole so that we can help, and we would be thankful for as much accurate information as you can provide.

If there are any questions that you do not want to answer, just let us know and we will move on to a different question. Before we begin the interview, do you have any questions for us?

Questionnaire:

- + Do we have permission to record this, can we quote you in our paper?
- + Who does your company distribute to?
- + What happens with expired drugs?
- + What is your interpretation of the law?
- + How did you find this information? Do you feel it was easily accessible?
- + Do you feel that the pharmacy should be responsible for contracting with a treatment company?
- + Who should be responsible for paying for the waste disposal?
- + How do you feel about the role of the government in this process?
- + Do you have any recommendations for the system in place?
 - + Can you think of anything important that we should know?

Interview with Treatment Company

Time: 9:00 AM Date: 12/12/16

Location: Medi-Tel Facility

Attendees: Eden Employee, Students, Medi-Tel Personnel Disclaimer: All Answers are translated from the original Albanian

Introduction:

We are American students doing research on the question of how pharmaceuticals are disposed. We are assisting the Eden Center, which studies environmental issues in Albania in the hopes of resolving them. We just wanted to let you know that what you tell us in the interview will be confidential, can be anonymous, and we are simply trying to collect data for our report. We will not identify you by name in any of the reports using any of the information obtained from this interview, and your confidentiality in this study will remain secure. This study is intended to understand what is currently happening in the city as a whole so that we can help, and we would be thankful for as much accurate information as you can provide.

If there are any questions that you do not want to answer, just let us know and we will move on to a different question. Before we begin the interview, do you have any questions for us?

Questionnaire:

- + Can we record this and use it our our report?
- + How many contracts do you have?
- + How many times do you pick up the waste?
- + How do you treat the waste?
- + Are you aware of the laws?
- + How is it with other companies? Is it competitive?
- + How do you market your company to get more contracts?
- + Do you have a register for the waste? Can we see it?
- + How much do you charge for this service?
- + Is there anything else you want to tell us?

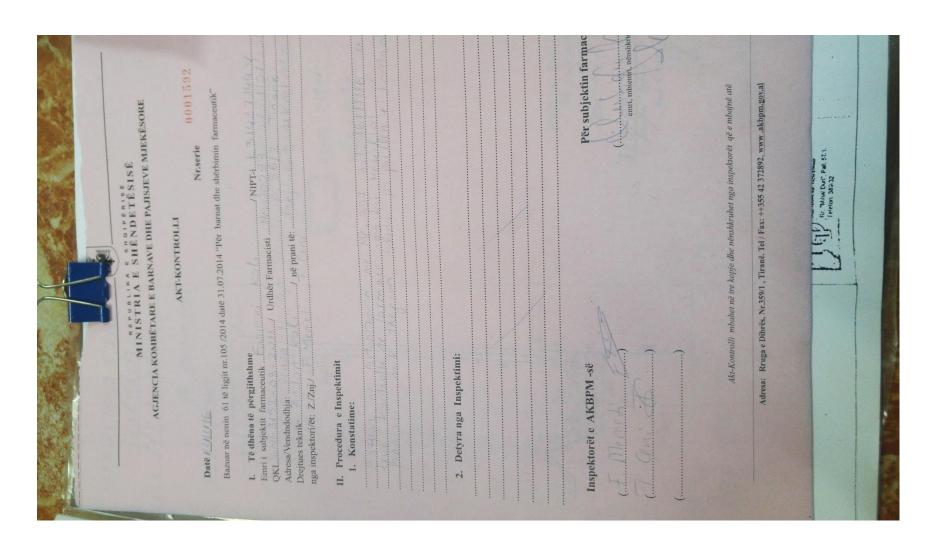


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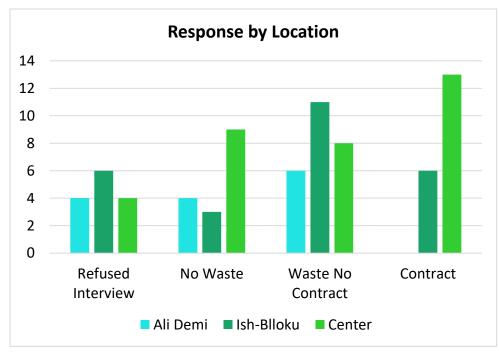
Pharmacy Contract



Appendix D

Detailed table of responses broken down by location and other factors

In addition to analyzing the interviews for themes and opinions from pharmacists, we sorted the data into relatively simple categories. The first of these was for those who refused to participate in our interview, which was shortened to *Refused Interview*. Next were those that claimed they did not produce any waste, or *No Waste*. All pharmacies we interviewed that claimed they did not produce any waste also said they did not have a contract. Some admitted to having waste but still did not have a contract, referred to as *Waste and No Contract* or *W/NC*. Finally, all those that had contracts also said they had waste, though in varying amounts, and were grouped into a final category of *Contract*. For quantifying purposes, these were given values of 0, 1, and 3 respectively, so that 'averages' as well as other data could be determined.



Code	Definition	Number of Pharmacies
FC	No treatment companies exist, or they were/are hard to find	11
Cost	Company cost too much money, cost could be an important factor in getting a contract	9
Trust	The pharmacy does not trust the treatment company	5
QKKB	This pharmacy had a contract with the QKKB	7
ET	This pharmacy had a contract with EuroTeam	3
Trash	Throws/ed expired drugs into the trash	6
Sewer	Flushes/ed expired drugs down the toilet	4
Manuf	Returns the drugs to their manufacturer	1
Depot	The drugs are given to drug depots or warehouses	2
Law	There (is) are no (enforcement of the) laws in place	11
Confused	They are confused about the laws in place or don't know anything about the law	21
Wrong	Believe they know the law/are following it when they don't/aren't	4
Info	Say they are (and appear to be) informed about the law	8
Small	If they mention that they are a small pharmacy	1
Little	Small amounts of expired drugs from the pharmacy	28
0	Would not speak to us	14
1	Denies producing waste	17

2	Produces waste but doesn't have a contract	24
3	Produces waste and has a contract	19
Angry	The pharmacists was dismissive, angry, no time, etc	16
New	The pharmacy was new, therefore won't have much waste or don't have their contract yet.	7
Help	They are interested in help, want more from government	13
Nohelp	Don't need anything/help	4
Nodif	We don't have any difficulties	6

Chart of Responses by Neighborhood

By Unit	Ali Demi = 14	Blloku = 26	Qendra = 34	Total = 74
Refused Interview	4 = 28.9%	6 = 23.1%	4 = 11.8%	14 = 18.9%
No Waste	4 = 28.9%	3 = 11.5%	9 = 26.5%	17 = 23%
W/NC	6 = 42.9%	11 = 42.3%	8 = 23.5%	25 = 33.8%
Contract	0 = 0%	6 = 23.1%	13 = 38.2%	19 = 25.7%

Appendix E

Busyness ranking



1: Busiest

This is a picture of a street in Qendra, it is very busy both in terms of foot traffic and motor traffic, which is why it received a 1 on our traffic level scale.



2:

This is a picture of Sami Frasheri in Ish-Blloku. This street receives a lot of foot and motor traffic, but not as much as others, so it received a 2 on our traffic level scale.



3:

This is a picture of a street in Ish-Blloku. This street is moderately sized with a moderate amount of traffic and was given a 3 by our traffic level scale.



4

This is a picture of a street in Ali-Demi. This street has small amount of traffic and received a 4 on our traffic level scale.



5: Quietest

This is a picture of a small side street in Ali-Demi. This street received very little to no foot and motor traffic, which is why it was given a 5 on our traffic level scale.

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