EVALUATION OF PRICE-DETERMINING MECHANISM OF DRAP AND PHARMACEUTICAL INDUSTRIES IN PAKISTAN

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CERTIFICATE

This is to certify that this thesis entitled **"Evaluation of Price-Determining Mechanism of DRAP and Pharmaceutical Industries in Pakistan"** submitted by **Ms. Amila Rafique** is accepted in its present form by the School of Economics, Pakistan Institute of Development Economics (PIDE), Islamabad as satisfying the requirements for partial fulfillment of the degree in Master of Philosophy in Economics.

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Abstract

Before the independence of Pakistan, drugs were regulated under the Drug act of 1940. This act remained dominant and well into the 70s. Soon after, Pakistan enacted its first major Drug Act, the Drugs Act of 1976, that was designed in response to scientific developments over time and to address the shortcomings of the 1940 Drugs Act. After the 18th Amendment, the Ministry of Health (along with the Drug Regulatory Administration or DRA) was decentralized from the federal level, and provinces were authorized to regulate the pharmaceutical industry. The provinces failed to regulate the drugs such as licensing, registration, price regulation, import and export etc. Therefore, a resolution was issued, calling for regulation of pharmaceutical sector federally.

In its place, the Drug Regulatory Authority of Pakistan (DRAP) Act of 2012 was enacted in place of Drugs Act of 1976. DRAP was established after the disastrous incident of the "Fake Drug Crisis" in 2012, in which many people lost their lives in Lahore, under the umbrella of the Federal Health Ministry of Pakistan. It is responsible for the implementation of pharmaceutical rules and regulations in Pakistan. In 2015, DRAP introduced a Drug Pricing Policy to regulate the drug prices, replacing it with a new one in 2018. This study was carried out to analyze the role of DRAP in determining prices of drugs in the pharmaceutical sector of Pakistan and to investigate the drug pricing policies of DRAP in influencing the performance of the sector. For this purpose, mixed methodology was used which covered both qualitative (semi-structured interviews) and quantitative (firm fixed method & Average Treatment Effect Method) approaches. The findings clearly show negativity due to strict pricing policy due to which all the firms are affected and faced losses. Their revenue decreases due to the losses caused by political involvement.

The results of study showed that analysis suggest that the existing drug pricing determining mechanism needs to be revised in lieu of its negative repercussions. A good drug pricing system by the DRAP's Drug Pricing Committee and the Federal Government that strikes a balance between affordability (for healthcare users) and profitability (in lieu of pharmaceutical firms). This study recommends that the government of any regulatory body should not interfere in pharmaceutical market without keeping in view the demand and supply of drugs. Further, the DRAP pricing policy should be more transparent and liberal which would improve the functioning of pharmaceutical firms.

Keywords: Sales Practices, Role of DRAP, Strategic Pricing, Pharma Industry, Pakistan's

economy, Opportunities, and Challenges, DRAP, MNCs, Generic Medicine

Author's Declaration

I, Amila Rafique, hereby state that my MPhil thesis titled "evaluation of price-determining mechanism of **DRAP** and pharmaceutical industries in 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.

At any time if statement is found to be incorrect even after my Graduation the university has right to withdraw my MPhil degree.

Date: 20/7/2022

Amila Rafique.

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"I begin with the name of "ALLAH", the most merciful and mighty."

I offer my countless salutation upon my "beloved Holy Prophet MUHAMMAD (P.B.U.H) the entire source of guidance for humanity as a whole forever.

I deeply express my sense of gratitude and indebtedness to my honorable supervisor Dr. Nasir Iqbal, Associate Professor and Registrar (acting) at Pakistan Institute of Development Economics (PIDE), Islamabad-Pakistan, for his valuable guidance, positive criticism and constant supervision that helped me to complete this research work.

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Last but not the least I cordially appreciate the cooperation of my friends, Junaid Ahmad Khan, Talha Ghafoor, Sadaat Ali and Zarak Jamal Khan in data collection, compilation, tabulation and analysis as well as their friendly attitude and nice company during my stay with them.

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Amila Rafique

July, 2022

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Abbreviations

DRAP	Drug Regulatory Authority of Pakistan
DCO	Drug Control Organization
API	Active Pharmaceutical Ingredients
CPI	Consumer Price Index
DTL	Drug Testing laboratories
RP	Reference Price
IRP	Internal Reference Price
ERP	External Reference Price
FDI	Federal Drug Inspector
IP	Intellectual Property
ISO	International Organization for Standardization
MNCs	Multi-National Companies
WHO	World Health Organization
NHI	National Health Institute
OECD	Organization for Economic Co-operation and Development

Chapter 1

Background and Introduction

1.1 Background

Before Pakistan's independence, the subcontinent's pharmaceutical business was governed under the Drugs Act of 1940, which laid out the groundwork for future legislation. The Act provided a framework for where drugs[1] were manufactured, distributed, sold, imported, and exported. A central drug laboratory was established to check the quality of the pharmaceutical products, and drug inspectors were assigned to carry out the provisions of this Act (Khan, Sohail et al. 2020). This Act remained the dominant legislation governing regulation of drugs in Pakistan, well into the 70s.

Most countries adopted or amended their drug laws, rules, regulations, and guidelines after 1970. It was also advocated at the international level to standardize pharma rules for industry and authorities to have a shared understanding. Afterward, the US, Europe, and Japan collaborated to harmonize regulatory criteria, which culminated in the 1989 World Health Organization (WHO) Conference of International Drug Regulatory Authorities (ICDRA) in France (Brooks and Bürgin 2021). Resultantly, Pakistan enacted its first major Drug Act, the Drugs Act of 1976, that was designed in response to scientific developments over time and to address the shortcomings of the 1940 Drugs Act. After the 18th Amendment, the Ministry of Health (along with the Drug Regulatory Administration or DRA) was decentralized from the federal level, and provinces were given the authority to regulate the pharmaceutical industry (Nisa, Nadeem, et al. 2021).

But concerns were raised about drug regulatory devolution at a time when governments around the world were moving toward regionalization models of drug regulation. It was

[1] 'Drug' is the clinical/professional name for allopathic medicines, which are the basis of this study. 'Medicine' denotes a wider category that includes homeopathic, Ayurvedic, etc. categories too.

observed that licensing, registration, price, import and export etc. among other things, cannot be governed at the provincial level, therefore all provincial assemblies issued resolutions calling for federal legislation in the pharmaceutical sector. Resultatntly, the Drug Regulatory Authority of Pakistan (DRAP) Act of 2012 replaced the Drugs Act of 1976, essentially a continuation of the previous Act complemented by several major and minor changes (Khan, Sohai,l, et al. 2020).

DRAP's founding coincided with the disastrous incident of the "Fake Drug Crisis" in 2012, in which many people lost their lives in Lahore (Atif, Malik, et al. 2020). It is responsible for the implementation of pharmaceutical rules and regulations in Pakistan, while being also responsible for manufacturing, distribution, storage, medical goods sale, imports, and export of Drugs. In 2015, DRAP introduced a Drug Pricing Policy to regulate the drug prices, replacing it with a new one in 2018 (Areeba and Ali 2021).

1.2 Overview of DRAP

In recent decades, the Pakistan's pharmaceutical industry has grown rapidly. Few production units operated in the country at the time of the Independence of Pakistan back in 1947 (Qurashi, Khalique, et al. 2020). Currently, around 730 pharmaceutical manufacturing units (including 22 Multinational Companies) are operating in Pakistan (Najmi, Ahmed, et al. 2021). An estimated ninety-five percent of raw material used in drugs production is imported, mainly from China and India, while only five percent is met from domestic producers. The pharmaceutical industry of Pakistan covers 80 percent to 90 percent demand of the country for the finished/final dosage forms and also 4 percent of the active ingredients. Specialized biological and final dosage forms like oncology, vaccine serums, etc., continue to be purchased from abroad. The estimated size is about $3.1 billion, which is about 0.3percent of the global volume (1.1 trillion dollars in terms of product sales).

Pricing is one of the most critical and contentious concerns in the Pakistani pharmaceutical industry. Administrative entities, such as Pakistan's Ministry of National Health Coordination and Regulation, are in charge of authorizing a certain amount to be approved. The proposition is then sent to the Cabinet for final approval. The purpose of administrative authorities is twofold: 1) to defend patients' rights and provide high-quality healthcare to the general public, and 2) to allow companies to make a profit so that they can continue to create the drugs that people require (Organization (OECD) 2014).

Between 2001 and 2013, the pharmaceutical industry of Pakistan faced its biggest challenge in the form of a ‘price freeze’ policy of drugs (Munir, Rasid, et al. 2021). The government of Pakistan set this pricing mechanism in 2001 and did not permit the pharmaceutical companies to increase their product prices (except for a few hardship cases). Other issues plague the workings of the overall health sector as well. For example, a survey found that hardly 15percent of essential medicines were available in the public sector, and 30percent were available in the private sector (Sado and Sufa 2016), something other surveys of similar nature have also found.. The government does not allow the market to determine the prices through competition (Greenaway, Haines, et al. 2021).

Post-2012, with the founding of the DRAP, there has been a welcome shift away from the destructive/damaging "price freeze" policy. For pricing, medicines are divided into two groups: first, the ones included in National Essential Medicine list (NEML), and second group consisting of all other drugs. There have been two pricing policies since DRAP's inception in 2015 and 2018, with the latter coming to the fore after the intervention of the Supreme Court of Pakistan. It marked a gradual shift away from complete pricing control toward one based on Reference pricing and Consumer Price Index (CPI), a mechanism that is more acceptable to the industry (Mehmood, 2022).

However, to maintain some control over pricing, legislation has been tinkered with. For example, the rule for 'hardship' cases was modified under SRO No. F.11-2/2020-DD (P) dated 15th July 2020, which reduced the number of decision-making days from 180 to 120. But, part 'vii' of 'b', states that if the Federal Government has a 'cogent' reason, it can nullify agreed-upon price increases in line with CPI, thus managing to keep a window open for the government to nullify agreed-upon price increases (Mehmood, 2022).

According to the drug pricing policy, in Bangladesh and India, the initiated brands' Maximum Retail Price (MRP) remained the same and based on the average price of the identical dosage. In 2018 Policy allows for reference pricing for new brands, while continuing on with provision f CPI based pricing under the 2015 policy (with a price cap of 7 percent of essential medicines)(Kesselheim, Avorn, et al. 2019). The maximum retail price of generics is 30percent lower than the original brand.

In terms of pricing, pharmaceutical businesses can utilize a variety of pricing techniques, including **cost-based**, **competition-based**, **value-based pricing,** and **reference-based pricing** (Steinbrenner and Turčínková 2021). There has been a push for value-based pricing of medications in recent years. The price of a drug is determined by the value added to the product by its stakeholders, which is known as value-driven pricing. Moreover, Canada, Australia, and a few countries in Europe have already adopted this value-based approach.

In Pakistan, primarily due to dearth of research, opinions differ on the pricing methodologies pursued by the pharmaceutical sector. Some, like Ahmed (2019) believe that pharmaceutical firms are bringing pharmaceuticals to market at exorbitant costs, raking in big profits at the expense of customers. Multinationals can make huge remittances abroad based on transfer pricing, but they can also get higher prices for dosage forms due to overpriced raw

materials. This circumstance requires a good pharmaceutical drug pricing system that strikes a balance between affordability (for healthcare users) and profitability (Ahmed 2019).

The issue with the government price determination mechanism is that there does not exist any yardstick with the government for price stability in the pharmaceutical sector. The proposed study tries to fill in the gaps to prepare recommendations that are appropriate for the local market in context of pharmaceutical sector pricing policies. This will assist policymakers and other stakeholders in comprehending, identifying, and implementing policies to keep pharmaceutical prices at an affordable level for the benefit of Pakistani citizens.

1.3 Globally used price mechanisms

Equitable access to health is the basic right of every citizen. Provision of medication plays a vital role to ensure health and reduce mortality worldwide. Medicine pricing is the main determinant to promote medicines and ease the access for a normal citizen. Prices of medicines show variation across the globe and thus, each country having different pricing mechanisms inside the country (Cameron, 2009). Some of the price mechanism techniques are; Cost plus pricing, break even pricing, reference pricing, value pricing, value-based pricing, segmented pricing, competition-based pricing, market skimming pricing, psychological pricing, market penetration pricing, product line pricing, promotional pricing, optional products pricing, captive product pricing, by-product pricing, product bundle pricing, free pricing, drug pricing is determined by the country sources, external pricing and price contracts.

1.4 Problem Statement

At present, drugs related matters are dealt with under the DRAP Act of 2012, which in effect is a continuation of the Drug Act of 1976. Except for drug sales, storage, and distribution which is the domain of the provincial governments, the federal government regulates every other aspect

of drug manufacturing like (licensing), registration, price determination, import, export, and monitoring, etc.

However, there have been reported instances whereby drugs have been sold at rates exceeding the ones fixed by the government or cases that stood in contradiction to official policies. For example, in a complaint letter dated 12th May 2019 Transparency International Pakistan wrote to the Secretary Ministry of National Health Services Regulation and Coordination about the extraordinary increase in drug prices by DRAP on 5th April 2019. The complaint letter reported that the factor on the cost of manufacturing was increased by DRAP five times from 70 percent in 2015 to 355 percent in 2018 which could not be supported on any rational basis under the Drug Pricing Policy (International 2019).

Going through the previous literature has revealed that the DRAP in coordination with pharmaceutical firms have no obvious and defined pricing mechanism. Therefore, the primary goal of this study is to analyze the current pricing model used by DRAP to set prices of different medicines and evaluate alternative pricing models to check if they are well suited to the conditions prevalent in pharmaceutical companies in Pakistan. Additionally, this research is to understand the impact of pricing mechanisms and strategies and also try to identify the challenges and issues the pharmaceutical firms face due to the medicine pricing regimes which is proposed by the DRAP.

Based on the narrative above, I am narrowing my research problem into "**Evaluation of Price-Determining Mechanism of DRAP and Pharmaceutical Industries in Pakistan"** and have set my topic into the following research questions and objectives**.**

1.5. Research Questions

1. Price determining policy at the federal/regulatory level?
2. How does drug pricing policy impact financial performance of the pharmaceutical industry?

1.6. Objectives of the Study

The primary objective of the study is to analyze the role played by DRAP in the process of determining drug prices in pharmaceutical industry of Pakistan. Besides, the study attempts to evaluate the impact of pricing policies of DRAP on the performance of the pharmaceutical industry.

- Main objective of the study was to deduce industrial monetary/financial performance in lieu of pricing regulation
- Novel methodology used in the paper, in terms of deducing results through Stock Exchange listed firms and their financial statements. Further, to investigate the drug pricing policies impact financial performance of the pharmaceutical firms.

1.7. Research Hypothesis

The purpose of the research analysis is to test empirically the following hypothesis, which is based on the study's goal. The hypothesis is stated as:

H0: Price determination with industry's consent will have a significant impact on the performance of the firm

H1: Price determination with industry's consent will not have a significant impact on the performance of the firm. Put another way, the hypothesis tests whether pricing policies have noticeable significance?

1.8. Research Gap

There are many studies globally in the context of the economic impact of Drug Pricing policies, but few studies are available both on the regulatory body as well as pharmaceutical industries price determining mechanism. Moreover, the studies conducted with reference to pharmaceutical industries in Pakistan are unclear about the pricing model used to determine drug prices in the country. This creates an information asymmetry for policymakers when it comes to determining which mechanisms should be applied to improve affordability and outcomes in terms of medicine prices. In Pakistan, according to S. Lee (2017), the pricing affordability and survey studies are still lacking. As such the set of complete tools are not available for the formulation of policies, regulation and implementation.

The study aims to fill the gap by not only analyzing the official pricing policy, but also the impact of its working on financial performance of listed pharmaceutical companies.

1.9. Significance of the study

Some facts about the industry are well-known. One of these is that pricing is a contentious issue, arguably the most contentious, between the industry and the government. However, other, equally important facts are lesser known! One of these is analysis of the pricing model that is used by regulator for pricing medicines/drugs, compared to the available global models. Then, there is the spillover analysis of what the official pricing policy does? For e. g, firms often complain that the nature of pricing implementation affects their financial performance. Yet there has never been any analysis of their financial statements to determine the validity of the claim.

In this context, this study is novel in its aim of gauging firms' behaviour to official pricing policies through their financial statements. Moreover, we try to examine the pricing model in context of global practices.

Therefore, the core task of this study is to evaluate the price determination mechanism under practice in the pharmaceutical industry in Pakistan. In this context, there are approximately three models used globally and we try to find which model is used in Pakistan; and what are the pros and cons of that model keeping in view the research question under study?

1.10. Comparison of post and pre-DRAP policies

It's instructive to analyze, albeit briefly, the difference between DRAP and its predecessors, Drug Regulatory Authority (DRA), in order to understand the context for our research effort (Mehmood, 2022)

In 2017, Dr. Sania Nishtar, who headed the Social Safety Net of the country during PTIs government, and is also considered one of the leading experts in the health department, stated that there was no difference between the autonomous regulatory body (DRAP) and its all predecessor. Further, since DRAP's performance as the main regulator is under consideration, and it's always feasible to compare the performance of the regulator with its predecessor. In the case of Pakistan, the pre- DRAP authority was the Drug Control Organization (DCO), working under the Ministry of Health (MOH) since 1976 and provided their services like DRAP. The following table, taken from Mehmood (2022) analysis of DRAP, briefly explains the situation and issues post and pre-DRAP.

Table 1- Comparison of DRAP and its predecessor		
Category	**DCO**	**DRAP**
Autonomy	• Drug Control Organization was working under the National Health Ministry. • Under DCO, all the operations needed approval from the federal govt.	• Drug Regulatory Authority of Pakistan has comparatively strong and greater autonomy. • It decides for all the operations and functions autonomously, but still works under National Health Services, Regulation and Coordination Division (NHSRC). • Major operation took after the approval of the policy board, provincial representatives, and federal secretaries.
Drug Pricing policy	• Before 2001, price increases, but after that, the freezing price policy was implemented. • Price freeze policy of drugs continued till 2013.	• When DRAP establish and functional then they disallow the freezing price policy of the drugs in Pakistan. • Because, the price freeze policy given a bad impact and outcomes. • New pricing policy was introduced in 2015. • However, the government disowns that policy several times after the commitment. • After the intervention of the Supreme Court, another pricing policy was introduced but persist pricing issue is still a political issue which means that it requires the nod of the cabinet rather than being decided by the demand and supply.
	• DCO failed to tackle the drug price dispersion issue with the mislabeled drugs,	• After the DRAP, the market imperfection issue still existed in Pakistan. • Price dispersion or price differentiation

Market Imperfection	same molecules, and techniques of deceptive marketing. • DCO unable to handle the critical issue of black marketing of the drugs in the country. • Various types of charges and taxes levied on the pharmaceutical industries.	is prevalent in the drug market. • Misleading of brand and misleading of advertisement still remain resolved. • The issue of black marketing has still existed. • Another issue for the pharmaceutical industry is the heavy charges and taxes.
Transparency	• For the public, little information exists regarding underlying regulations and operations. • Usually, the public learn through the World Health Organization (WHO) or other similar reports about DCOs activities.	• The majority of actions, notifications, and decisions are available on the official DRAP website. • Transparency system is comparatively higher than DCO. • DRAP officers are not ready to share the drug pricing policy's information with the public. • But short-term changes in the policies through the SROs are non-transparent.
Research	• Little/less record available in terms of the research. • Poor research available on the issues and problems of the pharmaceutical industry which hinder the market's smooth function.	• No research efforts or reports aimed at discussing recurring and critical issues. • No research wing existing in DRAP to the evaluation of the critical problems plaguing the pharmaceutical sector. • No attempt to build research connections with the relevant national and international academic institutions.
Intellectual	• The overall	• Minimal regulatory policy or

property protection	performance regarding IPP was poor. • No regulations or policy measures to prevent patent drugs and to protect cheaper drugs being sold in any market of the country. • Even though at Pakistan signed the Trade-Related Aspects of IPP agreement in 1995.	mechanism to protect patented drugs and Intellectual Property Rights. • Patented generic drug brands are available while copies of the original drugs are still a greater issue. • No/fewer rules and regulations existing to enforce the mechanism for IPP Trade-Related Aspects.
Quality of the medicines dispensing	• For a long time, lack of trained staff, and pharmacists with perfect and exact knowledge about the dispensing and drugs has been a problem in both health facilities and retail outlets. • Policies were proposed like the National Good Practices of Pharmacy Guidelines in 2011, but they were rarely carried out.	• As policy implementation leaves significant voids, ensuring quality dispensing remains a pipe dream. • Despite both Provincial and Federal regulator's efforts, the availability of required equipment and qualified pharmacists are considered a major problem.
Infrastructure	• Poor infrastructure in terms of serve provision and Research and Development that could not deliver the best quality of drugs to their consumers but	• Performance of DRAP is comparatively better than its predecessor. • Now, 12 DTL labs are working all over the country. • However, due to the better performance, one lab is certified by WHO standard, while none of them is

	also provide supportive efforts to the pharmaceutical industry. • Hardly, three DTL labs functionalize in Pakistan and no one is qualifying either USFDA or WHO standard.	still USFDA certified lab.

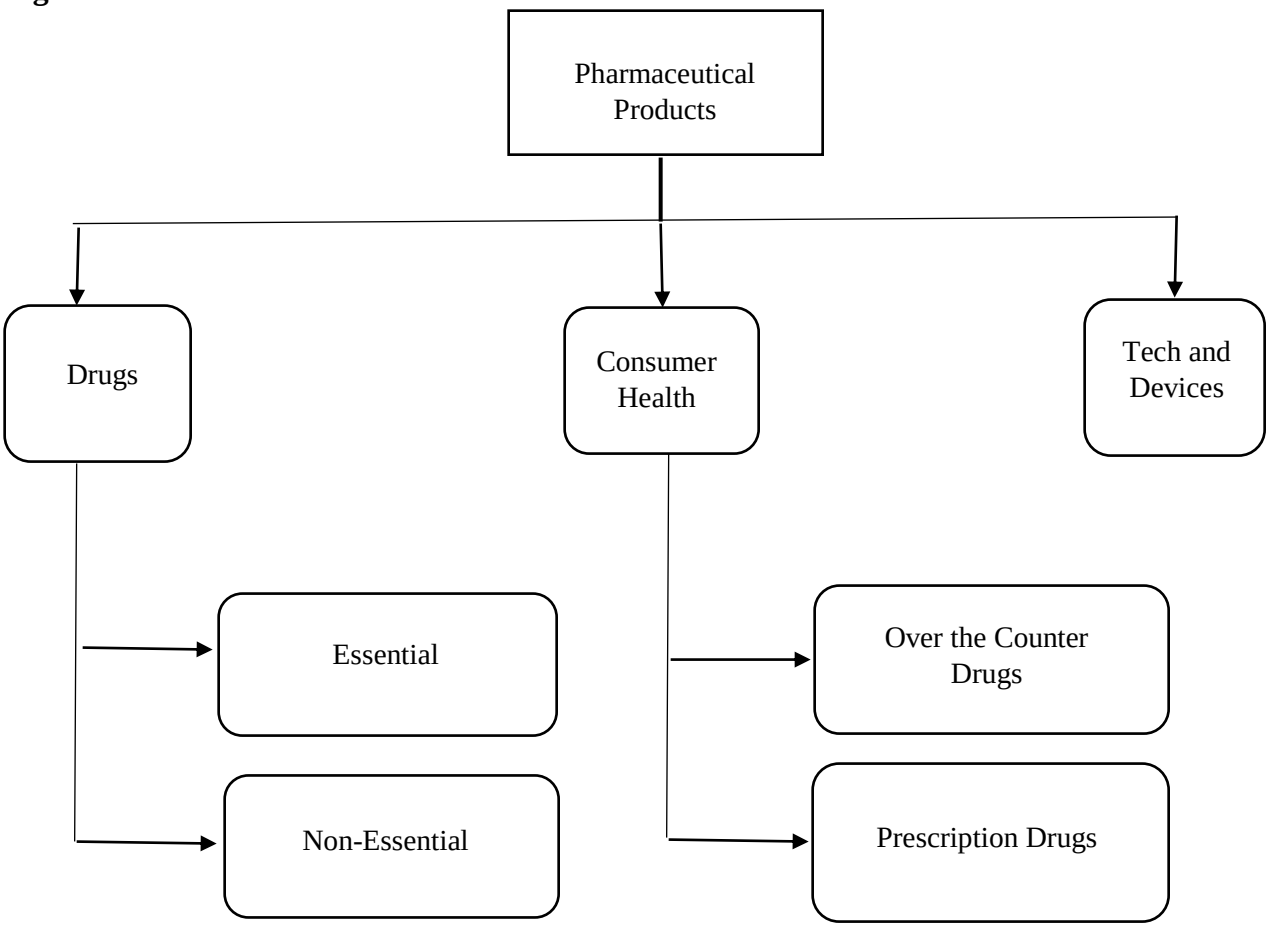
Chapter 2

Literature Review

Pharmaceutical Industry

The pharmaceutical industry is responsible for the production, branding, marketing, and development of essential pharmaceuticals. Pharmaceutical sector deals in counter, generic, branded and generic branded drugs in the country. Firms also engage in manufacturing or contract development where industry provides their comprehensive services to another manufacturing firms (PACRA, 2021).

Figure:1

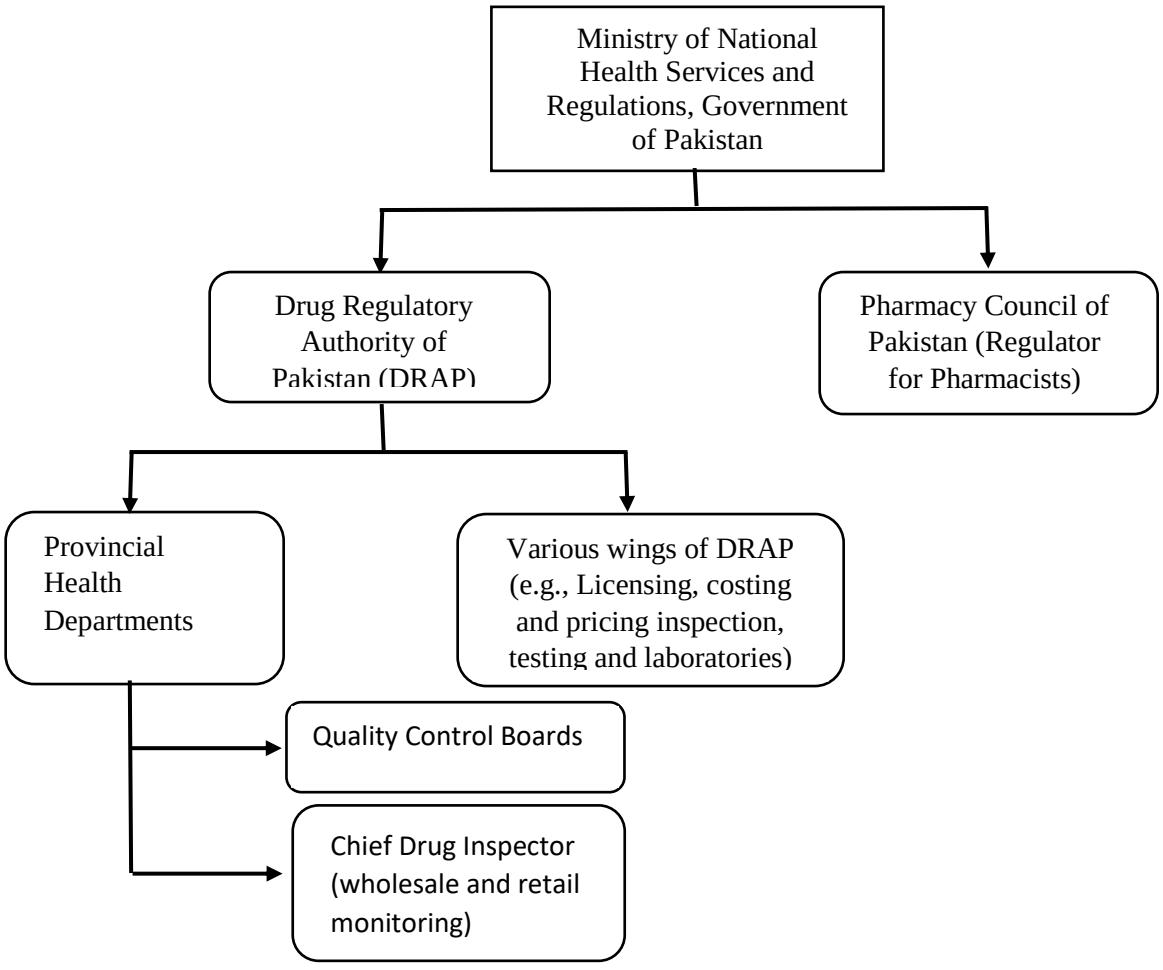


Source: DRAP 2022

2.1 Current Pharmaceutical Regulatory structure in Pakistan

In Pakistan, from licensing to pricing, registration, and final retail price, drugs are fully regulated by the government under DRAP Act of 2012, which is a continuation of the Drug Act of 1976, the fundamental and important legislation governed by the state. This act actually empowered the health ministry to structure the pharmaceutical sector. Following the 18th Amendment of the constitution, health was transferred to the provincial level and removed from the concurrent list. All the functions were transferred to the Division of Cabinet under the Act of 1976 as the health ministry was dissolved. But the function was again returned to the federal government as DRAP Act was approved in 2012. Further, the MNHSRC controls Pakistan Pharmacy Council (PCP). (Kabeer 2019).

Figure 2: Pharmaceutical Regulatory Structure in Pakistan



Source: Author

2.2 Contribution to Economy

Pharmaceutical industry's estimated contribution to the economy was PKR 416bln in FY19-20 and PKR 453bln in FY20-21, reflecting 9 percent YoY growth (PBS, 2020). Despite the huge number of licensed companies (620, with pharmaceutical industry officials claiming it to be at least 730), the pharmaceutical sector is occupied by the top MNCs and local companies. Ninety-Seven percent of market shares are held by the top 100 companies and remaining three percent is held by more than 500 firms.

Furthermore, eighty percent market share is held by the top 50 companies. The sector is highly dependent on the imports to meet the required raw material's demand. Ninety-Five percent Active Pharmaceutical Ingredient's (APIs) requirement are fulfilled by the imports and remaining 5percent by domestic production (PBS, 2020).

Table 2

Particulars	**FY19**	**FY20**
Gross Revenue	PKR 416bln	PKR 453bln
Contribution to GDP	1.16%	1.17%
Registered Firms	620	620
Structure	Competitive	
Imports	PKR148bln	PKR158bln
Exports	PKR29bln	PKR33bln
Regulator	Drug Regulatory Authority of Pakistan	
Association	Pakistan Pharmaceutical Manufacturers Association (PPMA)	

Source: IQVIA, PPMA, PBS, DRAP

2.3 Cost Structure of the Pharmaceutical Industry

The pharmaceutical cost product structure can be split into the following

2.3.1 Active and Other Ingredient Cost

The active ingredient cost mostly varies between 10-30 percent of the total product cost. Whereas, the cost of other ingredients is not more than 3 percent of the overall cost.

2.3.2 Packaging Martial and Manufacturing Cost

The packaging material ranges Rs 5-10 of 10 capsules/tablets per pack, 5ml per injection, 50 grams per tube of the ointments, and 60ml per bottle of liquid (Irfan 2018). The manufacturing cost depends on the produced quantity of the drugs in a plant. The generic substitution of the drugs gets 25-40% less price which almost become the reference price. All this is illustrated below through an example,

Retail Price	Rs. 300 for 10 tablets/capsules pack
Active ingredients in each capsule/tablet	10mg

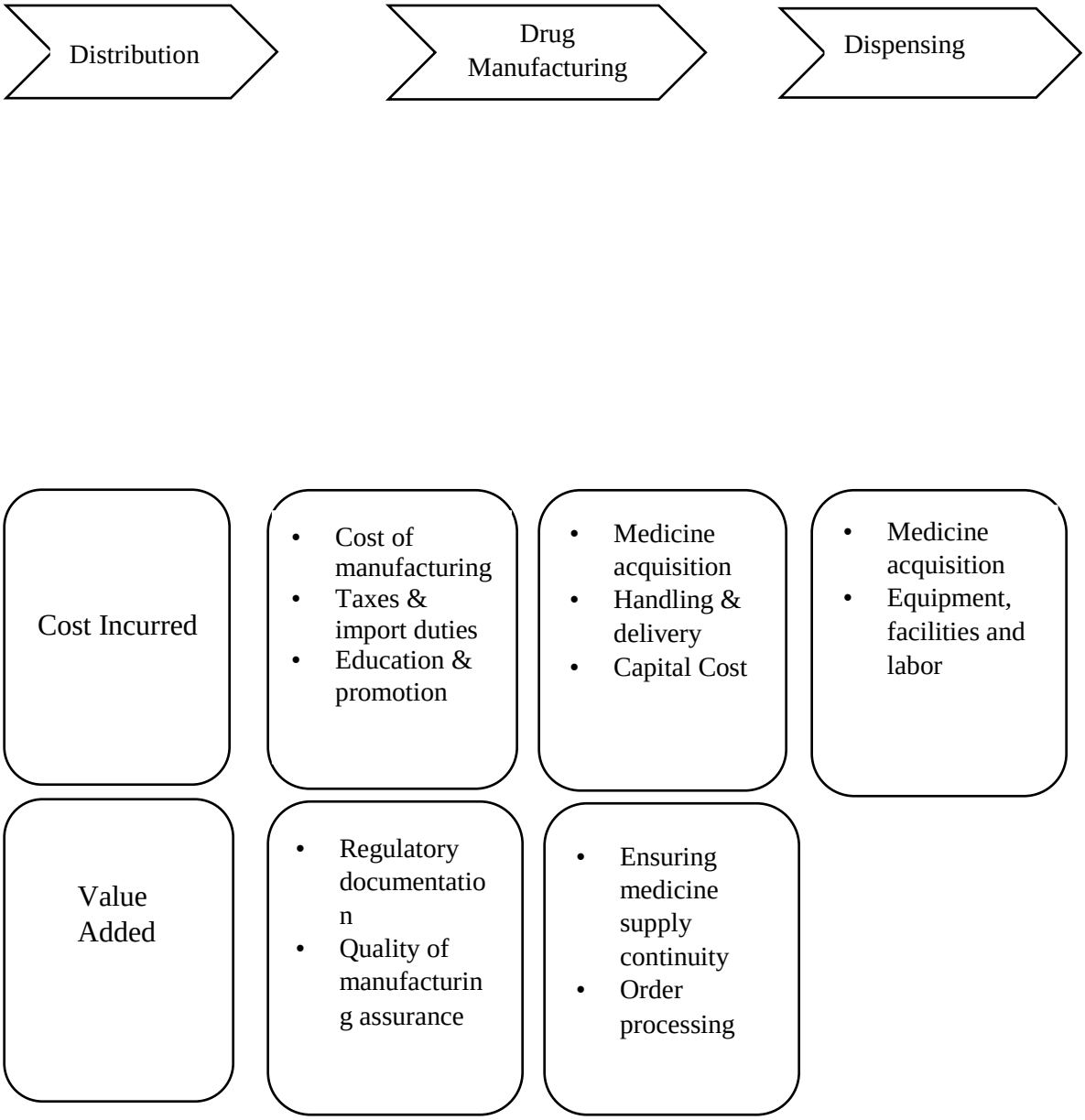
The cost of ex-factory for these products will be

Retail Price (15% margin of retailer)	300-45 = Rs. 255
Distributor Price (10% margin of distributor)	255-25.5 = Rs. 229.5 (ex-factory cost)

2.4 Pharmaceutical Cost and Value Chain

The structure of the pharmaceutical industry is quite complicated, and it is represented by a mix of direct (production) and indirect costs (regulation and development). Value chain contains all underlying costs including implicit, explicit, direct and indirect costs. The value chain of pharmaceutical sector is divided into three major components such as Dispensing, Distribution, and Manufacturing.

Figure. 3



Source: Author's Compilation

Various studies have analyzed different models for the price-determining mechanism in the pharmaceutical industry. Khan (2020) wrote on the historical evaluation regarding drug laws for regulating the health industry. He said that after Pakistan's Independence, multiple rules were enacted to standardize the pharmaceutical industry. In 2010, health services, including medicines, were transferred from the federal government to the provincial government. However, due to significant gaps in its implementation, provincial governments passed resolutions, asking the Federal Government to establish a centralized drug regulatory agency. The government created an independent agency called the Drug Regulatory Authority of Pakistan (DRAP) under the Ministry of State Health Services, Regulation, and Coordination (Khan, Sohail, et al. 2020).

Cost-based pricing is a pricing strategy in which a proportion of the overall cost is added to the cost of the product to establish its selling price, or, in other words, a pricing method in which the selling price is decided by adding a profit percentage to the cost of creating the product (De Toni, Milan, et al. 2017). It is a method of pricing that includes the expenses of making, delivering, and selling the product and a reasonable interest rate to account for the company's efforts and risks. It's a straightforward method of estimating a product's price by adding the targeted profit to the overall cost to arrive at the final market value. Thus, cost-based pricing could be defined as a pricing strategy that determines a product's price by first determining the product's cost, then adding the intended profit, and then determining the ultimate selling price (Khoso, I., Ahmed, R., R., &Ahmed, J., 2014).

In 2015, the first comprehensive Drug Pricing Policy (DPP) was implemented to ensure the long-term viability of the domestic pharmaceutical industry and the accessibility of medications. Moreover, Lee (2017) undertook a deep analysis of the price controversies in Pakistan. He analyzed all the medicines are regulated under the Drug Act 1976 and the DRAP

Act 2012, under which the medicine distribution, storage, and sale, are regulated at the provincial level while the pricing, export, registration, manufacture (licensing), import, and regulation of controlled substances fall under the jurisdiction of the federal government. The DRAP was established under the Act of 2012 to regulate the above matters, including pricing, under the leadership of the Federal Government. The Departmental Promotion Committe (DPC) is made up of representatives from the provincial health ministries, finance ministries, and consumer groups, as well as stakeholders as observers at committee meetings (Lee, Shahidullah, et al. 2017).

Lee (2017) further elaborates that the Pakistani government, specifically DRAP, in collaborative efforts with provincial health authorities, is in charge of regulating medicine prices and has implemented several restrictive frameworks to address the problem of medicine accessibility, particularly in terms of prices (Lee, Shahidullah, et al. 2017).

Mehmood (2022) opined that the majority of studies on pharmaceutical companies and government laws focus on one particular (or a few) criteria rather than a comprehensive picture. The issue of drug prices, for instance, has been discussed in several studies. He cites the other papers like Rizvi (1999) who blamed government actions, particularly the 'freeze' of medicine prices, as the principal cause of shortages (Robinson, Montefiori, et al. 1999). Pakistan has a shortage of vital medications. Third World Network Briefing (2001) published a paper on the subject that discussed the issue of high-priced imported medicines and the underground market in medicines, in Pakistan, the role of government-mandated quotas, and their implications on medication supply (Harkavy and Neuman 2001).

Neha P. Paranjape (2021) analyzed that the drug development sector is a complex regulatory, time-consuming, and difficult procedure. She observed that the market, competition,

patent life, and value of the drug are all factors that corporations must consider when establishing the price of a drug. Pharmaceutical businesses can utilize a variety of pricing techniques, including cost-based, competition-based, and value-based pricing. There has been a push for value-based pricing of medications in recent years. The price of a drug is determined by the value added to the product by its stakeholders, which is known as value-driven pricing. The value of a drug is determined by the advantages it offers over the standard of care, as well as the cost savings it delivers by preventing complications and hospitalization, which reduces the total burden on the healthcare system. Moreover, Canada, Australia, and a few countries in Europe have already adopted this value-based approach. The Medicare and Medicaid programs, the private payers, and the Veterans Administration are increasingly using it to negotiate prescription prices with biotech and pharma businesses (Paranjape, Staples, et al. 2021).

Paul H. Keckley (executive director) of health solution, Deloitte Centre proposed a value-based model for U.S. pharmaceutical companies and also calls for the best and most innovative approaches and methods to the commercialization and the price-determining mechanism. After analyzing, he concludes that both buyers and sellers took incentives when they used a value-based pricing model. Furthermore, payers and pharmaceutical corporations agree to link payment for treatment to the value achieved rather than volume in value-based pricing agreements. According to him, pharmaceutical companies determine the prices of the drugs in terms of value rather than in terms of volume (Keckley and Hoffmann 2010).

John Armstrong and Colleen Becker (2019) suggested that the value-based pricing (VBP) of pharmaceuticals is one cost-cutting strategy that has gained support in recent years. When drug producers and purchasers negotiate the pricing of a drug based on patient financial incentives, or health outcomes, value-based buying agreements are formed. Further, he argued that if the manufacturer guarantees the effectiveness of these new treatments, alternative

payment methods, or APMs, have arisen as a possible strategy to limit the upfront costs of these new drugs. Health insurance negotiates with private pharmaceutical companies for rebates, discounts, or other incentives based on the efficacy of a drug in treating an illness (Armstrong and Becker 2019).

KPMG International Strategy Group also emphasizes that pharmaceutical companies are under intense pressure to demonstrate the value of their goods in the face of frozen healthcare budgets and rising demand for treatment. It is no longer enough to show that pharmaceuticals are effective; they must now show superior results that justify the price tag when compared to conventional therapy — preferably with concrete evidence. As several Western economies are still in survival mode, multinational pharmaceutical corporations are being scrutinized by the public and politicians, with calls for a comparison to the conventional, sales-driven marketing approach. Value-based pricing is one payment strategy that is gaining popularity (VBP) (Maile, Mitra, et al. 2022).

Is VBP able to deliver on its promises? Is it just another convoluted method of offering discounts? Risk is distributed among payers and pharma companies under a VBP agreement, thus both parties should focus on the appropriateness of usage and outcomes. KPMG group believes, that VBP may contribute to the value that healthcare systems and patients are searching for with specific products and under particular conditions (Maile, Mitra, et al. 2022).

John Dunn (2016) analyzed that mandating a cost-plus pricing model is one way to limit the industry's ability to set prices. The government only allows the corporation to charge enough to pay production expenses and make a "reasonable return" on the product's sale under such regulations. This might be done to make the drug more available to the general public while also preventing the firm from making too much money. However, the trend of using a cost-plus

policy to control medical costs is fading. Both Germany and the United Kingdom have moved toward value-based pricing. The Affordable Healthcare Act also introduced customers in the United States to the value-based healthcare philosophy. There are numerous reasons for this, but basing price on a shared knowledge of performance and cost between the performance of seller and buyer has the potential to benefit both parties.

Peter J. Rankin undertook that few other worldwide markets allow free pricing, which is a dramatic and urgent consideration for pharmaceutical companies used to launching products in the US, UK, or Germany. Price talks can take a long time. The average period of pricing talks in France is more than double that of the European countries. Manufacturers may be required to make other concessions in terms of cost and quality in these talks. Manufacturers in the United Kingdom, for example, are bound by a certain degree of profitability. Manufacturers in other nations, such as Spain, are required to commit to specified sales targets. Manufacturers are held liable for recapturing the cost of goods sold that exceed volume obligations, either through price reductions or by paying back profits directly.

Nigel Gregson (2005) said that the limitations of a viable pricing range are decided by evaluating the product from two different points of view: the market and the corporation. The market viewpoint is primarily concerned with determining the product's worth to its purchasers from the perspective of the competitive environment. This market or 'value-based' approach to pricing is the main focus of pricing strategy creation, and it tends to set the maximum level on a viable price range. The market perspective setting must be accompanied by an internal corporate assessment of expenses and ROI needs (Gregson 2005).

The World Bank (2007) suggested the Medicine Transparency Alliance (MeTA) which is a multinational alliance that was founded in the middle of 2007. It will assist national initiatives

to improve transparency and build capacity in pharmaceuticals policy, procurement, and supply chain management through partner organizations (including the World Health Organization, the World Bank, DFID, and Health Action International). This approach entails clear international commitments to support national efforts, as well as targeted technical and financial assistance to improve openness and accountability. Such performance would aim to increase access to information regarding the quality, availability, and pricing of medicines, with robust civil society and consumer participation in the scrutiny and debate.

Moreover, the Indian government considers the pharmaceutical business to be a matter of industrial policy rather than public health. While access to medicine, as well as the pricing and quality of drugs, vary widely across India, the government employed industrial policy to kick start the sector in the 1970s. It created an incentive structure for home producers (pricing controls, local sourcing laws, and restrictions on API imports), encouraged development and research, and developed an enabling patent regime that included process patents for a limited time. Foreign companies were also compelled to invest a minimum amount of capital in R&D sectors in India, as well as reinvest a portion of their revenue in local R&D facilities.

According to Kah Seng Lee (2021), differential pricing is mostly regulated by pharma firms and the supply chain, but it can be influenced by a variety of circumstances. WHO/HAI uses a pricing comparison between nations to keep track of price changes. The picking of the target price to be utilized as a comparative basis is the most challenging part of this. Buyer strategies, on the other side, can impact medicine costs. Buyers could do a pharmacoeconomic analysis before attempting to negotiate. Governments could also participate in the drugs sector by seeking to impose price and profit control systems on manufacturers, conducting reference pricing and marketing health care costs, utilizing international benchmarking, lowering tariffs

and taxes, establishing production margins, and trying to implement capitation systems. Globalization is an important factor to consider (Lee, Kassab, et al. 2021).

Further, charges by traditional manufacturing and distribution have influenced pharmaceutical prices since the dawn of globalization. In the European Union (EU), drug parallel importation is frequent. It could be helpful to pharma traffickers since a branded medicine could be sold at a lower price in one sovereign nation and then shipped to another country at a lower price. Big industry participants are voluntarily lowering prices, making antiretroviral medicine more affordable in low-income nations grappling with the HIV/AIDS pandemic (Lee, Kassab, et al. 2021).

OECD (2018) highlighted the factors that explain all the level at which the prices of the drugs are set, including the competition degree in the market. In the competitive market, the prices of the drugs will be near the cost. If the prices will be higher than the market deviate from the perfect competition. Competitive authorities and the courts of Europe have made different methods to examine excessive prices over time. One of the best methods depends on the comparison between the prices and the production cost of the medicine. Moreover, the analysis of the cost/price may not be appropriate in some cases, e.g., due to the deficient data or due to the intangible good’s prices like IP rights. In Europe, the three-step method applies before the comparison of the medicine prices. Firstly, prices charged on comparable markets must be adjusted to reflect the characteristics of the market where the undertaking has a dominant position. Secondly, the safety margin varies from case to case to prevent the over enforcement. Lastly, it must be established that the dominant company's prices in the particular market are significantly higher than prices in comparable markets (Habimana 2022)

In the 1970s, the German authorities discussed many cases especially concerning the excessive pricing of pharmaceutical products. The representative case at that time was the Valium case. Following comparisons of prices quoted in Germany and other European markets, as well as a comparison of cost and profit, it was discovered that prices were 35-40 percent too high. The Bundskartellamt decision was upheld and appealed by the Berlin Regional Court which decrease the excessive prices based on benchmark prices because the court opined that the benchmark prices are the most adequate tool for comparison. That decision was further appealed to the Federal Court, which decided in the favor of the company. A recent case was filed in private court. After several years of gradual price increases, a pharmaceutical manufacturer raised prices by 400 percent all of a sudden. The applicant was entitled to damages equal to the difference between the price paid and the price that would have been imposed under competitive conditions, according to the court (Habimana 2022).

Further, in UK, Office of Fair Trading (OFT) continued to pursue a case in 2001 involving the overpricing of a sustained-release morphine product. Because there were two aspects to the case: anticompetitive low pricing for the hospital sector and exaggerated pricing for the community sector, it was unquestionably not a traditional excessive pricing case. While the OFT chose to prosecute the case as two separate violations, this particular case of excessive pricing could have been framed as ongoing reimbursement from the dominant company's predatory strategy rather than as a separate violation.

Similarly, in South Africa, the Competition Committee found in 2002 that antiretroviral manufacturers' treatments for HIV/AIDS patients had mistreated their dominant leadership roles by charging exorbitant prices, refusing to allow competitors access to critical facilities, and trying to engage in exclusionary practices. The Commission announced at the end of the investigation that it was referring to the case to the Highly Competitive Tribunal for

adjudication. The Pharmaceutical producers negotiated a settlement agreement before the case was referred and prosecuted, in which they publicly acknowledged no liability (OECD, 2018).

Annalisa Belloni (2014) analyzes the regulator of drug prices in Canada. According to him, all the patent medicine's prices regulate at the Federal level in Canada by reference pricing. The Patent Medicine Price Review Board (PMPRB) was established to ensure that patent drugs were not sold at an excessive price to Canadian consumers. Furthermore, the price of a patented drug may not exceed the highest price of the same drug in any of the seven foreign countries at any time (Annalisa Belloni, 2014).

Ellen Nolte (2013) identified that drug prices vary from country to country. Cross-national pharmaceutical price comparison is challenging due to the sales relative level differences across the globe. Furthermore, fluctuations in the rate of exchange, proportion, and pharmaceutical expenditures are also compared. Ellen Note also highlighted that the pharma market in the countries across the world does not work/follow the exact rules as the other markets. Market distortions arise both from the supply and demand sides, with multiple players involved, such as the prescribing physician, pharmacists, and patients, as well as third-party payers (for example, local or national governments, health insurers) offering partially or fully public subsidy for drugs. The correction of the market failure/distortion means curbing the spending of the pharmaceutical industries generally, and European governments and elsewhere have familiarized reimbursement and pricing policies.

Moreover, most countries in Europe direct price control form which also involves the maximum fixed price setting of all the medical products, as well as the use of the price influence measures like public procurement/price negotiation and, statutory prices. Conversely, the free pricing mechanism is considered uncommon and implemented only for certain products, such as

the newly launched patented pharmaceutical product mainly in the United Kingdom (UK) and Germany. The external Reference pricing model is used in European countries for determining drug prices.

Kai Ruggeri (2013) provides a pharmaceutical pricing overview of Germany, Italy, France, Spain, Canada, and the Netherlands. All countries set their drug pricing mechanism according to the External Reference Pricing principle except Germany. Further, he explained that External Reference Pricing principle provide the base for the negotiations among the pharmaceutical industrialists and the government agencies for medicinal products in all around the world (Ruggeri and Nolte 2013).

However, the role and responsibility of an organization or agency outside of government in determining value varies country by country. Italy, unlike the other countries examined here, no longer uses external reference pricing; in fact, this strategy was abandoned in 2001 due to a perceived lack of effectiveness in cost control. Although prices from other countries may be used to inform decisions, the main mechanism for determining prices is through negotiations between the Italian Medicines Agency (AIFA) and pharmaceutical companies. Similarly, Germany does not strictly adhere to an external reference pricing system. Since 2011, all newly licensed medicines have been subjected to a benefit assessment, which is used to determine the new product's price. If negotiations fail, an arbitration committee will determine the level of reimbursement based on European prices.

Finally, countries differ in terms of the sources they use to calculate prices in other countries. Payment for privately-owned data from research firms was the most common technique in the countries studied, with some interaction with different national health offices.

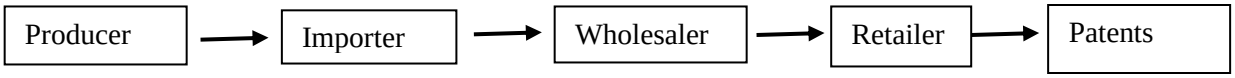
Yemen, Walid Kassab (2020) described that different drug pricing procedures and policies were implemented in order to counter the increasing trend of drug prices. Most countries in the world implement two or more or a combination pricing mechanism to regulate and determine the pharmaceutical product cost/pricing. Control measures of the pharmaceutical prices are the mechanism that is used by middle- and low-income countries to keep the medicine prices under check while increasing the affordability. He further explained economic theory as if marginal cost of the product does not change then the reaction of the market to the price cap adjustment shows an increase in the supply. The cost of the supply chain to the rural areas are especially high due to lack of denser populations. However, increasing the marginal cost can obscure the reaction of the market to the cap adjustment of the prices and decrease the supply of the market (Lee, Kassab et al. 2020).

Yemen Walid Kassab also provide the five stages for the clarification of the price component impact such in at stage 1 that is focuses on the Manufacturer selling prices which is consisted on the freight and insurance cost. For the domestic production of the medicine, the cost is the survey or recommended pack size, coupled with the transportation cost when the drugs are transported from one place or city to another city or place using the national transport system to procurement pharmaceutical unit. For the imported drugs, the prices consisted on MSP cost, freight cost, insurance cost and international cost. Stage 2 describe the landed price, that is consisted on the other charged prices components on delivery and procurement. Furthermore, the landed drug prices included banking fee for the transaction of the foreign currency, port fees (handling, docking, in-port insurance and storage), inspection cost (either post or pre-shipment), mark-up of importers, custom clearing expenses, and the import tariffs. The landed prices of the medicines also consisted on the transport charges either incur locally or internationally to the wholesaler, purchasing warehouses, and the importer (Lee, Kassab et al. 2020).

Moreover, the drug selling prices are made up of the several components such as Manufacturer Selling the Prices (MPS). The MSP also consist on the tariffs, taxes and freight cost by the national government, procurement cost, overhead cost and the other expenses which is incurred during the drug production. Each level supply chain in the pharmaceutical sector has its own production cost other than MSP which ultimately add on the medicine prices. When an imposed composition is made up of the combination of the small price component, its effects are multiplied across the chain of the supply, and contributing to the price increment. Therefore, it is complicated for the national governments, scheme providers of the social insurance, and the non-governmental organizations to revise and regulate these components of the drug prices. He further elaborates that serious action for the reduction of the selling medicine prices should be taken by the authorities and regulatory bodies, increase efficiency of the system of medicine distribution, and ensure about the comparison of the international price reliability if the ERP is used frequently.

Moreover, stage 3 included the landed price with the wholesale price. According to Kassab, all the additional costs incur due to the overheads of the wholesalers, such as handling costs, distribution costs, profit margins, quality control fee, warehousing and storage costs, and retailer's cost. Stage 4 involves the retail price. The retail price included the GP clinics, hospitals, pharmacies selling prices that is based on the wholesale selling prices with addition of the expenses of the retailer. Stage 5 highlights the dispensed price. The dispensed prices are the combination of stage 4 and the taxes (General Sales Taxes (GST), Value Added Taxes (VAT)) and dispensing fees whichever are implementable and applicable.

Figure 3: Traditional Supply Chain



Mehmood (2022) tries to compare the narratives of the industry and the regulator by analyzing main issues between them. Pricing was the major issue that pushed all the producers to take the specific action such as putting a full stop on the certain drug's production that had negative impact on the welfare repercussions

Third World Network (2001) paper touched upon high priced issue of the imported medicines and black market. Author was also discussing the government role regarding mandated quotas and its impact on the supply of the drugs in Pakistan. He also analyzed the drug's availability in the hospitals of public sector. Moreover, main regulator's (Drug Regulatory Authority of Pakistan) performance and the issues which leads to the expansion of the informal channels like black market. He also included that drug pricing policies which leads to the preference for producing those drugs which have huge price margin with incentivize the rent-seeking and hoarding in the country. The WHO (2017) assessed the system of the transparency especially in the policies of the public sector regarding pharmaceutical industry. They found through their transparency system that perception of the corruption for the different categories of the regulations differs with some lower and some higher.

Naina R. Verghese (2019) touched upon the very important issue of Asia Pacific Region (APAS). She highlights that health expenditures were increasing day by day from last 15 years in several countries such as Indonesia, Singapore, Philippines, Vietnam, Myanmar, and Thailand. All countries try to practice multiple drug pricing strategies in Asia Pacific Region simultaneously. He identified following strategies of drug prices such as Internal and External Reference pricing, Pharma economic Evaluation, Agreements of Special Pricing, Cost Plus

pricing, and Premium of Price Maintenance. Governments usually use Internal Reference Pricing to determine the highest reimbursed medicine prices either equivalent to the similar percentage or lowest priced medicine.

Wei Tian (2016) looks at the Chinese National Essential Medicine policy and he analyzed those 307 generic medicines including 205 Western and 102 Traditional medicines covered by the NEMS policy from 2009. The National Essential Medicine policy also authorized that all the healthcare institution of the government must sell generic/essential medicines with no or zero mark-up pricing policy. Many studies regarding the NEMS implementation have shown that it decreased the retail prices of the medicines and also the availability of the generic medicines (Tian, Yuan et al. 2016)

Chapter 4

Methodology

The methodology of the study is presented in this section, which includes the procedures and processes used to conduct the analysis. Among the subjects covered are theoretical basis, empirical framework for quantitative analysis, data collection, variable construction, and qualitative analysis. The findings of quantitative data, as well as the experiences or recommendations of expert stakeholders compiled using a qualitative approach (semi-structured interview), will serve as a baseline for this study's recommendations. This section will go over the data sources and methodological framework that will be used to attain the aforementioned goals.

My first objective is fulfilled by the qualitative study and the second objective is fulfilled by the Quantitative study.

4.1 Rational of Mixed Method

A mixed method approach was used in this study for two reasons. The first reason was the nature of the research questions, which is the most significant factor in deciding how to approach a project (Creswell, 2003). This study aimed to examine Pakistan's pricing mechanisms and explain those policies, which needed the application of both quantitative and qualitative methodologies for measurement and explanation.

The complexity of the issues under consideration was the second reason for using mixed method approach. Costing of drugs and arriving at a final MRP is a complicated endeavour, influenced by a variety of factors (WHO & HAI, 2008). Direct price restrictions (maximum set prices, negotiated prices, international price comparisons, and price cuts or freezes) to indirect techniques (profit regulation or reference or index pricing) are examples of medicine pricing

policies (Mrazek & Mossialos, 2004). They may have a direct (e.g., through price changes) or indirect (e.g., through changes in medicine use) impact on medical spending (Aaserud et al., 2006). Many scholars, however, argue that complex phenomena "cannot be fully grasped using either simply qualitative or solely quantitative methodologies" (Teddlie & Tashakkori, 2003, p. 17). As a result, a mixed-methods approach was selected as the best way to gain a full and complete grasp of the complicated issues under investigation.

4.2 Qualitative Method: (Priority Data)

4.2.1 Importance

The investigator keeps an emphasis on finding the meaning that the contributors hold about the problem or issue, not the sense that the investigators bring to the research or authors express in the literature, in the whole qualitative research process.

4.2.2 Study Design: Interpretive Qualitative Research and Emergent

A form of interpretive review in which investigators make an elucidation of what they see, hear, and comprehend is called Interpretive Qualitative Research. Their elucidations cannot be detached from their backgrounds, past, contexts, and previous understandings. This signifies that the principal plan for research cannot be firmly prescribed, and after the investigator enters the field and starts to gather data, all stages of the process may change or be altered. For example, the forms of data assemblage may change, the questions may be altered, and the participants studied, and the places visited may be modified and revised. Understanding the problem or matter from participants and dealing with the research to gain that information is the key concept behind qualitative research.

In Pakistan, Drug Regulatory Authority of Pakistan (DRAP) determines the pricing policies of the drugs with the consent of the government. The audio recorded and written

interviews were analyzed using by thematic analysis. All interviews from DRAP officials, and pharmacist were conduction in national language (Urdu) and then all the interviews were transcribed, translated carefully to the English language.

This chapter of my study presents the results and findings of the qualitative analysis regarding the pricing policy of the drugs and the determining mechanism of the DRAP. The aim of the qualitative research is to find the insight about the price determining mechanism and missing information.

4.2.3 Data Collection Method

Interviews (semi-structured) were conducted. The data collection method also involved a review of published literature that is identified from the bibliographic databases like PubMed, and also using all the common search engines including non-governmental and governmental agencies and other organizations for analyzing the pharmaceutical policies across the world. Furthermore, I also review the pharmaceutical policies of the World Health Organization (WHO) and the Organization for Economic Corporation and Development (OECD). Moreover, data was collected through a questionnaire. Experts from pharmaceutical firms, pharmacies, and the DRAP officers are invited to fill out the detailed questionnaire.

The main questions to be asked pertained to;

1. How DRAP determines the prices of a drug?

2. What are the primary targets/concerns while implementing and designing pricing policies of the drugs?

3. Should medicine be exempt from tariffs/taxes? Existence of any subsidy, if any

4.2.4 Sample

A total of 16 pharmacists, DRAP officials and ministry of health officials from Islamabad, Lahore, and Karachi were interviewed. In short, individuals interviewed belonged to:

a) Health Ministries, (M/o NHSR & C)

b) Drug Regulatory Authority of Pakistan (DRAP)

c) Planning Commission of Pakistan (Islamabad)

d) Pharmaceutical Companies located in Pakistan

4.2.5 Data Record Procedure

Conduct a semi-structured interview and take notes.

4.2.5.1 Interview Protocols

I. Guidelines for the interviewer to follow to ensure that standard procedures are obeyed from one interview to another.

II. The questions (usually an ice-breaker query in the start followed by 4-5 queries that are often the sub-questions in a qualitative research plan, tailed by some closing statement or a question, such as, "Who should I visit with to learn more about my questions?

III. Reviews for the 4-5 questions, to follow up and inquire individuals to describe their ideas in more detail or to expound on what they have said.

IV. Space between the questions to record responses.

V. A finishing thank-you statement to recognize the time the interviewee expended during the interview.

4.2.6 Unit of Analysis

The unit of analysis for this study is the drug pricing policies under various Acts. Besides, annual reports on drug pricing mechanisms from different stakeholders will also be reviewed to add to the analysis of the policy document.

4.2.7 Method of Analysis:

A qualitative method of analysis was carried out using thematic analysis. Thematic analysis is widely used for the analysis purpose of qualitative research. This type of analysis focused on the identification, analysis, and explanation of concepts and patterns of meaning within qualitative data. The qualitative information is grouped into different themes and concepts for the sake of analysis and then a relationship is developed among those themes and concepts. The average duration of the interview was 20.6 minutes (range 19 to 25 min). The mean age of participants was 39 years (range 38 to 48 years). The data analysis yielded three main themes. The themes consisted of current scenario of drug pricing mechanism, Primary Target while implementing and Designing Drug Pricing Policies, and Failure of Drug Pricing Policy Implementation in Pakistan.

Following are the primary conclusions of these interviews, which were derived from long brainstorming sessions with the respondents:

Theme 1: Current Scenario of Price Determining Mechanism

When asked about Pakistan's drug pricing mechanism, one of the respondents was the Chief of Health, who had worked in the Ministry of Health for nearly 30 years in critical roles, provided the background of drug pricing for a better understanding. The respondent stated that in the past, prices were set for each drug under section 12 of the Drug Act of 1976 based on needed data submitted by the producer since the drug's registration began. For more than a decade, the usual

formula for determining MRP was Prime cost (cost of raw ingredients + cost of packaging material + direct cost) + 75 percent markup for all dosage forms and 115 percent for injectable.

At present, the firms sent their cost proposal to the DRAP, DRAP sent this proposal to the pricing committee. After that pricing committee applies reference pricing model and sends it to the cabinet for final approval. So, the final decision is implemented on the drugs on all over pharmaceutical industries of Pakistan (Not on all drugs, but drugs in question or under consideration). When I asked him about the reference pricing mechanism then he replied, "Yes, pricing committee used reference pricing model because we import raw material from India, and Bangladesh for the medicine production. In India and Bangladesh, nature of the diseases, size of the tablets, packing of the medicine is same." Moreover, he included the recent pricing policy 2018 was set by the Supreme Court in November 2018.

Director of costing and pricing also highlighted the price determining mechanism of DRAP. He said that our pricing committee after reviewing the cost proposal of the firms, decides what value to keep. The pricing committee strives to set a price that minimizes the firm losses and allow people to buy medicines easily. When they were asked, why national and multinational pharmaceutical firms exit from the market? The pharmacist affirmed that the prices of the raw material increased day by day but the pricing policy remained unchanged from 2000 to 2013, during that time, both national and multinational companies suffered so much that the number of MNCs dwindled to 22 from above 40 when the policy was implemented. He further explained, due to the strict pricing policies, they exit from the market because firms wanted to make maximum profit as possible, but it could not happen because it was not affordable for the people of the country. Finally, all my respected respondents agreed that price determining mechanism at present in Pakistan is a reference price model. The objective of the pricing

committee and the cabinet is to provide the maximum profit to the firm as well as to the people of the country. Keeping the above issues in view, it can be recommended

Theme 2: Primary Target while Implementing and Designing Drug Pricing Policies

When I interviewed the Director of the pricing committee, he elaborated that legislation mandating the DRAP pricing committee to negotiate drug prices with manufacturers, they should include provisions for what happens if the parties cannot reach an agreement. Negotiation is unlikely to result in cheaper prices without this authorization. When negotiations fail, one of three ways can be utilized to set lower costs for high-priced drugs: (i) the DRAP pricing committee could set prices unilaterally, (ii) the pricing committee could set prices through notice and comment rulemaking, or (iii) an impartial arbitrator might set prices.

A government program could establish a drug's price based on either much lower pricing in other high-income nations or the drug's "worth," as determined by health benefits or treatment-cost reductions in relation to the drug price. Given the difficulty and unpredictability of setting rates or determining value, a legislatively mandated range for the DRAP pricing committee would make implementation easier and save time for patients, payers, and taxpayers.

Three main goals are used to design and implement the prices as; i) To ensure that all medications imported or manufactured locally, distributed, sold, and used in the are effective, safe, and of high quality. This goal will be achieved by ensuring the proper function and operation of a national drug price strategy, which will be championed by Pakistan's primary institution, the National Drug Regulatory Authority. ii) To ensure that sufficient quantities of high-quality Essential Medicines are identified accurately, taking into account the population's needs as well as the patient caseload and case mix in primary care and hospitals. Essential pharmaceuticals must be made available at all times at affordable prices to address the

requirements of the whole population, with a special focus on the poor and vulnerable. iii) To encourage the use of medications in a reasonable, safe, and cost-effective manner: The use of medicines must be guided and controlled, both to reduce the risk of harm and to maximize the curative effect of used medicines while lowering costs, thereby maximizing the ability to reach and treat the entire population with effective and safe treatment while staying within budget constraints. Key mechanisms, such as active implementation of standard treatment guidelines in hospital therapeutic committees, active supply of consumer-independent medication information, and actions to raise awareness and minimize preventable adverse and side effects of drugs, will be implemented.

Theme 3. Failure of Drug Pricing Policy Implementation in Pakistan

The failure to negotiate/resolve the long standing issues related to pricing result in many negative spillovers, like shortages that result in price increases. In February 2016, the subject of price increases was raised in Pakistan's federal parliament, when legislators asked NHSRC and DRAP to take strong action against pharmaceutical corporations that were unilaterally raising prices of medicines. In addition, a subsidy for drugs whose prices had risen was proposed. The price raise was widely panned, with the Senate's Standing Committee on National Health Services, Regulations, and Coordination (NHRSC) stating that these firms should not be allowed a second opportunity.

Given the regulatory issues and refusal to increase prices as per the pricing policy, pharmaceutical businesses in Pakistan have been employing a variety of strategies to avoid regulatory scrutiny. For e. g, there is increasing trend to shift towards neutraceuticals.

4.3 Theoretical Framework

In Pakistan, DRAP and government try to regulate drug prices by directly negotiating the drug prices with the manufacturer and then implanting the policy tools to limit the markups on the patent protected drugs. Reference Pricing (RP) is a frequently used strategy that involves benchmarking medicine pricing against prices from other nations.

4.3.1 Price Policy Impacts on Pharmaceutical Firm's performance over the time

This section examines the relationship between pricing policies and pharmaceutical sector performance, as well as the variations over time. Theoretically, there is a lack between how a pricing policy is framed and how firms respond, which include their profits. Costs in all nations that utilize the reference pricing model reduce over time in comparison to prices in countries that do not use the reference pricing model. We use a fixed effect, Treatment Effect Model, to calculate the pricing policies and display the coefficients versus the earnings of the firms.

To gauge the effects, we start with the following equation,

$$P_{ijkt} = \theta_{i\,t} + \gamma_{j\,t} + \beta_{k\,t} + \delta_{t} + \varepsilon_{ijkt}$$

i indicates the pricing policy before 2015, *j* indicates between 2015 and 2018, and *k* denotes after 2018 pricing policy of the drugs. Moreover, *t* represents time period and δ_t represents year fixed effect.

Pricing policy and company performance were modelled as a fixed effect γ_j in a log pricing policy regression with other fixed effects.

$$\ln (P_{ijkt}) = \theta_{it} + \gamma_{jt} + \beta_{kt} + \delta_{t} + \varepsilon_{ijkt}$$

We investigate the impact of pricing policy on the profit and performance of a company. To do so, we run the regression analysis based upon the following equation.

$$\ln (P_{ijkt}) = \theta_{it} + \gamma_{jat} + \beta_{kt} + \delta_{t} + \varepsilon_{ijkt} \text{ where}$$

- γ_{ja} = is a fixed effect for pharmaceutical firms between 2015 and 2018 which can be taken as a reflection of firms' response to price regulations. We also include before and after impacts of pricing policies on the firm's performance by running the fixed effect. Fixed effect θ_{it} is used for before 2015 and β_{kt} is used after 2018, when drug prices are determined by the DRAP.

4.3.2 Dynamic Model

Pharmaceutical companies design the price-determining mechanisms based on their total cost, and index is j; t_i is the time period during which the government's changing pricing regulations are in effect.

The firms' goal is to maximize their profit. We denote the last policy of DRAP as;

$$T_i = \max_{i \in \Gamma 1} t_i$$

In each period of pricing policies, firms are solving

1. What final drug pricing policy should be followed by the DRAP for pharmaceutical firms?

After establishing pricing policy, the best strategy will be determined by the price equilibrium. Firms in Pakistan, on the other hand, have a restricted or no ability to set their own selling prices. All businesses are obligated to observe the government's and DRAP's pricing policies.

δ = denotes DRAP pricing policy

$$\delta_{lt} = \{\delta ijkt\}_{j \in N,\, ti \in \Gamma}$$

Furthermore, price policies have an impact on sequence during the time period t.

$\delta_{lt} = \{\delta_{ijkt\ j \in N,\, i \in \Gamma}$ where

$$\delta_{ijkt} = \begin{cases} \delta_{ijkt}, & if\ \ \delta_{ijkt} \trianglelefteq 0 \\ 0 & otherwise \end{cases}$$

We presume that after a policy is implemented, enterprises will not be able to change their pricing policy on their own. For each DRAP strategy, this assumption implies that knowing δ_{lt} for all t is sufficient.

4.3.3 Pricing Mechanism

The reference pricing (RP) model is used to determine the DRAP base price for new drugs. We examine the impact of variable pricing on the profit performance of the company. Three price policies are defined (1976, 2015, and 2018). The profit of the firms (I), policies of DRAP (δ), performance of firms (j) belonging to the listed (registered) firm (m), in year (t).

$$\text{Pro}_{(K)} I_{jt} = \delta_{ijkt} + V_{ijkt}$$

The error term V_{ijkt} is parametized as

$$V_{ijkt} = (\zeta_k + (-\sigma_k)_{\varepsilon ijkt}$$

Where;

σ_k = exist in interval, ε_{ijkt} is denoted the distributed according to the Std. error extreme changes/variations in the policies.

ζ_k = this distribution satisfies the assumption that error term $V_{ijkt.}$

δ_{ijkt} = Firm heterogeneity generates profit across the country while also posing a threat to the firms' survival.

Our specification for

$$\delta_{ijkt} = \alpha_{ijk} + \beta pro_{ijk} + \eta NF_{ijk} + \zeta_{ijk}$$

α_{ijk} = captures DRAP preference for each pricing policy.

βpro_{ijk} = β is the coefficient that allows the probability of the variations of pricing policies, whereas, 'pro' is the profit of the firms.

ηNF_{ijk} = Control variable.

ζ_{ijk} = random shocks of the change pricing policies of DRAP.

4.3.4 Price Setting Equation

DRAP determines drug prices under its drug pricing policy, determined by its 'Costing and Pricing' division. Firms send request to price a new drug, but its DRAP that determines the final price, and the Cabinet that approves it. The precise nature of negotiations/communications between DRAP and firms is difficult to convey in a model. Presumably, the government is attempting to balance multiple objectives, such as ensuring access to important pharmaceuticals and encouraging costly innovation. We take a more agnostic approach and use a flexible control function to model prices.

There are two parts to our price-setting equation. The first element is what we refer to as the government pricing, p_{ijt}^{gov}. In the absence of reference pricing, this is the price that the firm and the government agree on. We model the government price as a function of as well as three additional control variables to account for the potential impact of the government's other price-control initiatives.

This variable is important to determine the probability of policy variations, according to Kyle (2006); we include it to see if we can discover a substantial effect on firm performance. As a second control, we incorporate a flexible function of the DRAP's as well as the government's or cabinet's pricing policies. All of the following factors point to pricing policies having a negative

impact on the firm's performance: competitive pressure may drive prices down, and governments may benchmark prices to the lowest price available within a group of substitutable drugs.

The specification of the DRAP and government price is;

$$P_{ijkt}^{gov}(F_{it}(\delta_t, \delta_{ijkt}) = \theta_i * \gamma_j * per(\beta Z_{ijkt} + BFln(F_{it}(\delta_t, \delta_{ijkt}^{\pi k}))$$

Where;

θ_i and γ_j are the fixed effect of the firms. Z_{ijkt} is the matrix of the pricing policies. $(F_{it}(\delta_t, \delta_{ijkt}^{\pi k}))$ are realized the fluctuations which depends on the random fluctuating policies.

4.3.5 Reference Price Function

The empirically implemented reference price function is given by

$$P_{ijkt}(\delta_t, F_{ijkt}(.)) = R_{ijkt}(\{P_{ijkt}(\delta_t, F_{ijkt}(.)\})_{k \in (Rijkt \cap Eit - 1)}$$

The overall price setting equation is;

$$P_{ijkt}(\delta t, F_{ijkt}(.))$$

$$= \begin{cases} P_{ijkt}^{gov}(\delta_t, F_{ijkt}(.)) & if\ P_{ijkt}^{gov}(.) \geq P_{ijkt}^{gov}(.) \\ (i - u_i)P_{ijkt}^{gov}(\delta_t, F_{ijkt}(.)) + u_i P_{ijkt}(\delta_t, F_{ijkt}(.)), & if\ P_{ijkt}^{ref}(.) \leq P_{ijkt}^{gov}(.) \end{cases}$$

4.3.6 Price and Reference Price Parameters

Before moving on to the dynamic model, we'll go through the price variation that allows us to see how reference pricing affects performance. Our identification technique is based on two crucial elements: the functions that each country uses to create the reference pricing mechanism, and the asymmetry in reference pricing application that stems from the premise that the reference price only matters if it is lower than the government price.

Let the model predicted price policy and P_{ijkt} the observed PP is;

$$\mathrm{Ln}P^{0}_{\mathrm{ijkt}} = \begin{cases} \ln(P^{\mathrm{gov}}_{\mathrm{ijkt}}(.)) + \eta_{ijkt}, & if\ (P^{\mathrm{ref}}_{\mathrm{ijkt}}(.)) \geq (P^{\mathrm{gov}}_{\mathrm{ijkt}}(.)) \\ \ln(1-u_j)(P^{\mathrm{gov}}_{\mathrm{ijkt}}(.)) + u_j(P^{\mathrm{gov}}_{\mathrm{ijkt}}(.)) + \eta_{ijkt}, & if\ (P^{\mathrm{ref}}_{\mathrm{ijkt}}(.)) \geq (P^{\mathrm{gov}}_{\mathrm{ijkt}}(.)) \trianglelefteq \end{cases}$$

4.4 Quantitative Study

4.4.1 Purpose of the Quantitative Study

The purpose of my quantitative study is to investigate the impact of the DRAP and government policies on the pharmaceutical firm's performance (in terms of price setting?). In this study, Treatment Effect model, and Firm Fixed Effect model are used to investigate the impact of the DRAP policies on the pharmaceutical firm's performance.

4.4.2 Data and Variables

I have collected data from the annual reports of top listed pharmaceutical firms in Stock Exchange of Pakistan. In this part of the study, five variables are used for obtaining results spanning a time period 2008 to 2021, i.e., a total of thirteen years. In this study, one dependent variable is ROA (Rate of Return) and four independent variables DER (Debt Equity Ratio), CR (Current Ratio), NWC (Net Working Capital), and D. policy (DRAP policies).

4.4.3 Dependent Variable

Performance of the pharmaceutical firm's performance in terms of profit is taken as dependent variable in this research. ROA is an indicator of the firm's performance in my research, while it is mainly used for estimating the profitability of the firm. Moreover, ROA is used as a proxy variable for measuring the performance of the firms.

4.4.4 Independent Variables

In this study, independent variables are DER, NWC, and CR and D. policy. The debt equity ratio (DER) is used to compare the debt and equity funding portions of a company. Outsiders such as

insurance companies, banks, and financial institutions supply debt financing, whereas equity finance corporations employ their own funds when their financial situation is good. The debt equity ratio is used to calculate the impact of debt and equity on a company's performance. Because current liabilities and current assets are only used to meet current obligations, the current ratio (CR) is used to determine if a corporation is in a position to fulfill its short-term obligations or liabilities using its current assets. Because liquid assets are necessary to meet the operation needs of the working time period, net working capital (NWC) is primarily employed for operational liquidity.

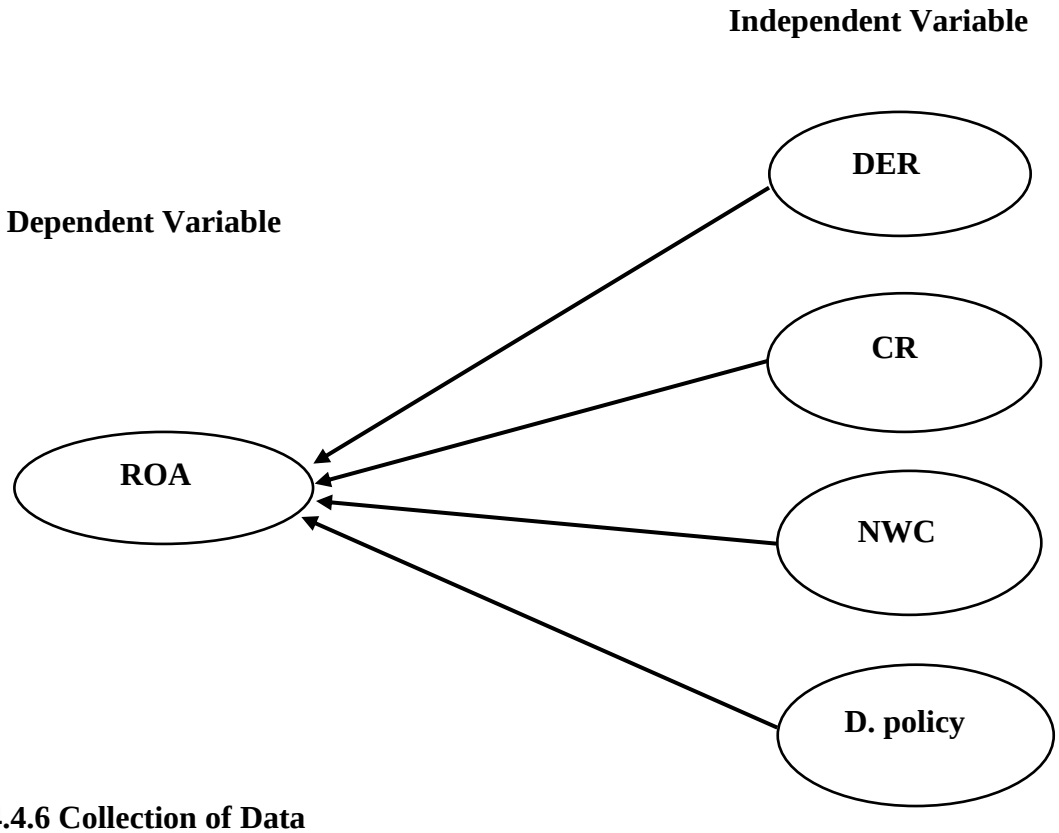
Table 3

Variables	**Description and Formulas of Variables**
ROA	Net Profit/ Total Asset
DER	Total Debt/ Total Equity
CR	Current Asset/ Current Liabilities
NWC	Net Working Capital/ Net Asset
D. policy	DRAP policy (before 2015, between 2015 to 2018, above 2018)

4.4.5 Research Design and Sample

Deductive approach is used because all the available data is in numerical form. Numerical data of pharmaceutical firms are used to analyze the firm's performance in lieu of the fluctuating pricing policy by using quantitative approach. Sample of 12 pharmaceutical firms was taken that are registered in Pakistan Stock Exchange (PSE). We take only those pharmaceutical firms whose data is available.

Figure. 4.



4.4.6 Collection of Data

For this research, secondary data of firms is used for the time period 2008 to 2021. All data is available through companies' annual financial reports; thus fourteen years' quantitative data of the pharmaceutical firms are collected for the purpose of analysis. List of the pharmaceutical companies are obtained from the PSX. Further, data on current assets, current liabilities, net working capital, total assets and total sales were taken from the annual financial reports.

4.4.7 Data Analysis Method

ROE can be used to evaluate a company's financial performance. This metric is used to determine how much of the stock made available by investors (total own equity) may be financially rewarded using the company's net income as the primary source of dividend payment

(Penman, 2007). Return on equity varies over time (depending on the business context in which the company works) and from one company to the next (depending on the management's operational and financial policies) (Jaba et al., 2016a). Panel data analysis should be utilized to compare ROE changes between enterprises and across time while controlling for determinant factors (ROA). We can examine the change in ROE over time and the substantial variances that may occur among companies using this form of analysis.

4.5 Methods

A. Firm Fixed Method

Differences in cross sections can be accommodated by differences in their intercepts, according to the fixed effect model. This model assumes that for each cross section, a constant intercept is produced, making time examination less realistic. This approach provides for heterogeneity or individuality between the twelve most prominent pharmaceutical companies listed on the Pakistan Stock Exchange by allowing each to have its own intercept value. The fixed effect arises from the fact that, while intercept varies among countries, it does not change across time, indicating that it is time invariant.

Fixed effect regression equation for panel data is:

$$Y_{i\,t} = \alpha_0 + \beta Xit + \varepsilon it$$

i is number of pharmaceutical firms where *t* is time period.

4.5.1 Model Equation

In this model, liquidity measures (NWC, CR), Debt to Equity Ratio (DER), DRAP policy, are independent variable whereas firm performance (ROA) is dependent variable that are used for data modeling.

$$(ROA)_{it} = \alpha_i + \beta_1 DER_{it} + \beta_2 CR_{it} + \beta_3 NWC_{it} + \beta_4 D.policy_{it} + e_{it}$$

This is the equation used to evaluate the impact of DRAP policies on company performance. The entire return on assets (Net Profit) at time t for given time period and is represented by ROA_t. $\beta_{i1}DER_t$ is an independent variable and β is a coefficient of debt equity ratio. All these variables ($CRt_,$ $NWC_{t,}$ D. $policy_t$) shows positive and negative effect on the performance of pharmaceutical firms. α shows the constant values and e_t shows the error term of the data.

B. Average Treatment Effect Method

The term 'treatment effect' refers to the causal influence of a binary (0–1) variable on a scientific or policy-relevant outcome variable. Effects of government policies and programs, such as those that finance training for the unemployed, are instances of economics. Matching estimator, regression models, social experiments, and instrumental variables can all be used to estimate treatment effects. I have also used fixed effect model because it captures the difference of the firms and then fixed their variation or heterogeneity. If we have control and uncontrolled group of firms, then we use difference-in-difference for better comparison but we have just controlled group of firms and all firms working under the DRAP and federal government regulation, due to the control group we used appropriate model which is average treatment effect model. Primarily our focus is on firm fixed effect. For checking robustness, we used firm fixed effect and check the reliability of the DRAP pricing policy's impact on the performance of the firm and then we also used average treatment effect.

The word "treatment effect" comes from a body of medical literature that examines the causes of binary, yes-or-no "treatments," such an experimental medication or a novel surgical technique. But the expression is now much more widely used. The most extensively studied treatment effect in economics is arguably the causal effect of a subsidized training program (see, for example,

Ashenfelter, 1978, for one of the first examples, or Heckman and Robb, 1985 for an early survey). The most significant econometric issue that occurs in the estimation of treatment effects is generally omitted variables bias, commonly referred to as selection bias. The potential-outcomes paradigm allows for the best visualization of the relationship between omitted variables bias, causation, and treatment effects.

A conceptual framework that postulates a collection of potential outcomes that could be seen in various configurations of the world can help to clarify the idea of a causal influence. The potential outcomes framework was first developed by statisticians in the 1920s to discuss treatment effects in randomized experiments. Since then, it has evolved into the conceptual hub for both experimental and non-experimental studies across a wide range of disciplines (see Holland, 1986 for a survey and Rubin, 1974, 1977 for important early contributions). Though the latter is typically connected to a linear regression framework, potential outcomes models are fundamentally the same as the economic switching regressions model (Quandt, 1958). For this model, Heckman (1976; 1979) created straightforward two-step estimators.

Average Treatment Effect Model equation is:

$$ATE = E\,(Y_i\,(1)/\,T_i = 1) - E\,(Y_i\,(0)/\,T_i = 1)$$

This equation defines the ATE. Sometime it is used to establish what could be the possible impact which relate to the economics. At least two time periods are required for the estimation

- The pre-intervention
- The post-intervention

So given two periods where the sample is fairly stable (balanced panel), the comparison can be done through estimating the differences.

4.6 Results and Interpretation

In this study, panel data is collected by using the secondary source. Panel data is analyzed by using Treatment effect, and Fixed Effect models. All the estimation process is done through the Stata17 software. The result of the Stata17 software is considered reliable at national and international level.

4.6.1Firm Fixed Effect Model

Table 4

NET PROFIT	COEFFICIENT	STD. ERR.	T	P > | T |
DEBTEQUITY RATIO	0.7684611	.2911888	2.64	0.009
CURRENT RATIO	0.8615671	.3972436	2.17	0.032
NETWORKING RATIO	0.0596781	.0585904	1.02	0.310
BEFORE_2015	-0.312836	.2112352	2.43	0.02
BETWEEN_2015_2018	1.411858	.6933081	2.04	0.04
ABOVE_2018	-0.3668398	.2223961	2.67	0.01

Above table shows that before and after DRAP policies have significant negative impact on the performance of the firms in terms. From 2000 to 2013, the drug prices all over the country remained the same under Government's 'price freeze' policy. The pharmaceutical firms faced critical situation during this time period. Many multinational companies (MNCs) and national companies exited the market due to the losses in their revenues. The results also confirm this, that before 2015, firms bore losses due to this policy. In 2015, government and DRAP came up with a new pricing policy to alleviate industry's issues related to drug pricing. Meanwhile, the rupee-dollar exchange rate kept rising, thus increasing the expenditures of the raw material day-by- day. Due to the high expenditures in terms of manufacturing the drugs, there were reported instances of firms ignoring the Drug pricing policy and official rates of the Government, increasing drug prices without permission from the government.

4.6.2 Average Treatment Effect Model

Table 5

Net profits	Coefficients	Std. error	Z	P > | z |
before_2015	10.60595	.5514908	19.23	0.00
between_2015_2018	11.81667	.6954493	16.99	0.00
after_2018	9.622917	.6647514	14.48	0.00

The above results shows that when the DRAP formulates the policies for the pharmaceutical firms without negotiating with the firm's about the cost structure expenditures and forward it to the federal government for the final approval. The potential outcome framework (Neyman, 1923; Rubin, 1974), we posit the existence of the policies Y_i (1) denote the time period before 2015 otherwise 0 (Y_i (0)).

	Before_2015	BETWEEN_2015_2018	AFTER_2018
POM	10.60595 (0.5514)	11.81667 (0.6954)	9.622917 (0.6647)
ATE		1.21072	-0.983033
Odd Ratio		1.1141	0.9073

In above table, the first row shows that the DRAP's policies, before_2015 policy which is consider the base policy and the second row shows that the POM stands for Potential Outcomes, and in third row, ATE stands for Average Treatment Effect. If odd ratio is greater than one, then it means that the impact of the policies is positive on the performance of the firms. Similarly, if the odd ratio is less than one, then the impact of the policies is negative on the performance of the firms. The average treatment effect for the time period between 2015 and 2018, when 1.21 is average treatment effect, is positive because the firms did not follow the pricing policy. The

value 1.21 as average outcome means that the treatment effects increase the outcomes. The positive average outcome means that there is no policy and firms earn 1.21% net profit. Whereas, above 2018, the firms bear loss of 0.98% in their net revenues due to the strict pricing policies implemented by DRAP.

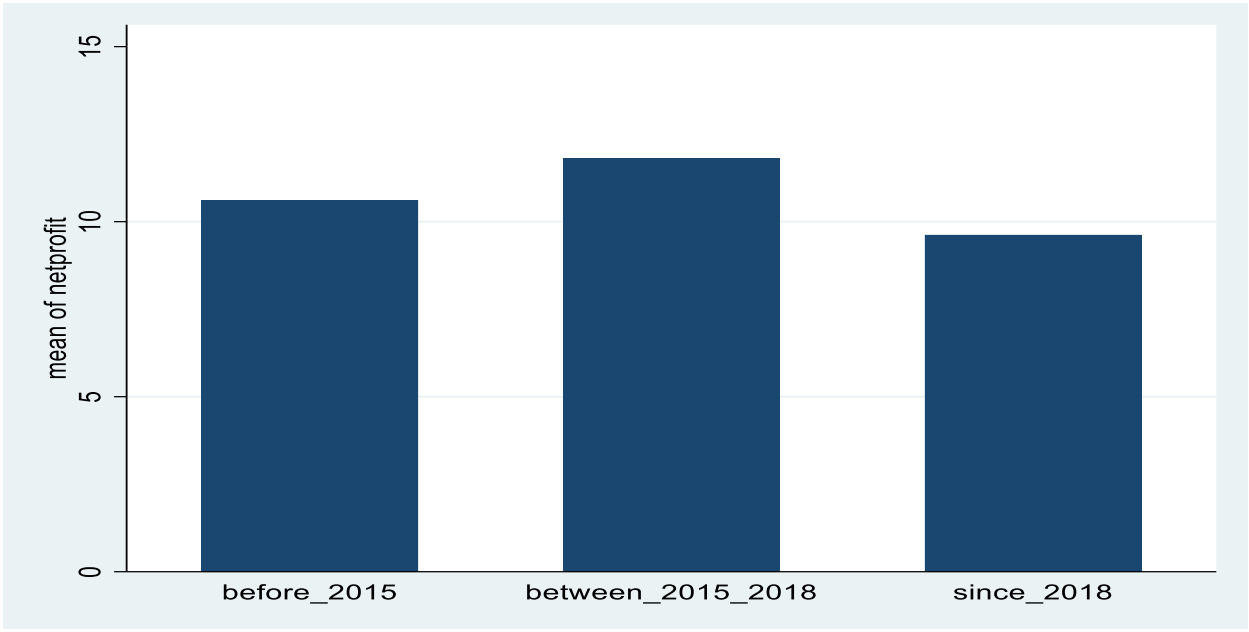
The government controls pharmaceutical costs and determines how much they can rise annually, which is the single most crucial aspect to comprehend about the sector. The Drug Act, which also established the Drug Regulatory Authority of Pakistan, established the legal framework by which the government of Pakistan regulates the whole pharmaceutical business. In order to ensure that pharmaceutical companies may continue to turn a profit on their products while simultaneously limiting price increases for the general population, DRAP first implemented pricing policy in 2015 and then again in 2018. However, the government controls both the retail price and the retailer's margins, the business as a whole effectively has its gross profit margins mandated by regulatory fiat. Pharmaceutical corporations contend that in order to be able to cover the expense of the research and development that goes into generating new and novel cures, they need both patent protections for the recently discovered pharmaceuticals that they have developed and the freedom to set their own prices (Tirmizi 2021).

Despite, pricing policies of 2015 and 2018, being passed that now permit increases in medicine costs related to the CPI, the amount of price adjustments permitted was quite small. The majority of price increases were limited to 10–12%, and court remedy was frequently sought by firms against such limitations. Senior policy representatives recognize court litigation as a significant obstacle, which contributes to ad hocism in pricing control. In place of cost-plus pricing, which determines the selling price by adding a predetermined markup to a product's unit cost, the 2018 Pricing Policy adopted reference pricing in place of the former policies of price freeze (Tirmizi 2021).

My statistical results clearly show that the DRAP policies are not appropriate for the pharmaceutical firms. When the DRAP and federal government impose their pricing policies on the firms, their net profit start to decline. Before_2015, when the government imposes price freeze policy, the results clearly shows the decreasing trend in their net profit margin. Whereas, in between 2015 to 2018, when the firms did not follow the existing pricing policy of the government and DRAP (Pricing Policy of 2015), the result shows positive impact on the performance of the firms. While, after 2018, when the drug pricing policy was introduced after the intervention of the Supreme Court of Pakistan, the net profits of the firms again started to decline.

Moreover, many MNCs have departed the market as a result of excessive price control, and FDI inflow has also been severely constrained. Over the years, this has led to ongoing drug shortages. Domestic manufacturers have taken over from these multinational corporations, but their departure creates problems in terms of improved production, a major investment base, and improvements to quality and capacity, as well as higher efficiency, skills transfer, and technology (Ammara 2020). Additionally, the market has gradually but consistently shifted slightly of deregulated industries like nutraceuticals (where prices are not controlled, and companies can generate more profit).

Graph 1



Source: Author's Calculation

The graph shows the year before 2015 and after 2018, there was a treatment. This could be a change in DRAP or government policy, or any other type of intervention. We applied if the treatment was successful. The graph clearly shows the results and declares that the outcome of interest altered. Before 2015 and after 2018, we can see that the mean of the net profit outcome has decreased due to the DRAP and federal government pricing policies. Whereas, we can see the mean of the net profit outcomes has increased because firms do not follow the given pricing policy and increased the prices from 200 percent to 300 percent of the medicines.

4.7 Discussion

Between 2015-2018 firms earned profits and their performance became better but as we know that Pakistan is a low-income country and majority of the population is poor. They cannot afford high prices of the medicine. The prices of medicines increased between 2015 to 2018 by 200% to 300% than the existing (2015) pricing policy. In 2018, the Supreme court of Pakistan (in HRC No.2858/2006), took action against the pharmaceutical firms in last week of November and

ordered them to follow the given pricing policy which was introduced in 2018 again after the approved amendments from the Federal Government and The Drug Regulatory Authority of Pakistan (DRAP). In 2018, the drug pricing policy was formulated keeping in view both the people of the country and the pharmaceutical firms. The negative results also show that due to strict pricing policy of 2018, all pharmaceutical firms faced loss again.

The study conducted by Mehmood (2022) shows that the drug prices are fluctuating from 1976 till 2022. Since 95% raw material is imported from countries like China, India, and Bangladesh. Pakistan has to face political and economic instabilities due to depreciation in the value of local currency, consequently causing hikes in the prices of raw materials. Yet, prices did not rise accordingly. In such situations, the expenditures of the firms became higher than the revenues and some had to face losses. Sometimes these firms cannot survive due to such uncertainties and exit the market. The casual effect treatment is the difference in potential outcomes. The average outcome means that when all the firms are affected by the pricing policy. Average outcome effect is just the difference between the average outcome under the policy and the average outcome without policy.

The key findings of my qualitative study are that the price determining mechanism is the reference pricing model by the DRAP, but they send their proposal to the cabinet for final approval. Thus, from a regulatory point of view, drug pricing is a political decision rather than financial one. They usually ignore the cost proposal of the pharmacists of Pakistan and approve the proposal as they eschew the drug price level as per political considerations. That's why, DRAP does not disclose the price ceiling formula behind the pricing mechanism. For example, DRAP failed to provide the information about drug pricing to the Supreme Court of Pakistan in 2019, when the Transparency International complain about the highest prices after prices set at the 7 percent MRP on the Generic medicine increment and 10 percent on the non-generic

medicine but the pharmaceutical firms increase 200 to 300 times more than the fixed price. DRAP could not satisfy the Supreme Court with its arguments.

Likewise, when I interviewed a health ministry officer and asked him to share an exact formula, he replied that it does not matter how we set the prices because it will finally have to be approved by the cabinet and they set according to their own formula. Moreover, dollar prices also effect the policies of the country. Drug prices can be reduced and made more reasonable for end users by lowering the modest amount of fixed mark-up.

Pricing concerns have been partially resolved with a revised pricing policy; however problems still exist because a rollback of this policy is anticipated. The COVID-19 has caused a delay in the pricing policy modification, which is presently underway. Pricing restrictions have reduced profitability and slowed capacity investment. It has had an impact on social goals (including accessibility, affordability, and quality) as well as the development of the industry.

In contrast to many other countries, Pakistan has strict regulations and controls on medicine prices. After careful consideration, DRAP determines the maximum suggested retail price for any medication. Through the Cabinet, the government approves the retail pricing. Manufacturers may increase the cost of necessary medications by as much as 70% of the increase in the consumer price index as part of the clearance procedure (CPI). Because prices are generally decided by political pressures rather than market forces, there is little pricing incentive in Pakistan’s economy, which has hurt this industry's ability to compete. A price freeze was maintained between 2000 and 2013 despite a steady rise in the cost of production and the price of raw material imports. According to estimates (which were covered in section 4 Political Economy), Pakistan lost PKR 112 billion yearly as a result of the price freeze on drugs. Ironically, out-of-pocket medical expenses rose throughout this time, indicating that the claimed goal of reducing medical expenses was mainly unsuccessful.

Finally, given to adverse nature of regulations, especially strict regulations governing drug prices, pharmaceutical firms have adopted in terms of their strategies and product mix. Substantial amount of drugs, for example, that did not meet the financial feasibility criteria were stopped producing altogether. In their place, firms starting concentrating upon products that experience comparatively less tax regulations, like baby milk, diapers and nutraceuticals (a specific category of drugs). Moreover, another strategy to counter tight regulatory environment came in the form of on demand production, like injectable (vaccine for e.g.). These kinds of strategies help to explain how pharmaceutical firms have stayed afloat during tough times. However, the consumer is at a tremendous disadvantage since critically needed drugs persistently experience shortages.

In short, the regulatory aim of dictating prices has been a failure! Pharmaceutical firms weathered the storm by changing their strategies, but the consumers have borne the blunt of these strategies as critically needed drugs become inaccessible.

Chapter 5

5.1. Conclusion

As previously stated, the majority of the countries studied here some sort of reference pricing to inform pricing decisions for new (innovative) pharmaceutical goods, however the relative importance of this technique compared to other pricing strategies varies. Italy, unlike the other countries examined here, no longer uses external reference pricing; in fact, this technique was abandoned in 2001 due to a perceived lack of proof of cost-control success. As previously stated, the major procedure for determining pricing is through talks between the regulatory body and pharmaceutical companies, though prices from other sources may be used as well. Similarly, Germany does not rigidly adhere to an external reference price system.

Pakistan's pharmaceutical industry has struggled to compete in the export market, trailing far behind competitors like India. The industry's structure shows that there is a high level of allocative inefficiency, with the top 100 firms grabbing 97 percent of market shares and 650 firms contending for the remaining 3%. These features, combined with rigorous price regulations and long-term price freezes, show that the business is capturing rents.

In terms of policy consistency, there a plenty of SROs that are continually changing policies. Because the industry is never sure what the near future will hold, this tends to create uncertainty. From the industry's standpoint, doing business is still difficult, albeit there have been some changes since the DRAP has been established and intervention of the supreme court of Pakistan. The most problematic issue is still tightly regulated pricing; firms are subjected to a slew of fees, there are various taxes on items, and even terminating a corporation can be time-consuming. The next step of our research focused on situating these emergent policy implications within Pakistan's broader political landscape and pharmaceutical sector.

Finally, DRAP should focus solely on laws and enforcement, while this separate government entity should handle business, marketing, pricing, and incentives. Certified global consultants (whether from the WHO or pharmaceutical consultants or commercial) who provide technical and institutional support for each of DRAP's main regulatory and quality management functions would be useful to the company. DRAP should continue its changes for quality regulation and enforcement, including as meeting international standards, clearing certifications according to the WHO Global Benchmarking Tool, and becoming a member of the Pharmaceutical Inspection Corporation Scheme (PIC/S), which might open the market to countries with strict regulatory authorities.

Way Forward

The key way forward involves enhancing DRAP's technological and regulatory capabilities. DRAP primarily serves as a pricing controller and has not been successful in carrying out its regulatory duties for the industry. The weak regulatory and governance structure for the pharmaceutical industry was singled out by all stakeholders as the main cause of the sector's slow growth. This may be partially ascribed to the wide-ranging effects of putting DRAP under the Ministry of National Health Services Regulations & Coordination's supervision. Due to the ensuing political-economic conflict between the two entities, this lessens its effectiveness. Over the past few years, the relationship with DRAP has improved, and the stakeholders are pleased with the modifications made to the price regime and the automation of the registration procedure.

A removal of the medicine price caps set since 2001 that are choking off earnings, stunting growth, and limiting access to some treatments The performance of the industry would increase if the DRAP implemented a more lenient and open pricing policy. A predictable price path will also guarantee adherence to the established pricing regime. It is important to choose an adequate

frequency for reviewing both the drug list and the price list. Stability is the key. According to a predetermined method, pricing resets might occur annually and drug coverage could be reviewed every three years.

The National Essential Medicine List of 2016 should be regulated, and price for the remaining medications should gradually become deregulated as decided together with industry participation. Governments have ensured the supply of medications for uncommon ailments or those that were not economically feasible to develop, as seen in the Orphan Drugs Act in the United States and Regulation (EC) No 141/2000 in the European Union. To identify pharmaceutical items, such as cancer treatment medications, that can be given the orphaned status, a process akin to this can be established in Pakistan. The government can then take action to guarantee their constant supply and fair access. To guarantee that price-controlled pharmaceuticals are manufactured effectively and in sufficient quantities, incentives will need to be handled. The list of ailments that should be controlled should be based on those that are of great priority in Pakistan, are most frequently marketed, are necessary for specialized, expensive treatments like cancer, or both.

5.2. Recommendations

Keeping the above issues in view, it can be recommended that the government of any regulatory body should not intervene in the market or any other activity like price setting activity. Government should intervene at that time when the market fluctuates and fails to provide the services to the economy. Because fluctuating pricing policies create severe problems for the pharmaceutical firms. It can also be recommended that the DRAP's pricing policy might be more liberal and transparent, which would help the industry function and perform better.

The National Essential Medicine List (2016) should be regulated, but the rest of the market should be deregulated in stages, as determined collaboratively with industry input. The United States' Orphan Drug Act and the European Union's Regulation (EC) No 141/2000 are instances of how governments ensured the supply of medications for uncommon diseases or those which were not cost-effective to produce. In Pakistan, a comparable process may be created to discover pharmaceutical goods that could be designated as orphaned, such as cancer-treatment medications.

Finally, the government can then take steps to ensure their steady supply and equal distribution. To ensure that price-controlled pharmaceuticals are produced efficiently and in sufficient quantities, incentives need to be handled.

5.3 Limitations of the Study

The main limitation of my study is that the necessary data on the regulation of the pharmaceutical sector does not exist in a centralized location or repository. There is no long-term or centralized data store for the Drug Regulatory Authority of Pakistan and also its predecessor's regulatory data. The DRAP officials are frequently reluctant to discuss the details of their data and work, and available data on DRAP's official website is patchy rather than continuous. However, data limitation is that we used twelve those registered firm's data which is available in their yearly financial reports. For example, they have been tight-lipped about the use of money taken from industry through the Central Research Fund (CRF). Moreover, there is no or little information about the provincial and the federal regulatory coordination.

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Appendix A

Explanation of the Key Terms

Drug Regulatory Authority of Pakistan (DRAP)

The Drug Regulatory Authority of Pakistan was founded in 2012 under Section 3 of the DRAP Act. It is responsible for coordinating and enforcing the Drugs Act of 1976, which governs aspects of the pharmaceutical industry such as licensing, registration, pricing, quality assurance, laboratory testing, controlled medications, and pharmacy services.

Multinational Companies (MNCs)

A Multinational Corporation (MNC) operates in at least one region other than its home country and has facilities and other assets there. A multinational corporation typically has headquarters and/or factories in various countries, as well as a centralized headquarters where worldwide management is coordinated. Multinational firms do business in at least two countries. MNCs can have a significant economic effect on the country in which they operate.

Generic Medicine

A generic drug is a pharmaceutical that is designed to be identical to a brand-name drug in terms of dose form, strength, mode of performance characteristics, administration, quality, and intended use.

Appendix B

Questionnaire

Interviewee Name:

Designation/Department:

Experience:

Thesis Title: Evaluation of Price determining Mechanism of DRAP and Pharmaceutical Industries in Pakistan

Questionnaire for Decision Making Framework.

Question # 01: Who determines Drug Pricing Policy? DRAP, Health Ministry, or a combination of two?

Question # 02: Are you/ Have you been ever involved in to assist Decision Making Process in Pricing/control regulation/ such dimensions?

Question # 03: What are the government's primary targets/concerns while designing and implementing drug pricing policies?

Question # 04: Existence of any subsidy if any?

Question # 05: Should Pakistan use price control measures to manage medicine prices? If yes

Sub Questions		Supporting Questions
A) Can External (International) reference pricing (ERP) be an effective pharmaceutical pricing strategy for Pakistan?	If yes, then	Under what conditions should it be considered for use? What are the potential positive outcomes of using this strategy and what are the risks? What best practices should be followed in the establishment of an effective external reference pricing

		system? iv) What are the resources and skills required for effective implementation?
B) Can cost plus price-setting or value Based Price-setting be an effective pharmaceutical pricing strategy for Pakistan?	If yes, then	Under what conditions should it be considered for use? What are the potential positive outcomes of using this strategy and what are the risks? What best practices should be followed in the use of a cost-plus pricing strategy? What are the resources and skills required for effective implementation?

Question # 06: Should Pakistan adopt measures to control add-on costs in the supply chain? If yes

Sub Questions		Supporting Questions
A) Should wholesaler and retail markups be controlled in Pakistan?	If yes, then	i) Under what conditions should controlling the markups of supply chain agents be considered? How can 'reasonable' markups be estimated? What best practices should be followed in controlling supply chain markups (flat, regressive, regressive but not apply across the total procurement price) etc? & What are the potential positive outcomes of each strategy and what are the risks?
B) Should medicine be exempt from taxes/or tariffs?	If yes, then	i) What mechanisms are needed to ensure that cost savings obtained through exemption are passed on to patients?

Question # 07: Should Pakistan promote the use of quality-assured generic medicines as a strategy to manage medicine prices? If yes

Sub Questions		Supporting Questions
A) What prerequisites are needed to promote increased use of generic medicines?		
B) Should optional/mandatory generic substitution by dispenser/pharmacist be used to promote increased use of generic medicines?	If yes, then	Are domestically manufactured generics equal in quality to originator brands? How does DRAP ensure quality of generic medicines?
C) What is the role of (generic) competition in the pharmaceutical market as part of a strategy for managing prices?	If yes, then	Under what conditions should it be considered for use? What are the potential positive outcomes of using this strategy and what are the risks? What best practices should be followed? What are the resources and skills required for effective implementation?
D) Should internally reference pricing (by product or therapeutic group) be used to promote increased use of generic medicines?	If yes, then	Under what conditions should it be considered for use? What are the potential positive outcomes of using this strategy and what are the risks?

		What best practices should be followed? What are the resources and skills required for effective implementation?
E) Should strategies be adopted to encourage the use of generic/lower-cost products among providers (prescribers and dispensers)?	If yes, then	What strategies should be considered for use (e.g payment structure, financial incentive to encourage prescribing and dispensing lower-cost products, education strategies) etc ? Under what conditions should it be considered for use? What are the potential positive outcomes of using this strategy and what are the risks? What best practices should be followed? What are the resources and skills required for effective implementation?
F) Should strategies be adopted to encourage the use of generic/lower-cost products among consumers?	If yes, then	What strategies should be considered for use (e.g. generic restrictions and substitution requirements, education strategies) etc ? Under what conditions should it be considered for use?

		What are the potential positive outcomes of using this strategy and what are the risks? What best practices should be followed? What are the resources and skills required for effective implementation?

Question # 08: Importance of Academic participation\Research in the determination of cost, price, quality, and distribution of the medicines?

Question # 09: Any information on the utilization of Central Research Funds (CRF)? What is used for research into new chemical entities?

Question # 10: Given the persistent shortages of medicines, which the industry officials primarily blame on pricing regulations, can we term the pricing regulation a failure in terms of the overall welfare of the people?

Question # 11: Pakistan still has to import millions of dollars of medicines (like cancer drugs) every year. If drug pricing were market-determined, would imports lessen substantially?

Question # 012: Any further guidelines/recommendations for data collection/Interviews?

Inform Consent

Thesis Title: Evaluation of Price determining Mechanism of DRAP and Pharmaceutical Industries in Pakistan

Consent to take part in research

I… voluntarily agree to participate in this research study.

I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.

I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.

I have had the purpose and nature of the study explained to me and I have had the opportunity to ask questions about the study.

I understand that I will not benefit directly from participating in this research. I agree with my interview being audio-recorded/field notes.

I understand that all information I provide for this study will be treated confidentially.

I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of the people I speak about.

I understand that disguised extracts from my interview may be quoted in dissertation and published papers.

I understand that if I inform the researcher that I or someone else is at risk of harm they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.

I understand that a transcript of my interview in which all identifying information has been removed will be retained till the completion of the study. (Maximum 03 months)

I understand that under freedom of information legalization I am entitled to access the information I have provided at any time while it is in storage.

I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Signature of research participant Date:

Signature of researcher Date:

Appendix C

Pharmaceutical Firms Enlisted on the top of Stock Exchange of Pakistan

Symbol	**Short Name**
ABOT	Abbot Laboratories Limited
FEROZ	Ferozsons Laboratories Limited
GLAXO	GlaxoSmithKline (Pakistan) Limited
GSKCH	GlaxoSmithKline Consumer Healthcare Pakistan Limited
HINOON	Highnoon Laboratories Limited
IBLHL	IBL HealthCare Limited
MACTER	Macter International Limited
OTSU	Otsuka Pakistan Limited
SAPL	Sanofi-Aventis Pakistan Limited
SEARL	The Searle Company Limited
WYETH	Wyeth Pakistan Limited
AGP	AGP limited