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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 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. In 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 operators, treatment operators and 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.
Chapter 2: Background

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 as it relates to our research there. 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 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 issues. 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 ppt and 1 ppb, can have toxic effects. Antibiotics are among the most common drugs found in the water supply. These drugs are particularly dangerous because they cannot kill bacteria in such low concentrations. Instead, they allow the bacteria to grow resistance, and any individual bacterium that has this resistance can transmit it to any of its fellow 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 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. Landfills used today are designed to contain household waste, not to prevent pharmaceutical waste from leaching out into the water supply. Frequently, specialized landfills are not used and the hazardous pharmaceutical runoff is allowed to escape which has negative implications on the environment.

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 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 below summarizes the pharmaceutical waste management methods as described above.

**Table 1: Pharmaceutical Waste Management Methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>Safety</th>
<th>Ease</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landfill</td>
<td>High possibility to leak into waterways</td>
<td>Easiest method</td>
<td>N/A</td>
</tr>
<tr>
<td>Returning to Original Source</td>
<td>Depends on the source and how they dispose of the pharmaceuticals</td>
<td>Can be difficult if pharmaceuticals are expired (most common) and must cross international borders</td>
<td>N/A</td>
</tr>
<tr>
<td>Incineration</td>
<td>Possibility for toxic gaseous by products</td>
<td>Access to able facilities is difficult</td>
<td>&gt;US $2.2/kg - US $4.1/kg</td>
</tr>
<tr>
<td>Encapsulation</td>
<td>Can handle all types of pharmaceuticals in both solid and liquid states</td>
<td>Can send to an encapsulating company or use a machine</td>
<td>Machines can be purchased to complete this task</td>
</tr>
</tbody>
</table>

(World Health)
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 1 on the following page from Smith (2002) shows a suggested system for pharmacies to use.

To simplify this process, 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 3  Recommended Pharmaceutical Waste Streams
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 Global Environment Fund, UNICEF, the World Health Organization, the CEE Bankwatch Network, and the American Embassy. In 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.

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 GDP can be found below.
Figure 4: Growth in the pharmaceutical industry of Albania
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; Mclsaac, 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. Self-medication is the act of using medication to treat common illnesses or health problems, and many people will self-medicate 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 self-medicated with antibiotics, which was correlated with responses that reported low and medium levels of education. Jorgji 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 State 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 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 write-offs 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-Bloku, the Center, and Ali Demi, located respectively in the south-central, central, and eastern sections of Tirana. There are at least 27 pharmacies located in Ish-Bloku, at least 34 in the Center, and at least 14 in Ali Demi. Ish-Bloku 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. This has allowed the pharmaceutical market to thrive in this region because people can afford to pay for the medications. The Center is the busiest part of Tirana, and it was expected therefore be more controlled than other areas. By comparison, Ali Demi is less central to the city of Tirana, and has somewhat less prosperous customers frequenting their pharmacies. However, 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), 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

1 In Albanian, Urdhri i Farmacisteve te Shqiperise
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. 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 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 to their regional environmental agency (For Hazardous Waste Management, Chapter 3 Article 8, 2006). The Ministry of Health established a public treatment company, the National Center for Drug Control2 (QKKB) to contract with some of these pharmacies, as well as performing other regulatory functions in the market. It monitors distributions, attempts to lower prices for consumers, 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 periodic 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 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

2 In Albanian, Qendra Kombëtare e Kontrollit të Barnave
been some scandals involving these waste removal companies. In 2015 the Euroteam 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 5 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 above shows there are often multiple ministries that control a single issue. In the case of pharmaceutical waste, both 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 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 and Medical Devices). Further, the National Environmental Agency\(^3\) 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). Further, a preliminary study conducted by the EDEN Center suggested that very few of the pharmacies they spoke to 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.

\(^3\) In Albanian, Agjencia Kombëtare e Mjedisit
Chapter 3: Methodology

The goal of our project was to assess how pharmacies in several neighborhoods of Tirana dispose of expired or unused medications and to identify possible causes of improper pharmaceutical waste management. This information will allow for the identification of viable solutions to improve pharmaceutical waste disposal practices and therefore reduce 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 particular how pharmacies dispose of expired or unused drugs within several neighborhoods in Tirana;
- Understand the challenges that are preventing proper pharmaceutical waste management;
- Gain a broader understanding of the stakeholders’ roles and perspectives for the pharmaceutical waste management system;
- Demonstrate the need for more information on the subject of pharmaceutical waste management;
3.1 Assessing the Current Practices in Albania

To meet our goal, we examined the practices of approximately 10% of the pharmacies in Tirana using a structured questionnaire with both closed and open ended questions. These different neighborhoods 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 regions that were wealthier would be more compliant than less wealthy areas because the pharmacies may 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 multi-method 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 and Likert scale 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, approximately, 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 was used to analyze the interview data from all three regions of Tirana. 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 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. In addition to the questionnaire, we developed a Likert scale to provide us more information about the common reasons for a pharmacy to not have a contract with a treatment company. This Likert scale can also be found in Appendix B.

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 the Ministry of Health, treatment companies, distributors, and warehouses. 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 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.

We conducted interviews with officials from the Ministry of Health. The Ministry of Health developed regulations regarding pharmaceutical waste management and is involved with their enforcement. The interviews consisted of questions including:

+ How do you enforce the laws regarding pharmaceutical waste?
+ Do you provide pharmacists with information about the regulations for proper pharmaceutical waste disposal or contact information for treatment companies?
+ Which treatment companies have you interacted with?

Further questions and procedures can be found in Appendix C. These responses were compared to the responses of the pharmacists and other stakeholders to identify the most important factors for disposal practices and the potential opportunities for improvement.

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 responses from the treatment companies 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 the Center, Ish-Blloku, and Ali Demi. 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.
Figure 6 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 7 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 8 below, and the highest percentage of pharmacies that refused to participate in the study were located here.

Figure 7: Sample Ali Demi Street

Figure 6: Ali Demi Pharmacy Locations and Traffic Levels

Figure 8: Responses in Ali Demi
As you can see in Figure 9 above, Ish-Bloku has 26 pharmacies that are spread out with some small clusters. Ish-Bloku is one of the wealthier areas within Tirana, with very busy streets. An average street in Ish-Bloku is shown in Figure 10. The responses received in Ish-Bloku were varied, as can be seen in Figure 11, but most pharmacists did not have a contract despite producing pharmaceutical waste.

Figure 9: Ish-Bloku Pharmacy Locations and Traffic Level

Figure 10: Sample Ish-Bloku Street

Figure 11: Responses in Ish-Bloku
The 34 pharmacies in the Center, shown in Figure 12, were located very close together. The Center is very popular with extremely busy streets. Figure 13 exemplifies the populated streets common in the Center. This area had the highest percentage of pharmacies with a contract, and the overall high level of compliance is visible in Figure 14.
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% pharmacists refused. There were a variety of explanations for their refusal in all of the districts we studied. A fair amount of pharmacists, primarily located in the Center, felt that they knew the law well enough and failed to see the necessity 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. Many pharmacists said that they are very careful with the amount that they order to make sure that waste is not produced. 58% of the pharmacies that were visited acknowledged that they did produce pharmaceutical waste. Of those pharmacies, many said that they only had a small amount of waste. Small was not used consistently though because there are no standards for amounts of waste and many different pharmacists had their own perceptions. The word “small” was used in many different contexts by the pharmacists. 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. The Center was the busiest, most interior area that we analyzed. While answers were varied, the Center 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. As the streets get busier the 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

<table>
<thead>
<tr>
<th>Responses by Traffic Level</th>
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</thead>
<tbody>
<tr>
<td>Refused Interview</td>
</tr>
<tr>
<td>Does Not Produce Waste</td>
</tr>
<tr>
<td>Produces Waste, Does Not Have a Contract</td>
</tr>
<tr>
<td>Produces Waste, Has a Contract</td>
</tr>
</tbody>
</table>

**Figure 15: Responses by Traffic Level**

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 groups of responses, 23% who 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 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 the majority of the insightful
responses we received. They had many different reasons for not using a treatment company and from these we have been able to better outline the flaws in the waste management system.

**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-Bllouk 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 for the establishment of a proper waste disposal 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 that was expressed to us by pharmacy owners. Concerns about cost may be a legitimate expression of their inability to pay, rather than a complaint. Most of these pharmacies are individually owned, which limits their capital resources. Further, the control of the wholesale price by the Ministry limits the flexibility in 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**

Finally one of the most surprising answers that we received was that a quarter of the pharmacists interviewed either could not find a treatment company or believed that none existed. This meant that they were incapable of following the regulations, assuming they wanted to. Additionally during our own extensive research we were completely unable to find contact information for 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 sort of contact information for these companies but we were not able to find much. If the treatment companies marketed themselves better, they could drastically increase their own business and reduce the amount of improperly disposed of waste.

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

“To get a contract I would have to call multiple ministries.”
4.4 How often does the inspector come?

It is difficult for the pharmacists to rely on a system that is not consistent.

During our interviews, we asked the pharmacists how frequently the inspectors came to the pharmacies. Many of the responses varied with the amount of times the inspector came per year. Table 2 below shows the frequency of inspector visits per year in 48 different pharmacies that we interviewed.

<table>
<thead>
<tr>
<th>Visits Per Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td># Pharmacies</td>
<td>11</td>
<td>17</td>
<td>9</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2: Frequency of Inspector Visits Per Year

The number of visits ranged between 0-12 times per year, but were still very inconsistent, with many pharmacists 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”. It is difficult for the pharmacists to rely on a system that is not consistent and does not send any notice. 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 3 below is a heat map that shows the relationship between the number of inspector visits to a pharmacy per year (ranked between 0 and 3+) and if the pharmacy has a contract and/or waste. This figure shows the correlation between the frequency with which the inspectors visit and the responses they provided about their disposal practices in the 48 pharmacies that responded to this question. Pharmacies that told us about their inspector visits either had a contract (Contract), did not have a contract but did admit to producing waste (Waste), or claimed they did not produce waste, and therefore did not have or need to have a contract (No Waste).

<table>
<thead>
<tr>
<th>Visits Per Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract</td>
<td>27%</td>
<td>17%</td>
<td>29%</td>
<td>60%</td>
</tr>
<tr>
<td>Waste</td>
<td>36%</td>
<td>60%</td>
<td>67%</td>
<td>20%</td>
</tr>
<tr>
<td>No Waste</td>
<td>36%</td>
<td>20%</td>
<td>14%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Table 3: Heat Map of Inspector Visits Correlated to Contracts and Waste

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 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.

“There is no one enforcing the laws so we have no need to follow them.”
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 a contract with a treatment company in order to dispose of the waste. Through all of our interviews, 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. 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 what they needed to be complying with. 21 out of the 74 pharmacists that were interviewed claimed that they were confused or lacked knowledge about the laws and regulations regarding pharmaceutical waste. All of these responses help us to understand the issues behind proper waste management.

“‘No one provides information about the laws and regulations.’”

While some pharmacists were aware that they did not know the laws, there were still some that 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, they do not completely understand the laws or they do not want to follow them.

4.6 What do you find challenging?

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

Ali Demi was 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 the Center were less interested in discussing the challenges they faced. Many did not feel the need to suggest any recommendations they had. Several expressed that they were well informed, well behaved, and thus did not need to speak to us further. In general, they seemed un receptive 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.

“We feel very uninformed about the laws”
Many pharmacists felt that the cost of disposing of pharmaceutical waste properly was a significant disincentive.

“We feel like we’re losing lots of money because we follow the law.”

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-Bllaku pharmacists 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. Some pharmacists suggested that the government should take the financial burden off of the pharmacies. 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.

“Heck Blloku pharmacists 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. Some pharmacists suggested that the government should take the financial burden off of the pharmacies. 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.

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

“The government is not here to help us.”

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 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.

“Pharmacists do not want to break the law, but are forced to by the cost of complying.”
Chapter 5: Recommendations

Improving Access to Information

The most prevalent issue that we found while completing this study 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. We have developed a pamphlet that can be found in Appendix * which could be distributed to pharmacists and pharmaceutical students. This would give pharmacists the information they need to effectively contract with a treatment company.

Improving Ministry of Health Controls

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 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 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 revealed many questions about the current system. While we have been able to outline major recommendations that will drastically improve the system as it currently stands, we recognize that more options could be identified and analyzed if more data was collected, perhaps on the pharmacies across Albania in addition to those in the capital city. 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.

Likert Scale

<table>
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<tr>
<th>Cost</th>
<th>In Favor</th>
<th>No Impact</th>
<th>Against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding Regulations</td>
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<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Finding Companies</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Company Reputation</td>
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<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Consequences of Not Having a Contract</td>
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<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Respect for the Law or Government</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Concern for the Environment</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix C

Interview with Ministry Official

Time
Date:
Location:
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:

+ How do you enforce the laws regarding pharmaceutical waste? How often are inspections conducted, and how often are sanctions given out?

+ Do you provide pharmacists with information about the regulations for proper pharmaceutical waste disposal or contact information for treatment companies? How do you help pharmacies that are newly established?

+ Which treatment companies have you interacted with? How do you regulate their actions?
Interview with Treatment Company

Time
Date:
Location:
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:

+ How many contracts do you have with pharmacies in Tirana? How many contracts could you potentially handle? Are you actively seeking out more contracts, until you are at capacity?

+ How much waste do you dispose of? How do you dispose of this waste?

+ How do you charge for this service? How do government subsidies factor into this?

+ How do you market your company to gain additional contracts?
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, 2 and 3 respectively, so that ‘averages’ as well as other data could be determined.

KeyWords and Tags
FC → No contracting companies exist, or they were/are hard to find
Cost → Company costs too much money, cost would be an important factor in a contract
Trust → Don’t trust the companies
QKKB → Have a contract with the QKKB
ET → Have a contract with EuroTeam
Trash → Throws/ed expired drugs into the trash
Sewer → Flushes/ed expired drugs down the toilet
Manf → Returns the drugs to their manufacturer
Depot → The drugs are given to drug depots or warehouses
Law → There (is) are no (enforcement of the) laws in place
Confused → They are confused about the laws in place or don’t know anything about the law
Wrong→ Believe they know the law/are following it when they don’t/aren’t
Info→ Say they are (and appear to be) informed about the law
Small → If they mention that they are a small pharmacy
Little → Small amounts of expired drugs from the pharmacy
0 → Would not speak to us
1 → Denies producing waste
2 → Produces waste but doesn’t have a contract
3 → Produces waste and has a contract
Angry → The pharmacists was dismissive, angry, no time, etc
New → The pharmacy was new, therefore won’t have much waste or don’t have their contract yet.
Help → are interested in help, want more from gov’t
Nohelp → Don’t need anything/help
Nodif → We don’t have any difficulties
<table>
<thead>
<tr>
<th>By Unit</th>
<th>Ali Demi = 14</th>
<th>Bbloku = 26</th>
<th>Center = 34</th>
<th>Total = 74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refused Interview</td>
<td>4 = 28.9%</td>
<td>6 = 23.1%</td>
<td>4 = 11.8%</td>
<td>14 = 18.9%</td>
</tr>
<tr>
<td>No Waste</td>
<td>4 = 28.9%</td>
<td>3 = 11.5%</td>
<td>9 = 26.5%</td>
<td>17 = 23%</td>
</tr>
<tr>
<td>W/NC</td>
<td>6 = 42.9%</td>
<td>11 = 42.3%</td>
<td>8 = 23.5%</td>
<td>25 = 33.8%</td>
</tr>
<tr>
<td>Contract</td>
<td>0 = 0%</td>
<td>6 = 23.1%</td>
<td>13 = 38.2%</td>
<td>19 = 25.7%</td>
</tr>
</tbody>
</table>
Works Cited


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