EVALUATING DRUG PRICING MECHANISM OF PAKISTAN AND THE WAY FORWARD

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CERTIFICATE

This is to certify that this thesis entitled: **"Evaluating Drug Pricing Mechanism of Pakistan and the way Forward"** submitted by **Ms. Fozia Tabussom** 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 Health Economics.

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Abstract

Pakistan is a lower-middle-income country where health markets are primarily dominated by public sector. Federal Ministry of National Health Services Regulation and Coordination is in charge of healthcare at the center along with health departments of provinces looking after the major health care services provision across Pakistan. Increased prescription expenses and overall out-of-pocket expenditure burden indicate the poor performance in health care. These concerns are compounded by decreased health-care investment and a lack of effective health-insurance programmes. Among the major woes are frequent increases in drug prices. The purpose of this study is to analyse the welfare impact on families in Pakistan which is a result of medicine inflation resulting in welfare loss. The influence of medicine pricing on consumer well-being in Pakistan is examined in this study. This study is based on HIES data from 1992/93 through 2018/19. In this work, we estimate parameters and price elasticities using the AIDS model. Drug prices have risen faster than the overall CPI throughout the time period of our study. As a result, consumers have faced large economic losses in every year from 1993 to 2019, with a continuous welfare loss for all consumers. Qualitative analysis, conducted by interviews using semi-structure and open ended questions, showed beyond doubt disequilibrium in government interventions through higher prices, poor quality and unavailability of drug.my research recommend establishment of an independent drug pricing sector that will guarantee lowest possible prices on drugs while ensuring the drug quality it must be free of any political influence – just implementing the WHO regulatory principles.

Keywords: Pharmaceutical Industry, Drug Pricing, Pakistan, Welfare Impact, Almost Ideal Demand System

List of observations

DRAP	Drug Regulatory Authority of Pakistan
MRP	Maximum Retail Price
API	Active Pharmaceutical Ingredient
WHO	World Health Organization
OOP	Out of Pocket
LMIC	Low and Middle Income Countries
MNHSRC	Ministry of National Health Services Regulatory and Coordination
GST	General Sale Tax
EMs	Essential Medicines
CPI	Consumer Price Index
OB	Originator Brand
CVD	Cardiovascular Disease
PIDM	Program International Drug Monitoring
GDP	Gross Domestic Product
WTO	World Trade Organization
PSLM	Pakistan Social Living Standard Measurement Survey
OECD	Organization for Economic Co-operation and Development
R&D	Research and Development
PV	Pharmacovigilance
AMR	Antimicrobial Resistance
PIC	Punjab Institute of Cardiology
GMP	Good Manufacturing Practice
NDP	National Drug Policy
NHA	National Health Account
CEO	Chief Executive Officer

PE&R	Pharmaceutical Evaluation& Registration
MD&MC	Medical Devices and Medicated Cosmetic
QA&LT	Quality Assurance and Labotery Test
MIS	Management Information System
FFP	Final Finished Product
FDA	Food and Drug Administration
SRA	Stringent Regulatory Authority
ICH	International Council for Harmonization
CTD	Common Technical Document
DRB	Dynamic Reference Base
OTC	Over the Counter
EEC	Enrollment Review Committee
RRA	Reference Regulatory Authority
FID	Federal Inspector Drug
PIC/S	Pharmaceutical Inspection Corporation Scheme
GLD	Good Labotery Practice
MIS	Management Information Services
CRF	Center Research Fund
AIDS	Almost Ideal Demand System
CV	Compensating Variation
HIES	Household Integrated Economic Survey
PBS	Pakistan Bureau of Statistics
SRO	Statutory Regulatory Offer
DML	Drug Manufacturing License

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CHAPTER 1

Introduction

1.1 Introduction and Background

All pharmaceutical products sold in Pakistan have to be first approved by DRAP and a maximum retail price (MRP) set before they are sold. This industry has evidently gone through three distinct stages, as is apparent. The period from 1948 and 1971 is known as the "first phase." During the first phase, the country's pharmaceutical sector was non-existent after independence, and most pharmaceuticals were imported by dealers primarily headquartered in India.

The growth of pharmaceutical industry started from 1948.The market is now worth $3.2 billion, and there are approximately 750 drug manufacturing companies in Pakistan that manufacture 70% of the drugs and medicines sold in the country. In addition, 95% of the Active Pharmaceutical Ingredients (APIs) used in drug manufacturing are imported from other countries.

Pakistan spends a total of USD14 per capita on health each year, which is significantly lower than the USD 34 recommended by the World Health Organization for developing countries(Shehla Zaidi, Bigdeli, Aleem, & Rashidian, 2013). The public sector accounts for only 32 % of total health expenditure, with the remaining 64 % borne primarily by households through Out of Pocket (OOP) expenditure (Organization, 2002). Non-salary

items such as pharmaceuticals are only accessible for purchase in the public sector at a rate of 22 % of the operating budget (Belay, Couffinhal, Haq, Kazi, & Loevinsohn, 2010). The amount expended on drugs in public sector is below the critical threshold of $2 per capita per year recommended by the WHO to avoid medicines shortages (Organization, 2002). Evidence suggests that there is a significant shortage of medicines in public-sector institutions, with patients being compelled to purchase medications from private retail pharmacies as a result of a lack of available drugs (Ball, Grubnic, Birchall, & accountability, 2014).

1.1.1 Analysis of the Problem

The Pakistan governments, as well as governments in other LMIC, has been dealing with the problem of high drug prices and limited accessibility of drugs, which has made medication less accessible(Lee et al., 2017). Access to expensive and high-quality Essential Medicine is a critical component of a successful healthcare system. As part of the SDG 3, it is intended to guarantee equal access to cheap (EMs) as a fundamental human right for everyone(Organization, 2007). In Pakistan, medicine is delivered free of charge in the public sector. In the private sector, the patient is required to pay out of his or her own money.

In Pakistan, 45.5 % of the population lives lower the poverty line, which is the maximum in the world(Haider, 2014). Inflation is increasing, as seen by the CPI, which increased by 1.3 % on a year-on-year basis in September 2015(M. Atif, Ahmad, M., Saleem, Q.,

Curley, L., & Qamar-uz-Zaman, M, 2017). Furthermore, inadequate cost results in underutilization of valuable medications. The Ministry of NHSRC (National Health Services Resources and Coordination) has implemented a number of policies that benefit the poor in order to make health care more affordable. For example, there is no tax freedoms on the importation of medicines, raw materials, and equipment, exemptions from GST on medicines, as well as complete tax freedoms for medications supported by donor organizations, are among the measures being considered (S. Zaidi, Bigdeli , Aleem , & Rashidian 2013).

1.1.2 Medicine in Public Health System

The public health system continues to face pertinent and crucial challenges in terms of the availability of pharmacies and pharmacy stores that carry both Essential Medicine and Non-Essential Medicine. There is a distinction between the price of Essential Medicine and the price of Non-Essential Medicine in Pakistan. The DRAP publishes and keeps up-to-date the Essential Medicines (EM) list. Currently, just 15 % of the demand for vital pharmaceuticals in the public sector is being satisfied, compared to 31 % in the private sector, owing to manufacturing constraints and regulatory delays in licensing and distribution. Production of original brands and considerable price variations, in the face of pricing controls enforced by the DRAP, cause customers to express worry about the affordability of goods and services. Low-income nations have lower medication prices

than high-income ones, while countries with similar levels of wealth pay radically different prices for pharmaceuticals.

1.1.3 The Price Hike

Pakistan's price increases continued from December 2001 to June 2016, without taking into account the yearly Consumer Price Index (CPI). This upset the pharmaceutical demand and supply balance, resulting in a lack of vital medicines on the market. This is why we believe that the remedial action implemented by the DRAP to connect the yearly rise in pharmaceutical costs with the CPI of the instantly earlier financial year is an important step forward in the fight against rising medicine prices(S. Zaidi et al., 2013).

Prices of pharmaceuticals have been growing faster than both medical care prices and consumer prices in general, as assessed by the CPI for medical care and the Consumer Price Index for all commodities. Since pharmaceutical prices are a major focus of public policy debates these days, it is difficult to understand how the change in drug prices, as measured by the CPI for prescription drugs and medical supplies (CPI-drugs), compares to the concepts of price change that policymakers and analysts may have in mind (Schweitzer, 2018).

Distributors concentrate on low-cost items with a small number of producers, then establish a supply monopoly and raise prices. The worldwide drug situation has significantly improved in recent years, particularly in terms of the availability of cheaper

medications. Most significantly, practically every government has put in place policies to encourage people to take more basic medications. This is very significant. The important weapons for expanding access to pharmaceuticals and lowering drug prices is the fundamental level of competition. Despite the usage of low-cost generic medications, the treatment costs of communicable and Non-communicable disease remain costly in Pakistan.

1.1.4 Welfare and Drug Prices

The health of an individual is closely related to their well-being. In accumulation to the necessity of concentrating on community health, there is a positive association between the health of the population and the economic progress of a country(Bloom, 2008). One of the most essential components of community health is access to greater pharmaceuticals, which represents a large part of total health spending. While price controls for industrial products are indeed rare in Pakistan, price controls for pharmaceuticals have been used somewhere else in the world as a tool to reduce OOP for cost-conscious consumers and, in particular, to increase access for patients in low-income countries(Dean, 2018).

The manufacturers expressed their dissatisfaction with the price restriction since their manufacturing costs were growing of the fast depreciation of the Pakistani Rupee as a result. Because of the substantial reliance of manufacturers on imports of raw materials, this harmed manufacturers; claim the once-a-year price rise is not sufficient

compensation for their losses. As a result of this, the prices of critical medications have climbed by 9 %, while the prices of all other pharmaceuticals have increased by 15 % (S. Zaidi et al., 2013). For example Folic Acid is an essential drug for pregnant women. Its retail price set by the government is 34 paisa per tablet. Globally prices increased, and in Pakistan the cost of producing it shot up to Rs.1.25, but the government never increased its price and as a result there were shortages. Now doctors prescribe the substitute to it, which is less effective and is an alternative medicine (not allopathic) (S. Zaidi et al., 2013).

Studies have revealed that general availability of medications has increased in 2019 compared to 2017, that is, before the introduction of this strategy, with the exception of lower price generics in the public sector, which have showed a decline in accessibility in 2019. The prices of medications have climbed dramatically; making the vast majority of Essential Medicines (EMs) required treating common ailments expensive. The price increases for LPGs have been significantly larger than those for original brand drugs (OBs). Both years, the most unaffordable medications were those used to treat ulcers, diabetes, and cardiovascular disease (CVD).

1.2 Problem Statement

Pakistan is home to a major pharmaceutical manufacturing industry as well as a vast population with low health-related outcomes. With an increase in the price of drugs and medications, the welfare loss to households is more than it would otherwise be. Because

of drug policy, households will incur greater drug spending and suffer greater welfare losses when the medication price rises by an amount greater than the Consumer Price Index (CPI). The topic of pharmaceutical pricing is complicated because it incorporates a number of factors, including the cost of raw imported materials, direct and indirect production costs, shipping and port charges, and the payment of taxes and tariffs, among others. CPI which measures the average cost of goods and services in Pakistan has climbed by more than 230 % in the previous 15 years. Over the same period, the rupee (the Pakistani currency) has fallen by more than 70% versus the US dollar, increasing the price of production for manufacturers and having a cascading impact across the pharmaceutical supply chain (DRAP, 2015).

1.3 Research Gap

The rise in the overall CPI may have negative repercussions on welfare. As a result, consumers have been paying more prices for drugs products, resulting in increasing health-care expenses and a persistent loss of welfare for all low-income households. However this loss in welfare needs to be measured in order to review the drug pricing mechanism in Pakistan. The previous studies focused on the issues relating the drug pricing mechanism and discussed the problems of high drug prices in Pakistan but did not consider the welfare impact on household due to price hike in the medicine market.

1.4 Objective of the Research

- To study whether the medicine Inflation behaves independently or is related to general prices
- To review the drug price shift with the currency exchange rate changes
- To study the Welfare impact on household due to price hike in the medicine market

1.5 Research Questions

- What is the impact of medicine inflation on poor household welfare?
- How are changes in drug prices, specifically rise on drug prices, related to various factors like pricing policy, CPI, Exchange Rate, etc.?

1.6 Hypothesis

- Medicine Inflation behaves differently from the general CPI.
- Medicinal inflation has a strong correlation with exchange rates.
- Medicine inflation leads to significant reduction in welfare of household especially poor.

1.7 Organization of Thesis

Chapter 1 portions to introduction, chapter 2 gives overview of the literature, and chapter 3 discuss the structure of pharmaceutical industry of Pakistan and chapter 4

highlights the regulatory structure of pharmaceutical industry, chapter 5 discuss data and methodology and chapter 6 discuss the qualitative analysis. Chapter 7 contains conclusion and recommendations.

CHAPTER 2

Literature Review

This section is based on the earlier research studies which explain the historical background of the domestic pharmaceutical industry and the association among the drug pricing policies and the performance of the pharmaceutical industry. This study consists of the literature review for Pakistan and foreign studies.

2.1 History of Pharmaceutical Industry of Pakistan

The global expenditure on pharmaceuticals continues to rise. Spending on pharmaceuticals surged by 50% between 1995 and 2006, according to the World Health Organization In a number of different nations throughout the world, the average annual growth rate of pharmaceutical spending outpaced both overall health expenditure and the growth rate of GDP (Docteur, Paris, & Moise, 2008).As a result, governments and people are under growing pressure to ensure that vital medications can be afforded by everyone(Dukes, 2003). There is no national pricing or purchasing strategy in the United States is high-income country(Critchley, 2006). Organizational and institutional policies, on the other hand, are rather frequent Pakistan is a developing country in South Asia and is one of the world's fastest growing economies. It spends 1.2 % of its GDP on health care in 2019-20. It delivers services to just 22 % of the population, putting it at a disadvantage in comparison to the private sector as a whole (S. Zaidi, Bigdeli, M.,

Aleem, N., & Rashidian, A, 2013). According to reports, the average family pays for 64 % of all health-care spending. It is estimated that the expenditure on medication accounts for 43 % of overall household expenditures in the country (S. Zaidi, & Nishtar, N. A, 2011).The use of generic drugs is helpful in Pakistan since it decreases the cost of medications, making them less burdensome on the patient's wallet(Jamshed, 2011).

The health sector may be classified into two categories: the public sector, which provides healthcare services primarily through government financial assistance and donor contributions, and the private sector, which operates on a commercial basis. The government's spending on the health sector is minimal, accounting for around 3.2 % of the country's GDP, which is significantly lower than that of comparable peer nations such as Bangladesh and Sri Lanka. The majority of health-related expenses (78 %) are paid out of pocket(Shaikh, 2007). The power is being transferred from the federal to the local level, with the duty of the province government primarily for the public sector. (PSLM, 2005-2006). Patients are forced to try to find medical care in the private sector due to a shortage of key medical services in the public sector such as professional personnel, important pharmaceuticals and medical supplies, a scenario created by the fact that government expenditure in Pakistan is 70% out of pocket(WTO, 2009). The health system is mostly focused on metropolitan areas, with the private sector holding a dominant position, posing challenges for rural areas. According to the Pakistan Social and Living Standards Measurement Survey, people are increasingly seeking medical treatment in the private sector or from other sources (PSLM). It is essential for a

functional health system to ensure that people have dependable access to inexpensive, appropriate, and high-quality medications on a regular basis(WHO, 2007).

2.2 Review of Studies on Pricing Structure of Pharma Industry of Pakistan

The literature on Pakistan's pharmaceutical sector is minimal, and studies on persistent shortages or even non-availability of pharmaceuticals is particularly scarce. It's tough to locate a peer-reviewed publication of significance on this subject in a reputable journal. Whatever information there is about the availability of drugs is mainly found in news articles and news broadcasts that focus on medicine shortages and pricing difficulties.

(Rashid, 2015) examined the DRAP via the lens of three policies (regulation of the industry, encouragement of its development and ensuring availability of drugs). She believes that serious inadequacies in the regulator's effectiveness are impeding the industry's progress. Rashid et al. (2019) conducted the second study that just examined the performance of DRAPs, with the major topic of their research being the quality of medications and drug pricing. They discovered major inadequacies in the regulator's effectiveness in terms of assuring prescribed pharmaceutical quality. They also recommend that the broader framework for assuring quality be improved, for example by increasing GMP inspections (GMPI).

(MEHMOOD & POLICIES) makes an attempt to contrast these two opposing narratives by examining the challenges facing the regulator and the industry He discovered that,

while the business had challenges to address (lower-tier producers providing substandard pharmaceuticals, for example), the fundamental obstacles impeding the sector's efficient operation and expansion could be traced back to the way the industry had been controlled historically. The problem of administered pricing was particularly perplexing, since it compelled producers to take measures (such as ceasing manufacturing of specific pharmaceuticals) that had overall negative welfare consequences.

The majority of research on the pharmaceutical business and public sector laws focuses on a single (or a few) criteria rather than a comprehensive picture. Various researches, for example, have addressed the issue of drug scarcity. Shamim Rizvi (1999) criticized government actions, including "freezing" medicine prices, for Pakistan's shortages of crucial pharmaceuticals. Third World Network Briefing (2001) addressed the topic of high-priced imported medications and the illicit market in pharmaceuticals, highlighting the role of government-mandated quotas in Pakistan and their implications on drug supply.

(Shehla Zaidi et al., 2013) examined drug availability in government/public sector hospitals and determined that the World Health Organization's (WHO) required reduced expenditures per capita (less than $2) for ensuring a consistent supply of critical pharmaceuticals were not being reached. According to Noureen and Zaidi (2013), researchers at Agha Khan University, the availability of necessary pharmaceuticals in the public sector is a dismal 3.3 percent, significantly lower than Zaidi et al estimates of 15

percent. Interestingly, their findings appeared to match earlier estimates by The Network for Consumer Protection (2006), who discovered a comparable proportion in terms of median availability of necessary pharmaceuticals at public sector stores. According to Gilani, Babar, and Malik (2013), the non-availability of vital drugs in government facilities explains why 67 percent of total patients contact private physicians, increasing their healthcare expenses. Hira Rashid (2015) examined the functioning of the major regulator (DRAP) as well as the reasons that led to the proliferation of informal channels (the "black market"). Sayeed and Dawani (2020) determined that pricing regulations lead to a preference for producing pharmaceuticals with a large profit margin, as well as promote hoarding and rent-seeking. (M. A. Khan, Kundi, & Saqib, 2019) investigate tort law in relation to damage caused by substandard medications(Shehla Zaidi et al., 2013). They believe that tort laws are limited in their scope, efficacy, and execution. (Zahoor et al., 2010) examine the returns of the business over a decade and conclude that regulations are to blame for the industry's poor performance, which may have been better had the rules been friendlier. The World Health Organization (Organization, 2017)evaluated the openness of public sector policies relating to the pharmaceutical business.

They discovered that perceptions of corruption vary by regulatory category, with some being greater and others being lower.

Previously, the author investigated the impact of government controls, especially the policy of freezing drug prices on the pharmaceutical market in Pakistan, as well as the broader ramifications in terms of welfare. He utilized four criteria to quantify losses caused by the price-freezing strategy. According to his calculations, the annual loss amounts to Rs. 112 billion. A study conducted by Agha Khan University on the topic of access to vital medicines indicated that medical practitioners had inadequate expertise and drug dispensing practices. It also indicated that, on average, the number of prescription medications is larger than in Low and Middle Income Countries (LMICs).

When it comes to worldwide level data and research on pharmaceuticals and the availability of vital medications, the literature is fairly substantial. Vernon reports that, despite billions of dollars in investment and significant study, just three out of ten drugs make it to market. For these drugs, the average time to pay the cost of production (research, salaries, etc.) and make a profit (over costs of production) is at least 15 years. With a government rule that suppresses market-based prices, there is less motivation to do research and develop new medicines. Maria Kutyavina discovered that the years for recouping expenditures and producing a profit for a specific medicine are at least 16, with the cost of discovering a New Chemical Entity (NCE) being at least $800 million. There is no incentive to study and release new drugs in the absence of a pricing incentive that ensures profit. This concept applies to Pakistan's pharmaceutical business as well.

2.3 Review of Low and Middle Income Countries

In LMICs, access to and appropriate use of medications are frequently inadequate (LMICs). According to the WHO, the average availability of critical medications in LMICs is 35 % in public sector institutions and 66 % in private sector facilities on a national level. Medicines account for a significant part of health spending in LMICs, ranging between 20 % and 60 %, compared to just 18 % of health spending in developed nations (A. Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009). Furthermore, between 50 % and 90 % of expenditure on pharmaceuticals in LMICs is borne by the patients themselves(WHO, 2004). When it comes to financial inclusion, this inequitable style of financing generates considerable access obstacles for the poor and/or results in excessive family expenses. The impoverished, as well as other segments of the population frequently rely on the private informal sector for their medical needs, particularly in rural regions. Prescription and delivery of medications that are excessive and unsuitable are common (Organization, 2008).

Pharmaceuticals may be extremely beneficial to people's health. At the same time, pharmaceuticals account for a significant portion of total expenses. In 2000, the share of government spending on health that was spent on pharmaceuticals averaged 16 % in LMICs and 13 % in middle- and high-income countries(WHO, 2004). The majority of nations are facing significant rises in their pharmaceutical expenses. Between 1991 and 2001, the total public and private expenditure on medicines increased by more than 70% in real terms (adjusted for price movements) in numerous OECD nations, according to the World Bank (OECD, 2003). Between 1990 and 2000, pharmaceutical spending

climbed by 63 % and 97 %, respectively, in nominal terms (i.e., without adjusting for price fluctuations) in low- and middle-income nations, respectively (WHO, 2004). These increases put pressure on policymakers and insurers to keep medication expenditures under control, and to do so without having negative consequences for the health of the population, or without raising health-care consumption or other expenses.

Globally, high-income nations continue to be the most important markets for the pharmaceutical sector. These nations had a population of 16 % of the world's total in 2006, yet they accounted for 78.5 % of the world's total pharmaceutical spending. Comparatively, just 21.5 % of global pharmaceutical spending went to LMICs, which account for 84% of global population residing in LIMCs. As a result, there is a large gap in per capita pharmaceutical expenses, with low-income nations spending USD 7.61 per capita on pharmaceuticals and high-income countries spending USD 431.6 per capita on pharmaceuticals. Nonetheless, low- and middle-income countries (LMICs) are becoming an increasingly important market since pharmaceutical expenditures in LMICs grow at a quicker rate than in high-income nations(Lu, Hernandez, Abegunde, & Edejer, 2011).

The factors that contribute to increases in worldwide pharmaceutical spending are numerous and may be divided into two categories: changes in consumption and changes in prices. As a result, when evaluating pharmaceutical budgets, pharmaceutical policies must be developed that address both pricing and the degree of consumption that is projected to occur within the budgetary constraints(Chen, 2008).Some academics and

press publications have raised the problem of Pakistan's high drug prices, which has received widespread attention(Saleem, 2016).

Healthcare spending on medications amounts for 20-60% of total health expenditure in middle-income nations, compared to 18% in countries be appropriate to the OECD. Up to 90 % of the populace in poor nations purchases medications through out-of-pocket expenditures, making medication the second most expensive item in a family's budget after food. People who are unable to afford medication may be forced to forego therapy or incur financial obligations. As a result, medications remain out of reach for broad segments of the global population, and the cost of providing them is a significant drain on government budgets (A. Cameron, Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R, 2009) By assisting in ensuring that medications are used appropriately and that patients are encouraged to finish the course of treatment, improving the overall quality of medical care can help to minimize the spread of drug free-for-all.

In middle-income countries such as Egypt, Jordan, and Morocco, the overall health spending on medications accounts for around 35% of total health expenditure. The surveys also reveal that families spend a significant amount of money on medications out of their own pockets(report, 1993). In 2015, brand pharmaceuticals accounted for 73.3 % of overall drug spending, while generic medications accounted for only 11.3 % of total drug spending.

The rates of medication prescription and use in Pakistan are higher than the average rates of drug usage in developing nations(Shehla Zaidi et al., 2013). If medicine is not provided during a provider-patient contact, this culture of pharmaceutical usage is primarily responsible for patients' perceptions that they have gotten poor care(Sudhinaraset, Ingram, Lofthouse, & Montagu, 2013).

2.4 Review of Drug Policies of Pakistan

The absence of a good medication pricing formula is primarily responsible for the policy problems around drug price that have arisen. Public sector hospitals are unable to provide a comprehensive range of vital pharmaceuticals, either as a result of insufficient operating budgets or as a result of inefficient administration(Kshirsagar, 1989).According to the Federal Cabinet, the main features of a national drug policy have been approved, which will focus on rationalizing drug prices, promoting the "essential drug" concept and rational use of drugs, as well as encouraging local production, particularly the basic manufacture of active ingredients. In addition, the strategy aims to improve quality control, eliminate "fake" pharmaceuticals, build a system of drug supply and distribution, and support research and development efforts. The Health Ministry is responsible for developing a "complete master plan" that identifies objectives and resources required to carry out the strategy, as well as identifying resources and technical assistance that might be made available.[i](WHO, 2019).According to the Drug Pricing Policy, the Maximum Retail Price (MRP) of originator brands shall be fixed on the basis

of the average price of the same dosage form and strength of the same brand in India and Bangladesh, respectively. If the original brand is only available in one of these countries, the manufacturer's recommended retail price (MRP), after taking the exchange rate parity into consideration, will be established at the par. While the maximum retail price (MRP) of a generic medicine should be established at 30 % cheaper than the maximum retail price (MRP) of the original brand, this %age may be reduced to 20 % in cases where regulatory conditions are met (Aaserud, 2006).

The price of Norethisterone increase is used for birth control pills, menopausal hormone therapy, and the treatment of gynecological problems, has been raised from Rs62 to Rs100, according to the government. From Rs786 to Rs1080 per capsule, the price of Tamsulosin capsule (a medication used by men to treat the symptoms of an enlarged prostate) has been raised. It has been decided to increase the price of Neurobion pill, which is used for the stoppage and cure of Vitamin-B deficiencies, from Rs535 to Rs977. It has been decided to increase the price of Adrenaline injection, which is used in emergencies and allergic responses to insect stings/bites, food, medications, and substances, from Rs217 to Rs597. In a similar vein, the prices of medications used by diabetics and others suffering from high blood pressure have gone up as well. The government, according to Mohammad Nadeem, an Islamabad resident, has left many impoverished patients with little choice but to cease therapy or reduce the dosage as a result of the recent increase in medicine price(DAWN, 2020).

2.5 Review of Multinational Companies in Pakistan

The drug prices of national pharmaceutical companies are lower because they have the option of obtaining raw materials from countries where they are available at a lower cost; however, the lack of low prices is due to the fact that they are manufacturing generic products rather than using low-cost raw materials. One of the major factors contributing to the pricing disparity is that the national pharmaceutical business does not spend as much in R&D as global corporations. MC invests a significant portion of their net profits in research and development, yet there is no such investment in R & D in Pakistan. National enterprises have double power to set their pricing at a lower level since they have not invested a single penny in research and development and because they have access to cheaper raw material resources than multinational corporations (Ahmed & Jalees, 2008).

The pharmaceutical and healthcare sectors in Pakistan are extremely competitive and difficult to work in. There are around 735 pharmaceutical businesses functioning in Pakistan (DRAP only lists 645), with several of the world's largest global pharmaceutical corporations having a presence in the nation. The business offers several development potentials for drug manufacturers, with the opportunities being fueled by the growing burden of chronic disease in Pakistan.

However, the sector is confronted with a number of obstacles, the most significant of which are regulatory and price challenges. Because of the government's emphasis on

increasing the pharmaceutical and healthcare markets, the industry is positioned for strong development, with several potential for attracting international investment. A study of the healthcare and pharmaceutical markets in Pakistan is presented in this industrial scenario by the author.[1]

2.6 Concluding Review

Pharmaceutical enterprises development and expansion have been significantly hampered by government's implementation of certain restrictions. Many pharmaceutical firms' lives might be ended by the wrong set of laws or policies. The implementation of appropriate policies will not only aid in the growth and development of this industry, but it will ensure that drugs are available at the appropriate time and place. Pakistan was given full membership in the WHO Program for International Drug Monitoring in November 2018. To secure the provision of high-quality drugs, Pakistani authorities must be educated on low-cost technology and techniques. The absence of a good medication pricing formula is primarily responsible for the policy problems around drug price. Pakistan is a developing country in South Asia and is one of the world's fastest growing economies. It spends 1.2% of its GDP on health care, putting it at a disadvantage to other developed countries. The majority of health-related expenses (78%) are paid out of pocket. The government's spending on the health sector is minimal, accounting for

[1]https://www.businesswire.com/news/home/20190524005256/en/Pakistan-Healthcare-and-Pharmaceutical-Market-Report-2019---ResearchAndMarkets.com

around 3.2% of the country's GDP. People are increasingly seeking medical treatment in the private sector or from other sources. Access to and use of medications is frequently inadequate in low- and middle-income countries (LMICs). Medicines account for a significant part of health spending in LMICs. Between 50% and 90% of expenditure on pharmaceuticals is borne by the patients themselves.

CHAPTER 3

Structure of Pharmaceutical Industry in Pakistan

3.1 Background

Pakistan did not have any of its own pharmaceutical production facilities. With no other option except to import medicine, which was extremely expensive, the country was unable to meet its medical demands. By 1980, the national pharmaceutical business had developed to a scale that was suitable for the time period in question. Over the period 1980-1999, the development of Pakistan's pharmaceutical sector resulted in the country's ability to distribute finalized medical products. The market capitalization of the sector was $1.3 billion in 2007(WHO, 2004).In 2011, Pakistan's pharmaceutical industry was worth $1.64 billion, with an annual growth rate of 11% (Babar, Ibrahim, & Hassali, 2011). About $2 billion was predicted to be generated by Pakistan's pharmaceutical sector in 2012. Pharmaceutical production and manufacturing in the Asia-Pacific region grew at a pace of 17% in 2013, above the global average of 8%. The industry now sits at the top of the global ranking(Ahmed & Batool, 2017).In the pharmaceutical business is currently worth $2.6 billion(M. Atif et al., 2017) Pharmaceutical companies in Pakistan number 750, of which 24 are MNCs. Controlled-price commodities regulated by Pakistan's government are all available, and the country has more than. In 2015, 50,000 medications and 1100–1200 molecules registered(Rashid, 2015).at the moment, the registered drugs are above 90,000. Bu not all registered products are produce. For

example, a report in 2016-17 stated that out of the around 70,000 registered medicines. Hardly 10,000 were being produce! Ninety five percent of the Active pharmaceutical ingredients (API) are imported. National and multinational pharmaceutical businesses compete for a part of the market. In the early 1990s, MNCs controlled the country's pharmaceutical sector; however, this is no longer the case. National enterprises now outnumber multinational corporations 70:30 and supply 70% of the country's medical needs.

3.2 Pharmacovigilance

It is defined by WHO as "the research and actions associated to the identification, assessment, identification and mitigation of significant negative pharmaceutical effects or other potential drug issues," according to the organization.

Pharmacovigilance involves the detection, classification, evaluation, analysis, and mitigation of detrimental effects or any other drug-related concern (PV). When it comes to healthcare, you can't have healthcare system without a PV system, which is essential for patient safety. PV has been ignored in Pakistan, which is regrettable. More than 200 individuals died in the PIC in 2011 as a result of a locally made medicine that acted on the cardiovascular system(Ghane, Saberi, & Davoodabadi, 2013).A total of 450 people were also admitted to hospitals with potentially fatal adverse medication reactions (ADRs). Pakistan's government and healthcare institutions were shaken by the tragedy. Provincial legislatures have issued resolutions pushing the federal government to create

a drug-regulatory agency. The DRAP was founded at that time, and it has performed well in maintaining the quality of sold medications since then; nevertheless, a completely functional PV division has yet to be developed(Zaheer-Ud-Din Babar, 2013).

3.3 Fake Medicines

In Pakistan, fraudulent medications have had a significant effect on both the local market and the export of locally made drugs. In addition to the incident at the Punjab Institute of Cardiology (PIC) (More than 50 individuals died as a result of another medicine contamination incident, as previously mentioned.). A cough syrup with a tainted excipient was the subject of the second occurrence. Pakistani-made pharmaceuticals have been prohibited in Sri Lanka as a result of these two events(Rashid, 2015).Since then, the issue with bogus medications has not improved. In 2015, a DRAP and FIA team raided a factory in the Kahuta industrial district near the capital city and found fake medications being manufactured. DRAP looks useless, as it runs on a modest budget of about US$ 4.77 million and employs just 275 employees, including drug inspectors, to regulate a pharmaceutical company in a nation where GMP breaches are frequent. Though the government is working to solve the issue, more drug inspectors must be employed, the Drug Act of 1976 must be modified, and stricter regulations must be adopted(Hanif, 2015).

3.4 Drugs Supply System in Pakistan

The contract is awarded to the pharmaceutical company with the best bid, which is announced in the media. Additionally, pharmacies choose pre-qualified and licensed drug providers for their bids in medical shops and pharmacy depots (pharmacies) (MOH, 2010). When it comes to drug procurement, the provincial government plays an vital role in centralizing the process so that it may be tailored to meet the specific demands of the province's healthcare facilities. Licensed wholesalers and pharmacy stores can provide 20–25% of the drugs required for emergency treatment to public hospitals on their own. On the other hand, private hospitals have their own prescription drug purchasing policies. Pakistan's National Drug Policy (NDP) lays down the requirements governing the country's systematic procurement operations. Purchasing should be based on generics, according to the NDP, and competition among drug providers should be encouraged to ensure that pharmaceuticals are of uniform quality. Licenses for pharmaceutical manufacturers should be reviewed or withdrawn if there is any doubt about their quality(WHO, 2003).

3.5 Drug Distribution Mechanism in Pakistan

The Drugs Act of 1976 governs the distribution procedure in Pakistan. Medicines are distributed in an efficient and well-regulated way, according to a WHO report. Throughout both public and private in Pakistan, there are different distribution networks. The producer distributes the medications directly to pharmacies and medical shops,

whereas distribution businesses provide medicines to pharmacies and medical stores. Between manufacturers and retailers, these distributors serve as a supply source. Until the items reach the final consumer, the pharmaceutical distribution process requires stable storage conditions. To preserve the quality of medicines, a distributor is required under the Drugs Act of 1976 to maintain specified storage situations and DRAP, provincial health ministries have been working hard to ensure that standard storage conditions at distributor warehouses and retail establishments are maintained. Despite these attempts, however, the country's medication supply management system still has flaws. According to a Pakistani research, certain public sector medication storage facilities do not meet the acceptable storage standards(Hafeez et al., 2004).

3.6 Drug Financing System in Pakistan

Pakistan spends 2.4 percent of GDP on health, with total health expenditures of $15 per capita/ per annum. According to the (NHA), just 32% of overall health spending is paid by the public sector, which includes the Ministry of Health, parastatal institutions, and Armed Forces (FBS) facilities. Private health spending accounts for 64% of overall health spending, with 97.5 percent coming from out-of-pocket expenditures by families and just a small percentage covered by pre-payment schemes. International development partners only account for 1.9 percent of overall health spending.

Medicines account for around 47 percent of Pakistan's overall health spending(MOH, 2010). The public sector accounts for only 27% of medical spending, is while the private

sector accounts for over three-quarters, with families bearing the brunt of the cost through out-of-pocket expenditures (WHO 2004). In the private sector, approximately 43% of users pay for medications within the institution, while 57% pay for medicines outside the facility at pharmacies or drug stores.

The government of Pakistan sponsors public sector hospitals, which provide patients with a portion of their care for free, including drugs and hospitalization. Patients receive free emergency care and hospitalization, but they must compensation for drugs that are not accessible in the hospital. Furthermore, patients who are admitted to the hospital for particular treatment must pay for their hospital stay in private rooms. The government covers 32 percent of overall health expenditures, while patients finance 64 percent.

Non-salary items, such as pharmaceuticals, account for just 22% of the government's operating budget, compared to the WHO's recommendation of US$ 2 per inhabitant each year. The population's out-of-pocket expenses are enormous, with yearly per capita spending of just US$ 14, far less than the WHO-recommended US$ 34. A patient may expect to pay around US$1.91 (PKR200) per prescription at a public healthcare facility and more than US$2.39 (PKR250) at a private healthcare facility, according to estimates Although the government is now trying to implement a Universal Health Insurance (UHI) scheme, the benefits in term of affordability of prices has yet to be realized(Aslam et al., 2016).

3.7 Out-Of-Pocket Health Expenditure

Out-of-pocket (OOP) prescription expenditures have been labeled a drain on consumers' financial resources, particularly among the poorest segments who are worst impacted by OOP drug expenses. In the instance of non-affordability, the consequences reach well beyond poor health. Datta, Hussain, and Fatehin (2020) found that drug spending had a 'crowding out' impact on food intake, with the effect being much larger in poor households that are already food insecure(Datta, Husain, & Fatehin, 2020).

The costs of pharmaceuticals, which are important to the end user, are an excellent proxy for determining the success of laws in the pharmaceutical business. Since 2003-04, data on per capita medication expenditures in Pakistan is included in the table below.

Table 3.1: Out of Pocket Health Spending

Year	Expenses On Drugs, As %age Of Total Health Expenses	Per Capita Expenses On Drugs
2004	25	
2008	56	Rs.900
2010	56	Rs.920
2012	50	Rs.822
2014	53	Rs.1338
2016	50	Rs.1400
2018	51	Rs.1580

Source: National Health Account Surveys and Household Income Expenditure Survey,

Mahmood, Shahid (2022). 'An analysis of DRAP', PIDE

Out-of-pocket (OOP) prescription expenditures have been described as a drain on consumers' financial resources, particularly among the poorest segments. Non-affordability has far-reaching consequences that go beyond poor health. Datta, Hussain, and Fatehin (2020) found that medicine costs had a 'crowding out' impact on food intake, with the effect being much larger in poor households that are already food insecure.

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3.8 Consumption of Drug in Pakistan

The common consensus is that drug usage is likely to be high and above the area norm. In Pakistan, this involves self-prescription and drug usage. However, not everyone in the industry believes this to be the case. Their view is based on a) the number and type of drugs ingested by Pakistani individuals every month, and b) the presence of a youth protuberance, which eliminates drug overuse since young people consume less of it. In summary, even inside the pharmaceutical sector, perspectives range on this issue.

3.9 Concluding Review

Pakistan's pharmaceutical industry was worth $1.64 billion in 2011, with an annual growth rate of 11%. About $2 billion was predicted to be generated by Pakistan's pharmaceutical sector in 2012. Pharmaceutical companies in Pakistan number 650, of which 24 are MNCs. Pharmacovigilance involves the detection, classification, evaluation, analysis, and mitigation of detrimental effects or any other drug-related concern. PV has been ignored in Pakistan, which is regrettable. Private hospitals have their own prescription drug purchasing policies. Pharmacies choose pre-qualified and licensed drug providers for their bids in medical shops and depots. Pakistan spends 2.4 percent of GDP on health, with total health expenditures of $15 per capita/ per annum. Just 32% of overall health spending is paid by the public sector.

CHAPTER 4

Regulatory structure of the pharmaceutical sector in Pakistan

This chapter gives a high-level overview of the regulatory sector, the Pakistani pharmaceutical industry structure, regulatory sections, and pharmaceutical industry profile

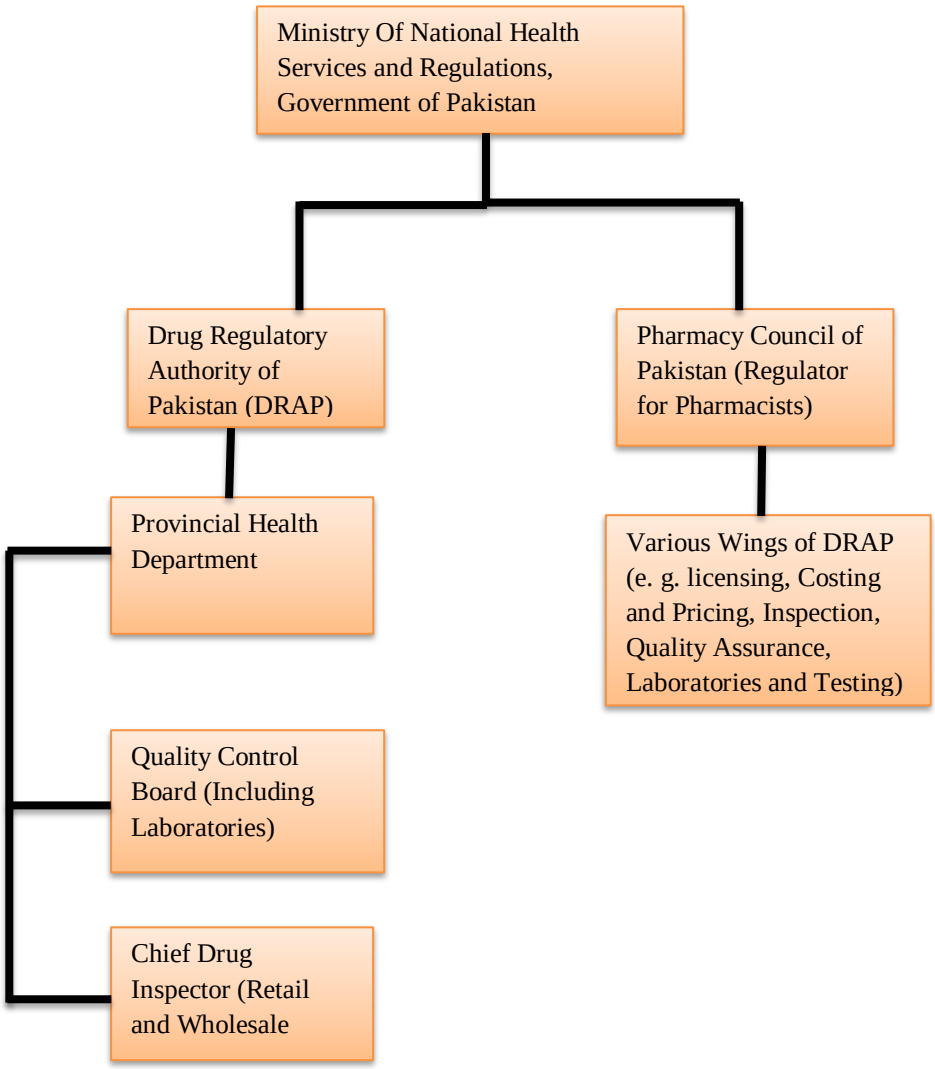

Figure 3.1 Regulatory Structure of the Pharmaceutical Sector in Pakistan[2]

[2] http://www.researchcollective.org/Documents/Dawani_and_Sayeed_2019_PakistanPharmaSector-190801.pdf

4.1 An Analysis of the Drug Regulatory Authority of Pakistan (DRAP)

To govern the manufacture, storage, distribution, sale, import, and export of beneficial commodities in Pakistan, the DRAP was founded in 2012 under the DRAP Act. The major goal of DRAP is to assure the safety, efficacy, and quality of pharmaceutical goods for Pakistan's citizens, patients, and customers.

Under the supervision of the Chief Executive Officer (CEO), DRAP has the following 13 divisions:

1. Licensing
2. Pharmaceuticals Evaluation & Registration (PE&R)
3. Biological Drugs
4. Controlled Drugs
5. Health & OTC
6. Medical Devices & Medicated Cosmetics (MD&MC)
7. Pharmacy Services
8. Quality Assurance & Laboratory Testing (QA&LT)
9. Costing & Pricing

10. Legal Affairs

11. HR & Administration

12. Management Information System (MIS)

13. Budget & Accounts

The Licensing Division is in charge of issuing licenses to manufacturers of active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs), as well as dealing with related issues. However, despite extracting a percent of gross sales from the industry since 1976, the regulator could not even set up a single USFDA. A level labotery in the country, a golden standard in term of drug quality and export potential. It is necessary to increase licensing criteria to worldwide standards in order for stated units to meet strict regulatory authority (SRA) requirements, which would improve Pakistan's image and boost exports. There is also a need to make it easier for enterprises in Pakistan to develop APIs. After completing the necessary assessment and evaluation, the Pharmaceutical Evaluation and Registration (PE&R) Division is responsible for granting registration of pharmaceutical products for humans and animals.

Other Board-assigned responsibilities are also carried out by Pharmaceutical Evaluation & Registration (PE&R). In March 2018, Pharmaceutical Evaluation & Registration (PE&R) revised and implemented its product registration requirements (Form 5-F / CTD)

in accordance with the International Council for Harmonisation (ICH) principles, although certain critical items remain lacking, including:

1. The APIs source is not fixed throughout the registration process, allowing the registration holder to modify the API source without DRAP permission.

2. Because DRAP does not require Bio-equivalence (BE) tests, which are required in African nations, the efficacy of Pakistani generic drugs is questionable.

3. The Pharmaceutical Evaluation and Registration (PE&R) has approved over one million drugs, including irrational formulations whose safety and effectiveness must be confirmed. By demanding a Common Technical Document (CTD) dossier at the time of regeneration, these goods can be screened out.

4. Product registration delays are another long-standing issue in Pharmaceutical Evaluation and Registration (PE&R), which can be addressed by providing enough skilled personnel to analyze submitted data within 60 days. Price fixing for items certified by the Dynamic Reference Base (DRB) should be completed within 60 days. It is necessary to rationalize the registration time, which should not exceed 240 days.

5. A single registration letter is sent out, including a number of goods. There is a requirement to issue a separate registration letter for each product that includes the registration number, complete composition, pack size, approved price, source of Active

Pharmaceutical Ingredient (API), approved specifications of Final Finish Product (FPP), and other key features of the registered product.

6. Product registration renewal is another dull area that requires improvement. For product renewal, a record of the Common Technical Document (CTD) should be needed, allowing the number of registered items to be rationalized according to regeneration. As with the registration letter, a proper product renewal letter should be produced.

7. There is a need to instruct DRAP and the pharmaceutical sector on how to develop/register pharmaceuticals in accordance with International Council Harmonisation (ICH) principles, so that these products may be registered in developed nations and exported from Pakistan.

After the necessary screening and review, the biological pharmaceuticals division is in charge of registering biological goods for human and animal use. The registration of biological products is done in accordance with WHO rules. The majority of biological goods, which must be manufactured locally, are imported. Delays in biological product registration must be addressed in order for patients to get timely supplies of these biological goods.

The division of restricted substances is in charge of allocating quotas for psychotropic, narcotic, and precursor compounds. Because the quota is shared with the Ministry of Narcotics Control, the procedure is delayed. The quantity allotted is insufficient to fulfill

the needs of legitimate producers, resulting in a controlled medicine scarcity on the market. For authentic manufacturers, it is necessary to revisit the assigned amount and control method.

Since the publication of the Alternative Medicines and Health Goods (Enlistment) Rules in 2014, the health and over-the-counter (OTC) products section of DRAP has been undergoing litigation. This section is in charge of licensing and enlisting herbal, unani, Ayurveda, Chinese, homeopathic, nutraceuticals, and dietary supplements for both humans and animals. For this division, the limited personnel and long file to H&OTC applications are a challenge, hurting DRAP performance and resulting in litigation. Currently, the minutes of the Enrollment Review Committee (EEC) are not available on the DRAP website, causing candidates to be suspicious of a fair evaluation and enlistment. H&OTC Division does not follow any internationally recognized reference regulatory authorities (RRAs) rules that can be compared and justified.

The Medical Device and Medicated Cosmetic (MD&MC) Division is in charge of registering both human and animal medical devices and medicated cosmetics. MD&MC is DRAP's most innovative branch, and it requires worldwide standards to be created. The Medical Device Rules of 2018, which were promulgated only two years ago, are currently undergoing review, demonstrating the speed with which the rules were drafted. Medical gadgets are still being marketed without being registered on the market. The

standards for registering medicated cosmetics have yet to be announced, giving producers a competitive advantage and resulting in items of questionable quality on the market.

Although the Pharmacy Services Division is in charge of implementing optimal pharmacy practices in Pakistan, the sale of prescription drugs without a prescription in every corner of the country demonstrates the Division's and provincial regulatory bodies' poor performance. Furthermore, drugs are sold without the supervision of a pharmacist, which is questionable. It is not being done to monitor and report Adverse Drug Reactions (ADRs) to healthcare items, which demonstrates a professional attitude among healthcare practitioners and pharmacists.

Three major tasks are assigned to the Quality Assurance and Laboratory Testing Division. The first responsibility is to ensure that suspect production facilities follow Good Manufacturing Practices (GMP). This Division has regional offices in Lahore, Karachi, Peshawar, and Quetta for this purpose, and has appointed an insufficient number of area Federal Inspectors of Drugs (FIDs) who are not well trained to follow and implement WHO Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidelines in manufacturing facilities. The second job is to oversee post-market monitoring of marketed products, including product recalls, in terms of safety, effectiveness, and quality. This task isn't being carried out in its entirety. The third duty is to adopt Good Laboratory Practices (GLP) in public laboratories so that items may be randomly

checked. It is necessary to update these laboratories and obtain international certification, such as WHO, so that the public may trust their findings.

The Costing & Pricing (C&P) Division is in charge of setting prices for pharmaceutical items, but it has been chastised by all parties, including industry, the general public, and the government, for its slow and confusing operations. They've been chastised by the industry for delaying price fixing and providing insufficient help in pricing hardship situations. As a result, low-cost items have been phased out or have remained scarce. Within 60 days, both DRAP and Cabinet must complete the price fixing procedure. Generic pricing should be set uniformly and submitted on the DRAP website, with no more than a 20% price differential between generic and brand leader. Annual price increases should be authorized without DRAP permission and posted on the DRAP website in accordance with the Pricing Policy for 2018.

The Legal Affairs Division is in charge of DRAP's legal concerns both inside and outside the organization, such as miscellaneous boards and courts. This division is responsible for the rational dissemination of rules and regulations in accordance with international principles, as well as the protection of DRAP against unwarranted lawsuits. Due to the legal authorities of this Division's lack of technical capabilities, the list of court cases is growing by the day. It is critical to employ advocates with a pharmaceutical experience so that DRAP can steer the program in the proper direction by deferring unnecessary litigation.

The Human Resource and Administration Division is in charge of DRAP official recruiting and development, as well as administrative issues. DRAP is now running without 70% of directors from relevant divisions, including the CEO. How can an organization work well in such a situation? All empty positions must be filled immediately, either by internal promotions or by transparent employment of external expertise.

All DRAP tasks are automated by the Management Information Services (MIS) division, although essential functions have yet to be digitalized. Digital transformation is critical since it will speed up the process and provide transparency in functions. All necessary information, such as FDA and WHO websites, should be posted to the DRAP website.

The Budget and Accounts Division is in charge of DRAP's day-to-day operations as well as future developments. It is necessary to use the Central Research Fund (CRF) to improve the DRAP / Pharm business through joint ventures in order to accomplish higher targets, such as FDA, WHO, PIC/S, and so on. [ii]

4.2 Regulatory Issues (Registration/Inspections)

The technical head is the drug controller, and the departmental head is the director general. Provincial headquarters function as field offices, monitoring and enforcing drug manufacturing licenses and regulations.

4.3 Drugs Act

The selling of pharmaceuticals in Pakistan is regulated under the Drug Act of 1940. The government developed the idea of the Generic Names Act of 1972 in 1972. This law requires manufacturers to exclusively make, distribute, and sell pharmaceuticals with generic names. However, owing to pressure from global pharmaceutical firms, this measure was never adopted. In 1976, the government passed a comprehensive drug statute, which was quickly implemented. The Drug Act of 1976 regulated the registration, licensing, manufacture, marketing, quality control, and research and development of medications in the nation(A. Khan et al., 2011).

4.4 Registration and Standardization in Licensing in Pakistan

The pharmaceutical business is being chastised and questioned by the government and the general public for the availability of fake medications on the market, which is driving down pharmaceutical quality. Due to the surge in local manufacture, similar-sounding products are increasingly accessible on the market, causing confusion among doctors and pharmacists. In 2006, A Husain and ZU Babar released an unpublished study titled "Registering Confusing Medicine Names: An Unchecked Practice Affecting Public Health in Pakistan. “Due to Non-following to GMP is a major source of worry in Pakistan. The quality of APIs is represented by the GMP and technique followed in creating oral tablets, according to pharmaceutical manufacturers (Rehman, H., 2010). In Pakistan, the Rules of Licensing, Registration, and Advertising of Drugs for GMP requirements were first introduced in 1976 and have not been changed since then (Zaidi,

S.Bigdeli, M., Aleem, N., &Rashidian, A., 2013). This signifies that in the current registration procedure, international standards or WHO rules and regulations have been amended(Louis et al., 2016). (W.H.O, 2016). In Pakistan, more than 90,000 medications have been registered; nevertheless, few physicians are concerned about the protection and effectiveness of low-cost generic pharmaceuticals, resulting in a significant demand for original goods in the nation (Jamshed, S.Q., Hassali, M.A., Ibrahim, M. I., &Babar, Z.U., 2011). In terms of affordability, this situation is impacting the low-income population (Glassman 2006). Further sacrifices on medication quality are not possible, and concerns about generic antirejection drugs must be reduced (Godman, B., and Baumgärtel, C., 2015). The registration of (APIs) as raw materials for medications in Pakistan is currently inefficient and causes worry for the system. To boost quality and export potential, the registration procedure should be changed to follow the international, WHO, and International Council for Harmonisation (ICH) approved Common Technical Document (CTD) format. It will not only boost standard, cost-effective generics and drug protection inside the country, but also in other regions (Khan, B. Godman, B., Babar, A., Hussain, S., Mahmood, S., &Aqeel, T., 2016). Soon, Pakistan will introduce the Common Technical Document (CTD) format for online registration, allowing for paperless and efficient registration that meets international standards. Pakistan's present licensing structure does not meet international standards, and the country's capacity to simultaneously create completed goods and APIs is restricted. Consistency, dependability, clarity, liability, and monitoring differ on GMP inspections under the

current licensing system. The pharmaceutical industry's GMP compliance is putting its export prospects in jeopardy. To become a member of the Pharmaceutical Inspection Corporation Scheme (PIC/s), a solid system for managing and implementing all operations and product life cycles is necessary, as well as a progressive licensing system based on risk management (DRAP, 2020). This system will issue licenses that require licensees to follow all (GMP), Pharmaceutical Quality Management System (QMS), and ICH criteria. Additionally, the inspection system and recordkeeping system have been improved to meet international standards.[iii]

4.5 Concluding Review

The major goal of the DRAP is to assure the safety, efficacy, and quality of pharmaceutical goods. Despite extracting a percent of gross sales from the industry since 1976, the regulator could not even set up a single USFDA level labotery in the country. Price fixing for items certified by the Dynamic Reference Base (DRB) should be completed within 60 days. Product registration renewal is another dull area that requires improvement. There is a need to instruct DRAP and the pharmaceutical sector on how to develop/register pharmaceuticals. The Health and over-the-counter (OTC) products section of DRAP has been undergoing litigation. This section is in charge of licensing and enlisting herbal, unani, Ayurveda, Chinese, homeopathic, nutraceuticals, and dietary supplements. Prescription drugs without a prescription are sold in every corner of Pakistan. Drugs are sold without the supervision of a pharmacist, which is questionable.

The Costing & Pricing (C&P) Division has been chastised by all parties for its slow and poor performance.

CHAPTER 5

Methodology and Data

5.1 Methodology and Data

In this section we will discusses the data and methodology background.

5.2 Methodology

The chapter discusses the methodology, data description, model specification, procedure and steps involved. The approach we utilized to study the influence of medicine costs on Pakistani household wellbeing is described in this section. Using the AIDS model and its linear approximation (LA/AIDS), we determine the essential parameters for household demand. Then, to determine if the data reflects economic theory, we calculate the uncompensated pricing elasticities. To calculate the influence of medicine costs on household wellbeing, we employ the Compensating Income Variations method. This study utilizes the mixed research methods (qualitative and quantitative).For the qualitative analysis, semi-structure open ended interviews are considered.

5.3 Almost Ideal Demand System (AIDS) Model

(Deaton, 1980), The Almost Ideal Demand System was presented as a new demand system. Economists have adopted AIDS to the point that, according to Alston and Chalfant (1993), in the short time since it was formed. It appeals to me since it is highly

flexible and has practically all of the characteristics of a theoretical demand system. AIDS satisfies the axioms of choice and approximates any demand system with an arbitrary first-order approximation. It aggregates without generating linear parallel Engel curves over customers. It includes a simple estimator as well as a functional form that works with home budget data. By placing linear constraints on the fixed parameters, it fulfills the homogeneity and symmetry criteria, and its linear approximated variant eliminates the need for nonlinear estimation.

The AIDS model has been used in the literature on the welfare impact of medicine cost(Adagunodo, 2013).To investigates the influence of drug pricing change in Nigeria on consumer welfare using an AIDS model. Using the same technique (LA/AIDS), Aziz et al. (2016) explore the influence of medicine pricing on Pakistan household.[iv]

The system is built around an expense function of the following form:

$$ln[M(p,u)] = (1-u)ln[a(p)] + u\ ln[b(p)] \qquad Eq(5.1)$$

Where

$$ln[a(p)] = a_0 + \sum_{k} a_k [ln(p_k)] + \frac{1}{2}\sum_{k}\sum_{j}\gamma_{kj} * [ln(p_k)ln(p_k)] \qquad Eq(5.2)$$

$$ln[b(p)] = ln[a(p)] + \beta_0\ \Pi_k [p_k]\beta_k \qquad Eq(5.3)$$

Equations (5.2) and (5.3) are substituted into equation (1) to produce

$$ln[M(p,u)] = a_0 + \sum_k a_k[ln(p_k)] + \frac{1}{2}\sum_k\sum\gamma_{kj} * \left[ln(p_k)ln(p_j)\right] + \mu\beta_0\Pi_k\,[p_k]^{\beta} \quad \text{Eq (5.4)}$$

The Marshallian demand function for any good is generated in two steps. The compensated demand function may be obtained in the first step by computing the derivative of the aforementioned expenditure function with respect to In (p1) and using shepherd's lemma to an equation for expenditure share of good 'I'. The direct utility function, which is easily obtained by inverting the aforementioned expenditure function, may be substituted in the resultant equation. The eventual result would be a share of expenditure equation of the form:

$$S_i = \alpha_i + \sum\gamma_{ij}Inp_i + \beta_i\left(\frac{M}{p}\right) \quad Eq(5.5)$$

Where $\gamma_{ij} = \frac{1}{2}\left(\gamma_{ij} * + \gamma_{ij} *\right)$

In the aforementioned system, S i is the budget share of good I p i are prices, M is total spending, _1 is a constant intercept term, _ij and I measure the sensitivity of price and actual expenditure changes, respectively, and p is the price index.

The price index 'P' is defined

$$In = \alpha^0 + \sum_k\alpha_k Inp_k + \frac{1}{2}\sum\sum\gamma_{kj}Inp_kInp_j \quad \text{Eq (5.6)}$$

The parameters of equation (5.6) are nonlinear, and the demand function is provided. The AIDS is simply defined as "in the absence of change in relative pricing and actual expenditure (M/P), the budget shares are constant, and this is the appropriate starting point for model forecasts." Changes in relative pricing are represented by the term _ij, while changes in actual spending are represented by the B0 coefficient; both sum to zero and are positive for luxuries and negative for necessities. The structural parameters are unrestricted in this model, which abstracts from the theoretical features of the cost function. By repeatedly putting some unique requirements on the parameters This unconstrained model can be used to examine some of the demand theory's conclusions. To ensure that the parameters are consistent with theory, various constraints are placed on them. The equations (3.5) and (3.6) can be summarized as follows.

$\sum_i \alpha_i = 1, \sum_i \gamma_{ij} = 0, \sum_i \beta_i = 0$ Eq (5.7)

$\sum_i \gamma_{ij} = 0$ Eq (5.8)

$\gamma_{ij} = \gamma_{ij}$ Eq (5.9)

Equation (5.5) describes a system of demand functions that add up to total spending (si=1), are homogeneous of degree zero in prices and total expenditure combined, and satisfy Slutsky symmetry if equations (5.7), (5.8), and (5.9) hold. The set of adding-up constraints is represented by equation (5.7), the restriction of price homogeneity is

represented by equations (5.8), and the Slutsky symmetry requirement is represented by equation (5.9). To put it another way, equation (5.7) states that the budget shares must total up to one.

Because the budget shares sum up to one, the parameters ai must add up to one in equation (5.5), whereas the vector I and each column of the ij matrix must add up to zero. In terms of pricing and total expenditure, the system should be homogeneous to the degree of zero; doubling both should double unit values while leaving the budget shares same.

The adding-up and homogeneity constraints allow us to "complete" the demand system by adding another commodity defined as "all other commodities" and deduce its Own and Cross-elasticities from the adding-up and homogeneity constraints.

If and only if ij=ji, the demand system's Slutsky or substitution matrix will be symmetric. The symmetry restriction is frequently employed in demand analysis to improve the theoretical consistency of parameter estimations.

From an econometrics standpoint, the most important characteristic of Equation (5.5) is that it is extremely close to being linear. If 'p' can be calculated individually, the system's parameters will be linear. With respect to p, the constraints on a and ensure that eq (5.6) characterizes p as a linearly homogenous function of individual prices. In many

circumstances when prices are reasonably collinear, p will be used to approximate a price index. For instance, stone's usage of the phrase,

$$InP^* = \sum(S_k Inp_k) \quad \text{Eq (5.10)}$$

This index is determined prior to estimate, resulting in equation (5.5).

$$S_i = \alpha_i + \sum \gamma_{ij} Inp_j + \beta_i \left(\frac{M}{P^*}\right) \quad \text{Eq (5.11)}$$

Equation (5.11) is known as the Linear Approximate Almost Ideal Demand System (LA/AIDS) in this form, because it is simple to calculate. However, in general, the link between AIDS parameters and LA/AIDS parameters remains unknown.

5.3.1 Price Elasticities

Price elasticity is defined as the ratio of a percentage change in quantity requested to a percentage change in price that causes a change in quantity demand. In this case, the uncompensated elasticities of LA/AIDS might be defined as

$$\eta_{ij} = \frac{d\ lnQ_i}{d\ ln\ p_j} = -\delta_{ij} + \frac{dInS_i}{dInP_j} = -\delta_{ij} + \left\{\gamma_{ij} - \beta_i \frac{dInP}{dInP_j}\right\} / S_i \quad \text{Eq (5.12)}$$

These elasticities are concerned with provisions inside the group that hold total group spending as well as all other prices. The word ij stands for the Kronecker delta, which is equal to if i=j and 0 if ij are not equal. The term in equation (12), (dInP/ dInP j), may be

expanded as (dInP/dInP j) to produce the right formula for the elasticity of AIDS. When we insert this expression into equation (5.12), we get the formula for elasticity.

$$\eta_{ij} = -\delta_{ij} + \frac{\gamma_{ij}}{s_i} - \frac{\beta_i \alpha_i}{s_i} - \frac{\beta_i}{s_i}\sum_k \gamma_{kj} InP_k \quad \text{Eq (5.13)}$$

When this method does not function correctly for LA/AIDS because we use a different price index instead of the price index stated in equation (5.6). The pricing index used in LA/AIDS is:

$$InP^* = \sum_k s_k InP_k \quad \text{Eq (5.14)}$$

We derive the formula for the LA/AIDS price index and the following expression for the stone price index with respect to the jth commodity price.

$$\eta_{ij} = -\delta_{ij} + \frac{\gamma_{ij}}{s_i} - \frac{\beta_i s_j}{s_i} - {}^{\beta_i}/_{s_i}\left[\sum_k s_k InP_k(\eta_{kj} + \delta_{kj})\right] \quad \text{Eq (5.15)}$$

In matrix form, this expression is:

$$E = A - (BC)(E + I) \quad \text{Eq (5.16)}$$

where typical elements are $\alpha_{ij} = -\delta_{ij}\left(\frac{\gamma_{ij}}{s_i}\right) - \beta_i\left(\frac{s_j}{s_i}\right)$ in A (an $n \times n$ matrics); $b_i = \left({}^{\beta_i}/_{s_i}\right)$ in B(an $n \times 1$ matrics) ; and $\eta_{ij} = -\delta_{ij} + \frac{\gamma_{ij}}{s_i} - \frac{\beta_i s_j}{s_i} - {}^{\beta_i}/_{s_i}\left[\sum_k s_k InP_k(\eta_{kj} + \delta_{kj})\right]$ in E A (an $n \times n$ matrics)

For the elasticities $[\eta_{ij}]$ yields, after some simplification,

$$E = [BC + 1]^{-1}[A + I] - I \quad \text{Eq (5.17)}$$

The identity matrix is represented by I,

The formula for calculating income elasticities,

$$N = (I + BC)^{-1}B + i \quad \text{Eq (5.18)}$$

The expenditure/income elasticities vector is represented by N (n x 1), and in the equation above, I is a n unit vector.

5.3.2 Changes of Drug Prices and Welfare Implication

Drug price variations can be evaluated using a specific measure of consumer welfare as well as real and hypothetically determined drug costs. One method for determining, which is frequently used in the literature, these hypothetical medicine prices, is to look at existent drugs and then calculate the welfare impact. When examining the effect of removing a single drug structure, this method is appropriate. However, when using this approach, analyzing the increasing effect of eliminating all biases that exist as a result of past taxation becomes challenging.

We adopt a different strategy here, which is to put medicine costs at a benchmark level and the real benchmark level, then assess the impact of changing prices. The current study is based on the most recent year of data, which is 2018/19. The following periods are taken into account when calculating the benchmark medicine prices: 1992/93 to 2018/19, 1996/97 to 2018/19, 2001/02 to 2018/19, and 2007/08 to 2018/19 are the years in question.

The next issue is determining how to assess welfare. The effect of price changes on a consumer's welfare can only be quantified in monetary terms since customers' utility is not measurable.. This metric the benefit being easy to compute, but these are poor indicator of the genuine welfare impact since it implies that customers' decisions are unaffected by price changes. Another strategy, this one integrates the concept of consumer surplus and allows for The definition of consumer surplus is dependent on the assumptions that utility is cardinally quantified and that money's marginal value is constant; however, various consumer surplus extents exist that do not need these two assumptions. Consumer surplus approaches are classified into four categories: CV, EV, CS, and ES. The effects of pharmaceutical price increases on consumer welfare are calculated using compensating variation. The most appropriate illustration is the revenue loss that compensates for price decreases and income gain from price increases. Demand swings in response to price changes(Muhammad Atta-ul-Islam Abrar, 2016).

Examine the amount of utility at the initial prices by inverting the expenditure function to obtain the IUF under the AIDS equation (5.1) for utility.

$$U = \frac{\log(M) - \log[a(p)]}{\log[b(p)] - \log[a(p)]} \quad \text{Eq (5.19)}$$

We derive the functions log [a (P)] and log [b (P)] for replacing from equations (5.2) and (5.3).

$$U = \frac{\log(M) - \alpha_0 - \sum_k \alpha_k log(p_k) - \frac{1}{2}\sum_k \sum_j \gamma_{kj} * \log(p_k) log(p_j)}{\beta_0 \Pi_k (p_k)^{\beta_k}} \quad \text{Eq (5.20)}$$

p_k^0 Denoted the old price and p_k^1 denoted the new prices M^0 represent the initial total expenditure. To begin, use the IUF (5.19) to compute the value of utility:

$$U^0 = \frac{\log(M^0) - \alpha_0 - \sum_k \alpha_k log(p_k^0) - \frac{1}{2}\sum_k \sum_j \gamma_{kj} * \log(p_k^0) log(p_k^0)}{\beta_0 \Pi_k (p_k^0)^{\beta_k}} \quad \text{Eq (5.21)}$$

To get the value of utility and the value of the log of spending at the new prices expenditure functions, use equation (5.1) above.

$$\log(M^1) = \alpha_0 + \sum_k \alpha_k log(p_k^1) - \frac{1}{2}\sum_k \sum_j \gamma_{kj} * \log(p_k^1) log(p_k^1) + U^0 \beta_0 \Pi_k (p_k^1)^{\beta_k} \quad \text{Eq (5.22)}$$

Substituting for $U0$, we obtain:

$$\log(M^1) = \alpha_0 + \sum_k \alpha_k log(p_k^1) - \frac{1}{2}\sum_k \sum_j \gamma_{kj} * \log(p_k^1) log(p_k^1) +$$

$$\left[\log(M^0) - \alpha_0 - \sum_k \alpha_k log(p_k^0) - \frac{1}{2}\sum_k \sum_j \gamma_{kj} * \log(p_k^0) log(p_k^0)\right] \Pi_k (\frac{p_k^1}{p_k^0})^{\beta_k} \quad \text{Eq(5.23)}$$

It's worth noting that in the case of AIDS, we can only estimate the share equations; we can't estimate the expenditure function or the IUF. This signifies that, with the exception of 0, all of the system's parameters are guessed. However, as we can see from equation (5.23), when estimating the spending at new prices but at an old level of usefulness, this parameter is ignored. This indicates that, despite not being able to estimate 0, we can do all of the calculations required for our welfare study.

As a final point, M^0 denoted the initial total expenditure and M^1 denoted the computed the new total expenditure. To determine the percent CV by converting old prices to current prices.

$$CV = \frac{M^1 \_ M^0}{M^0} 100 \quad \text{Eq (5.24)}$$

When using this approach, we choose a representative consumer whose total spending (representing income) equals the mean per capita total expenditure derived from the whole sample. The real prices are set to be the same as those in the current fiscal year 2018/19, and the benchmark prices are calculated by applying the CPI inflation rate to the prices of medicine categories over a given time period. If the expected benchmark prices for drug categories are lower than the observed prices, the CV given above will be

negative, indicating that the representative consumer would have spent less to maintain his or her current level of well-being if drug prices increased at the rate of CPI inflation rather than the observed inflation rate.

5.4 Data Source

Rather than cross-sectional or time series data, pooled data is used in this investigation. Time series data is better ideal for examining economic linkages on theoretical grounds, but it has a number of drawbacks in practice, such as strong correlation among explanatory factors. Similarly, using cross-sectional data, we are unable to derive price coefficients since the pricing structure remains constant for all customers at any given time.

The information comes from a variety of Household Integrated Economic Surveys (HIES) conducted across Pakistan from 1992 to 2018.[v] The HIES is conducted by PBS, and the dataset is not a panel because the same homes are not surveyed in each trend. This dataset categorizes families according to their income levels and shows how much they spend on certain items. Food and beverages, medicine/medical care, transportation and communication, clothes, textiles and footwear, recreation and entertainment, and miscellaneous are the six categories on which we base our analysis. There are six categories that we employ. Food and beverages, transportation and communication, apparel, textiles and footwear, recreation and entertainment, and miscellaneous are included to compare their prices and price elasticities to those of medicine/medical care,

as well as to determine their shares of total household expenditure by Pakistani households.

5.5 Data on Prices

From 1992/93 to 2018/19, data for Pakistan as a whole is aggregated for 12 time periods and five income groups (quintiles).The PBS created these income groupings for the HIES based on the earnings of Pakistani families. The CPI and prices for the six goods examined come from various issues of the Pakistan Economic Survey published by the Ministry of Finance. 2007/08 is the base year for all price indexes.[vi]

CHAPTER 6

Descriptive Analysis

6.1 Spending Share by Product Group in Pakistan

The information comes from a variety of Household Integrated Economic Surveys (HIES) conducted across Pakistan from 1992 to 2018. The HIES is conducted by PBS, and the dataset is not a panel because the same homes are not surveyed in each trend. This dataset categorizes families according to their income levels and shows how much they spend on certain items. Food and beverages, medicine/medical care, transportation and communication, clothes, textiles and footwear, recreation and entertainment, and miscellaneous are the six categories on which we base our analysis. There are six categories that we employ. Food and beverages, transportation and communication, apparel, textiles and footwear, recreation and entertainment, and miscellaneous are included to compare their prices and price elasticities to those of medicine/medical care, as well as to determine their shares of total household expenditure by Pakistan households. Figure 6.1 show the total average expenditure increase in overall year 1992/93 to 2018/19.

Table 6.1: Total Household Average Expenditure (Rupee)

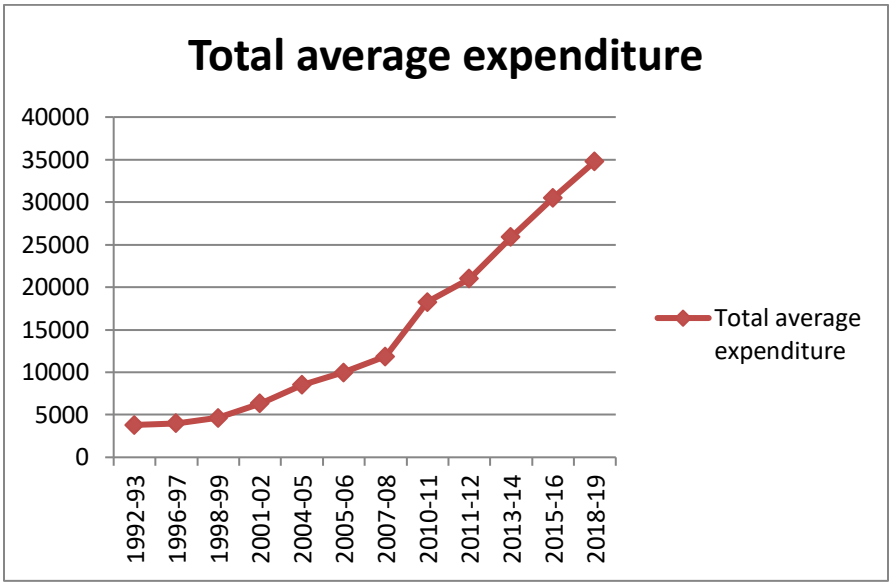

***Figure 6:1*: Total Household Average Expenditure**

In the above Figure 6.1 represent the total household average expenditure 1992/93 to 2018/19. The total household average expenditure increase in all over years. In the figure above show the increasing trends. Because the heath is the induce demand.

Figure 6.2: Total Average Expenditure Share on Medicine

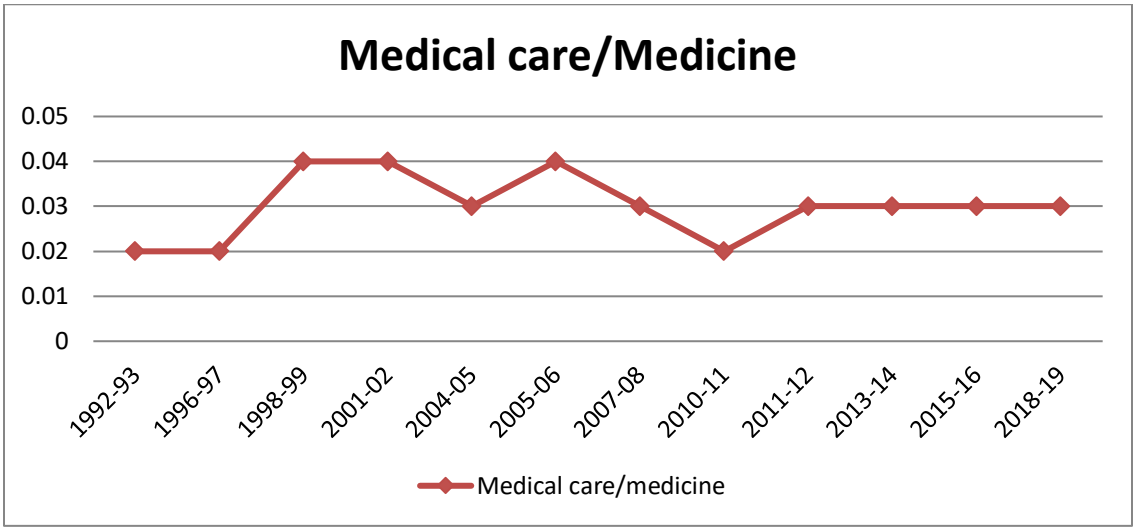

***Figure 6.2*: Total Average Expenditure Share on Medicine**

Figure 6.2 shows total expenditure share on medicine 1992/93 to 2018/19.The total medicine share on medicine remain same 1992/93 to 1996/97 and increase the more 1998/99 to 2001/02.In 2004/05 again decrease and 2011/12 to 2018/19 remain the same trend.in he above figure shows the red line total expenditure share on medicine increasing and decreasing trend.

Figure 6.3: Medicine Spending Tendency in Pakistan

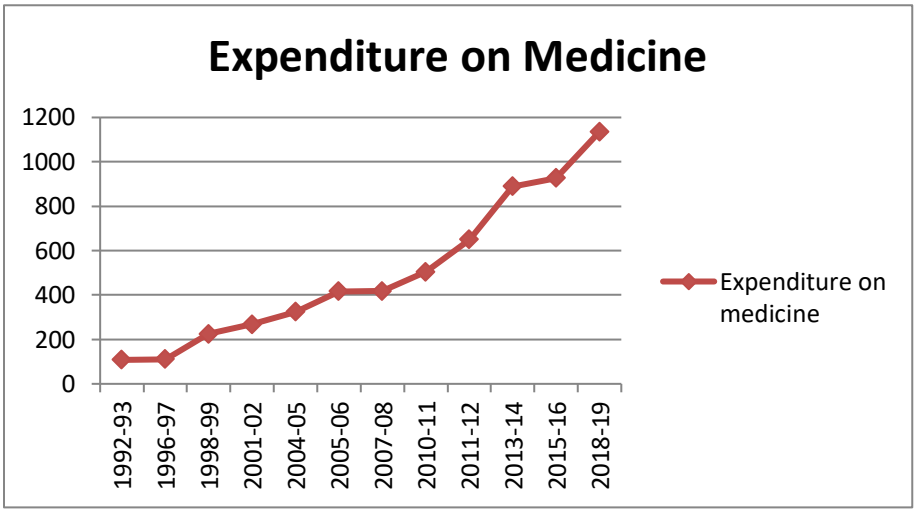

***Figure 6.2*: Medicine Spending Trend in Pakistan**

Figure 6.3 depicts the growth in medicine expenses from 1992/93 to 2018/19. Since medication is the main demand and medicine is a basic requirement in Pakistan, the consumer pays the majority of the out-of-pocket medical expenses. When drug prices increase, it has a greater impact on low-income individuals and families.

6.4 Ratio Inflation Rate in CPI and Price Guides of Medicine

As indicated in the figure 6.4 the growth in drug prices exceeds the increase in the overall CPI. Using the CPI and prices of medicine from 1992/93 to 2018/19, the real prices of medicine are made to equal the prices prevalent in 2018/19, and the benchmark prices are generated by applying the CPI inflation rate to the prices of other categories across the sample period.

Table 6.3: Percentage Inflation Rate in CPI and Price Indices of Medicine

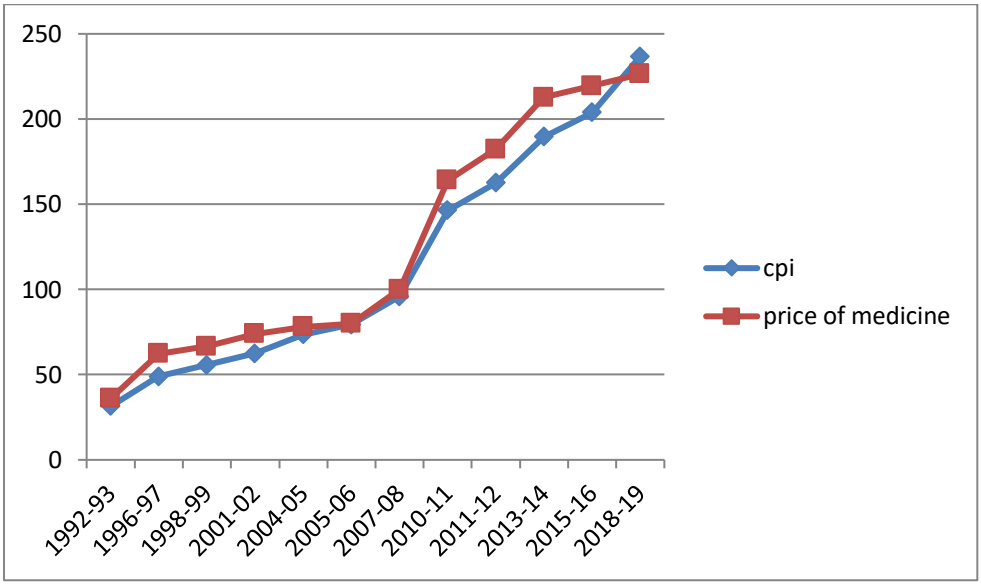

Figure 6.3: **The Relationship between Medicine Prices and CPI**

In the figure above 6.3 represent the relationship between medicine prices and CPI. The red line represents the price of medicine and the blue line represents the CPI. The medicine prices and CPI increasing the same rate but the medicine prices increase slightly more than the CPI.

CHAPTER 7

Empirical Results

We have estimated the non- linear versions of the Almost Ideal Demand System (AIDS) for Pakistan. But the results of non-linear AIDS are more significant than those of the linear AIDS. Therefore we are presenting here the results for non- linear AIDS. The non-linear AIDS for Pakistan is estimated using seeming unrelated regression procedure. The data for each of the Pakistan are pooled for twelve years and twelve income groups for the years 1992-93, 1996-97, 1998-99 and five income groups for the years 2001-02, 2004-05, 2005-06, 2007-08, 2010-112011-12,2013-14,2015-16 and 2018-19. The total number of observations for Pakistan is 81 each.

We have estimated the non- linear AIDS model using seemingly unrelated regression procedure by imposing certain conditions on the parameters. The imposed conditions are adding-up, homogeneity and symmetry. Parameters estimates of the non- linear AIDS model.

Table 7.1: Parameters Estimate of Non-Linear AIDS for Pakistan

	Food	**Medical care/medicine**	**Transport and Communication**	**Apparel, textile and Footwear**	**Recreation and Entertainment**
α_s Std.Error	1.070 (0.0256)	0.017 (0.0083)	-0.055 (0.0101)	0.119 (0.0104)	-0.008 (0.0031)
β_s	-0.095176	-0.001607	0.016562	-0.009922	0.002003
γ_s Food & Beverages	-0.095176	-0.064536	0.007285	-0.191079	0.039974
Medical care/medicine	0.014730	-0.021126	-0.030916	-0.096674	0.053703
Transport and Communication	-0.030712	0.010735	0.020252	0.020764	-0.062317
Apparel, textile & Footwear	0.019909	-0.034396	-0.091718	0.113710	0.007296
Recreation and Entertainment	-0.012784	-0.009515	-0.001073	0.038280	-0.017476

Significant at 1%**Significant at 5%***Significant 10%

In case of Pakistan the intercept terms for Food & Beverages, medical care& health, Apparel Textile & Footwear, are positive with reasonable magnitudes and are highly statistically significant, which indicates that significant portions of expenditures on these commodities are independent of the changes in prices and incomes. The intercept term for Transport & Communications and recreation& entertainment is significant but negative, which indicates that the share of Transport & Communications and recreation entertainment will be negative if price and income effects are ignored. The nature of a good *i* as luxury or necessity is determined by the parameter βi. If $\beta i > 0$, the good *i* is luxury meaning that the expenditure on good *i* will increase with increase in income. If

$\beta i < 0$, the good *i* is a necessity meaning that the expenditure on good *i* will decrease with increase in income. The results in case of Pakistan show that βis for Food & Beverages, medical care &health, Apparel Textile & Footwear, are negative and statistically significant indicating that these are necessities in Pakistan. The βis for Transport & Communications and recreation & entertainment are positive and statistically significant indicating that these are luxuries in Pakistan.

The change in the share of *i*th good due to one percent change in its own price or the price of any other good with constant expenditure is measured by γij.

Price Elasticites of Non-Linear AIDS for Pakistan

Table 7.2: Uncompensated elasticities with Non-linear AIDS

Elasticities	Food	Medical care/medicine	Transport and Communication	Apparel, textile and Footwear	Recreation and Entertainment
Food	**-0.7095**	-0.1217	0.0057	-0.3950	0.0786
Medical	0.3951	**-1.5980**	-0.8796	-2.7475	1.5240
Transport	-0.4865	0.2459	**-0.9631**	0.4792	-1.3524
Apparel	0.1917	-0.4463	-1.1841	**-0.89621**	0.0931
Recreation	-2.3880	-1.9149	-0.1988	7.7931	**-1.0154**

Diagonal Elasticities are own-price elasticities and on-diagonal and off-diagonal are cross price elasticites.

The price elasticities for Pakistan are shown in tables 7.2. All the own-price elasticities are negative in Pakistan. In Pakistan own-price elasticities of &beverages, medical care& health, transport &communication, apparel textile &footwear, recreation &entertainment

are -0.70, -1.59, -0.96, -0.89 and -1.01 respectively, which means that there will be 0.70%, 1.59%, 0.96%, 0.89% and 1.01% decrease in the consumption of these commodities in Pakistan if there is a one percent increase in their prices. The own price elasticity of medicine is -1.59 percentage shows that 10% increase in prices would reduce demand for medicine by 15%. However, medicines are assumed to be a necessity and price inelastic. The results hold true for a large percentage of medicine b/c there are good substitute available. A case in point is anti –biotic. They are manufactured by around 350 firms in Pakistan and majority of them act as substitute to each other. Most doctor/hospital use alternative when a particular brand is unavailable becomes expensive.

The cross-price elasticities with positive sign show that these goods are substitutes while the negative sign of cross-price elasticities shows that these goods are complements. The estimated elasticities of income/expenditure, uncompensated/Marshallian own, cross-price and uncompensated own, cross-price are shown in Table 7.2.

Table 7.3: Income Elasticity

Elasticity	Food	Medical care/medicine	Transport &communication	Apparel, textile &footwear	Recreation & entertainment
Income elasticity	0.8105	0.9543	1.3599	0.8725	1.4061

Income elasticities provide the estimates of how much change in the consumption of a particular commodity arises due to a relative increase in income. It identifies the nature

of commodity; either the specific commodity is necessity, luxury or inferior, depending upon income elasticity. All estimated income elasticities are positive in all Pakistan's regions, so there is no inferior commodity among the selected commodities. In the case of overall Pakistan, the estimated income elasticities of food, medical care/medicine, apparel, textile and footwear are less than one, which shows that these commodities are necessities. In contrast, estimated income elasticities of transport and communication, recreation and entertainment are greater than one, which shows that these are luxuries. Necessities are the commodities which people buy all the time and easy to afford.

Therefore, transport and communication, recreation and entertainment are the most affordable commodities compared to food, medical care/medicine, textile and footwear. These are the products that people are much more likely to buy when their income rises. Necessities are income inelastic commodities, and the share of expenditure on these commodities decreases as income rises. In contrast, luxuries are income elastic commodities and the share of expenditure on transport and communication, recreation and entertainment increases as income rises.

Table 7.4: Compensated Elasticities with Non-Linear AIDS

Elasticities	Food	Medical care/medicine	Transport &communication	Apparel ,textile &footwear	Recreation & entertainment
Food	**-0.3023**	-0.0881	0.0682	-0.3271	0.0854
Medical care/medicine	0.8022	**-1.5644**	-0.8170	-2.6796	1.5308
Transport &communication	-0.0793	0.2794	**-0.9005**	0.5470	-1.3455
Apparel , textile &foot wear	0.5988	-0.4127	-1.1215	**-0.8283**	0.0999
Recreation &entertainment	-1.9808	-1.8813	-0.1362	7.8609	**-1.0085**

Compensated own and cross-price elasticities of demand for various food items are presented in Table7 .4. Hicksian elasticities are adjusted for income changes; it shows after compensating the consumer how much change in the demand for a particular commodity a rises due to a relative increase in prices. It only includes the substitution effect. If there is no difference between the own price compensated and uncompensated elasticities, indicate that compensation for a particular commodity is worthless. Whereas, in food beverages, medical care health, transport &communication, apparel textile &footwear and recreation &entertainment the compensated and uncompensated own-price elasticities are approximately similar due to their small share in total income. The cross-price compensated elasticities in food beverages; medical care health, apparel textile &footwear have a negative sign indicating that is a complementary good against

different commodities items. If the cross-price elasticity is negative, then the two goods are compliments, whereas its positive value indicates that the two goods are substitutes

Welfare Impact on Household

Table 7.5: Welfare Impact on Household

Drug inflation set equal to CPI inflation till 2018-19 from the year	Percentage change in expenditure in Pakistan
New 1992-93	-17.63563
New 1996-97	-27.60726
New 1998-99	-21.65462
New 2001-02	-21.01876
New 2004-05	-9.51353
New 2005-06	-3.63458
New 2007-08	-7.68069
New 2010-11	-19.55391
New 2011-12	-18.96480
New 2013-14	-13.52322
New 2015-16	-11.25160

Drug costs have grown at a greater rate than the overall CPI during the previous three decades CPI. . The real prices of pharmaceuticals are established equivalent to the prices common in the current year 2018-19 using CPI and drug prices from 1992-93 to 2018-19, and the benchmark prices are produced by applying the CPI inflation rate to drug prices over a period of time. If the benchmark drug prices are lower than the actual prices, the compensating variation will be negative, indicating that the illustrative consumer would have spent less to keep their current level of happiness if drug prices improved at the rate of CPI inflation rather than the actual inflation rate. However, because drug costs have grown at a higher rate than the CPI inflation rate, consumers are spending more. As a result, customers lose out on their own best interests.

Consumers in Pakistan have gained or lost welfare as a result of drug pricing policies. Our findings show that consumers in Pakistan have been paying greater drug prices than the benchmark level, resulting in high expenditures in all years from 1992 to 2018 and that there has been a consistent welfare loss for all consumers.

Our findings show that consumers suffer a greater loss of welfare in the reason for this is the faster and more intense increase in drug prices from 1992 to 2019 when compared to the increase in drug prices.

CHAPTER 8

Qualitative Analysis

8.1 Qualitative Analysis

This section describes qualitative analysis to explore the drug pricing issue and performance of pharmaceutical industry. The following methodology adopted.

8.2 Questionnaire Development and Sample Selection

On the basis of empirical work done on pharmaceutical industry and performance, a questionnaire was developed to carry on some interviews. The key respondents were mainly targeted from DRAP, Ministry of Health, Ministry of planning Commission and The respondents were research economist at PIDE and have relevant experience on pharmaceutical industry and policy regulations. The experts were contacted through phone calls and personal visits.

8.3 Semi Structure and Open Ended Questionnaire

Semi- structure interviews were carried out by the experts at different department including DRAP. The qualitative analysis was designed to get the useful information and to get the in-depth analysis about the pharmaceutical industry structure and its link with the drug polices in Pakistan. Surveys results have shown important findings given in the following section.

8.4 Thematic Analysis of Qualitative Research

Domain framework	Theme/subtheme(barriers)	Codes
Drug pricing	Rise price unlawfully Price setting issue Lack of safety and efficiency Unavailability	• Governments control the drug pricing • Make sure the safety and efficiency
Availability and affordability of medicine	Poor quality Unaffordability	• Open market competitiveness • Encourage domestic production, availability and affordability
Government interventions	Disequilibrium in market	• Free market mechanism • Encourage to enhance to competitive environment In the drug industry • Local market through encourage the pharmaceutical industry
Demand and supply of medicine	Lack of supply Shortage of medicine	• Lack of supply due to high price • Lifesaving drug high demand and supply limited • Poor people experience welfare loss
Research and Development in pharmaceutical industry	Lack of advance technology Lack of research and development	• Import new technology • Encourage research and development
Drug policies	Ineffective drug policies	• Policies lack true implementation • Reforms are critical process

		• Individual expenditure welfare loss • Deregulation policy

8.5 Drug Policies of Pakistan

The qualitative analysis revealed that government control the drug pricing in order to make sure the safety and efficacy of public health. Though, the government policies in the past years did not bring positive outcome as well. For instance in 2013, through price freeze policy government fixed the prices of pharm drugs, in a response to this policy many pharmaceutical firms cut down the production of drugs which resulted in supply shortage. While towards consumer side their out of pocket expenditures increased. At the same time pharmaceutical firms raised the prices which was unlawful and the issue continued till 2015.

The policies of 2015 and 2018 brought no clear incentive as policies lack true implementation; reforms are critical process, individual experience welfare loss, while the firms in drug industry could not take part in decision making process. Further in the developing economy prices of drugs lack equity theory meant that policies should be formulated on equitable basis and fair system.

8.6 Government Interventions

Interviews are conducted from the health experts, the question regarding aspect availability of medicine with respect to the quality and affordability revealed that drugs

have poor quality control and let the Government decide the prices of drugs. Government intervention brings disequilibrium in the market through higher prices, poor quality and unavailability of drug. Further it was also revealed that due to the lack of research and development local pharmaceutical companies make poor quality medicine as compared to the multinational companies. Free market mechanism should be encouraged to enhance the competitive environment in the drug industry. For instance the covid-19 vaccine is imported as not available in Pakistan. Therefore it should be prepared in the local market through encouraging the pharmaceutical industry. Further the lack of advance technology is another obstacle in our pharmaceutical industry. It should be encouraged through research and development.

Price increase strategies should be revised in order to bring the equilibrium in the market. In order to make the pharmaceutical industry export competitive we should focus on the open market competitiveness, deregulation policy, encourage domestic production and availability and affordability.

Interview conducted from other health expert informed that in 1978 DRAP act government control the drug policy mechanism as market was limited due to the absence of raw material and could not make complete product and therefore we relied on imports. Demand was present but on supply side we experienced disequilibrium. Lifesaving drugs have high demand but supply is limited as these are imported and private market is involved. Government intervention is necessary as it ensures the availability of these

drugs in the market. Price freeze policy 2001-2013out of pocket expenditure increased and inflation is another crucial indicator of higher drug prices. Covid-19 also has great impact on the global pharmaceutical industry. If market alone will decide the pricing strategy it will result in market distortion. As market aims for profit maximization, when profit is not achieved it will result in disequilibria. Drug shortage will create the black market. Socio economic changes due to the covid-19 the drug pricing policy of 2018 had undergone major changes. It was proposed that we should support free market mechanism where demand and supply are in equilibrium but in Pakistan due to the high poverty and income disparity, situation is opposite and poor people experience welfare loss. Therefore it is recommended that drug pricing strategy should have partial control and SDGs must be ensured.

CHAPTER 9

Content Analysis of Drug Policies in Pakistan

Review of Drug Policies in Pakistan

Uncertainty in policies can induce negative repercussions in an economy. With businesses being unsure of whether a policy would continue or not, it can be difficult to plan for the future, especially long-term investments. Pakistani governments, over time, have been notorious for being inconsistent in their policies. What we normally witness is either the same government making frequent changes to the existing policies, or a new government coming up with a set of new policies. The favored instrument for carrying out these frequent changes is the Statutory Regulatory Offer (SRO).

The pharmaceutical sector of Pakistan, like many other sectors, has been at the receiving end of frequent policy changes since decades. And the situation continues unabated in post-DRAP era. The following is a selective list of instances whereby government over-turned its own regulations concerning various areas that fall under its ambit.

a) An April 2020 notification allowed holders of valid Drug Manufacturing Licenses (DML) to manufacture hand sanitizers as per the prescribed formulae, but only for three months! There were similar notifications allowing hand sanitizer manufacturing on the 10th, 14th and 17th April 2020. But suddenly, within a month, all these 4 notifications

were withdrawn on 21st May 2020 under Cabinet's directive! There was no reason mentioned for the decision.

b) The rules for Alternative Medicines and Health Products were approved through an SRO 412 (I)/2014 (titled 'Alternative Medicines and Health Products (Enlistment) Rules, 2014'), dated 27th May 2014, which was amended through another SRO in 2016.[3]

c) While SRO No. 28(1)2013, dated 22nd January 2013 and SRO No. 334(1)2010, dated 18th May 2010 (and likewise SROs) were aimed at discouraging imports, SRO No. 577(1)2016, dated 15th May 2016 allowed a 5 year exemptions for import of drugs meant for donations. But there is no fool-proof mechanism to check the abuse of this exemption by individuals or companies, especially by informal market participants.

d) Under SRO No. F.11-2/2020-DD (P) dated 15th July 2020, the rule for applying for 'hardship' cases was modified to reduce the number of days from 180 to 120, which are ultimately approved by federal government after being forwarded by DRAP. An important part of this is part 'b', whereby Federal Government can nullify agreed upon price increase in line with Consumer Price Index (CPI) if it has a 'cogent' reason, thus keeping a window open for government nullifying agreed upon price increases.

e) Policy inconsistency was recently witnessed in terms of importing much needed COVID-19 vaccines. SRO, No. 113(I)/2021, dated 2nd February 2021 was issued by

[3] F-3-5/2013-DDC (Alt. Med.), dated 10th June 2016

Drug Regulatory Authority of Pakistan (DRAP), allowing unfettered, unrestricted import of vaccines from abroad, allowing the importer to sell it as per the market price. However, on 18th March 2021, another SRO (No. 308(I)/2021) rescinded the previous SRO, leaving the population without a shot at more vaccines.

f) SRO No. 307 (I)/2021, dated 18th March 2021, regarding COVID-19 vaccines. SRO stipulates that the vaccine shall be first approved by DRAP. Recently, however, new vaccines landed in Pakistan (bought by federal government) without DRAP even knowing anything about it.

g) Four SROs were issued between 6th and 17th April 2020, all cancelled by SRO (F. NO 4-2/2017-DD (H&OTC) in lieu of Cabinet's decision on 5th May 2020

h) In 2013, SRO No. 1002(1)/2013, dated 27th November 2013, was initiated to end the more than decade long 'prize freeze' policy. Within 2 days, it was cancelled after the then PM ordered to cancel drug price increases.

The above were a few instances that reflect poorly upon consistency of policies by the government and its regulator.

Aside from the issue of lack in consistency of policies, there is also the fact that DRAP, like its predecessor DRO, displays a reactive rather than pro-active approach in many cases. This also is one factor that leads to changes in policies/ regulations. For example, SRO No.F.296-DRB/2020 (PE&R) (ft.), dated 4th February 2021, directs manufacturers

to disclose ‘gluten/lactose’ on labels/packs. But this happened only after persistent complaints by patients suffering from Celiac disease. Similarly, through notification No. F.1-21/2019-Add; Dir. (PE&R), DRAP called for clearing manufacturing license of Fludrocortisone tablets (for Congenital Adrenal Hyperplasia) in Pakistan on fast track basis as debilitating shortages started to surface in Pakistan. But DRAP only came to know about it after complaints from PM Citizen’s Portal.[4]

[4] F. No 4-2/2017-DD (H&OTC) (Pt), 6th April 2020

CHAPTER 10

Conclusion

10. 1 Conclusion

In this study look at how household welfare has changed as a result of changes in medication price policy. The research is based on data from the PBS and HIES from 1992-93 to 2018-19. For the estimation, the E-Views package is used. For estimating the parameters, especially the price elasticities, Deaton and Meulbauer (1980) proposed the AIDS model.

In terms of the economic theory, statistical fitness, and empirical findings presented here are reliable. In Pakistan, medicine is a necessity, while transportation, communication, and recreation and entertainment are all considered luxuries. AIDS parameter estimates are used to compute the own and cross-price elasticities and negative signs all own-price elasticities are correct. On the other hand, cross-price elasticities have mixed results.

The growth in medicine costs has been more than the rise in overall CPI during the historical, according to the welfare study. As a result, from 1992 to 2018, consumers have been paying higher prices for the drug, incurring high expenditures and a dependable welfare loss for all consumers.

Because the gap between drug price rises and the consumer price index has narrowed between 1992 and 2018, consumer welfare loss has decreased. As a result, consumer spending on medicines has tidily dropped, resulting in a decrease in consumer welfare loss.

The study suggests that if a drug policy is implemented in which the increase in medication prices exceeds the growth in the consumer price index, consumers would spend more money on drugs and suffer greater welfare losses.

10.2 Recommendations

The research clearly establish has that drug prices have increased ever time. In fact, if we consider the statistics outside of these reported in NHA, we will find that the price increases is more than what is reported officially! In lieu of this, and the fact that expenses on drugs constitute almost half the portion of health expenses (especially for poorer quintiles), the following recommendations is made.

- Government should tackle this issue both form supply and demand side.
- Supply side, it is imperative to reviews/ analyze why, despite 750 drugs producer operating in the country, these are persistent drug shortages that are responsible for drug prices inflation in large past.

- Second, government also needs to revisit its welfare mechanism like universal health coverage, BISP, Zakat, etc, and see how these handouts could be tailored towards compensating loss of purchasing power due to expenses on drugs.
- On demand side, there an urgent need to ensure quality in drugs dispensing as Pakistan, on average, are prescribe more medicine than are actually required. This only leads to higher expenses on medicine, which can be curtailed through regulatory oversight in this case.

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