Regulatory Burden in Pharmacy Segment of Pharmaceutical Sector of Pakistan.

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CERTIFICATE

This is to certify that this thesis entitled: **"Regulatory burden in Pharmacy Segment of Pharmaceutical sector of Pakistan."** submitted by Shaheryar Ahmad is accepted in its present form by the PIDE School of Social Sciences, Pakistan Institute of Development Economics (PIDE), Islamabad as satisfying the requirements for partial fulfillment of the degree in Master of Philosophy in Public Policy.

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I Shaheryar Ahmad hereby state that my MPhil thesis titled Regulatory Burden in Pharmacy Segment of Pharmaceutical Sector of Pakistan is my own work and has not been submitted previously by me for taking any degree from Pakistan Institute of Development Economics or anywhere else in the country/world.

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ABSTRACT

For decades, Pakistan has experienced an increasingly burdensome regulatory environment, transforming the economy into a "permission economy" marked by excessive and inefficient regulations. This regulatory burden has had detrimental effects on various economic activities, like investment, and overall GDP growth. The prevailing regulatory regime in Pakistan represents a classic case of regulatory failure, as the government attempts to address this issue by implementing more regulations without thoroughly evaluating the underlying causes. Consequently, various regulatory bodies have emerged, often with overlapping functions, thereby exacerbating the regulatory burden on different sectors of the economy. This study aims to explore the specific regulatory burden faced by the pharmacy segment within the pharmaceutical sector of Pakistan. Its primary objective is to measure the costs associated with regulation that individual entities operating within the healthcare sector bear. These costs include the expenses related to learning and understanding regulatory requirements, compliance efforts, as well as the psychological impact of navigating the complex regulatory landscape when establishing and operating a pharmacy. Furthermore, the study seeks to examine the implications of this regulatory burden on GDP growth. To achieve these objectives, the study relies on primary data collected from the Islamabad Capital Territory (ICT), providing a focused and localized perspective on the regulatory burden within the pharmacy segment. The findings of this study will contribute to the existing body of knowledge on the regulatory burden and its implications for the pharmacy segment in the pharmaceutical sector of Pakistan. By quantifying the costs associated with regulation and exploring its impact on GDP growth, policymakers and regulatory authorities can gain valuable insights to inform evidence-based decision-making. Furthermore, the study may provide recommendations for streamlining and rationalizing the regulatory framework, thereby fostering a more conducive environment for pharmacy businesses and promoting sustainable economic growth in the pharmaceutical sector of Pakistan.

Keywords: regulatory burden, pharmacy segment, pharmaceutical sector, Pakistan, GDP growth, compliance costs, learning costs, psychological costs, regulatory failure, permission economy

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List of Abbreviation:

API - Active Pharmaceutical Ingredient

C&P - Costing & Pricing

CNIC - Computerized National Identity Card

DHO - District Health Office

DRAP - Drug Regulatory Authority of Pakistan

FBR - Federal Board of Revenue

FDI - Foreign Direct Investment

FPP - Finished Pharmaceutical Product

GDP - Gross Domestic Product

GDP - Gross Domestic Product

IBCC - Inter Board Committee of Chairmen

IHRA - Islamabad Healthcare Regulatory Authority

MD&MC - Medical Devices & Medicated Cosmetics

MIS - Management Information System

NOC - No-Objection Certificate

NTN - National Tax Number

OECD - Organization for Economic Co-operation and Development

PCDA - Pakistan Council of Drug Approval

PDRA - Pharmaceutical Drug Regulatory Act

PE&R - Pharmaceuticals Evaluation & Registration

PIDE - Pakistan Institute of Development Economics

QA&LT - Quality Assurance & Laboratory Testing

SMEs - Small and Medium-sized Enterprises

U.S.A. - United States of America

VAT - Value Added Tax

Chapter 1

Introduction.

The pharmaceutical sector plays a critical role in ensuring that vital medicines, especially life-saving medicines, are available and affordable, thus ensuring overall health and wellbeing. In countries like Pakistan, where access to affordable medical care and pharmaceuticals is still a challenge, pharmacies are crucial points of contact between the public and healthcare experts. The pharmaceutical sector in Pakistan, however, faces a variety of regulatory challenges and inefficiencies that restrict its ability to effectively carry out its vital function. Lack of effective regulatory organizations, weak regulatory frameworks, and the accumulation of unnecessary laws have all led to a situation where it is difficult to get affordable, effective, and safe medicinal products (Tauqeer et al., 2019). The expense incurred due to these regulatory issues therefore impacts not just pharmacies but also the overall healthcare system, which has an impact on the availability and caliber of healthcare services and products. Understanding and addressing these regulatory issues is crucial to the proper operation of the pharmaceutical sector and the advancement of Pakistan's healthcare system as a whole. Being an important part of this equation in terms of providing much needed drugs and other pharmaceutical products, it is critical to investigate and explore the regulatory burden faced by pharmacies in Pakistan and its implications for the healthcare system in order to offer insights and recommendations for regulatory reforms that can, in turn, better working of pharmacies and improved access to healthcare services for all people.

1.1 Background:

The ability of a country’s citizens to preserve their own health is a fundamental right that must be given top priority in any society. Access to affordable medicines and high-quality healthcare services is crucial for preserving peoples' welfare and quality of life on an international scale. Pharmacies serve a significant role in the healthcare system by serving as the first point of contact for consumers searching for medications and expert advice on their healthcare needs.

The study bears great importance within the specific context of the pharmaceutical business in Pakistan. This study aims to elucidate the concealed challenges that pharmacists in the nation contend with as a result of intricate regulatory frameworks. The aforementioned burdens, which include expenses associated with compliance, knowledge, and psychology, have frequently been disregarded in scholarly discourse. The primary objective of this study is to provide a comprehensive understanding of the complexities involved in this phenomenon and analyze its

potential consequences. Moreover, this study aims to fill a significant need in the current body of literature, as there is a dearth of research that has extensively examined the particular regulatory obstacles encountered by pharmacies operating in Pakistan. This study explores unexplored areas by utilizing extensive approaches, such as surveys and interviews with pharmacy owners and operators, with the objective of revealing the complete scope of regulatory burden. It is imperative to acknowledge that this study distinguishes itself by its distinctive methodology in estimating these expenses, so making a substantial contribution to our comprehension of the healthcare regulatory environment.

Similar to many developing countries, Pakistan faces significant challenges in ensuring access to affordable pharmaceuticals and basic healthcare services. Due to Pakistan's steadily rising healthcare prices, a significant tion of the population finds it difficult to pay for required medications and treatments (Khalil et al., 2017). According to the World Bank, out-of-pocket medical costs in Pakistan accounted for more than 78% of all healthcare spending in 2018, placing a heavy financial burden on both individuals and families (Sirag & Mohamed Nor, 2021).

It has also been more challenging for citizens to access high-quality healthcare due to Pakistan's badly run public health facilities. The public health infrastructure's hospitals and clinics regularly struggle with funding, staffing, and maintenance issues (Basu et al., 2012). As a result, there is a reliance on private pharmacies and healthcare providers, and both the quality and accessibility of healthcare services are compromised.

In Pakistan, the pharmaceutical business has additional regulatory challenges that affect how effectively and efficiently it runs. The difficulties a business faces due to regulations might be in terms of the supply and demand of medications. In terms of the supply of medicines, these difficulties can include medicine shortages caused by manufacturing issues, a lack of raw materials, logistical issues, and business issues. Businesses also face issues with demand as a result of regulations, such as higher product demand, seasonal demand, and unpredictable customer demand (Shukar et al., 2021). Without adequate monitoring, low-quality and counterfeit drugs may pose major risks to the public's health.

The impact of regulatory frameworks on Pakistan's pharmacy business has received little attention from researchers, despite the critical role that laws play in preserving the efficacy, affordability, and quality of drugs. The regulatory challenges that pharmacists face and their effects on the country's pharmacy system have not been properly studied by many research.

The primary objective of this study is not alone to reveal the regulatory burdens, but also to make a significant contribution to the current body of knowledge. This study assesses the monetary worth of the constraints imposed by the complex network of licenses, permissions, and approvals that Pakistani pharmacies are obligated to navigate. Previous studies have noticeably lacked a comprehensive analysis of this nature. This study has the potential to serve as a fundamental contribution to the comprehension of regulatory burden within the pharmaceutical industry of Pakistan, providing policymakers, regulators, and other relevant stakeholders with significant perspectives. The aforementioned insights possess the capacity to stimulate regulatory reforms, optimize the regulatory landscape, and ultimately augment the efficiency of the healthcare system. Furthermore, this research extends beyond the confines of theory by examining practical ramifications. Through the process of cost calculation, a comprehensive understanding may be gained regarding the implications of these restrictions on pharmacy owners and the broader healthcare sector. The utilization of an empirical technique in this study results in distinct perspectives and conclusions, which serve to differentiate it and surely contribute to the ongoing dialogue surrounding healthcare regulation in Pakistan.

1.2 Importance of Regulations

Regulations play a crucial role in establishing the business environment and ensuring the smooth functioning of various industries, including the pharmaceutical industry. They seek to ensure a fair and competitive market, protect the health and safety of the general public, and correct market flaws. In this section, we'll go more deeply into the relevance of regulations and how they affect Pakistan's pharmacy sector.

1. Maintaining Viable Business Climate: Regulations aim to provide a supportive corporate environment by outlawing unfair practices, price rises, and monopolistic behavior. They ensure that businesses operate in an equitable environment, promote healthy competition, and protect customers from unfair practices. Regulations are also put in place to ensure that businesses transmit the benefits of windfall revenues along to customers or taxpayers. This helps maintain the cost and availability of essential medicines and reduces the likelihood of excessive price increases (Baldwin et al., 2012).
2. Effective Marketing Operations: By setting standards for pharmaceutical product labeling, packaging, and advertising, regulations help effective marketing operations. These recommendations ensure that accurate information is provided to consumers so they may make informed decisions about their healthcare (Martin et al., 2018).

3. Information Accessibility in Markets: Regulations are crucial to ensure that reliable and accurate information is readily available in markets. This helps clients make educated decisions and encourages transparency and confidence in the pharmacy and pharmaceutical business (Oxman et al., 2009).
4. Effective Allocation of Limited Resources: Regulations assist in ensuring the availability and distribution of essential medicines, among other limited resources, in an efficient manner. They defend reasonable pricing, prevent hoarding, and deal with supply shortages (Tanveer et al., 2020).
5. Safeguarding Future Generations' Interests: Regulations are required to protect future generations' interests, particularly environmental sustainability. They created standards for the management of waste, the prevention of contamination, and the use of sustainable manufacturing techniques in the medicine business (Ekeli, 2015).
6. Promoting Justice, Social Policy, and Planning: Regulations are a means of advancing justice, social policy, and planning in the healthcare sector. They enable fair access to healthcare services, promote public health initiatives, and close socioeconomic gaps in healthcare delivery (Gostin, 2000).

1.3 Inefficient regulations and Regulatory Burden:

If regulations are properly implemented, they significantly contribute to achieving desired policy objectives. The regulatory consequences in the majority of the nations, however, have been somewhat lackluster. This regulatory failure leads to an overregulation of the market since more regulations are required to remedy it (Hagger et al., 2009). The main cause of the failure is that regulators frequently do not have access to data on the cost and demand structure of a sector, which is essential for economic regulation. Second, producers find it very difficult to follow the complex and technical requirements established by the appropriate bodies. Third, occasionally laws are used to impact individual gains rather than to correct market failure. It is plain to see that these limitations might wind up impeding efforts to achieve the same level of economic and social development for which they were designed. These kinds of regulations ought to be abolished in a perfect society since they hinder trade, investment, and economic efficiency or protect certain interests from rivals (Kemal, 2002).

These ineffective and futile policies may have such high hidden costs that the entire economy may suffer if they are not modified. Overregulation that is ineffective comes with a price in the form of regulatory burden in the form of compliance costs, information costs, and

psychological costs. To stimulate innovation, drive competition, cut costs, and boost global market competitiveness, regulations must be altered (Kemal, 2002).

The argument that excessive regulation chokes off any system rather than ensuring effective operation is supported by this. The same is true for the health sector in Pakistan; studies on the regulatory burden in this industry were conducted by the Pakistan Institute of Development Economics (PIDE Sludge Audit vol 1). According to these studies, the costs of establishing a pharmaceutical unit, a private diagnostic center, and a pharmacy, respectively, total 10.3%, 49.15%, 36.3%, and 46.5% of the total project value. Unnecessary restrictions and administrative hurdles hinder Pakistan's healthcare sector. The regulatory complexity involved with building and running pharmacies, pharmaceutical units, private diagnostic centers, and other healthcare institutions dramatically raises project costs. PIDE has previously examined the regulatory burden in the healthcare sector and shown how it impacts project costs and overall effectiveness.

This research aims to investigate the regulatory load that Pakistani pharmacies must endure in greater detail. The licenses, registrations, no-objection certificates (NOCs), and permissions required for the establishment and operation of a pharmacy will be specifically covered. By analyzing the particular regulatory challenges and their effects, this research seeks to provide light on the importance of regulatory reforms in the pharmaceutical sector. The results will further our understanding of Pakistani healthcare legislation and offer policymakers, regulators, and other interested parties suggestions for enhancing the efficiency of the healthcare system and streamlining the regulatory environment.

1.4 Statement of Problem:

Pakistan has become a "permission economy" due to over and inefficient regulations. This regulatory burden has suppressed economic activities, investment, and ultimately GDP growth. The regulatory regime of Pakistan is a classic case of regulatory failure, and the government is trying to address this failure by making more regulations without assessing the underlying reasons. Resultantly, each sector of the economy has been regulated by multiple regulatory bodies with overlapping functions (Haque, 2022). The proposed study intends to explore the regulatory regime of a particular segment of the pharmaceutical sector; Pharmacy. The purpose of the research is to measure the cost of regulation that an individual entity, operating in the pharmacy sector, bears in the form of learning, compliance, and psychological costs. To achieve this objective, the study aims to bring forward evidence based on primary data from surveys trough the registered pharmacies.

1.5 Research Problem:

Based on the narrative of statement of problem as stated in the preceding text I am narrowing my research problem into "Regulatory Burden in Pharmacy Segment of Pharmaceutical Sector of Pakistan". My topic is further bifurcated into following research questions and objectives.

1.6 Research Question:

- How much overall regulatory burden is faced by the business in starting and running pharmacies of Pakistan?
- What is the information cost, and psychological cost of regulatory burden in starting and running a pharmacy in Pakistan?

1.7 Objective:

The objective of the research is to calculate a monetary value of the existing regulatory burden caused in terms of obtaining licenses, permissions, and approvals from concerned health regulatory authority like District Health Office (DHO), Islamabad Healthcare Regulatory Authority (IHRA), Federal Board of Revenue (FBR), and other involved directly and indirectly.

1.8 Thesis Structure:

The regulatory burden experienced by pharmacies in Pakistan's pharmaceutical industry is thoroughly investigated in this thesis, which is divided into a number of parts.

- The background of the study was explained in detail in Chapter 1 (Introduction), which also identifies the many challenges to guaranteeing that people have access to affordable medications and high-quality healthcare services. It emphasizes the significant role that regulations play in the pharmaceutical business and investigates the concept of regulatory burden, shedding light on its complex effects on healthcare service.
- The literature review in Chapter 2 has an overview of the existing research, examining global perspectives on the regulatory burden in the healthcare sector and focusing in particular on the unique challenges encountered by pharmacies in Pakistan. It looks at the adverse effects of regulatory burden on businesses and healthcare provision in general.
- A thorough review of the data collection techniques, such as surveys and interviews with pharmacy owners and operators, is provided in Chapter 3's methodology section. Additionally, it describes the chosen research approach. In addition, it explains data analysis procedures, how samples are selected, as well as the ethical concerns surrounding the research, and explains the methodology that was employed.

- Chapter 4's in-depth analysis of Pakistan's past drug legislation analyzes the development of important drug regulations and the modifications made to them through time. The chapter examines the impact of these acts on pharmaceutical regulations and provides details on the duties of the regulatory bodies in charge of enforcing them.
- Chapter 5 offers a comprehensive breakdown of how to open a pharmacy in Pakistan. The necessary licenses and regulatory body approvals, as well as other conditions for licensing and registration, are discussed. The procedures for establishing and operating a pharmacy are detailed, along with the paperwork and compliance needs. The challenges and obstacles faced are mentioned, emphasizing the heavy regulatory burden pharmacy operators face.
- There are two sections in Chapter 6's Findings and Conclusions. Section 1 provides a calculation of the entire regulatory burden that firms in Pakistan's "pharmacy segment" must endure to be in compliance with the law in order to create and run a pharmacy. The second section of the chapter examines the information cost, psychological cost, and cost to GDP resulting from regulatory burden on Pakistan's pharmaceutical industry.
- The research's findings are summed up in Chapter 7's conclusion and suggestions, which emphasize the consequences of regulatory burden on the pharmacy sector of Pakistan's pharmaceutical business. The report provides policy recommendations for regulatory improvements based on its results in an effort to reduce the burdensome regulatory environment that pharmacies must operate in and raise the accessibility and affordability of healthcare services.

Chapter 2

Literature Review:

Regulations are rules and administrative codes issued by governmental agencies at all levels, municipal, county, state and federal (Aragòn, Marcus, & Vogel. 2020). Even though they are not laws, regulations have the force of law because they are established under the power provided by statutes, and they frequently carry consequences for infractions. This gives rules, even those that are not laws, the weight of the law.

A set of laws, rules, and policies enacted by the government and implemented by a specific institution with the intention of maintaining social order constitutes a regulation. According to Hazen (1991), excessive regulation deters investors from making long-term decisions in volatile and unpredictable markets. Excessive regulation has created an environment where it is hard to forecast what will be demanded of people and when, making it challenging to plan well for either a personal or professional life. Because of this, people frequently choose to live a sedentary lifestyle and pass quick judgements over making sure investments in their futures.

2.1 Effects of Over Regulations

Overregulation may have a negative impact on the business environment and ease of doing business in a variety of ways. Despite the fact that regulations are crucial for consumer protection, sustaining fair competition, and safeguarding the public interest, too strict laws can hamper economic growth and provide challenges for businesses. The following are a few effects of overregulation:

- Rising costs of compliance: Overregulation usually creates a complex web of rules that businesses must adhere to. This might result in greater administrative and legal costs for businesses, especially small and medium-sized enterprises (SMEs) who lack the resources to manage complicated regulatory frameworks. Studies have shown that compliance costs may divert funds from initiatives to promote innovation, expansion, or job creation (Stewart, 1981).
- Less entrepreneurship and innovation: According to van Waarden (2001), restrictive rules may discourage entrepreneurship and innovation by encouraging a culture of risk aversion. When faced with onerous regulatory constraints, businesses find it difficult to experiment with new ideas, products, or services because they may have to pay high compliance costs or undergo drawn-out approval processes (Wang & Wang, 2021) . This limits opportunities for economic expansion, the creation of new jobs, and innovation.

- Barriers to entry into the market: According to Aidis et al. (2010), excessive regulation might make it difficult for new and smaller enterprises to enter the market. Complying with complicated regulations and licensing requirements may take a lot of time and money, which discourages new businesses from entering the market. Customers may have fewer alternatives and less competition as a result.
- Delays in decision-making and bureaucratic inefficiencies: Too many regulations can cause delays in decision-making and bureaucratic inefficiencies. The survey found that businesses could have delays in obtaining licenses, permits, or approvals, which might impede their operations and expansion plans. Burdensome bureaucratic procedures can hinder international trade and deter foreign direct investment (Kurer, 1993).
- Discrimination and favoritism: According to Cross (1998), overregulation may lead to a concentration of power and influence in the hands of a select few big businesses or niche interest groups. If they have the resources and lobbying expertise to do so, they might be able to affect rules in a way that benefits their own interests, leveling the playing field. Less competition, a slower-moving market, and continuing economic imbalance might ensue as a result (Van den Huevel, 2008).
- Reduced foreign investment: Excessive regulations may deter foreign investors from establishing businesses abroad or expanding their current operations there. Investors seek out circumstances in which their interests are safeguarded by clear and predictable rules. Overregulation can make the business climate less attractive to foreign investment by raising risk and uncertainty. This may prevent prospective job chances and economic progress, according to Rose-Ackerman and Tobin (2005).
- Slowed economic growth: Generally speaking, excessive regulation can slow down economic growth by restricting business expansion, reducing productivity, and deterring investment. It may reduce employment opportunities, obstruct the growth of new businesses, and reduce overall economic output.
- Inconsistency: This refers to regulations that are unclear, not applied consistently, or not clearly, and about which interpretations regulators may even differ. As a result, agencies typically lack knowledge of the actions performed by the other (OECD, 2002), which prevents them from being consistent with one another. Businesses may encounter unanticipated issues if they incorrectly think a rule is less strict than it actually is (or vice versa). It can be challenging to assess if a company's operations are legitimate wherever it conducts business since regulations differ between countries and industries.

This highlights the need for a balanced regulatory structure to provide consumer protection and preserve the general welfare. The goal should be to strike a balance between regulating and supporting an environment that is business-friendly and promotes innovation, entrepreneurship, and economic growth.

2.2 Regulatory Burden

Regulatory burden refers to the costs and challenges that businesses face while trying to comply with the law. It covers the costs of administration, compliance, knowledge, and emotional support. Overly onerous or inadequate regulations may impede business operations and economic growth (Chittenden et al., 2002). The impact of regulatory burden on market efficiency, innovation, and competitiveness is a subject that politicians and academics are becoming increasingly interested in.

The costs and challenges businesses have as a result of complying with laws and regulations are referred to as the regulatory burden. These costs may be divided into three groups: administrative and compliance costs, information costs, and psychological costs. Excessive or inefficient rules can seriously restrict business operations, which can therefore limit economic advancement (Van den Huevel, 2008). Excessive or inadequate regulations may hurt businesses and the economy by, among other things, restricting innovation, discouraging investment, and stifling market competition. Administrative costs are the expenditures required to fulfill the administrative requirements imposed by regulations. These costs may include the labor and supplies necessary for filing, keeping records, reporting, and other administrative tasks (Gyourko, Saiz, & Summer, 2008). Compliance expenses are the expenditures incurred by businesses to ensure that legal requirements are met. This includes the costs associated with establishing and maintaining the systems, processes, and procedures necessary to adhere to regulations. Compliance costs refer to the expenditures incurred by businesses to ensure that their operations comply with regulatory requirements. It will cost money to invest in systems, equipment, specialists, training, and other resources to pay for these costs. Compliance costs may be particularly onerous for small and medium-sized firms (SMEs) with limited resources and expertise. Information costs are the expenses charged by businesses for obtaining and disseminating knowledge about regulatory obligations. These costs may cover things like the time and resources necessary to go through and interpret complex laws, speak with a lawyer, and stay up to date on legislative changes. Information costs are the expenses businesses make to get, understand, and keep up with regulatory information and changes. This includes the cost of researching legislation, hiring legal counsel, and understanding intricate rules and regulations.

For businesses, operating may be made even more challenging by a lack of access to accurate and timely regulatory information. Psychological costs are a representation of the strain, uncertainty, and anxiety company owners and managers have when navigating complex regulatory frameworks and the fear of non-compliance fines. Regulations may cause businesses to face non-financial challenges, such as psychological costs (Sprinkle & Maines, 2010). These costs could include the stress, worry, and difficulty that business owners and employees experience as they try to comply with a number of rules, deal with regulatory uncertainty, or worry about being fined for non-compliance (Chittenden wt al., 2002).

All of the above mentioned costs, as well as breakdown of various categories of costs, are summarized in the following table-

Term	Definition
Administrative Costs (in the U.S.A. these are usually referred to as Process Costs)	Administrative Costs relate to the paperwork burdens imposed on the administrative structures of a business as a result of a regulation. These are necessarily carried out in order to comply with the requirements of a specific regulation. For example labor and time costs of preparing VAT and Income Tax Returns
Indirect Costs	Indirect Costs are not linked with actual compliance costs but are seen as being indirectly related to the purpose of the regulation. For example psychological and opportunity costs; positive/negative impacts on competitiveness and net cash-flow benefits
Recurring Costs	These are regarded as continuous costs of meeting regulatory requirements.
Non Recurring Costs	Non-recurring costs can be referred to as temporary or one-off costs. For example the initial cost of learning about a specific regulation

Fixed Costs	Fixed costs are the costs of maintaining the systems or knowledge or equipment needed to comply with a regulation. They will not vary with the volume of products or employees. For example every company must have a standard contract of employment regardless of whether they are employing 10 or 100 staff
Variable Costs	Variable costs increase or decrease with the number of employees, products or volume of output covered by the regulation. For example, the number of safety guards on equipment will vary with the number of machines in the plant.

2.3 Methods for estimating the impact of regulations

There are several methods that may be used to assess the implications of regulations. Cost-benefit analysis is the method that is most often used (Froud et al. 1998; Pearce 1998).

• Cost-benefit analysis: looks at trade-offs between a policy's costs and benefits. This technique is seen as being very crucial for enhancing regulatory analyses. The apparent difficulty in identifying and quantifying the costs and benefits of rules has drawn criticism, nevertheless (Hahn 1999; Kenneth et al 1996; Moyle 1999; Morrison et al 1998). Despite this critique, proponents of cost-benefit analysis contend that it is the finest method currently available for guiding policy choices and enhancing economic efficiency (Pearce 1998; Lutter 2000; Hahn 1998; Hahn and Litan 1998).

Five broad ways to assessing the costs of regulation are described by Hahn and Hird (1991).

- When measuring the cost of regulation change, econometric studies frequently measure output markets directly or using production and cost functions. Econometric studies have the potential to be very effective at assessing the effects of legislation. The fact that significant volumes of data are needed to do the statistical computations is, however, one of their drawbacks.

- Expenditure evaluations: These methods often depend on company survey data to calculate compliance costs. Even while these polls offer measurable data, there are a few issues. First, responder biases, such as when a company inflates prices in an effort to sway legislators to seek regulatory relief. Second, it is impossible to provide a counterfactual. For instance, an automaker may decide to install stronger bumpers in response to consumer demand without being compelled to do so by law. The effect of the legislation would be overstated if the whole cost of such bumpers were taken into account.
- Engineering methods: calculate the price of installing equipment directly to abide by a requirement. This method, however, does not account for modifications that could be brought about by a legislation, such as modifications in customer preferences. Customers could, for instance, favor vehicles with superior safety measures (such as bumpers with more strength). Although rules may speed the adoption of certain safety elements, it would be improper to permanently ascribe the installation's cost to regulations. Engineering studies may therefore be unsuccessful in establishing the counterfactual, much like spending evaluations.
- Studies on productivity: calculate the difference between productivity changes that have been seen throughout time and those that would have happened in the absence of regulations.
- General equilibrium models are used to analyze how a perfectly competitive market reacts to new regulations or policies, such as changes in production or employment levels. This strategy needs a lot of data, but it could give a better picture of the consequences of regulation.

The Standard Cost Model (SCM), created by the Netherlands, is one of the earliest approaches for calculating the administrative costs on businesses. The SCM calculates the administrative expenses that central government regulation places on company. Business interviews are the main method used to assess expenses. These interviews produce data and allow for the precise specification of the amount of time and resources that businesses spend adhering to regulations. Information duties, data needs, and administrative operations are broken down into separate, measurable components by the SCM. The SCM then calculates the costs of these components based on three cost parameters: 1) price, which includes a tariff, wage costs and overhead for administrative tasks performed internally, or hourly costs for external services; 2) time, which includes the amount of time needed to complete the administrative task; and 3) quantity, which includes the number of businesses affected by the activity and how often it must be performed each year. These components work together to construct the fundamental SCM formula, which

is: Price x Time x Quantity equals cost per administrative action. (Chittenden, Kauser, & Panikkos, 2002)

The SCM was first used by the Netherlands at the end of 2002 to gauge the full degree of business pressures. At the end of 2002, the expected total administrative costs reached €16.4 billion (3.6% of the Dutch GDP). More than three-quarters of the administrative constraints on company are imposed by the ministries of finance, health and social affairs, and justice. Early in 2006, Denmark finished calculating the baseline for all administrative burdens. All business-related regulations in 16 different ministries are measured as part of the baseline measurement.

The rationale behind using standard cost model was that the purpose of the research was to find the cost of doing business in term of regulations and their compliance. The econometric studies measure from the production perspective, engineering methods measures the cost of installing regulation from the perspective of regulator, productivity study measure only the productivity of the industry before and after certain regulations and the general equilibrium model looks at overall economy wise effect of regulation. The best suited methodology for the study is SCM because it measures the cost of regulation on businesses in term of information, administration and compliance to fulfill regulatory obligations

Many European nations have embraced the SCM because it enables the identification of regulatory simplification opportunities, for example through benchmark studies comparing nations using the same approach. The joint benchmark's main objective was to examine how EU law is implemented at the national level and evaluate the outcomes in terms of administrative costs. The most effective means to apply European regulations may then be determined by comparing national systems. Intriguing alternatives for streamlining European regulations can also be found in measuring administrative burdens. In terms of administrative burdens, Denmark, the Netherlands, Sweden, and Norway finished the first international benchmarking exercise on VAT in 2005. The benchmark examined a number of EU VAT laws, their application at the national level, and the amount of administrative work they entail. In addition, the OECD began a benchmarking study in 2006 that will examine the international transport regulations in various OECD nations (Helm, 2006).

2.4 Over regulations in Pakistan's health care system

The goal of welfare is used as justification for enforced regulations according to official statistics, efforts to help the poor and ensure affordability through rules like price control have failed. Despite a price freeze from 2001 to 2013, the price has climbed by nearly 50% in 2018 in comparison to the 2000s. Instead, the price regulation has resulted in shortages, low FDI, and

inferior quality products (Mehmood, 2022). Drug shortages, especially, are quiet debilitating as they can increase risks to lives. A recent PIDE paper ("Welfare impact of Generic Drug Shortages in Pakistan.") calculated the monetary cost of drug shortages based on 50 life-saving drugs that experience persistent shortages. It estimated the price to be 80 million Rupees, paid by the consumer All of this is a result of government regulations put in place under the guise of welfare but which are ineffective and are undermining Pakistan's pharmaceutical sector. Imagine the effects of all the burdensome rules that are ineffective and ineffectively regulate prices.

The number of regulations that apply to a particular industry is one of the most crucial variables in determining the regulatory burden. The burden of regulations will increase as there are more restrictions. The complexity of the regulatory framework has an impact on the regulatory burden. A company may have to work with several regulatory bodies, each of which has its own regulations and processes for obtaining licenses or permits. This raises transaction costs for both businesses and customers. in 2009 (Younis et al.). Complexity is another element that affects regulatory burden. Some businesses have to face complicated regulations because they need for specific knowledge and technical competence from regulators, who may not necessarily possess these qualities themselves. This may cause exorbitant delays, which raise the cost of compliance for businesses subject to the requirements. The frequency of change also has a significant impact on this because it raises the transaction costs associated with preparing applications and adhering to new requirements without any assurance that they won't change again soon after. Frequent changes increase uncertainty about what actions will be required of you next. The following examples show how the entire cost of healthcare is significantly impacted by the reduction in regulatory load in Pakistan's healthcare system:

The pharmaceutical industry in Pakistan has been subject to various studies, revealing several challenges and issues. Mahmood (2022) argued that pharmaceutical regulation, such as freezing drug prices for 'welfare' purposes, adversely affects Foreign Direct Investment (FDI) and leads to price increases and drug shortages. Third World Network Briefing (2001) highlighted the problems of costly imported medications and the presence of a black market, examining the impact of government-mandated quotas on drug supply. The Network for Consumer Protection (2006) found that essential pharmaceuticals were often unavailable at public sector pharmacies. Additionally, the primary regulator, DRAP, and pricing policies were implicated in the growth of illicit markets, hoarding, and rent-seeking (Rashid, 2015). Khan & Mushtaq (2019) investigated tort laws related to harm caused by poor medicine and found them inadequate in reach and applicability. Zaidi et al. (2013) analyzed industry returns over ten years and attributed

poor performance to regulatory limitations, suggesting that more liberal rules could have improved the industry's performance.

These studies underscore significant issues with Pakistan's excessively regulated "regulatory framework" in both general and pharmaceutical-specific contexts, rendering the market ineffective. Therefore, further in-depth research is needed, particularly focusing on the pharmacy sector and the impact of regulations. To address these concerns, it is essential to examine the regulatory burden and identify and eliminate ineffective rules. The health industry in Pakistan would attract pharmaceutical firms' investment if we lessen regulatory burden. Reducing regulations governing medication registration and pricing, boosting market competitiveness, and raising public knowledge of safety concerns with pharmaceuticals and biomedical devices are all ways to lessen the regulatory load on the health industry. The government's and its agencies' determination to lighten the regulatory burden on the pharmaceutical sector, which will enable them to conduct business without difficulty or hindrance, is the most crucial aspect in this. The pharmaceutical sector in Pakistan is very controlled. This particular point was raised by a webinar series on the pharmaceutical sector, which noted that nothing in the industry can be created without first receiving clearance from the Drug Regulatory Authority Pakistan (DRAP). Regulatory compliances induced by DRAP for production, manufacturing, and licensing have also been the subject of several other research, although they still need to be examined in order to determine how the regulations would impact the local pharmaceutical market at the community level.

A heavy regulatory burden in Pakistan limits the expansion and efficiency of the in various segments of pharmaceutical industry including pharmacy market (Mahmood, 2022). Excessive restrictions have been connected to rising costs, shortages of necessary medications, and low foreign direct investment (FDI). Comprehensive study that focuses especially on the regulatory load in the pharmacy market is urgently needed to solve these issues of pharmacy market where a very less attention has been given by researchers and policy makers. Policymakers and stakeholders may create targeted changes to reduce the regulatory load and enhance the overall performance of the pharmacy sector by comprehending the scope of the burden and its effects at the community level. The following study's objective is to determine the regulatory burden associated with opening a pharmacy in Pakistan.

To lessen the burden on pharmacies and encourage their effective operation, the current regulatory framework must also be changed. This reform need to focus on streamlining and simplifying rules, getting rid of pointless requirements, and improving uniformity and clarity in

how they are applied. To properly implement these reforms, cooperation between the government, regulatory agencies, industry players, and research institutes is required. Thus, a thorough analysis of the present regulatory environment is needed to enable evidence-based decisions and reform initiatives. This evaluation should examine how regulations affect pharmacies' capacity to offer accessible and inexpensive medications, their expenses associated with compliance, and the general quality of healthcare services.

Chapter 3:

Research Methodology

The research methodology chosen for this study is qualitative, enabling a comprehensive exploration of the regulatory burden faced by businesses in the pharmacy segment of Pakistan's pharmaceutical sector. Data is collected through questionnaire, surveys, and face-to-face interviews from relevant stakeholders. The primary objective of this research is to identify the number of regulatory compliances businesses encounter and assess the extent of the regulatory burden caused by these compliance requirements.

To achieve this objective, the research involves analyzing statutory documents and conducting surveys among pharmacies operating in Islamabad to identify the regulatory compliances they need to adhere to. This analysis provides valuable insights into the regulatory landscape and the procedures required for a pharmacy to operate in Islamabad. Subsequently, the procedures and compliance requirements for establishing and maintaining pharmacies across the four provinces are examined. If there are variations in the procedures at the provincial level, the necessary calculations are performed to account for these differences.

Given that the study approach revolves around the Standard Cost Model (SCM), it is crucial to explicate the fundamental conceptual underpinning. The Standard Cost Model (SCM) framework offers a systematic methodology for comprehending the financial ramifications associated with regulatory burdens. The research facilitates the measurement of both direct and indirect expenses related to adherence to regulatory obligations within the pharmacy sector of Pakistan's pharmaceutical industry. This study utilizes the Standard Cost Model (SCM) framework to investigate the routes and mechanisms by which different elements contribute to the regulatory burden experienced by enterprises operating in this particular area. The aforementioned model functions as a comprehensive framework for evaluating the financial consequences of regulatory measures on pharmacies, enabling a thorough examination of expenses associated with compliance.

After analyzing the procedures and compliance requirements, the overall burden existing in the entire pharmacy sector is calculated. This is done by considering the total number of registered pharmacies in each province and in Islamabad Capital Territory (ICT) using the Standard Cost Model (SCM). The SCM enables the estimation of the total regulatory burden in the pharmacy segment, which can be further used to calculate its impact on the Gross Domestic Product (GDP).

The study also aims to identify the psychological stress experienced at different stages of obtaining approval for starting a pharmacy. This is assessed using Likert scale-based surveys. Additionally, the research investigates the regulatory compliances that businesses have to repeatedly fulfill, such as license renewals and registrations, in order to sustain their operations. These findings are valuable for the pharmacy councils and healthcare regulatory authorities, as they can use them to improve service delivery and identify methods to streamline the regulatory process and reduce the burden involved. The study contributes to enhancing the efficiency and effectiveness of pharmaceutical regulations.

3.1 Research Design:

The research design selected for this study is qualitative, as it has allowed for an in-depth exploration of the regulatory burden faced by businesses in the pharmacy segment. This design has facilitated a comprehensive understanding of the experiences, perceptions, and challenges encountered by pharmacy businesses in complying with regulatory requirements. Through the use of structured and semi-structured interviews, as well as surveys, this research has collected extensive and detailed data to effectively address the research questions at hand.

The research design chosen for this study is qualitative, which aligns with our objectives to comprehensively explore the regulatory burden faced by businesses in Pakistan's pharmacy segment. This qualitative approach allows us to delve deeply into the experiences, perceptions, and challenges encountered by pharmacy businesses in complying with regulatory requirements. We have employed structured and semi-structured interviews and surveys to collect extensive and detailed data, ensuring that we address the research questions effectively.

The qualitative research design has been well-suited for this study as it emphasizes obtaining a holistic and nuanced understanding of the subject matter. It has enabled researchers to delve into the complexities and intricacies of the regulatory burden experienced by pharmacy businesses, exploring the various factors that contribute to it. By utilizing interviews and surveys, researchers have engaged directly with participants, allowing them to express their perspectives, insights, and experiences related to regulatory compliance.

Structured interviews have been employed to gather data in a standardized manner, ensuring consistent questioning and enabling the collection of comparable responses. On the other hand, semi-structured interviews have offered flexibility and allowed for probing deeper into specific areas of interest, facilitating a more comprehensive exploration of participants' experiences with regulatory burden. Additionally, surveys have been utilized as a data collection method to obtain a broader perspective from a larger sample size. Surveys have been administered

to a representative sample of pharmacy businesses, enabling researchers to collect quantitative data on the prevalence and impact of regulatory burden. By incorporating Likert scales and open-ended questions, surveys have captured both quantitative ratings and qualitative insights, offering a comprehensive understanding of participants' perceptions and attitudes towards regulatory compliance.

Through the implementation of this qualitative research design, the study has aimed to gain a comprehensive understanding of the regulatory burden faced by pharmacy businesses. The structured and semi-structured interviews, as well as surveys, have enabled researchers to collect rich and detailed data, providing valuable insights into the experiences, challenges, and perceptions of pharmacy businesses regarding regulatory compliance.

3.2 Research Site:

The selection of Islamabad, the federal capital area of Pakistan, as the focal point of research is motivated by various variables that increase the importance and relevance of the study. To begin with, Islamabad serves as an interesting subject of analysis due to its specific regulatory framework, which is attributed to its position as the federal capital. Furthermore, with its focus on Islamabad, this research gives a solid basis for comprehending the demands and procedures associated with regulatory compliance within a specific and well defined geographic region. The specific concentration on this area enables the collection of complex and all-encompassing information directly from pharmacies that are operational in the capital city. Consequently, this approach offers a representative sample of the wider regulatory obstacles encountered by pharmacy enterprises throughout Pakistan. Furthermore, the choice of Islamabad as the research site offers the advantage of convenient access to regulatory bodies. This allows for effective involvement with important stakeholders and the collection of primary insights into the regulatory environment. The research focuses on pharmacies in Islamabad, aiming to collect detailed data on regulatory compliance requirements and processes. By focusing on this specific geographic area, we can provide a microcosm of the regulatory challenges faced by pharmacy businesses in the broader context of Pakistan's pharmaceutical sector.

3.3 Sampling:

Simple convenience sampling is employed to select respondents from pharmacies in Islamabad. This sampling technique ensures equal chances of selection for each pharmacy, increasing the representativeness of the sample and allowing for generalization to the broader population of pharmacies. The pharmacies working in different sectors and areas of Islamabad

based on the size of pharmacy ranging from large pharmacies (D. Watson, Shaheen and etc.) to total sixty pharmacies were included in research.

3.4 Data Collection:

The survey is a pivotal component of the research methodology, aligning closely with the objectives of the study. By employing surveys, the aim is to obtain a comprehensive and quantitative understanding of the regulatory burden experienced by pharmacy businesses. The survey questionnaire is designed to address the research questions effectively. It collects data on the number of regulatory compliances businesses encounter, the extent of the regulatory burden caused by these compliance requirements, and the psychological stress experienced during the approval process. Furthermore, the survey explores the regulatory compliances that businesses must repeatedly fulfill, such as license renewals and registrations, providing valuable insights into the ongoing burden faced by pharmacy operators. These survey findings are essential for contributing to the efficiency and effectiveness of pharmaceutical regulations, as they offer a quantitative perspective on the prevalence and impact of regulatory burden in the pharmacy segment

- Primary Data: Primary data is collected through closed-ended questionnaires, structured interviews, and semi-structured interviews. Questionnaires are used to gather quantitative data, while interviews provide qualitative insights into the experiences and perspectives of pharmacy owners and managers from 60 pharmacies. Data collection instruments are carefully designed to address the research questions and capture relevant information.
- Secondary Data: Secondary data from existing government documents and regulations are also utilized to complement the primary data. These documents provide additional context and background information on the regulatory environment for pharmacies in Islamabad.

3.5 Data Processing:

Data processing has been a crucial step in conducting research and analyzing the collected data to gain meaningful insights. In this research study, the collected data from pharmacies has played a vital role in identifying and understanding the regulatory obligations, time requirements, and costs associated with compliance in the pharmacy segment of Pakistan. This data has served as the basis for calculating the overall regulatory burden and estimating its monetary value using the Standard Cost Model (SCM).

The first step in data processing has involved organizing and structuring the collected data in a systematic manner. Once the data has been organized, the regulatory obligations faced by pharmacies have been identified and documented. This process has entailed thoroughly examining the collected data and relevant statutory documents to understand the specific compliance activities that pharmacies are required to undertake. Examples of these obligations may have included obtaining licenses, permits, and certifications, maintaining records, undergoing inspections, submitting reports, and adhering to quality standards. By documenting these obligations, researchers have gained a comprehensive understanding of the regulatory landscape in the pharmacy sector.

After identifying the regulatory obligations, the next step has involved analyzing the data to calculate the overall regulatory burden. This analysis has aimed to assess the impact of these obligations on the pharmacy segment in terms of time requirements and financial costs. The SCM has been employed as a powerful tool to estimate the monetary value of the regulatory burden.

The SCM has taken into account both direct and indirect costs associated with compliance activities. Direct costs have encompassed the financial expenses directly attributed to regulatory compliance, such as application fees, licensing fees, training costs, and other administrative expenses. These costs have been carefully evaluated and quantified based on the data collected from pharmacies. By utilizing the SCM and considering both direct and indirect costs, the research study has aimed to provide a comprehensive understanding of the monetary value of the regulatory burden in the pharmacy sector. This data processing stage has ensured that the collected data has been analyzed effectively and has enabled researchers to draw meaningful conclusions about the financial implications of regulatory compliance for pharmacies in Pakistan.

3.6 Data Analysis:

The data analysis in this research study adopts a qualitative approach to conduct a situational analysis of the regulatory burden in the pharmacy segment of Pakistan. To determine the financial implications associated with compliance to regulatory requirements in the pharmacy sector, a standard cost model (SCM) is employed. The utilization of the SCM as conceptual frame work allows for a comprehensive understanding of the cost of regulation or regulatory burden within this context.

The data analysis process begins by assessing the direct monetary cost of compliance. This involves considering the administrative requirements and paperwork involved in meeting regulatory obligations. By examining the various administrative tasks and associated costs, such

as fees and documentation expenses, the research aims to quantify the direct financial burden imposed on pharmacies.

Additionally, the transaction cost is factored into the analysis. Transaction costs refer to the expenses incurred during the process of complying with regulatory requirements. These costs may include expenses related to communication, coordination, and interactions with regulatory authorities. By considering transaction costs, the research seeks to capture the full extent of financial burdens faced by pharmacies in adhering to regulatory compliance.

In addition to direct monetary costs, the research also considers indirect costs associated with regulatory compliance. Indirect costs are determined by evaluating the time spent on direct engagement in regulatory compliance, agency time, and overhead time. The average earning of a pharmacy per hour, which is 1458.33 rupees, is used to calculate the financial value of the time spent on compliance activities. This average income value of 350,000 rupees per month, obtained through a survey conducted among pharmacies, provides a benchmark for estimating the indirect costs incurred by pharmacies due to regulatory burden. This calculation results in identification of regulatory burden in starting and running a pharmacy which then is used to calculate overall regulatory burden in pharmacy segment of health sector of Pakistan using total number of registered pharmacies in Pakistan, which is more than 80,000 according to International Pharmaceutical Federation (FIP)

By employing the SCM and accounting for various elements of compliance-related expenses, the data analysis aims to provide a comprehensive understanding of the financial burden imposed by regulatory measures on the pharmacy segment in Pakistan. The SCM allows for the quantification and aggregation of both direct and indirect costs, enabling researchers to assess the overall financial impact of regulatory compliance on pharmacies.

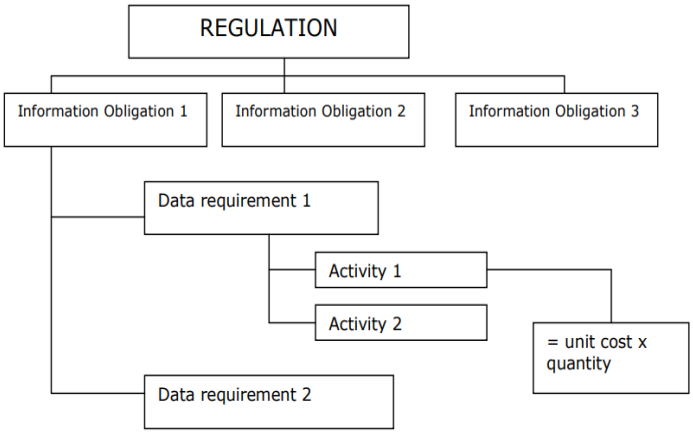

Figure 1: Standard Cost Model (SCM)

The utilization of the SCM in this research operationalizes the measurement of regulatory burden by providing a standardized approach to assessing the financial implications of compliance. By considering both direct and indirect costs, the SCM enables researchers to capture a comprehensive view of the financial burden faced by pharmacies in adhering to regulatory requirements. The analysis conducted using the SCM facilitates a thorough understanding of the economic impact of regulatory measures on the pharmacy sector, contributing to the overall aim of enhancing the efficiency and effectiveness of pharmaceutical regulations.

The stress percentage represents the distribution of stress across steps has been calculated by multiplying the total process time (Including travel, wait, and transaction time) of each step with the stress level.

3.7 Units of Data Collection:

- DHO (District Health Office) Islamabad:

  The inclusion of the District Health Office (DHO) in the data collection process is essential as it is responsible for regulating and managing pharmacies in the district. By analyzing the statutory documents obtained from the DHO, researchers can gain insights into the legal obligations and requirements imposed on pharmacies. This information is crucial for understanding the regulatory framework and compliance measures that pharmacy businesses must adhere to.
- Pharmacies in Islamabad Capital Territory: By focusing on pharmacies in Islamabad Capital Territory, the research aims to gather data directly from the owners, proprietors, or representatives of these establishments. Through structured surveys conducted via random sampling, researchers can collect information on the regulatory compliance experiences faced by pharmacies when starting their businesses and the ongoing obligations they need to fulfill, such as license renewals and obtaining No Objection Certificates (NOCs). This unit of data collection allows for capturing firsthand accounts and perceptions of the regulatory burden in the pharmacy segment.
- Regulatory Bodies Involved in Cross Cutting: To comprehensively assess the burden of regulatory compliance, it is crucial to consider the involvement of regulatory bodies that have cross-cutting responsibilities. For example, the Federal Board of Revenue (FBR) for taxation requirements and the Capital Development Authority (CDA) for land approvals may impose additional regulatory obligations on pharmacies. Including these regulatory bodies in the data collection process enables a holistic understanding of the regulatory burden faced by pharmacies in relation to various cross-cutting regulatory authorities.

- Regulatory Officials: Including regulatory officials in the data collection process, such as representatives from the District Health Office or other relevant regulatory bodies, offer valuable perspectives from the regulatory side. Interviews or structured discussions with these officials can shed light on the rationale behind specific regulatory requirements, their enforcement practices, and potential areas for improvement. This data collection unit provides a comprehensive understanding of the regulatory landscape and facilitates dialogue between regulators and pharmacy stakeholders.

3.8 Ethical Considerations:

Ethical guidelines and principles are followed throughout the research process. Informed consent is obtained from participants, and their confidentiality and anonymity are ensured. The research is conducted with integrity and transparency, adhering to ethical standards of academic research.

Chapter 4:

Historical Evolution of Drug Acts in Pakistan.

Pakistan's Drug Act 1940 was the first comprehensive law aimed at regulating the drug industry in the country. The act provided the legal framework for the control of the import, export, manufacture, sale, and distribution of drugs in Pakistan. The significance of the Drug Act 1940 was that it provided a basic framework for drug regulation in the country and helped to ensure that only safe and effective drugs were available in the market. The act also helped to prevent the sale and distribution of counterfeit drugs, which were a serious problem in the country at the time. However, the Drug Act 1940 had several flaws. One of the main flaws was that it did not have enough provisions to regulate the promotion, advertising, and marketing of drugs. This allowed companies to make exaggerated and misleading claims about their products, which put the health and safety of consumers at risk.

The Drug Act 1976 was an amendment to the Drug Act 1940 and was enacted to address some of its flaws. The act introduced several new provisions, such as the regulation of the promotion, advertising, and marketing of drugs. It also provided a framework for the establishment of a national drug regulatory authority. The significance of the Drug Act 1976 was that it introduced new measures to regulate the drug industry in Pakistan and helped to ensure that drugs were safe, effective, and of good quality. The act also helped to prevent the sale and distribution of counterfeit drugs, which were still a serious problem in the country.

However, the Drug Act 1976 had several flaws as well. One of the main flaws was that it did not have enough provisions to regulate the import and export of drugs. This allowed companies to import and export drugs that did not meet quality, safety, and efficacy standards. The DRAP Act 2012 was enacted to replace the Drug Act 1976 and provide a comprehensive framework for drug regulation in Pakistan. The act established the Drug Regulatory Authority of Pakistan (DRAP), which is responsible for ensuring that all drugs in the country meet quality, safety, and efficacy standards. The DRAP Act 2012 also introduced several new provisions, such as the regulation of the clinical trials of drugs and the monitoring of the safety and efficacy of drugs after they have been approved for use.

The significance of the DRAP Act 2012 is that it provides a comprehensive framework for drug regulation in Pakistan and helps to ensure that drugs are safe, effective, and of good quality. The act also helps to prevent the sale and distribution of counterfeit drugs and provides a framework for the regulation of clinical trials and post-marketing surveillance. However, the

DRAP Act 2012 also has several flaws. One of the main flaws is that it does not have enough provisions to regulate the pricing of drugs. This has led to high drug prices, which make it difficult for many people in Pakistan to access the drugs they need. Another flaw is that the DRAP Act 2012 does not have enough provisions to regulate the promotion, advertising, and marketing of drugs, which can lead to the sale and distribution of drugs that are not safe, effective, or of good quality.

4.1 Drug Act 1940:

Pakistan adopted the Drug Act of 1940 after it became an independent country. It became known as the "Pakistan Drugs Act," enacted to regulate the manufacture, sale, and distribution of drugs and medicines in Pakistan. The main objective of the Act was to ensure the safety, efficacy, and quality of drugs available in the market. However, despite its good intentions, the Drug Act 1940 faced several challenges and criticisms over the years that have led to its failure in achieving its goals. Some of the reasons for its failure include:

- Lack of enforcement: The Drug Act 1940 failed to ensure effective enforcement of its provisions, and many unregistered and substandard drugs continue to be sold in the market. This resulted in widespread availability of counterfeit and fake drugs, posing a significant threat to public health (Zaidi & Nishtar, 2011).
- Inadequate regulations: The regulations under the Drug Act 1940 were outdated and not in line with current scientific knowledge and global standards. This resulted in a lack of control over the quality and safety of drugs, leading to increased incidents of adverse reactions and drug resistance.
- Lack of resources: The Drug Act 1940 lacked sufficient resources, including personnel, funding, and infrastructure, to effectively enforce its provisions and carry out its objectives. This has limited its ability to effectively regulate the drug market and ensure the safety of the public.
- Corruption: Corruption and bribery are widespread in the drug industry, and the Drug Act 1940 failed to address these issues effectively (Zaidi & Nishtar, 2011). This has led to a proliferation of substandard and counterfeit drugs, putting the health of the public at risk.
- Limited penalties: The penalties for violating the provisions of the Drug Act 1940 were not stringent enough to act as a deterrent to those who engage in the manufacture and sale of counterfeit drugs. This resulted in a continued flow of substandard and fake drugs in the market.

The Drug Act 1940 failed to achieve its goals due to a combination of factors, including lack of enforcement, inadequate regulations, lack of resources, corruption, and limited penalties. To address these challenges, it was crucial to take steps to improve the implementation and enforcement of the Act and ensure the availability of safe and effective drugs in the market that lead to the induction of Drug Act 1976

4.2 Drug Act 1976:

The Pharmaceuticals Drugs Act, 1976 of Pakistan governed the regulation of the pharmaceutical industry in Pakistan. It laid down the rules for licensing, registration and advertising of pharmaceutical products. The 1976 act mandated that all pharmaceutical companies must obtain a license from the government in order to manufacture, import or sell drugs in the country. The license is issued by the Ministry of Health and was valid for a period of five years, after which it must be renewed. In terms of registration, the act required that all drugs sold in Pakistan must be registered with the government. The registration process included a review of the safety, efficacy and quality of the drug by the government. The advertising of pharmaceutical products was also regulated by the 1976 act. The act prohibited false or misleading advertisements and requires that all advertisements be approved by the government before they are released to the public.

The Pharmaceuticals Drugs Act, 1976 has been an important piece of legislation in regulating the pharmaceutical industry in Pakistan, but had the same flaws as the 1940 Act like issues of inappropriate implementation and incapacity to efficiently regulate. These inefficiencies and the eighteenth amendment lead to the need and introduction of Drug Act 2012.

4.3 Drug Act 2012:

There was a considerable gap between federal and provincial regulatory authorities to control the pharmaceutical industry after Pakistan's constitution's 18th amendment. Drug Control Administration and the Federal Ministry of Health were devolved and transferred to provincial governments, but the pharmaceutical business was greatly disturbed because there were no rules to resolve the licensing, registration, price, import, and export issues. Resolutions requesting that federal legislation be made at the federal level were voted by provincial assemblies.

In order to regulate the licensing, registration, pricing, quality assurance, laboratory testing, controlled medications, pharmacy services, etc., parts of the pharmaceutical business, the DRAP Act, 2012 was published and established a well-defined regulatory authority. For the efficient operation of DRAP, the Authority consists of a Chief Executive Officer (CEO) and 13

Directors. The Pharmaceutical Drug Regulatory Act 2012 of Pakistan (PDRA) is a comprehensive piece of legislation that governs the regulation of pharmaceutical products in Pakistan. The act establishes the Drug Regulatory Authority of Pakistan (DRAP) as the primary agency responsible for regulating the pharmaceutical sector in the country.

Key provisions of the PDRA include:

- Establishment of DRAP: The PDRA establishes DRAP as the central authority responsible for regulating the pharmaceutical sector in Pakistan.
- Licensing and Registration: The PDRA requires all pharmaceutical companies to obtain a license from DRAP and to register their products with the authority.
- Quality control: The PDRA requires all pharmaceutical products to meet specified standards of quality and efficacy before they can be sold in the market.
- Advertising and Promotion:

4.4 Drug Regulatory authority of Pakistan (DRAP):

DRAP provides services such as drug registration, licensing, monitoring, and inspection to ensure the safety, efficacy, and quality of drugs and medical devices in Pakistan. It also works to promote rational use of medicines and to cooperate with international organizations to harmonize drug regulations and standards. Pakistan. DRAP has following 13 divisions under the leadership of Chief Executive Officer (CEO):

1. Licensing: Licensing Division is responsible to grant license to Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP) manufactures and also handle its associated matters. It is all the times objectionable that why even a single unit among 700 DRAP approved units could not qualify USFDA standards.
2. Pharmaceuticals Evaluation & Registration (PE&R): PE&R Division is responsible to grant registration of pharmaceutical products for human and animals after requisite assessment & evaluation. PE&R is also performing other functions as assigned by the Board. PE&R has upgraded and implemented its product registration requirements as per ICH guidelines in Mar, 2018.
3. Biological Drugs: After the necessary screening and review, the division of biological pharmaceuticals is in charge of registering biological goods for use on humans and animals. The registration of biological products is done in accordance with WHO rules. Most biological goods, which should be produced locally, are imported. In order for

patients to receive timely supplies of said biological goods, registration delays for those products must be addressed.

4. Controlled Drugs: The section in charge of controlling drugs is in charge of allocating quotas for substances like psychotropic, narcotics, and precursor compounds. The process is finally delayed because the quota in question is distributed jointly with the Ministry of Narcotics Control. There is a shortage of controlled pharmaceuticals on the market as a result of the allocated quantity being insufficient to satisfy the needs of legitimate makers.
5. Health & OTC: The licensing and recruitment of producers and goods, including nutraceuticals, herbal, unani, ayurveda, Chinese, homoeopathic, and food supplements for both people and animals, are within the purview of this section. This division's challenges include a lack of staff and a backlog of H&OTC applications, both of which have an impact on DRAP performance and have led to legal action.
6. Medical Devices & Medicated Cosmetics (MD&MC): The MD&MC Division is in charge of registering both human and animal medical devices and medicated cosmetics. The DRAP division most in need of development in accordance with international standards is MD&MC. After only two years of being in effect, the Medical Device Rules of 2018 are currently being revised, demonstrating the haste with which they were created. Medical gadgets are still being offered on the market unregistered.
7. Pharmacy Services: The Pharmacy Services Division is in charge of implementing the finest pharmacy practices in Pakistan, however the sale of prescription drugs without a prescription in every region of the country demonstrates how well this Division and the provincial regulatory bodies are performing.
8. Quality Assurance & Laboratory Testing (QA&LT): Three main tasks are the responsibility of the Quality Assurance and Laboratory Testing Division. The first responsibility is to ensure that production facilities with doubtful GMP compliance. This Division's regional offices are located in Lahore, Karachi, Peshawar, and Quetta for this purpose, and an insufficient number of local Federal Inspectors of Drugs (FIDs) who lack the necessary training to follow and put the WHO guidelines into practice in manufacturing facilities have been appointed. Observing post-marketing surveillance of marketed products with regard to safety, efficacy, and quality, including product recall, is the second responsibility. The genuine spirit of this function is not being carried out. Implementing GLP in public laboratories is the third responsibility so that products can be randomly checked.

9. Costing & Pricing: Costing & Pricing (C&P): C&P Division is responsible for the fixation of prices of pharmaceutical products but all stakeholders i.e. industry, public, government etc. criticize C&P due to sluggish and ambiguous working
10. Legal Affairs: The Legal Affairs Division is in charge of handling all legal issues relating to DRAP both inside and outside of DRAP, such as with courts and other external bodies. In order to shield DRAP from pointless litigation and to promulgate rules and regulations in a manner consistent with international standards, this Division is essential.
11. HR & Administration: The recruiting and training of DRAP officials as well as administrative issues are within the purview of the Human Resource & Administration Division.
12. Management Information System (MIS): All DRAP functions are automated by the Management Information Services (MIS) division, however basic functions have not yet been converted to digital forms.
13. Budget & Accounts: The Budget & Accounts Division is in charge of providing a budget for DRAP's daily operations and upcoming projects.

4.5 The Alternative Medicines & Health Products Rules, 2014

Alternative medicines (unani, ayurvedic, homoeopathic, Chinese, biochemical, etc.), health and over-the-counter products (non-drugs) (probiotics, cleaners, food supplements, nutraceuticals, baby milk, medicated cosmetics, etc.), and medical devices were defined and included under the definition of drugs so that appropriate legislation and registration could be done to control these fields.

The adoption of drug laws in Pakistan has never been a government's top priority. After Pakistan had been independent for 29 years, the first drug law was enacted. Later, drug regulations were announced, but their shoddy execution failed to improve Pakistan's pharmaceutical and drug regulatory systems. The fake and illegal drug mafia was at its height during this period in Pakistan. On the one hand, the federal regulatory body was unable to help the pharmaceutical industry modernize so that they could produce medicines in accordance with FDA, EMA, WHO, and other international standards. Provincial regulatory organizations, on the other hand, were unable to modernize sale and distribution networks. Drugs are still marketed as grocery goods even today without a doctor's prescription or a licensed pharmacist.

Table 1: Drug Acts of Pakistan

Drug Act	Main Point of Focus	Central Regulatory Authority	Year of Enforcement	Other Information
Drugs Act, 1940	Regulation and control of import, manufacture, distribution and sale	Drug Regulatory Authority	1940	This was the first drug act in Pakistan, enacted during the British colonial era.
Drug Control Ordinance, 1976	Control of import, manufacture, distribution and sale of drugs and medicines	Drug Regulatory Authority	1976	This ordinance provided for the establishment of the Drug Regulatory Authority of Pakistan (DRAP) to regulate drugs and medicines in the country.
Drug Regulatory Authority of Pakistan Act, 2012	Establishment of DRAP and its powers and functions	Drug Regulatory Authority	2012	This act replaced the Drug Control Ordinance, 1976 and strengthened the regulatory framework for drugs and medicines in Pakistan. The DRAP was given more powers to ensure the safety, quality and efficacy of drugs and to take action against those who violate drug laws.

Punjab Drug Rules, 2007	Regulation of drug manufacturing and distribution in the Punjab province	Punjab Healthcare Commission	2007	These rules were enacted to regulate the quality, safety and efficacy of drugs manufactured and distributed in the Punjab province of Pakistan.
Sindh Drugs Act, 2017	Regulation of drug manufacturing and distribution in the Sindh province	Sindh Healthcare Commission	2017	This act provides for the regulation and control of drugs and medicines in the Sindh province of Pakistan. It establishes the Sindh Healthcare Commission as the central regulatory authority for drugs in the province.
Khyber Pakhtunkhwa Drugs Act, 2019	Regulation of drug manufacturing and distribution in the Khyber Pakhtunkhwa province	Khyber Pakhtunkhwa Healthcare Commission	2019	This act regulates the manufacture, distribution and sale of drugs in the Khyber Pakhtunkhwa province of Pakistan. It establishes the Khyber Pakhtunkhwa Healthcare Commission as the central regulatory authority for drugs in the province.

4.6 Health Care Regulatory Authorities of Pakistan:

On the basis of the Acts following are the regulatory authorities directly involved in healthcare system of Pakistan at federal and provincial level that are responsible for regulating the care system of Pakistan.

Table 2: Federal healthcare regulatory authorities in Pakistan

Federal Regulatory Bodies		
DRAP	Established under DRAP Act 2012	Drug Regulatory Authority of Pakistan (DRAP) is responsible for providing effective coordination and enforcement of The Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods. Therapeutic goods regulated by the DRAP include: • Pharmaceutical and biological drugs for human or veterinary use, • Medical Devices and Medical Cosmetics • Health & OTC (non-drugs) also known as alternative medicines such as: Ayurvedic, Chinese, Unani, Homeopathy, Nutritional products, Food supplements for human beings, animals
Pharmacy Council of Pakistan	Pharmacy Act, 1967	To regulate , pharmacists, pharmacy support personnel and pharmacy premises in Pakistan and Recognition Status of Pharmacy teaching institutes
National Council for Homoeopathy	Constituted under Unani Ayurvedic and Homoeopathic Practitioners Act, 1965	To regulate the qualifications and to provide for the Registration of Practitioners of Unani Ayurvedic and Homoeopathic Practitioners.
Islamabad Healthcare Regulatory Authority (IHRA)	Islamabad Health Regulation Act, 2018	Regulate the quality of healthcare service delivery in Islamabad by four departments: • Registration and Licensing • M&E/Inspection • Legal and Complaints • Clinical Governance and Training
National Council for	Established under section 3	

Tibb, Islamabad	of Unani Ayurvedic and Homeopathic Act 1965	
Pakistan Medical Commission (PMC)	Founded in 1962	• National Licensing Examination (NLE) • National Equivalence Board (NEB) Examination for foreign medical and dental Students • Medical and Dental College Admission Test (MDCAT) • Inspection for Medical and Dental Collage • Registration for inspection of teaching Hospital • Credential Verification
Pakistan Veterinary Medical Council (PMVC)	Established in 1999 under Pakistan Veterinary Medical Council Act 1996	For nation and international Practicing the Registration from PMVC is necessary
Pakistan Nursing Council (PNC)	Constituted under the Pakistan Nursing Council Act (1952, 1973)	• PNC sets the curriculum for the education of Nurses, Midwives, LHVs and Nursing Auxiliaries. • PNC inspects educational institutions for approval based on established standards • PNC provides registration (license) to practice. • PNC maintains standards of education and practice. • PNC works closely with the four provincial Nursing Examination Boards (NEBs). • PNC plays and advisory role for the overall benefit of Nurses, Midwives, LHVs and Nursing Auxiliaries in the country. • PNC maintains an advisory role for the Federal and Provincial governments regarding nursing education and nursing services. • PNC communicates policy decisions regarding nursing education and the welfare of nurses, taken in Council

		meetings, to Governments, Nursing Institutions, NEBs and Armed Forces Nursing Services for implementation.

Table 2 provides a glance at federal level, explaining that alone there are eight key regulatory authorities involved in regulating and oversighting the health care system in Pakistan. At provincial level, there ten key health care regulatory authorities in Punjab, two in Khyber Pakhtunkhwa, three in Sindh and two in Baluchistan that are detailed as follow:

Healthcare regulatory Authorities in Punjab:

- Punjab Pharmacy Council: An Autonomous Statuary body functioning under Federal Legislation (Pharmacy Act, 1967).
- Directorate General of Health Services (DGHS): Directorate General of Health Services (DGHS) is the main programmatic coordination, implementation and monitoring arm of the provincial health department of the Government of Punjab and is headed by the Director General Health Services.
- Nursing Examination Board Punjab (NEB) "Works on The Punjab Health Foundation Act 1992.
- Punjab Health Foundation (PHF): The Punjab Health Foundation Rules 1993: Following are the Functioning Units of P&SHD: Centralized Drug Sale Licensing (CDSL), Directorate General of Health Services (DGHS), Health Information & Service Delivery Unit (HISDU), Project Management Unit (PMU).
- Provincial Quality Control Board (PQCB).
- Primary and Secondary Healthcare Department (P&SHD).
- Directorate General of Health Services (DGHS).
- Health Information & Service Delivery Unit: "The Health Information and Service Delivery Unit (HISDU) was created to facilitate the Primary and Secondary Healthcare Department (P&SHD) in its mission to completely automate and computerize the health system.
- Provincial Quality Control Board, Lahore (Punjab): A Drug regulatory body working under the administrative control of P&S Healthcare Department, established under section 11 of Drug Act 1976, to ensure the availability of quality drugs throughout Punjab.

- Punjab Healthcare Commission: Punjab Healthcare commission act 2010.

Healthcare regulatory authorities in Khyber Pakhtunkhwa:

- Health Regulatory Authority KP: Constituted under Khyber Pakhtunkhwa Care Commission Act 2015.
- Khyber Pakhtunkhwa Health Care Commission (KP HCC): Khyber Pakhtunkhwa Healthcare Commission Act, 2015.

Healthcare regulatory authorities in Sindh:

- Department of Health, Sindh.
- Sindh Healthcare Commission (SHCC): "The Sindh Healthcare Commission (SHCC) Bill, 2013, was passed by the Provincial Assembly of Sindh on 24th February, 2014. It assented to the Governor of Sindh on 19th March, 2014 to be published as an Act of the Legislature of Sindh.
- Sindh Pharmacy Council (SPC): Functioning under the Pharmacy Act 1967

Healthcare regulatory authorities in Baluchistan:

- Department of Health Baluchistan: Provincial Health Department was established in 1971 when Baluchistan was declared as province after end of one unit
- Provincial Health Directorate Government of Baluchistan.

Chapter 5:

Setting up a Pharmacy in Pakistan.

The process of opening a pharmacy in Pakistan involves eight steps.

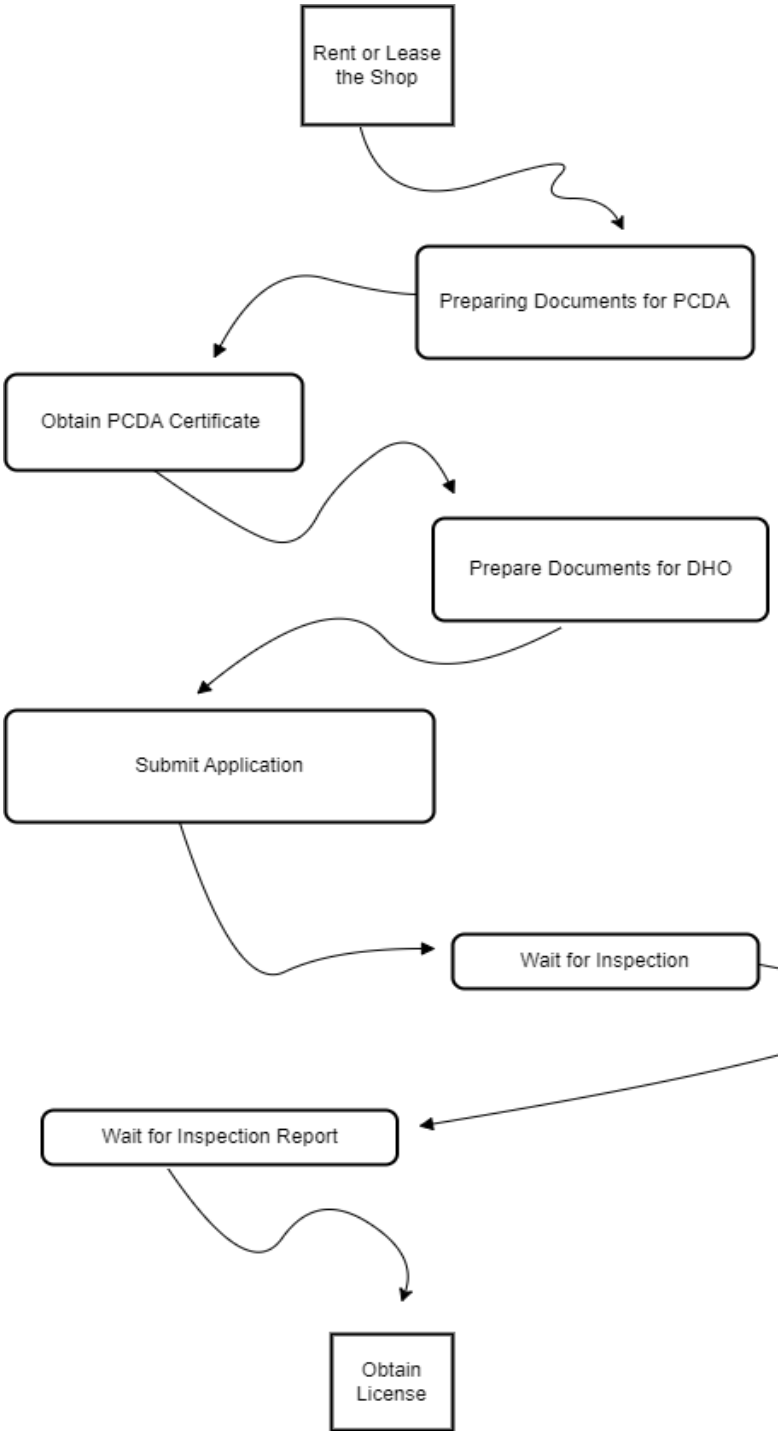

Figure 2: Steps involved for setting up a pharmacy in Pakistan.

The step-by-step process involves various tasks and subtasks, including finding a shop, lease agreement, registration with PCDA (Pakistan Chemist and Druggist Association), obtaining licenses from DHO (District Health Officer), and drug sale license renewal. Each step has subtasks such as obtaining NTN (National Tax Number), opening a bank account, preparing prerequisites and documents, submitting documents to DHO, and inspection and reporting. The comprehensive process of opening a pharmacy in Pakistan requires adherence to a series of steps and procedures. The figure 1 provide a comprehensive overview of the process, highlighting the key tasks involved and their respective subtasks.

5.1 Process of Opening a Pharmacy in Pakistan:

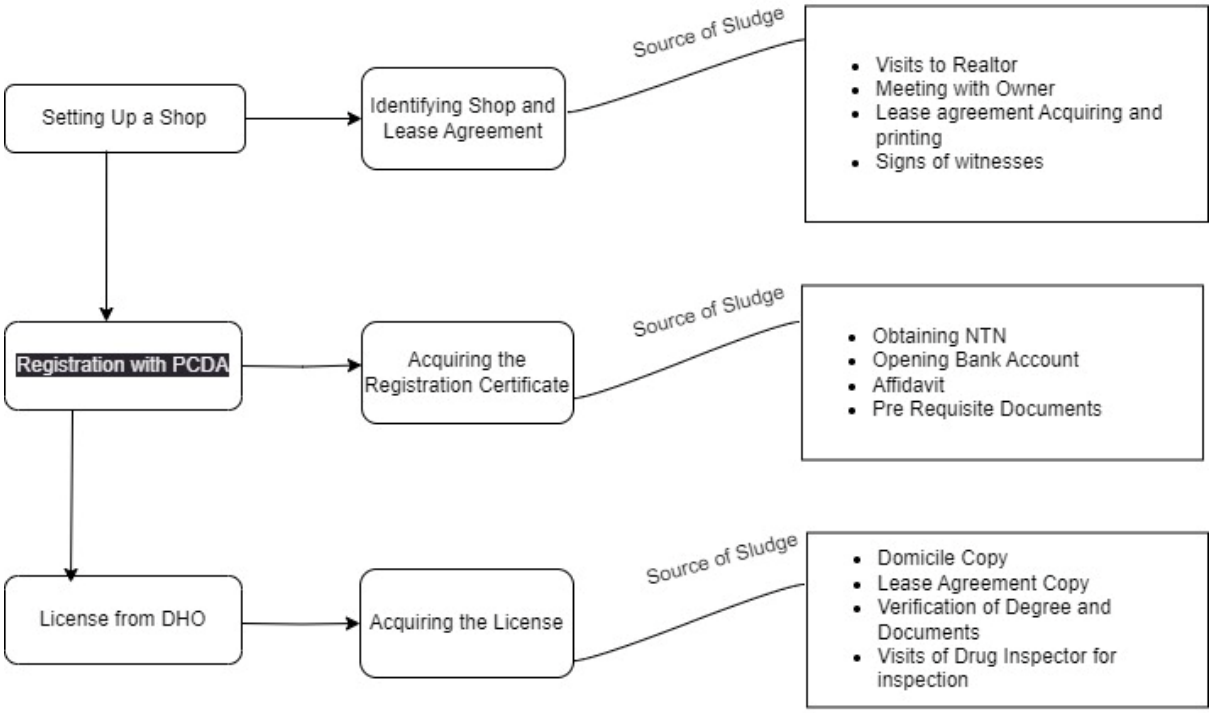

Figure 3: Sludge in opening a pharmacy in Pakistan.

An extensive description of the process involved in opening a pharmacy in Pakistan, highlighting the main tasks and their respective subtasks is provided as follow:

5.1.1 Setting up a shop

- Subtask 1.1: Finding a Shop: To establish a pharmacy, the first step is to find a suitable location. This involves visiting different realtors or property agents to explore available shop options. During these visits, requirements and preferences for the pharmacy's location, size, and accessibility is taken into consideration.
- Subtask 1.2: Identifying the Shop of Preference: After visiting various shops, it is important to carefully evaluate and compare them based on factors such as suitability,

compliance with legal regulations, and market potential. Consideration is needed be given to the proximity of the shop to residential areas, healthcare facilities, and the target customer base while identifying a shop.

- Subtask 1.3: Meeting the Owner: Once a preferred shop has been identified, a meeting should be arranged with the owner. During this meeting, terms and conditions for leasing the shop are discussed and negotiated. This includes rent amount, lease duration, and any additional clauses or agreements.
- Subtask 1.4: Lease Agreement: After reaching an agreement with the owner, the next step is to prepare and sign a lease agreement. This involves obtaining a stamp paper, printing and finalizing the lease agreement document, and ensuring that both parties sign the agreement. Additionally, an advance rent payment may be required, and the stamp paper is affixed to the agreement.

5.1.2 Registration with PCDA

- Subtask 2.1: Obtaining NTN (National Tax Number): To register the pharmacy, it is necessary to obtain a National Tax Number (NTN) from the Federal Board of Revenue (FBR). This requires submitting an application along with the required documents to the relevant tax office. The NTN is essential for taxation and record-keeping purposes.
- Subtask 2.2: Applying in PCDA: After obtaining the NTN, the next step is to apply for registration with the Pakistan Pharmacy Council (PCDA). This involves submitting an application form, along with the necessary supporting documents, to the PCDA office. The documents include educational certificates, attested copies of national identity cards, passport size picture and concerned form of application.
- Subtask 2.3: Getting Registered with PCDA: Once the application is submitted, the PCDA will review the documents and assess the eligibility of the applicant. Upon successful evaluation, the pharmacist will be registered with the PCDA, and a registration certificate will be issued.

5.1.3 Obtaining Licenses from DHO

- Subtask 3.1: Domicile Copy: To proceed with obtaining licenses from the District Health Officer (DHO), a copy of the domicile (proof of residence) is required. This can be obtained from the relevant authority by submitting the necessary documents and completing the application process.
- Subtask 3.2: Challan Deposit - National Bank Pakistan Visit: After obtaining the domicile copy, a visit to the National Bank Pakistan is required to deposit the specified fee or

challan. This fee is associated with the license issuance process and must be paid as per the instructions provided.

- Subtask 3.3: Finalizing the Documents: Once the fee is deposited, the necessary documents for license issuance should be prepared. These typically include the lease agreement attested copy, application forms, affidavits, photographs, D-Pharm degree attested copy, copy of the PCDA registration certificate, NTN from FBR, and detailed location and shop information.
- Subtask 3.4: Visit Facilitation Center: After preparing the documents, a visit to the designated facilitation center is required. At the center, the documents will be submitted, and the application process will be initiated. During the visit to the facilitation center, the challan and other required documents will be submitted as part of the domicile issuance process. The center will provide guidance and instructions on completing this step.
- Subtask 3.5: Issuance of E-receipt: Once the documents and challan are submitted, an electronic receipt will be issued as proof of payment and application submission. This receipt should be kept for future reference and follow-up.
- Subtask 3.6: Collect the Domicile – Visit: After a specified period, a visit to the relevant office is required to collect the domicile copy. This document is an important requirement for license issuance and should be collected as per the instructions provided.
- Subtask 3.8: Fee Submission: Along with the collected domicile copy, the required fee for license issuance is submitted at the designated office. The fee amount will depend on the type of license being applied for.
- Subtask 3.9: Application Submission: After submitting the fee, the complete license application, along with all the necessary documents, should be submitted to the designated office. The office will provide further guidance on this process.
- Subtask 3.10: Collecting the Certificate: Once the application is submitted, it will go through a review and verification process. Upon successful completion, the DHO will issue the license certificate, which should be collected from the respective office.

5.1.4 Drug Sale License Renewal - Once Every Two Years

- Subtask 4.1: Preparing Prerequisites and Documents for Drug Sale License: For the renewal of the drug sale license, similar prerequisites and documents as the initial license application are required. These include CNIC copies (4), attested lease agreement copy, affidavit, photographs, attested copy of D-Pharm degree, copy of the PCDA certificate, NTN from FBR, and updated location and shop details.

- Subtask 4.2: Submit Documents to DHO: After preparing the required documents, a visit to the DHO office is necessary to submit the renewal application. The documents will be reviewed, and the renewal process will be initiated.
- Subtask 4.3: Inspect and Reporting: As part of the renewal process, a drug inspector will visit the pharmacy premises for inspection. The inspector will assess compliance with legal requirements, storage conditions, and other relevant factors. After the inspection, a report will be submitted to the DHO.
- Subtask 4.4: Report Submission by Drug Inspector to DHO: The drug inspector will prepare a report based on the inspection findings and submit it to the DHO office. This report will play a crucial role in determining the renewal of the drug sale license.
- Subtask 4.5: Collect License: Once the renewal process is completed and the inspection report is satisfactory, a visit to the DHO office is required to collect the renewed drug sale license.

Obligations

Throughout the process of opening a pharmacy and maintaining its operations, various obligations need to be fulfilled. These include obtaining necessary equipment such as a refrigerator and air conditioner, as well as paying the required license fees.

Chapter 6:

Results and Discussions.

6.1 Regulatory Burden in Setting up a Pharmacy in Pakistan:

This section presents details and a discussion of the regulatory complexity associated with starting a pharmacy in Pakistan. The findings of this study offer a comprehensive evaluation of the time, money, overhead time, agency time, and overall cost of regulation for the various procedures involved in starting a pharmacy. The findings shed light on pharmacies and the strict regulatory restrictions that may affect them in Pakistan.

Table 3: Regulatory Burden across pharmacy segment of Pakistan

Regulatory Obligation	Cost of Regulations (In Rupees)
Setting Up a Shop	587,145.60
Registration with PCDA	709,640.44
License from DHO	1,163,015.18
Drug Sale License Renewal - Once every two year	476,868.52
Total Regulatory Burden in Setting up a Pharmacy	2,845,570.79
Regulatory Burden in Pharmacy Segment of Islamabad (797 Pharmacies)	2,267,919,922.29
Regulatory Burden in Pharmacy Segment of Pakistan (80,000 + Pharmacies)	227,645,663,467

The Table represents author's own calculation based on primary data.

The total regulatory burden in setting up a pharmacy is calculated to be PKR 2.84 million (Table 3). This includes the cost of labour hours and time spent setting up a store, registering with the Pakistan Council of Drug Approval (PCDA), receiving a license from the District Health, and paying other direct costs (application fees, regulatory obligations, such as buying a refrigerator and air conditioner) and indirect costs (costs associated with fulfilling obligations, such as buying an affidavit). The costs involved in opening and maintaining a pharmacy are high because of these regulatory restrictions.

The regulatory burden in pharmacy segment of pharmaceutical sector is staggering at PKR 2.267 billion, with 797 pharmacies in Islamabad alone. With over 80,000 pharmacies, the total regulatory burden in Pakistan is a staggering PKR 227.645 billion.

6.1.1 Cost of Regulation of Setting Up a Shop:

Table 4: Regulatory Burden involved in Setting up a shop for pharmacy.

Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time (Hours)	Agency Time (Hours)	Cost of Regulation (Rupees)
Setting Up a Shop	Finding a Shop	Visits to Realtor	0.75	3	1500	240	56	452,666.67
		Identifying the shop of preference	2.5	1	0			
		Meeting the Owner	2.5	1	0			
		Site Visits	2.5	1	500			
		Finishing the day	0.75	3	1500			
		Total	12		3500			
	Lease Agreement	Obtaining Stamp paper	1.25	1	600	56		134,479.17
		Printing and Finalizing Stamp paper	0.5	1	100			
		Signing Lease Agreement	1.75	1	0			
		Advance Rent Payment	0.25	1	45,000 Rs			
		Stamp Paper	-	-	50 Rs			
		Finishing the day	0.75	1	500			
		Total	4.5		46,250			

The Table represents author's own calculation based on primary data.

A number of subtasks must be completed in order to find a store, including looking for a suitable site, communicating with a realtor, selecting the best business location, meeting the owner, and visiting the area. Table 4 of the study's findings indicates that the entire operation costs 3,500 Rupees and takes around 12 hours of direct labour to complete. For this operation, the overhead time need is 240 hours, or 30 days, and the agency time requirement is 56 hours, or 7 days. The total cost of regulation for setting a shop within a pharmacy is projected to be PKR 0.452 million.

Another essential step in starting a shop is signing a lease. This calls for a variety of associated procedures, including obtaining, printing off, and finishing a stamp paper; signing the lease agreement; paying the first month's rent; and ensuring the stamp paper requirements are satisfied. The information shows that a lease agreement may be completed in 4.5 hours and costs 46,250 Rupees. Due to the overhead time of 56 hours, which is the equivalent of 7 days, the regulatory burden for this activity is PKR 0.134 million.

6.1.2 Cost of Regulation of Registration with PCDA:

Registration with the Pakistan Chemists and Druggist Association (PCDA) is a crucial first step in starting a pharmacy. To get a National Tax Number (NTN), one must get in touch

with the Federal Board of Revenue (FBR). The price of regulation for each task is displayed in Table 5.

The information indicates that obtaining a bank account is a step necessary for running a pharmacy effectively. There are other minor phases involved in this process, including gathering the essential data, obtaining copies of utility bills and the CNIC (Computerized National Identity Card), and obtaining the NTN from the FBR. The information shows that opening a bank account costs 3,530 Rupees and takes roughly 8 hours to complete. While the agency time needed for this task is just 120 hours, or 15 days, the overhead time needed is 160 hours, or 20 days. Calculated at PKR 0.423 million is the total cost of regulation for opening a bank account.

Frequently, an affidavit is required when starting a pharmacy. Obtaining an affidavit entails many processes, including obtaining a stamp paper, printing and finishing the stamp paper, signing and concluding the affidavit, and notarizing it. According to the survey, this task takes about 11.75 hours to complete and costs 950 Rupees. The overhead time required for this task is 8 hours, or one day, and the agency time will set you back 29,752.00 Rupees.

Table 5: Regulatory burden involved in registration with PCDA

Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
Registration with PCDA	Obtaining NTN	Applying in FBR	0.5	1	0		24	36,093.75
		Getting NTN	0.25	1	0			
		Total	0.75		0			
	Opening a Bank Account	Information Gathering	0.75	1	500	160	120	423,530.00
		CNIC Copy	0.75	1	510			
		Utility Bill Copy	0.25	1	10			
		NTN from FBR	0.5	1	10			
		Business Stamp	3	1	1500			
		Visit to Bank	0.75	1	500			
		Filling Bank Form	0.5	1	0			
		Applying for Bank Account	0.75	1	0			
		Finishing the day	0.75	1	500			
		Total	8		3530			
	Affidavit	Obtaining Stamp paper	1.25	1	650	8		29,752.08
		Printing Stamp Paper	0.5	1	100			
		Signing and finalizing the affidavit	9.75	1	0			
		Notarize affidavit	0.25	1	200			
		Total	11.75		950			
	Photos	Visit Studio	2.75	1	1500	8		21,187.50
		Attestation	2.75	1	0			
		Total	5.5		1500			
	Attested Copy of Matriculation	Copy Degree	0.5	1	510	120		202,078.75
		Visit to Concerned Board	0.5	2	1000			
		Submitting The Document	3	1	500			
		Collect the Attested Document	1.5	1	0			
		Online Appointment IBCC	0.75	1	0			
		Challan Deposit - National Bank Visit	3.5	1	500			
		Visit IBCC	3.75	1	1100			
		Finish the Day	0.75	3	500			
		Total	15.75		4110			

The Table represents author's own calculation based on primary data.

Getting images is an additional important stage in opening a pharmacy. This requires visit to the photo studio and attestation of the pictures. The research results indicate that this process costs 1,500 Rupees and take 5.5 hours to complete. This task does not require any agency time; the overhead time is 8 hours, or one day. Regulation-related expenses of PKR 21,874.5 were incurred for the entire time it took to complete the acquisition of attested photos.

To satisfy regulatory requirements while operating a pharmacy, you need to have an attested copy of your matriculation. Several steps must be taken in order to complete this obligation as well, including visiting to the concerned board, providing the required documentation, and acquiring the certified copy. The data indicates that this procedure takes around 15.75 hours to perform and costs 4,110 Rupees. While the overhead time for this task is 120 hours, or 15 days, the agency time is PKR 0.202 million.

6.1.3 Cost of Regulation of obtaining license from DHO:

One of the most important and tiresome step in starting a pharmacy is the District Health Office (DHO) licensing application procedure. Table 6 shows the cost of regulation for each stage of this procedure. Several subtasks need to be properly completed. These responsibilities include preparing the required documentation, submitting it to the DHO, conducting inspections, reporting, and eventually receiving the license.

Obtaining a copy of your domicile is a crucial step in opening a pharmacy. This comprises supplying the necessary papers and completing the application in order to obtain the domicile copy from the concerned authorities. The findings indicate that these tasks need a significant amount of time and money overall. The agency time taken is 136 hours (equal to 17 days), the overhead time required is 240 hours (equivalent to 30 days). The full cost of regulation for obtaining a domicile and a copy was estimated at PKR 0.583 Million.

Before submitting the licensing application to the DHO, all prerequisites and requirements must be fulfilled. This requires obtaining a domicile copy, completing the application form, compiling the required documentation, and satisfying any additional requirements the DHO may have. The results indicate that this work typically takes 12.5 hours to complete and costs 3,130 Rupees. This task has a regulatory cost of 0.103 million rupees and an overhead time of 56 hours, or seven days.

Once the documentation is submitted, the DHO conducts inspections to ensure the pharmacy is being set up in line with the laws and regulations. This comprises inspecting the

physical setup, ensuring that the required equipment and resources are available, and verifying that health and safety guidelines are being followed.

The drug inspector visits the DHO for license approval and issuance following the inspection. The research indicates that this activity necessitates a two-hour in-person inspection and a visit by a drug inspector. The agency time taken on this is 176 hours, or 22 days, and the regulatory costs totals at 16,312.50 Rupees.

If the inspections are successful and the necessary conditions are satisfied, the pharmacy owner can pick up the license from the District Health Office. Going to the office, turning in any outstanding paperwork, and finishing off any outstanding obligations are all part of this task. The process takes around two hours. according to the research. The agency time taken is 56 hours, or the equivalent of seven days. The anticipated cost of compliance with the regulations involved with acquiring the license from the DHO is 85,583.3 Rupees, with a further cost of the licensing fee (5000 Rupees)

Table 6: Regulatory Burden involved in obtaining license from DHO

Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
License from DHO	Domicile Copy	Challan Deposit - National Bank Pakista	3	1	500	240	136	583,512.50
		Finalizing the Documents	4	1	200			
		Visit Facilitation Center	0.75	1	500			
		Process - Challan Submission	2	1	0			
		Issuance of e-receipt	2	1	0			
		Finish the day	0.75	1	500			
		Collect the Domicile - Visit	2	1	6000			
		Fee Submission	2.5	1	0			
		Application Submission	0.5	1	0			
		Collecting the Certificate	1	1	500			
		Total	18.5		8200			
	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	0.25	1	540	56		103,025.83
		Lease Agreement Attested Copy	0.25	1	10			
		Affidavit	10.5	1	950			
		Photo	0.25	1	1500			
		D-Pharm Degree Attested Copy	0.25	1	10			
		Copy of PCDA Certificate	0.25	1	10			
		NTN from FBR	0.25	1	10			
		Location and Shop Details	0.5	1	100			
		Total	12.5		3130			
	Submit Documents to DHO	Visit DHO	0.75	1	500		8	16,312.50
		Submit Application	1	1	0			
		Finish the Day	0.75	1	500			
		Total	2.5		1000			
	Inspect and Reporting	Drug Inspector Visit	0.75	1	0		176	259,583.33
		Inspection	0.5	1	0			
		Finish the Day	0.75	1	0			
		Report Submission by Drug Inspector to	0		0			
		Total	2		0			
	Collect License	Visit DHO	0.75	1	500		56	85,583.33
		Collect License	0.5	1	0			
		Finish the Day	0.75	1	500			
		Total	2		1000			
		License Fee	0	1	5000			5,000
		Total	0		5000			

6.1.4 Cost of Regulation of Drug sale license renewal:

The total time and financial expenditures related to the renewal procedure are shown in Table 7. 19.75 hours were spent altogether on the direct completion of the activities. The overhead for a license renewal is 56 hours, while the agency time is 248 hours. The related expenses of regulation, minus the PKR 3,000 license renewal fee and the typical annual penalties, are assessed to be PKR 0.479 million. To maintain ongoing compliance with legal requirements and the continuous operation of their pharmacies, pharmacy owners must carefully follow the renewal procedure.

Table 7: Regulatory burden involved in renewal of license.

Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
Drug Sale License Renewal - Once every two year	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	0.25	1	540	56		103,025.83
		Lease Agreement Attested Copy	0.25	1	10			
		Affidavit	10.5	1	950			
		Photo	0.25	1	1500			
		D-Pharm Degree Attested Copy	0.25	1	10			
		Copy of PCDA Certificate	0.25	1	10			
		NTN from FBR	0.25	1	10			
		Location and Shop Details	0.5	1	100			
		Total	12.5		3130			
	Submit Documents to DHO	Visit DHO	0.75	1	500		8	16,312.46
		Submit Application	1	1	0			
		Finish the Day	0.75	1	500			
		Total	2.5		1000			
	Inspect and Reporting	Drug Inspector Visit	0.75	1	0		176	259,583.33
		Inspection	0.5	1	0			
		Finish the Day	0.75	1	0			
		Report Submission by Drug Inspector to	0	1	0			
		Total	2		0			
	Collect License	Visit DHO	0.75	1	500		56	85,947.92
		Collect License	0.75	1	0			
		Finish the Day	0.75	1	500			
		Total	2.25		1000			
	Obligations	Renewal Fee	0	1	3000			3000
	Annual Visits of Drug Inspec	Fine	0	0	10000			10000
	Tax Filing	Visit to Consultant	0.5	1	2500		8	14895.83333

The Table represents author's own calculation based on primary data.

6.2 Psychological Cost:

Low Stress Level	
Medium Stress Level	
Moderate Stress Level	
High Stress Level	
Extreme Stress Level	

Table 8: Psychological stress involved in setting up a pharmacy in Pakistan

Obligation	Requirement	Activity	Stress Level
Setting Up a Shop	Finding a Shop	Visits to Realtor	2
		Identifying the shop of preference	4
		Meeting the Owner	5
		Site Visits	4
		Finishing the day	2
	Lease Agreement	Obtaining Stamp paper	2
		Printing and Finalizing Stamp paper	4
		Signing Lease Agreement	5
		Advance Rent Payment	4
		Finishing the day	2
Information Gathering	Information Gathering	Visit to DHO	5
		Visit to PCDA	5
		Finish the Day	2
Registration with PCDA	Obtaining NTN	Applying in FBR	4
		Getting NTN	4
	Opening a Bank Account	Information Gathering	2
		CNIC Copy	1
		Utility Bill Copy	1
		NTN from FBR	1
		Business Stamp	3
		Visit to Bank	2
		Filling Bank Form	4
		Applying for Bank Account	5
		Finishing the day	2
	Affidavit	Obtaining Stamp paper	4
		Printing Stamp Paper	4
		Signing and finalizing the affidavit	5
		Notarize affidavit	5
	Photos	Visit Studio	2
		Attestation	4
	Attested Copy of Matriculation	Copy Degree	2
		Visit to Concerned Board	2
		Submitting The Document	2
		Collect the Attested Document	5
		Online Appointment IBCC	5
		Challan Deposit - National Bank Visit	5
		Visit IBCC	5
		Finish the Day	2

License from DHO	Domicile Copy	Challan Deposit - National Bank Visit	2
		Finalizing the Documents	5
		Visit Facilitation Center	5
		Process - Challan Submission	5
		Issuance of e-receipt	3
		Finish the day	2
		Collect the Domicile - Visit	3
		Fee Submission	5
		Application Submission	5
		Collecting the Certificate	5
	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	5
		Lease Agreement Attested Copy	5
		Affidavit	5
		Photo	3
		D-Pharm Degree Attested Copy	3
		Copy of PCDA Certificate	1
		NTN from FBR	1
		Location and Shop Details	2
	Submit Documents to DHO	Visit DHO	2
		Submit Application	5
		Finish the Day	2
	Inspect and Reporting	Drug Inspector Visit	2
		Inspection	5
		Finish the Day	2
		Report Submission by Drug Inspector to DHO	1
	Collect License	Visit DHO	2
		Collect License	3
		Finish the Day	2
Drug Sale License Renewal - Once every two year	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	5
		Lease Agreement Attested Copy	5
		Affidavit	5
		Photo	3
		D-Pharm Degree Attested Copy	3
		Copy of PCDA Certificate	1
		NTN from FBR	1
		Location and Shop Details	2
	Submit Documents to DHO	Visit DHO	2
		Submit Application	5
		Finish the Day	2
	Inspect and Reporting	Drug Inspector Visit	2
		Inspection	5
		Finish the Day	2
		Report Submission by Drug Inspector to DHO	1
	Collect License	Visit DHO	2
		Collect License	3
		Finish the Day	2

The regulations and associated stress levels with each regulatory obligation are shown in table 8 for opening a pharmacy in Pakistan. Finding a location, signing a lease, collecting data, obtaining an NTN (National Tax Number), opening a bank account, completing an affidavit, having one's picture taken, obtaining an attested copy of one's matriculation, obtaining a copy of one's domicile, preparing the requirements and paperwork for a drug sales license, submitting the paperwork to the District Health Office (DHO), inspecting and reporting, and receiving the license are some of the regulatory obligations that are needed to be fulfilled.

A stress rating from 1 (low stress) to 5 (severe stress) is assigned to each subtask. These stress levels are the signs of how complicated, challenging, or potentially challenging each regulatory obligation is thought to be.

- Going to a realtor, picking the business and the owner, making site visits, and finishing the day are the tasks for the "Finding a Shop" requirement. When looking for an appropriate retailer, the range of stress ratings for these jobs, from 2 to 5, suggests moderate to severe levels of stress.
- The lease agreement activity includes the tasks of getting the required stamp paper, printing and completing the lease agreement, signing the lease agreement, and making the down payment. Together, these activities facilitate the process of locating a suitable shop by establishing a legally enforceable contract. The range of stress scores for these regulations, from 2 to 5, demonstrates the various levels of stress caused by the regulatory obligations.
- Visits to relevant institutions like the Department of Health (DHO) and Pakistan Council of Architects and Town Planners (PCDA) are must to obtain the crucial information for starting a pharmacy. This task includes comprehending regulatory requirements, collecting guidelines, and gathering essential information to ensure conformity with legal and operational standards. The amount of stress for this work is in the range of a stress level of 5, which indicates a significant level of tension, due to the complexity and significance of the information being acquired.
- Submission of an application to the Federal Board of Revenue (FBR) and completion of necessary requirements in order to get National Tax number for business purposes is also a regulatory compliance for starting a pharmacy. This work has a stress rating of 4, which denotes a high degree of stress, because of the procedures and cooperation with the tax authorities.

- One must gather the necessary data, provide the needed documentation, which includes a copy of your CNIC, a utility bill, and your NTN from the FBR, and adhere to the bank's account opening regulations in order to open a bank account for the pharmacy. Due to the multiple requirements and phases it involves, like filling out paperwork, adhering to bank standards, and completing forms, this activity has a stress level of 5.
- The affidavit obligation requires stamp paper, printing and finishing the affidavit document, signing it, and having it notarized. The affidavit serves as a sworn declaration of specific facts on the pharmacy's ownership or management. The stress levels for this activity range from 4 to 5, which implies a high to severe degree of tension, due to the processes and legal implications involved.
- Visiting a studio to have official photos created for documents like licences and papers is the picture activity.
- A visit to the relevant education board, submission of the required documentation, and retrieval of the certified copy are all necessary steps in order to receive an attested copy of the Matriculation (10th grade) diploma. Given that it mostly entails coordinating with the studio and attestation, this task has a stress level of 2 to 4, which indicates a higher degree of stress. The next step is to acquire all necessary papers, attend the DHO, and submit the application. The bulk of jobs are given a stress level of 5, which denotes an extremely high level of anxiety around the documents and ensuring their accuracy.
- A drug inspector visits the pharmacy premises for the purpose of inspection and reporting at the inspection and reporting stage. This assignment has a stress value of 2, which indicates a considerably lower level of tension than the preceding stages. Nevertheless, it suggests that it can be challenging to adhere to the requirements of the Drug Inspector and the inspection process.
- The DHO must be visited in order to get the license and the drug sales authorization. A stress grade of 2 indicates a relatively modest level of tension for this activity. This suggests that the actual licensing collection process can be simpler than the preliminary procedures.
- Renewing a medication sales license requires a lot of steps and interactions with several organizations, and it must be done every two years. In fulfilment of prerequisite, a stress level 5 is involved in obtaining copy of the CNIC (Computerized National Identity Card), a certified copy of the lease agreement, an affidavit, and attested photographs. Attestation of copy of the D-Pharm degree carries stress levels of 3, while providing a copy of the PCDA certificate and NTN from FBR has stress levels of 1. Information about

the shop and its location is required where the stress level is 2. When the requirements and papers are ready, the next procedure, which has a stress level of 5, is to go to the DHO and submit the renewal application. A drug inspector follows that by doing an inspection with a stress level of 5 and writing a report for the DHO with a stress level of 1. A last visit to the DHO, which has a stress level of 3, is necessary for the renewed license. It is crucial to maintain accuracy, obey the regulations, and adhere to the renewal procedures throughout the process in order to renew the medication sales license properly

6.3 Information Cost:

Table 9: Information cost incurred by regulatory obligation in starting a pharmacy

Activity to gather information	Time Taken	Monetary Cost (Rupees)	Over Head Time (Hours)	Information Cost (Rupees)
Visit to Realtor	0.75	500	1	3052.1
Visit to DHO	0.75	500	1	3052.1
Visit to PCDA	0.75	500	1	3052.1
Visit to Bank	0.75	500	1	3052.1
Visit to Board for Degree attestation	0.75	500	1	3052.1
Visit to Facilitation Center	0.75	500	1	3052.1
Total Information Cost involved in Opening a Pharmacy	4.5	3000	6	18312.6

The table 9 illustrates the time and cost linked to information gathering for starting a pharmacy in Pakistan. Given the previous discussions regarding the burdensome regulatory environment and excessive regulation in the pharmaceutical business, it is crucial to take cost incurred in term of gaining information into account.

As can be seen from the table, diverse activities necessitate visits to a variety of institutions, including banks, boards for degree verification, facilitation centers, the District Health Office (DHO), the Pakistan Council of Drug Approval (PCDA), and realtors. Each visit is anticipated to last 0.75 hours, and the cost is 500 rupees.

Information costs and overhead time are also included in the table. Overhead time is the time spent on administrative tasks related to information gathering, such as scheduling appointments, organizing paperwork, and travelling between locations. One hour is anticipated to be required for each action. The information cost also accounts for the time required to gather information and make the necessary journeys.

The whole cost of the information for opening a pharmacy is 3000 rupees and 4.5 hours. This implies that investing a significant amount of time and money only in gathering information is an additional burden that a business has to face. When combined with the overall backdrop of overregulation and the high regulatory burden discussed above, the challenges faced by pharmacy

proprietors and potential company owners are made even more onerous by this added expenditure.

The 18,312.6 PKR total information cost, which takes into account both time and financial expenditures, highlights the financial struggles experienced by people attempting to get into the pharmaceutical sector. This cost adds to the already onerous regulatory burden and can deter potential company owners, particularly those with little resources, from looking into opportunities in the pharmaceutical industry.

6.4: Cost to GDP:

Table 10: Percentage cost to GDP incurred by regulatory burden in pharmacy segment of Pakistan.

Total Regulatory Burden in Setting up a Pharmacy		2845570.793
Regulatory Burden in Setting up a Pharmacy in Islamabad	Total Number of Pharmacies in Islamabad = 797	2,267,919,922.29
Regulatory Burden in Pharmacy Segment of Pakistan	Number of pharmacies in Pakistan = 80000	227,645,663,466.67
Cost to GDP (%)	GDP of Pakistan = 6662000000000	3.417076906

The Table represents author's own calculation based on primary data.

The regulatory burden in Pharmacy segment of Pakistan has 3.41% cost of total GDP of Pakistan as shown in table 10. By reducing the unnecessary administrative requirements and implementing efficient regulations the burden on economy can be reduced which will not only help to create suitable business environment but also decrease the cost of regulatory burden in pharmacy sector on GDP.

6.5: Analysis of the Results

This section, provides a comprehensive analysis of the survey results obtained from pharmacy owners and stakeholders across Pakistan. The survey responses shed light on various aspects of the regulatory burden faced by pharmacies, offering valuable insights into the challenges and experiences of businesses within this sector.

1. Overall Regulatory Burden

The survey findings reveal a substantial regulatory burden on pharmacies in Pakistan. According to the study, the total cost of regulation for setting up a pharmacy, as

reported by survey respondents, amounts to PKR 2.84 million. This includes expenses related to tasks such as finding a location, signing a lease, registering with relevant authorities, and obtaining licenses. The numbers indicate that the process of setting up a pharmacy is complex and resource-intensive, aligning with the overarching theme of the research, which highlights the challenges faced by pharmacy businesses.

2. Variation Across Regulatory Steps

The survey data provides insights into the varying levels of difficulty and costs associated with different regulatory steps. For instance, finding a suitable location and signing a lease are tasks that seem to incur moderate to high levels of stress and cost. The research indicates that these tasks cost approximately PKR 0.452 million and PKR 0.134 million, respectively. This suggests that real estate-related regulatory requirements can be particularly burdensome for pharmacy entrepreneurs. On the other hand, tasks like opening a bank account or renewing a drug sales license appear to be comparatively less stressful but still involve significant costs. These variations emphasize the need for a nuanced approach to regulatory reform, addressing specific pain points within the pharmacy sector.

3. Psychological Stress

The inclusion of psychological stress ratings in the survey is valuable for understanding the emotional toll that regulatory compliance takes on pharmacy owners. The survey responses indicate that certain regulatory tasks induce higher stress levels. For example, obtaining a domicile copy and handling inspections seem to cause notable stress, with stress ratings of 4 and 5, respectively. These ratings suggest potential anxiety and frustration associated with these processes. Recognizing the psychological impact of regulatory burden adds depth to the analysis, illustrating the human dimension of these challenges.

4. Information Costs

The survey results highlight the information cost incurred by regulatory obligations. This cost, which includes both time and financial expenses related to gathering information from various institutions, further underscores the complexities of navigating the regulatory landscape. The data shows that individuals seeking to start a pharmacy invest significant resources in acquiring the necessary information, which can be an additional deterrent for potential entrepreneurs. According to the survey, the total

information cost for opening a pharmacy is 3000 Rupees and 4.5 hours. This aspect of the findings reinforces the argument for streamlining regulatory processes and enhancing accessibility to information.

5. Cost to GDP

The survey contributes to the understanding of the economic implications of the regulatory burden. By calculating the percentage cost to GDP incurred by the pharmacy sector's regulatory burden, the research provides a macroeconomic perspective. The data shows that the regulatory burden in the pharmacy segment has a significant impact on Pakistan's GDP, amounting to 3.41% of the total GDP. This finding underscores the importance of regulatory reform not only for the well-being of individual businesses but also for the broader economic health of the country. It emphasizes that reducing regulatory burdens can stimulate economic growth and promote a more favorable business environment.

Overall Regulatory Burden: The survey findings reveal a substantial regulatory burden on pharmacies in Pakistan. The total cost of regulation for setting up a pharmacy, as reported by survey respondents, is notably high. This includes expenses related to tasks such as finding a location, signing a lease, registering with relevant authorities, and obtaining licenses. These financial burdens are compounded by the time and effort required to fulfill these regulatory obligations. The numbers indicate that the process of setting up a pharmacy is complex and resource-intensive, which aligns with the overarching theme of your research, highlighting the challenges faced by pharmacy businesses.

Chapter 7

Conclusion and Recommendation

Conclusion:

Research has conducted a thorough analysis of the regulatory obstacles faced during the establishment of a pharmacy in Pakistan. The primary results highlight the significant regulatory challenges encountered by entrepreneurs, as evidenced by a comprehensive compliance expense amounting to PKR 2.945 million. The burden associated with the establishment of a pharmacy has been thoroughly examined in a systematic manner, uncovering distinct financial and psychological problems at each stage of the process.

The financial expenses associated with regulatory compliance have been estimated, providing insight into the substantial economic ramifications for individuals and firms aiming to enter the pharmaceutical sector. The stress assessment used in this study involves assigning stress ratings to regulatory duties, offering a distinct viewpoint on the psychological impact that compliance imposes on entrepreneurs. This novel methodology highlights the emotional and cognitive difficulties that are associated with regulatory obstacles. The objective of our study is to enhance understanding of the intricate regulatory landscape inside Pakistan's pharmaceutical industry. This statement serves as a reminder for policymakers and regulatory authorities to thoroughly evaluate and revise current methods.

The findings presented in lines above reflect the difficulty of complying with regulations while opening a pharmacy in Pakistan, indicating that the total cost of the rules necessary to start a pharmacy is PKR 2.945 million. These costs include overhead, agency fees, direct costs, indirect costs, and the cost of renewing the medication sales license. The research separates the regulatory burden for distinct pharmacy setup tasks. The following are key conclusions:

- Acquiring a shop: Finding a good site and acquiring a shop for business costs 3,500 rupees and takes 12 hours of direct effort. An estimated PKR 0.587 million is faced by business in term of regulations overall to acquire a shop to start a pharmacy.
- Registering with PCDA: To register with the Pakistan Chemists and Druggist Association (PCDA), you must first get a National Tax Number (NTN) from the Federal Board of Revenue (FBR). The total cost of regulation for opening a bank account was calculated to be PKR 0.709 million.

- DHO licensing: Obtaining a license from the DHO requires a number of processes and pre requisites. These tasks are time-consuming and expensive and cause a regulatory burden of PKR 1.163 million.
- License Renewal for Drug Sales The process of renewing a license to sell drugs involves a number of steps and interactions with several organizations. The entire renewal process is quite time- and money-consuming. The total cost of regulation for license renewal is calculated at 476,868.2 rupees, excluding the license renewal price and the normal yearly fines.

The research accounts for both the monetary and psychological costs associated with each task. A stress score, which ranges from 1 to 5, is assigned to each subtask to indicate the perceived difficulty and potential challenges. The stress levels vary based on the activity; actions like obtaining an affidavit, opening a bank account, and gathering information are all connected with greater stress levels.

Recommendations:

In light of the findings of this research, the following are some proposals to lessen he burden of unnecessary regulations for opening a pharmacy:

1. Zero Waiting Period: A pharmacy should be able to open without having to first wait for an inspection and report. A person who wishes to start a pharmacy should be able to do so after submitting an application for a license. The inspection and the remaining criteria should be completed on the road to save time and money.
2. One-Stop Document Verification: Establish a single, centralized authority responsible for document verification. This authority, equipped with the latest technology and access to relevant databases, can quickly verify documents such as degrees, tax numbers, and utility bills. This eliminates the need for applicants to physically visit multiple institutions, saving time and expenses.
3. Digital Affidavit Generation: Develop a system for generating digital affidavits online. Applicants can fill out and digitally sign the required affidavits, reducing the need for physical stamp papers, notaries, and additional visits. This innovation expedites the process and minimizes associated costs.
4. Integrated Online Portal (IOP): Create an Integrated Online Portal (IOP) that consolidates all regulatory tasks and information. Through this portal, applicants can submit, track, and receive notifications on the status of their applications. This innovation streamlines the

entire process, reducing the time and effort required for document submissions and approvals.

5. Online Training Modules: Develop online training modules integrated into the IOP. These modules provide detailed guidance on regulatory compliance, reducing errors in applications. Completion of the training can be a prerequisite for application submission, ensuring that applicants are well-informed.
6. Standardize timelines and expenses. This will provide transparency and prevent regulatory organizations from imposing unfair fines. To avoid delays and confusion, the anticipated timeframes for each action should be specified in precise rules.

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Annexure:

Annex A:

Calculation of Regulatory Burden

Regulatory Burden								
Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time (Hours)	Agency Time (Hours)	Cost of Regulation (Rupees)
Setting Up a Shop	Finding a Shop	Visits to Realtor	0.75	3	1500	240	56 Hrs. (7 Days)	452,666.64
		Identifying the shop of preference	2.5	1	0			
		Meeting the Owner	2.5	1	0			
		Site Visits	2.5	1	500			
		Finishing the day	0.75	3	1500			
		Total	12 Hrs.		3500			
	Lease Agreement	Obtaining Stamp paper	1.25	1	600	56 Hrs. (7 Days)		134,478.96
		Printing and Finalizing Stamp paper	0.5	1	100			
		Signing Lease Agreement	1.75	1	0			
		Advance Rent Payment	0.25	1	45,000 Rs			
		Stamp Paper	-	-	50 Rs			
		Finishing the day	0.75	1	500			
		Total	4.5 Hrs.		46,250 Rs			
Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
Registration with PCDA	Obtaining NTN	Applying in FBR	0.5	1	0		24 Hrs. (3 Days)	33,093.66
		Getting NTN	0.25	1	0			
		Total	0.75		0			
	Opening a Bank Account	Information Gathering	0.75	1	500	160 Hrs.	120 Hrs.	423,529.04

			CNIC Copy	0.75	1	510	(20 days)	(15 Days)	
			Utility Bill Copy	0.25	1	10			
			NTN from FBR	0.5	1	10			
			Business Stamp	3	1	1500			
			Visit to Bank	0.75	1	500			
			Filling Bank Form	0.5	1	0			
			Applying for Bank Account	0.75	1	0			
			Finishing the day	0.75	1	500			
			Total	8		3530			
		Affidavit	Obtaining Stamp paper	1.25	1	650	8 Hrs. (1 Day)		29,752.00
			Printing Stamp Paper	0.5	1	100			
			Signing and finalizing the affidavit	9.75	1	0			
			Notarize affidavit	0.25	1	200			
			Total	11.75		950			
		Photos	Visit Studio	2.75	1	1500	8 Hrs. (1 Day)		21,187.45
			Attestation	2.75	1	0			
			Total	5.5		1500			
		Attested Copy of Matriculation	Copy Degree	0.5	1	510	120 Hrs. (15 Days)		202,078.29
			Visit to Concerned Board	0.5	2	1000			
			Submitting The Document	3	1	500			
			Collect the Attested Document	1.5	1	0			
			Online Appointment IBCC	0.75	1	0			
			Challan Deposit - National Bank Visit	3.5	1	500			
			Visit IBCC	3.75	1	1100			
			Finish the Day	0.75	3	500			
			Total	15.75		4110			

Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
License from DHO	Domicile Copy	Challan Deposit - National Bank Pakistan Visit	3	1	500	240 Hrs. (30 Days)	136 (17 Days)	583,511.18
		Finalizing the Documents	4	1	200			
		Visit Facilitation Center	0.75	1	500			
		Process - Challan Submission	2	1	0			
		Issuance of e-receipt	2	1	0			
		Finish the day	0.75	1	500			
		Collect the Domicile - Visit	2	1	6000			
		Fee Submission	2.5	1	0			
		Application Submission	0.5	1	0			
		Collecting the Certificate	1	1	500			
		Total	18.5		8200			
	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	0.25	1	540	56 Hrs. (7 Days)		103,025.60
		Lease Agreement Attested Copy	0.25	1	10			
		Affidavit	10.5	1	950			
		Photo	0.25	1	1500			
		D-Pharm Degree Attested Copy	0.25	1	10			
		Copy of PCDA Certificate	0.25	1	10			
		NTN from FBR	0.25	1	10			
		Location and Shop Details	0.5	1	100			
		Total	12.5		3130			

	Submit Documents to DHO	Visit DHO	0.75	1	500		8 Hrs. (1 Day)	16,312.46
		Submit Application	1	1	0			
		Finish the Day	0.75	1	500			
		Total	2.5		1000			
	Inspect and Reporting	Drug Inspector Visit	0.75	1	0		176 Hrs. (22 Days)	259,582.74
		Inspection	0.5	1	0			
		Finish the Day	0.75	1	0			
		Report Submission by Drug Inspector to DHO	0		0			
		Total	2		0			
	Collect License	Visit DHO	0.75	1	500		56 Hrs. (7 Days)	85,583.20
		Collect License	0.5	1	0			
		Finish the Day	0.75	1	500			
		Total	2		1000			
	Obligations	Fridge	0	1	50000			115,000
		Air Conditioner	0	1	60000			
		License Fee	0	1	5000			
		Total	0		115000			
Obligation	Requirement	Activity	Time Taken (Hours)	Repetition	Monetary Cost (Rupees)	Over Head Time	Agency Time	Cost of Regulation (Rupees)
Drug Sale License Renewal - Once every two year	Preparing Pre-Requisites and Documents for Drug Sales License	CNIC Copy (4)	0.25	1	540	56 Hrs. (7 Days)		103,025.60
		Lease Agreement Attested Copy	0.25	1	10			
		Affidavit	10.5	1	950			
		Photo	0.25	1	1500			
		D-Pharm Degree Attested Copy	0.25	1	10			
		Copy of PCDA Certificate	0.25	1	10			
		NTN from FBR	0.25	1	10			
		Location and Shop Details	0.5	1	100			
		Total	12.5		3130			

	Submit Documents to DHO	Visit DHO	0.75	1	500		8 Hrs. (1 Day)	16,312.46
		Submit Application	1	1	0			
		Finish the Day	0.75	1	500			
		Total	2.5		1000			
	Inspect and Reporting	Drug Inspector Visit	0.75	1	0		176 Hrs. (22 Days)	259,582.74
		Inspection	0.5	1	0			
		Finish the Day	0.75	1	0			
		Report Submission by Drug Inspector to DHO	0	1	0			
		Total	2		0			
	Collect License	Visit DHO	0.75	1	500		56 Hrs. (7 Days)	84,947.72
		Collect License	0.75	1	0			
		Finish the Day	0.75	1	500			
		Total	2.25		1000			
	Obligations	Renewal Fee	0	1	3000			3000
	Annual Visits of Drug Inspector	Fine	0	0	10000			10000
Total Regulatory Burden in Setting up a Pharmacy								2,936,669.74
								2,340,525,782.78
Regulatory Burden in Setting up a Pharmacy in Islamabad	Total Number of Pharmacies in Islamabad = 797							
Number of pharmacies in Pakistan	40000							117,466,789,600

Annex B:

Survey Questionnaire:

This survey is conducted to understand the sludge faced by in running and staring Pharmacies in Pakistan

As the objective of the survey is to ask about the cost of sludge involved in Pharmacy sector, we kindly ask you to answerfrom the local subsidiary's point of view.

No individual pharmacy information will be publicized as your answers will be dealt with as statistical figures.

If you should have any technical problems, please contact the people below. Any questions regarding the contents of the survey, please contact Shaheryar Ahmad, Shaheryar.pide21@pide.edu.pk

Pharmacy Name	
Year Established	
Status	

Question 1: How many permits renewals are required from you for running your pharmacy?__					
How many time you are required to get renewal each year:					
Name the organizations from which permits are required:					
How much time is taken each time for renewal					
Number of documents Require for the permits_____					
How Many times you have to visit a government office for renewal of required document?					
How many times you have used your links to get a job done_____					
0	1	2	3	4	More than 5
Scale stress from 1 to 5	1	2	3	4	5

Question 2: How many NOCs renewals are required from you for running your pharmacy_					
How many time you are required to get renewal each year:					
Name the organizations from which NOCs are required:					
How much time is taken each time for renewal					
How Many times you have to visit government office for renewal of required document? ----					
Number of documents Require for the NOC_____					
0	1	2	3	4	More than 5
How many times you are asked to pay other than notified fee to get a job done_____					
Scale stress from 1 to 5	1	2	3	4	5

Question 4: How many times you have visited any government office in last year_					
0	1	2	3	4	More than 5
How many times you have used your links to get a job done					
What government offices you visited last year?					
Question 5: How many times government officers have visited the Pharmacy for inspection					
How many times you have used your links to get a job done					
How many times you are asked to pay other than notified fee to get a job done					
Scale stress from 1 to 5	1	2	3	4	5
Question 6: How many times you paid fine in last year					

0	1	2	3	4	More than 5

How many times you have used your links to get a job done

0	1	2	3	4	More than 5

How many times you are asked to pay other than notified fee to get a job done

Scale stress from 1 to 5	1	2	3	4	5

Question 7: How many times you visited bank for your Pharmacy in last year

How many times you have used your links to get a job done

0	1	2	3	4	> 5

How many times you are asked to pay other than notified fee to get a job done

Scale stress from 1 to 5	1	2	3	4	5

Question 8: How many times you visited legal person in last year

How many times you have used your links to get a job done

0	1	2	3	4	> 5

How many times you are asked to pay other than notified fee to get a job done

Scale stress from 1 to 5	1	2	3	4	5

Question 9: How many time you visited courts or legal complier in pharmacy sector in last year

How many times you have used your links to get a job done

How many times you are asked to pay other than notified fee to get a job done

0	1	2	3	4	More than 5

Scale stress from 1 to 5	1	2	3	4	5

Question 10: How Much time you were Non-Operational because of fine, renewal delays and obligations -----

How many times you had to visit Government office to start operating again

What government office you had to visit?

How many times you had to use link to get job done?

How many times your asked to pay other than notified fee to get a job done?

0	1	2	3	4	More than 5

Scale stress from 1 to 5	1	2	3	4	5

Question 3: How many Licenses renewals are required from you for running your pharmacy?_____
How many time you are required to get renewal each year:
Name the governmental organizations from which Licenses are required:

How much time is taken each time for renewal?
How Many times you have to visit government office for renewal of required document? ----

Number of documents Require for the Licenses _____
How many times you have used your links to get a job done_____

0	1	2	3	4	More than 5

How many times you are asked to pay other than notified fee to get a job done_____

Scale stress from 1 to 5	1	2	3	4	5