# Economic Insight of Drug Pricing Policy of Pakistan



Ву

Irfan Ahmed

**Thesis Directed by** 

Dr. Fazli Hakim Khattak (Supervisor)

Dr. Atiq ur Rehman (Co-Supervisor)

Department of Health Economics

Pakistan Institute of Development Economics (PIDE)

Islamabad, 2018



Date of Examination:

# Pakistan Institute of Development Economics

## **CERTIFICATE**

This is to certify that this thesis entitled: "Economic Insight of drug pricing policy of Pakistan" submitted by Mr. Irfan Ahmed is accepted in its present form by the Department of Health Economics, Pakistan Institute of Development Economics (PIDE), Islamabad as satisfying the requirements for partial fulfillment of the degree of M. Phil in Health Economics.

Supervisor:	Dr. Fazli Hakim Khattak Assistant Professor PIDE, Islamabad
Co-Supervisor:	Dr. Atiq ur Rehman Assistant Professor PIDE, Islamabad
Internal Examiner:	Dr. Jahangir Khan Assistant Professor PIDE, Islamabad.
External Examiner:	Dr. Sheh Mureed Assistant Professor HSA, Islamabad
Head, Department of Health Economics:	Dr. Fazli Hakim Khattak Head Islamabad.

October 10, 2018

# THESIS COMPLETION CERTIFICATE

It is certified that the thesis entitled "Economic Insight of drug pricing policy of Pakistan" has been completed by Irfan Ahmed Registration No. PIDE2016FMPHILHE06 under my supervision. It is also certified has the thesis is based on original research work and meets all criteria and standards laid down for M. Phil degree.

The following areas have been critically monitored.

- 1. Conformance to APA format.
- 2. Precision & Correctness of the language.
- 3. Literature Review is relevant and comprehensive.
- 4. Relevance of references with the text.
- 5. Methodology and Estimation techniques are appropriate.

Name of Supervisor/s: Dr. Fazli Hakim Khattak

Designation: HOD HE, PIDE

Signature:

Date: October 10, 2018

# **CANIDATE DECLARATION FORM**

I, Irfan Ahmed

Son of: Riaz Ahmed

Registration: PIDE2016FMPHILHE06

Discipline M. Phil Health Economics

Candidate of M. Phil Health Economics at the Pakistan Institute of Development Economics do hereby declare that the thesis: "Economic Insight of drug pricing policy of Pakistan" Submitted by me in partial fulfillment of M. Phil Degree, is my original work, and has not been submitted or published earlier. I also solemnly declare that it shall not, in future, be submitted by me for obtaining any other degree from this or any other university or institution.

I also understand that if evidence of plagiarism is found in my thesis/dissertation at any stage, even after the award of a degree, the work may be cancelled and the degree revoked.

Signature of Candidate

Mr. Irfan Ahmed Name of Candidate

October 10, 2018
Date

# **Dedication**

# I dedicate this thesis to

my mother

&

my supervisor and well-wisher Dr. fazli Hakim Khattak

# Acknowledgement

I would like to give very special thanks to my supervisor Dr. Fazli Hakim Khattak for his time, patience, guidance, trust and support throughout my university life; and made this endeavour possible. I would also like to thank and give special recognition to my mother whose prayers and sacrifices helped me in attaining higher education.

**Irfan Ahmed** 

# LIST OF ABBREVIATIONS

API Active Pharmaceutical Ingredient

ARV Anti-retro Virals

CPI Consumer Price Index

CDs Communicable Diseases

DRAP Drug Regulatory Authority of Pakistan

DPC Drug Pricing Committee

DPP Drug Pricing Policy

DnTs Duties and Taxes

DP Differential Pricing

EU European Union

ERP External Reference Pricing

ECC Economic Coordination Committee

FDA Food and Drug Administration

GDP Gross Domestic Product

HAI Health Action International

HTA Health Technology Assessment

HIV Human Immuno Deficiency Virus

KG Kilogram

MNC Multi National Company

MRP Maximum Retail Price

NHS National Health Services

NHI National Health Insurance

NGO Non Governmental Organization

OOPS Out of Pocket Expenditure

OECD Organization for Economic Co-operation and Development

PBS Pharmaceutical Benefit Scheme

PH Public Health

RC Reference Countries

ROI Return on Investment

UK United Kingdom

WB World Bank

W.H.O World Health Organization

## **INDEX of TABLE**

- Table 1.1. Description of Pricing System of 06 Countries
- Table 4.1. Transfer Pricing of RAW Materials and Impact on Finished Products
- Table 4.2. Remittance in U.S \$ Through Transfer Pricing in Year 1984-85
- Table 4.3. Remittance in U.S \$ Through Transfer Pricing in Year 1987
- Table 4.4. Remittance in U.S \$ Through Transfer Pricing in Year 1994-95
- Table 4.5. Remittance in U.S \$ Through Transfer Pricing in Year 1999
- Table 4.6. Reduction in Prices of Some Raw Materials Over the Years
- Table 4.7. Prices of Drugs Quoted to Provincial Governments Versus Fixed Trade Prices by the Governments

## **INDEX of FIGURES**

- Figure 5.1. Drug Prices Between 50-500 PKR
- Figure 5.2. Drug Prices Between 500-2000 PKR
- Figure 5.3. Drug Prices Between 2000-4000 PKR
- Figure 5.4. Drug Prices Above 4000 PKR
- Figure 5.5. Drug Prices Between 50-500 PKR (reduced mark-ups)
- Figure 5.6. Drug Prices Between 500-2000 PKR (reduced mark-ups)
- Figure 5.7. Drug Prices Between 2000-4000 PKR (reduced mark-ups)
- Figure 5.8. Drug Prices Above 4000 PKR (reduced mark-ups)
- Figure 5.9. Drug Prices Between 50-500 PKR (Total Savings)
- Figure 5.10. Drug Prices Between 500-2000 PKR (Total Savings)
- Figure 5.11. Drug Prices Between 2000-4000 PKR (Total Savings)
- Figure 5.12. Drug Prices Above 4000 PKR (Total Savings)

#### **Abstract**

Drug can be defined as: "A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication". Economic insight is a concept which applies to gain an accurate and deep understanding of economic theory, principles or practices.

In Pakistan, out of pocket expenditure (OOPS) are around 70% of the total health expenditure and 55% of the total are spent on purchase of pharmaceuticals for treatment of the different diseases in the rural areas. Total annual market of prescription drugs in Pakistan is about PKR 343 billion. Majority of the medicines are purchased by the people from the pharmacies directly, making medicines the largest household expenditure after food. It results in catastrophe due to high cost medicines. It creates heavy load on government exchequer in term of drug import, manufacturing and purchasing of material (Active Pharmaceutical Ingredient (API) and raw materials).

The first comprehensive Drug Pricing Policy (DPP) was introduced in 2015 to guarantee the sustainability of indigenous pharma industry and convenience to medicines. According to DDP Policy, the prices of the new medicines shall be determined on the root like the average prices fixed in India and Bangladesh. When the medicines were not accessible in both these countries, the prices then were based on the lowest rank of developing countries which control medicines prices and wholesale prices in UK, Australia and New Zealand respectively.

The comparison of drug prices among countries is a complicated procedure because the similar medicine frequently sold in another countries in unlike strengths, pack size and even in different mode of administration with different tariffs, taxes and markups for public and private health care system.

The selection of the reference countries and methodology used for the drug pricing has been comparatively considered because selection of the reference countries (RC) chiefly using high ranking income countries with dissimilar market composition have escorted to high drug prices.

The proposed study aims at filling the gaps for preparation of the recommendations those fit in the local market requirements. This will help policy makers and other stakeholders to understand, identify and implement the policies to control pharmaceutical prices at the affordable level for benefit of the people in Pakistan.

A concurrent mixed method is used for data collection and analysis. The findings from both qualitative and quantitative study reveals that current Drug Pricing Policy, 2015 needs revision. Pharmaceutical companies are providing drugs to market at high prices and making huge profits at the cost of immense burden on the consumers. Multinationals are able to make enormous remittance abroad by transfer pricing but also manage to get higher prices in respect of dosage forms based on the over price raw materials. This situation demands for a proper pricing system for pharmaceutical drugs that creates a balance between affordability ( in lieu of healthcare users) and profitability ( in lieu of pharmaceutical industry).

# **Table of Contents**

Chapter 1	1
Introduction	1
1.1. Background and Introduction:	1
1.2. Description of Pricing Systems of few key Countries	8
1.3. Different types of price adjustment strategies used Globally	10
1.4. Cost Structure of Pharmaceutical Product for Understanding:	12
1.5. Problem Statement:	14
1.6. Research Gap:	15
1.7. Objectives:	16
Chapter 02	17
Literature Review	17
2.1. Tariffs and Taxation Review:	17
2.2. External Reference Pricing (ERP) Review:	19
2.3. Generic substitution Review:	24
2.4. Health Technology Assessment (HTA) Review:	27
Chapter 03	29
Methodology and Data Sources	29
3.1. Methodology:	29
3.2. Mixed Methods Research Concept:	29
3.3. Qualitative Method: (Priority Data)	34
3.4. Quantitative Method: (Supporting/Secondary Data)	36
3.5. Limitations of the Study:	37
Chapter 04	38
Qualitative (Priority Data) Study Findings:	38
4.1. Discussion and Key findings:	38
4.2. Summary:	51
Chapter 05	53
Quantitative (Supporting Data) Study Findings:	53
5.1. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices range between 50-500 PKR	

5.2. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges between 500-2000 PKR	
5.3. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges between 2000-4000 PKR	
5.4. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges Above 4000 PKR.	
5.5. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges betw 50-500 PKR.	
5.6. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges betw 500-2000 PKR.	
5.7. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges betw 2000-4000 PKR.	
5.8. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges Above 4000 PKR.	
5.9. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug pranges between 50-500 PKR.	
5.10. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 500-2000 PKR.	62
5.11. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 2000-4000 PKR.	63
5.12. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges Above 400 PKR	64
5.13. Summary	66
napter 06	67
onclusions and Policy Recommendations	67
6.1. Conclusion:	67
6.2. Policy Recommendations :	69
6.3. Potential Beneficiaries and Policy Implementation:	71
napter 07	72
efinitions	72
eferences	76
ppendices	79
1.1 Domestic tay rates on medicines in selected low- and middle-income countries ( Annendiy -1)	70

	1.2. General Framework/Typology of Reasons for Designing and Conducting Mixed Methods Reseated Adapted from Bryman (2006). (Appendix- II)	
	1.3. Characteristics to consider in developing a Questionnaire : ( Appendix-III)	
	1.4. SCHEDULED DRUGS ( Appendix- IV)	86
	1.5. Effect of Fixed Mark-ups on Drug Prices.	102
C	Questionnaire	.115
lr	nform Consent	.121

# Chapter 1

#### Introduction

#### 1.1. Background and Introduction:

Drug can be defined as: "A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication" (World Health Organization). Economic insight is a concept which applies to gain an accurate and deep understanding of economic theory, principles or practices.

The drugs account for approximately 20-60% of health expenditure in low and middle countries as contrast to 18-20% in countries of "Organization for Economic Co-operation and Development" (OECD) where 90% people in developing countries purchase medicines through "Out of Pocket Payments" (OOPS), making the medicines as the prime family spending after food. Resultantly, high cost medicines become exorbitant for large section of population and a key load on government budgets (Cameron et al., 2013).

The patient faces financial burden due to expensive medical treatments that make them worried about the treatment decisions according to their affordability and purchasing power. This is the major reason of reported suffering among patients as well as their families and usually disturb the social fabrics, and destroys the economic status pushing a lot of families in the loop of poverty. (Snell, 2003).

The pricing of pharmaceuticals involves a transaction between the buyer benefits at present (through better access at lesser price) and seller benefits in future (through better innovation) (Yadav, 2010).

Pharmaceutical market could be an example of market failure due to many internal and external factors. Market failure can be defined as those factors which obstruct with ability of market to proficiently produce and assign goods and related services. This can be explained as buyers of medicines do not get same degree of knowledge as some buyers give more than others against same medicine as they are naive of what each person is paying. The price distortion usually occurs when market fail to identify and correctly worth vital aspects of society for instance public goods (Pharaceutical pricing policy, 2012).

The prices of medicines in Pakistan increases from "December 2001 till June 2016" without captivating into concern the annual Price Index which un fortunately upset the demand and supply equilibrium of the pharmaceuticals (Zaidi, M, & A, 2013). To guarantee the sustainability of indigenous pharma industries and convenience of medicines, the first thorough Drug Pricing Policy (DPC), was introduced in 2015 (Drug Regularity Authority of Pakistan. 2015).

The Drug Act 1976 and DRAP Act, 2012 are the two Acts beneath which the sales, storage, and distribution of drugs at Provincial level while the Manufacturing (licensing), registration, pricing, import, export, and monitoring of controlled drugs at Federal level are regulated. DRAP was recognized under DRAP Act, 2012 which works under the Central Government to control the important matters like fixation of the drug prices. Prices are set by the Central Government through exercising the powers given vide section twelve of Drug Act, 1976, after the proposal of DPC constituted the "Statutory Regulatory Orders" (SRO) on 6<sup>th</sup> August, 2013, below the Cost and Pricing Section, DRAP. DPC is comprise of councils from "Provincial"

Health Departments, Ministry of Finance and Consumer bodies along with Stakeholders as observers to dealings of committee "(S. Lee, et al., 2017).

According to the Drug Pricing Policy, 2015, the prices of the new medicines shall be set on the base of the average prices fixed in "India" and "Bangladesh" and if medicines are not accessible in both these countries then the prices shall be set next to the lowest rank of developing countries that control medicines prices and wholesale prices in "UK, Australia and New Zealand" respectively. The yearly raise in the medicines prices in Drug Pricing Policy, 2015 are linked with the "Consumer Price Index" (CPI) which announces by the "Pakistan Bureau of Statistics, Government of Pakistan", with a ceiling cap of four percent for scheduled drugs and six percent for non-scheduled drugs (S. Lee, et al., 2017).

According to the Committee's recommendations,

- Scheduled drugs prices to be increased by 2.08%
- Non-scheduled drug prices to be increased by 2.09% and
- A huge increase on 4.16% in the price of low-priced drugs.
- Increase in threshold limit of low-priced drugs by 1.43% for 2015-16 and 2.08% for the year 2016-17 (https://propakistani.pk, 2018).

It is very important to look into the selection of the reference countries and methodology used for the drug pricing because selection of the reference countries chiefly using high ranking income countries with dissimilar market composition may escort to high drug prices (S. Lee, et al., 2017).

## **Organisation for Economic Cooperation and Development (OECD) Status:**

A range of pricing models for pharmaceuticals are used internationally for price adjustments. There are extensive range of price regulations in OECD countries, ranges from product to product pricing to partial- price freedom. 14 out of 16 European countries are using reference prices applied in other EU countries for the fixation of their new products. They select the price levels that suits the price levels to their authorities. The reference pricing currently applies in "Belgium, Denmark, Germany, Italy, the Netherlands, Norway, Portugal, Spain, France, Sweden, Australia and New Zealand" is that the constitutional health insurance system (HIS) reimburses price of a drug upto a fix amount which is well known as reference price that communicated by high concerned authorities.

Reference pricing (RP) is most frequent Global cost-containment instrument, adopting such pricing system and reference pricing for extraneous drugs too would have significant disadvantages in an Pakistan context. Even if Pakistan drug prices were referenced to poorer end of OECD, the prices of nearly all advanced drugs would still remain high and possible well beyond the access of common man. According to OECD, "in 2003 per capita drug expenditures averaged \$606 in France, \$507 in Canada, \$393 in Japan, \$353 in Australia, \$284 in the Czech Republic, and \$225 in Poland" (OECD Health Data, 2005)

The patient pays the divergence when the market price exceeds the reference price. While in nearly all countries, this practice is only useful at reimbursement level in addition to not for the market amount level, though the market prices may get determined via reference prices. Netherlands in this respect has gone into for an index pricing method which is yet again a price

tool at which insurers can pay back clients. A large figure of countries, such as "France, Australia, and New Zealand" have adopted the pharmaco Economic evaluation being a compulsory part of their price setting method (Naryan, 2007).

Additional approaches adopted by the EU countries for price control include fixing increase targets for community pharmaceutical spending and also many countries lawfully fix an general budget to request to enforce percentage restrictions on advance in pharmaceutical expenditure. Control over costs another method which is also achieved through analysis and inspection of the company's promotional expenditures and marketing practices(Naryan, 2007)

It is worth noticing that nearly in all OECD countries, drug price manage systems are vital part of a national universal health care system (Naryan, 2007). In most of European systems, cost controls are used to control the prices at which pharma products are reimbursed as part of national health system, which operated or funded and closely-regulated, by government, and provide universal health access for each citizen or resident. Such systems besides tend to be initiate in OECD countries. Nearly all developing countries don't provide universal health coverage. While few developing countries hold programs to give basic health coverage to most vulnerable members of the society, and also few type of drug price controls, such systems be likely to be greatly more flexible to cover merely a limited series of essential medicines (OECD, 2008).

In high ranking income markets nearly all drugs are paid via private otherwise public insurance, whereas, in small and lower middle returns markets most drugs are purchased by own pocket which show demand elasticity not always match with income levels because, the subsistence of insurance "private health plans, social insurance or nationalized health service)"

creates a block involving "true demand curve" and "copayment demand curve" means wealthier countries by means of insurance shows" lower demand elasticity" and manufacturer maximize its sales profit by selling to these inelastic segments at greater prices to maximize its margin. The existence of social insurance in high income countries creates oligopsony power as there is only specific or few significant payers in lieu of drugs in state which helps in negotiating good prices with the manufacturers which is not possible in low income markets where buyers mostly purchase drugs out of pocket which gives room to manufacturers to set higher prices (Yadav, 2010)

The medicines which are not considered essential and the buyer of these medicines realistically refuse to purchase will have more elastic price as compared to those medicines for which buyers willing to purchase are inelastic means buyers will be less perceptive to higher prices.(pharmaceutical pricing policy, 2012)

The access to pharmaceuticals can be improved by adapting the drug prices with respect to the purchasing authority of consumers living in different geological or socioeconomic segments of low and middle-income countries. Different studies suggest that by adopting the differential pricing strategy, the social welfare is improved, and it also opens some new market for drug companies in those countries anywhere affordability is considerably lesser than the prevailing prices in existing markets. The "Differential Pricing"(DP) of pharmaceuticals may benefit deprived countries without negatively affecting higher income countries, but presently the orderly use of such strategy has been restricted to "vaccines, contraceptives, and anti retro virals" (ARVs) in low income countries (Yadav, 2010).

The profitability of pharmaceuticals manufacturers can be seen through this example, "As Abbott pharmaceuticals use preferential pricing structure for their products through which African and least developed countries obtain lowest price of \$500 per patient per year, low income and lower middle income countries at \$1000 per patient per year and remaining countries get the regular price". Many multinational pharmaceutical companies now changing their prices in developing to better replicate each markets capacity to pay. For example, "Merck pharmaceuticals launched Januvia®, a drug used in type2 diabetes in India at a price less than US\$ 1 a pill, which is approximately a fifth of its price in the US market. For this, Merck consulted 350 Indian doctors and patients in deciding an India specific price and which so far has been successful in its differential pricing strategy for this particular drug" (Yaday, 2010).

The globalization has reduced opportunities for pharmaceutical companies to maximize profits, manufacturers have responded for their goods in a tactical manner. In response to ERP, they first introduce their products in those countries anywhere they can adjust prices freely or negotiate comparatively high prices (countries where they operating their headquarters) delay and abstain from launching in comparatively lesser price countries and maintain synthetically high list prices, even when they are willing for consent to confidential rebates. They also use the strategies of drug proliferation (e.g. release of products with different formulations, strengths and package size). The success of these strategies is evident in that the pharmaceutical industry continues to be one of the more profitable industries in the global economy (OECD, 2008)

The challenges faced by different countries are different but their common problem is lack of technical capability to analyze and understand the relation between price data and local policies and at the same time how effectively respond to high prices or unusual price variations to maintain the market balance in the similar time. (Cameron et al., 2013)

The comparison of drug prices among countries is a complicated procedure because the medicine habitually sold in another countries in diverse strengths, pack sizes and even in various mode of administration with different tariffs, taxes and markups for public and private health care system. The solely relying on external price reference with low income countries don't make it inexpensive as further measures are essential such as the number of days the country's lowest paid worker work to pay for the medicine. A measured used in studies conducted by "HAI and WHO" (Pharaceutical pricing policy, 2012).

## 1.2. Description of Pricing Systems of few key Countries

The following table is self explanatory and explains the different Health Care/Drug Coverage, Price Control Measures and Funding Mechanism of six countries. The countries used for comparison are those with strong GDP and high spending on health .

**Table 1.1. Description of Pricing System of 06 Countries** 

Characteristics	Countries					
	UK	France	Canada	Australia	China	Japan
1. Healthcare/ Drug Coverage	"Through National Health Services (NHS) which includes a complete drug benefit that is paid for most drugs prescribed in UK".	Through Universal Healthcare system,"Se curiteSocia le", which also includes drug benefits.	i) Provincial Subject handled at provincial level. ii) Level of drug coverage vary by province.	"Through Pharmaceutic al Benefit Scheme (PBS) which provides subsidized access to prescription medicines for Australian residents".	"Poor, Chinese public expenditure as a share to total health care spending total approximat ely 11%, well below the rest of the world, e.g. India (13%), the U.S. (23%), Brazil (49%) and the OECD average (72-80%)".	"Through National Health Insurance (NHI) system".
2. Price Control Measures	i) Prescribing guidelines. ii) Generic substitution incentives. iii) Patient copayments. iv)Pharmaco-Economic Guidelines.	i) Limit promotiona l spending to an agreed percentage cap. ii) Supply only "Medical justified" quantities of a drug.	i) Reference pricing. ii)therapeu tic groupings. iii) co- payments. iv)deducti ble v)reimbur sement restriction s. vi)Generic substitutio n.	i) Pharmaco-Economic Analysis. ii)"Therapeut ic reference pricing". iii)"Price- volume agreements". iv)"Generic substitution incentives".	Discountin g.	Cost plus methodol ogy.

3. Funding	i) General	Through	i)"1/3 <sup>rd</sup> by	PBS funds	Fee-for-	Insurance
Mechanism/Co	Taxation.	insurances.	Governme	approximatel	service	pays 70%
ntribution	ii) National		nt".	y 93% of	payments	while
	insurance		ii)"2/3 <sup>rd</sup>	Australian	by patients	patient is
	contributed by		by	prescriptions.	and	responsib
	UK citizens		Canadian		household	le for
	and residents.		population		or cash	30% со-
			through		payments	payments
			private		by	
			insurance		patients(out	
			plans		of pocket	
			sponsored		expenditure	
			by their		(OOPS).	
			employers			
			or			
			purchased			
			on an			
			individual			
			basis".			

# 1.3. Different types of price adjustment strategies used Globally

Some of the globally practiced price adjustment strategies are described below;

#### 1.3.1. Free pricing:

Regulatory is not involved at pricing level. Drug costs are controlled by the government on demand side during constrained repayment mechanisms such like public tenders and supply indentures.(Naryan, 2007)

#### 1.3.2. Pricing based on country source:

The manufacturer otherwise importer of drugs offers the data on pricing based on country in which the drug is originated. This model is substantiated to be economically failed since the price is fixed on the basis of negotiations or assist using a formula established in the country of origin to set the price.(Naryan, 2007)

#### 1.3.3. External reference pricing:

Many middle-income countries use this type of model. In this type of model number of countries are considered as reference standard and the manufacturer provides price information collected from these reference standards. After that a formula is useful to calculate the list drug price. (Naryan, 2007)

#### **1.3.4.** Volume/ price contracts:

This type of price restraintsis practical for those markets where the government can impose a price reduction if certain volume of drug issurpassed. (Naryan, 2007)

Numerous pricing tactics like "cost plus pricing, break even pricing, value-based pricing, competition-based pricing and economy pricing" were observed and utilized in the industry due to anomalous characteristics of pharmaceutical industry. (Khoso et al., 2014)

One must clearly know the technical terms the pharmaceutical company take into account during price setting in order to understand the pricing concept. These are,

a) "Cost plus pricing".

b) "Break even pricing".

c) "Value pricing".

d) "Value based pricing".

e) "Competition based pricing".

f) "Market skimming pricing".

g) "Market penetration pricing".

h) "Product line pricing".

i) "Optional products pricing".

j) "Captive product pricing".

k) "By product pricing".

1) "Product bundle pricing".

- m) "Discount and allowance pricing".
- n) "Segmented pricing".

o) "Psychological pricing".

p) "Reference pricing".

q) "Promotional pricing".

Details of each term are given in Chapter 7.

#### 1.4. Cost Structure of Pharmaceutical Product for Understanding:

The cost structure of pharmaceutical product can be divided in to following parts,

#### 1.4.1. Cost of active ingredient:

The cost of active ingredient usually ranges between 10-30% of total cost of the product.

#### **1.4.2.** Cost of other ingredients:

The cost of other ingredients are usually not higher than 3% of total cost.

#### 1.4.3. Cost of packaging material:

The price of the packaging material vary according to a stuff being used. In exact terms, price of packaging stuff ranges between "Rs. 5-10 per pack of 10 tablets/capsules, per 60 ml bottle of liquid, per 5 ml injection & per 50 grams tube of ointments". (Ahmed at al., 2014)

#### 1.4.4. Cost of manufacturing:

Depends on quantity being produced in a plant.

In Pakistan, the applicant of generic substitution of drug gets approximately "25-40% lower price" which becomes internal reference price for all other applicants. The Prices allowed to Multinationals are inflated, the other all indigenous companies get adequate profits at "40% lower price than the leader". (Kola & Landis, 2004)

This can be explained by following example:

Suppose,

Retail Price	Rs. 300 for a pack of 10 tablets
Active ingredient in each tablet	10 mg

The ex-factory cost for this product will be considered as;

Retail Price ( 15 % Retailer's Margin)	300-45= Rs. 255
Distributor Price ( 10 % Distributor's Margin)	255-25.5= Rs. 229.5
Total amount manufacturer get ( ex-factory	Rs. 229.5
price)	

Now suppose, the price of Raw material in Global market is US\$ 100/Kg. If we take US\$ 1= Pak Rs. 120. Then,

Cost of 1 Kg Raw Material	Rs. 12,000
Add 10 % Duty	Rs. 13,200

As mentioned above, each tablet contains 10 mg of raw material. The raw material consumer per pack will be 100 mg, the cost of which will be Rs. 1.32. If we put this figure in cost structure given over, and take estimated costs of the outstanding items, we can come at the sum cost of every pack (Uaq, Ahmed, Ahmed, Khoso, & Parmar, 2014)

"1.32 - Cost of Active Raw Material (Drug itself)+ 1.5 - Cost of excipients (Material used to give the medicine a particular form like tablets, syrups etc.) +10.00 - Cost of labor and other overheads + 6.00 - Packaging Material = 18.82 - In-Factory Cost of Product"

If we take the above costs against the ex-factory price of Rs. 229.50 as calculated above, the profit margin comes to 81% (Pollack, 2002)

#### 1.5. Problem Statement:

Pakistan has much extra limited fiscal as well as economic resources alongside a greatly larger population of low-wage urban workers and small farmers. Just replicating the existing western European price controls or the U.S free market approach would not address the requirements of the developing country in addition to millions of people who lack the ample access to health care.

13% inhabitants of Pakistan lives under the "International poverty line of US\$ 1.0 per day", for them even a plain analgesic can be exorbitant for long period of consumption. A study established that even backward in 2007, 1.7-7.7 days earnings (for generic medicines) and "1.9-36.4" days earnings (for branded/research medicines) were required to acquire a 1-month supply of medication for specific chronic diseases (Mendis, et al., 2007).

Government of Pakistan has launched Prime Ministers Health Program which can also be effected due to high prices of drugs because high drug prices lead to higher health care costs,

which, in turn, contribute to higher insurance premiums which in result of reduction in federal funding or loss in insurance coverage.

#### 1.6. Research Gap:

There are some studies conducted Globally in context of economic impact of Drug Pricing, but no study is conducted in Pakistan till date in which various stakeholders are involved and interviewed about local market requirements and for Policy formulation. This leads to information asymmetry for Policy makers regarding which mechanism may be adapted which should be more effective in terms of affordability and outcomes. According to (S. Lee, et al., 2017), In Pakistan, the pricing survey and affordability studies are still lacking.

There are few studies, survey and text where the issues of price fixation based on the balance of affordability and profitability (demand and supply side) are discussed. As such, complete set of tools is not available for policy formulation, implementation and regulation, and improve it as the basis of evaluation.

To fill this gap, this study aims at developing the applied pricing recommendations that fits in local market requirements and assist Policy makers and other stakeholders in identifying and implementing policies to manage pharmaceutical prices .

# 1.7. Objectives:

The present study focuses to achieve the following objectives:

- 1. critically analyze the current DRAP pricing policy to assist policy makers to manage pharmaceutical prices at the affordable level.
- 2. compare local pricing policy with International guidelines to direct such course of actions associated with the national objectives according to the Pakistani Healthcare system.
- 3. Recommends a balance between affordability (in lieu of healthcare authorities) and profitability (in lieu of pharmaceutical industry).

# Chapter 02

## **Literature Review**

This section presents a brief scrutiny of the literature on different factors involved in price fixation of drugs or medicines. The questionnaire is developed based on this literature review and understanding of the subject.

The literature has been reviewed to determine the current and previous understanding of pricing mechanism to observe the existing global situation with regard national scenario. To study the impact of aspects like tariffs, taxation, external reference pricing (ERP), generic substitution and health technology assessment (HTA), some studies have been conducted internationally. There is no separate study conducted in the context of Pakistan.

#### 2.1. Tariffs and Taxation Review:

(Olcay & Laing, 2005) conducted a study with the purpose of assessment of tariff rates imposed on pharmaceutical products (PPs) and returns spawned over 150 countries. Study was commenced as a part of CIPR (Commission on Intellectual Property Rights) where innovation, Public Health's work and other factors that ascertain approach to medicines. The results of this study are;

- a) As per available data of 59% countries, levy tariffs were observed on pharmaceutical API and 61% on FPPS levy tariffs were observed.
- b) <10% tariff rates are applied in 90% of countries on medicines.
- c) <0.1% of GDP was generated on tariffs of PPs in 92% of countries available data.

d) As per authors' findings manufacturers' ex-factory price, sales taxes such as mark ups, VAT, shown notable impact on medicine cycle other than tariffs.

The objective of European Commission Report, 2003 is to assess the duties and applied taxes applied to PPs used as therapy of major CDs e.g. malaria, HIV, & tuberculosis in about 57 countries. This report concludes that;

- a) For compounds along with medicines and vaccines, custom duties fluctuate between 0 and 35%. 5–7% is the average customs duty rate on the prices of products which are imported, levied on these products.
- b) Customs duties denote  $1/3^{rd}$  of the total duties & taxes put on PPs. On compounds, rates of "other duties" fluctuate between 0-22% while on medicines and vaccines the rates fluctuate between 0 and 15%.
- c) 0 >20% rates of VAT vary. Compared with European Union mean of 7%, the average VAT rate is generally elevated (11–12%).
- d) Overall duties & taxes (customs duty, VAT and other duties) imposed on the products studied differs from 0.01% (Malaysia) to an extreme of 60% (India), with international mean of 18%, based on data from European Union exports.
- e) Duties & taxes rates are decreased, on average 14%, in Least Developed Countries in comparison to the global average of 18%.
- f) On compounds, total duties and taxes are generally higher as compared to duties and taxes on manufactured medicines.

- g) From study linking the import values (weighted/inhabitant) and the rates of customs DnTs, systematic correlation cannot be illustrated.
- h) "17% of public health (PH)" spending of very low developed countries and for the countries encompassed by the study 9% on average are signified by DnTs collected from these products.

## 2.2. External Reference Pricing (ERP) Review:

A study conducted by (Hakonsen, 2009) with the objective of "description and assessment of price control strategies used in Norway from 1994 to 2004". The outcomes of this study are;

- a) In 2000, the key approach for price fixation of originator and non-originator drugs was familiarized i.e. ERP considering prices in nine EU countries.
- b) After initial marketing for the first two years, the price of new drugs is revised every 6 months.
- c) Authors claim that there will be considerable price reductions on many drugs due to coherent use of ERP and succeeding price revisions. Though, the amount of the price declines is not imparted.

(Garcia, 2011) conducted a study with the objective of "assessing influence of ERP on reference countries and pharmaceutical companies using of a mathematical model". The main points and outcomes of this study are;

a) A model is used where a drug is sold by pharmaceutical firm in 02 countries, a native country and a extraneous country. Either a price can directly be negotiated by each country with

pharmaceutical firm or they may engross in ERP. In case no country participates in ERP, the prices shall be negotiated by each country autonomously.

- b) The dedication by any country to engross, in ERP influences the dialogue in reference country and eventually ascertains firm's total benefit can be analyzed using three scenarios. The paper presumes that price-negotiating organization shave a little position in approval of drugs in Europe, and hence European countries are in a 'weak threats, situation. While countries like Canada or Brazil are in 'tough threats' situation where organizations can pressurize to ban the drug if negotiations fail. Mariñoso suggested that;
- i) The first scenario which stresses on timid threats situation and overlooks the existence of likely therapeutic alternatives. To comprehend the consequences driven by ERP only, this scenario signifies a first step. To justify the rivalry between firm's PP and therapeutic alternative which is at present in the market place in both countries, the first scenario is extended by the second. The initial domination is maintained by the third scenario but permits for robust threats by the organizations.
- c) The main results are as follows:
- I) ERP strategy by the native country enhances the negotiated external price under weak risks and in the absence therapeutic alternatives, which damages the foreign country. ERP, the native country desires to a liberated price intercession regardless of this price escalation, in case, the purchaser co-payment in native country is reasonably high. However, the claim size sprouts in home country in relation to external country. This preference reduces though not vanish. ERP policy causes an intensification in profits sprung from foreign country and diminution in those

sprung from native country, when matched with revenues resulting from autonomous price negotiation. The second consequence is sturdy enough that the overall revenues decline.

- II) Above outcomes are established for the case of therapeutic alternatives between drugs, apart from the size effect that is non existent because, for plainness, the irregularity in country size is overlooked.
- III) The native country welfares, while the ERP damages the firm in tough threats situations, as in the weak threats situations. However, negotiated rate in external country is unpretentious by ERP that it does not disturb foreign country contrary to weak threats situation.
- d) The authors accomplish that analysis proposes discernments on direction of outcomes of ERP policy, with reality that reference country may be debilitated, one of key results of the model used. They signify this kind of policy that advocates pharmaceutical pricing policies which should be globally harmonized.

(Richter, 2008) conducted a study with the objective of "examining the subject of ERP and product unleash decisions from a pharmaceutical firm's prospect using a theoretical mixed integer linear model, with argument of how outcomes might be helpful to individual countries in their price and recompense negotiations". The outcomes of this study are;

- a) To observe the launch of innovator, 1<sup>st</sup> in-class therapy for out-patient consumed in a group of countries instigating variety of ERP principles, a theoretical model was devised .Features of the model are recapitulated below:
- I) For a novel drug across all countries in which it has been introduced, pharmaceutical company desires to augment total revenue & ROI (return on investment).

- II) Parallel commerce (that instigates loss of revenue in country where goods are accepted since requirements fulfilled by cheap-priced product from other country) is incorporated in the model as a penalization since it is thought as a loss of profits.
- III) There are 04 main types of ERP.
- a) Price of product in country necessarily set at lesser percentage than price of product in a group of referred countries.
- b) Price of a product in country necessarily below or equal to mean price in a group of referred countries.
- c) Price of a product in country necessarily be least price of the product in a group of referred countries.
- d) Fraction of the price of product & its closest challenger(s) in those countries necessarily below or equal to fraction of price of product and its closest challenger in the referred countries in which product is vended.
- IV) Prices ought to be positive & may only cut back with passage of time.
- V) Projected market share of product should be considered when the quantity of the product required is set.
- VI) To find supreme solution, the model may be utilized to ascertain every possible mixture of launch cycle & price.
- b) It is merely a 'theoretical' model hence the paper does not deliver outcomes of the model. The author testifies that a constructed analysis of international tactical pricing problem challenged by pharmaceutical industries at comprehensive level is provided by the model, & inter-dependencies that occur during pricing evaluations because of ERP & parallel commerce are also considered. The author declares that the model is helpful for countries in understanding the consequences of

their distinct external pricing strategies on international repeated pricing fixture. Author also declares that one thing which is helpful for countries better plan to counter possibly unwanted actions is to understand how a pharmaceutical company is tending to act.

c) The use of ERP in countries such as "British Columbia, Canada; New Zealand; and Germany and other European countries" are the real-world examples.

(Stargardt & Schreyogg, 2006) accomplished a study with the objective of "using ERP taking into account both direct influence(from referencing to Germany directly) and indirect influence(from referencing to other countries that organize their own ERP schemes) for assessing the impact of pharmaceutical price variations in Germany on prices in other countries". Outcomes of this study are;

- a) Postulations used while analyzing price that changes, the testimonial drug in sensitivity investigation was sold in Germany; similar price drops in selling prices lead by a drop in maximum repayment prices due to ERP; the full cost of a price decline must be bear by the manufacturer; and all ERP schemes will be updated immediately.
- c) The authors find that they expected that once every year prices are apprised concurrently in all countries. In addition, spill-over consequences of price changes will be created by parallel commerce between European countries and the consequences of ERP and parallel commerce can't be parted.

- d) Burden of non-referencing countries will be increased by the addition of countries that use ERP. This may cause tactical manufacturer demeanor that disturbs price or accessibility of drugs in certain places. It will also cause increased price ranges than originally proposed by local market regulation & in certain cases, an introduction delay in countries with minor market sizes, particularly with lesser price levels.
- e) The authors recommend that a subjective indicator of prices from as much countries as conceivable and should also be used to establish reimbursement prices and to shun the negative effects of ERP hence declining the direct and indirect effect of individual countries.

#### 2.3. Generic substitution Review:

A survey organized in Brazil (Bertoldi, 2005) assessed the "knowledge and use of generic drugs by adults in a southern Brazilian city". 3.9% was proportion of me-too use, 86.0% understood that the cost of generics is low and 70.0% are aware that quality of branded medicines is same, 57.0% are aware of any packaging features that differentiates generics from other drugs. 48.0% of the participants wrongly classified a branded medicine (with brand like me-too name) as generic, when photographs were used. In the 15-day study period the participants who purchased medicines, 18.9% stated purchasing a generic, but the authors specified that the people often failed to distinguish between me-too and other like medicines, this result should be analyzed with care.

A survey conducted in Malaysia comprising of 3967 consumers establish that generic products triggered more side-effects is believed by 32% of participants and 64% make out that me-too medicines were of low cost than innovator products. (Al-Gedadi, 2008)

A 1995 study (Dowell, 1995) showed that 20% of patients (n=167) due to nature of interaction they got rather than change in medication, informed that they were "very unhappy" with their generic medications. The results should be inferred with care since this was a minute study more than 15 years ago at one general practice in the UK.

Research in Spain indicates that patients' acknowledgement of generic medicines and their contentment with the medicines can be increased with the aid of patient education (Valles, 2002).

(Aaserud, 2006) conducted a study with the objective of "determining the influences of pharmaceutical pricing and acquiring policies on drug use, health-cared employment, health outcomes and budgets". The outcomes of this study are;

- a) One study of index pricing and 10 studies of reference pricing were encompassed in the review.
- b) Data was offered in one study of reference pricing comparative to generic drugs.

**Pavcnik** (2002) (108) concluded that an average of 11% reduction in the prices of generics whereas there is an additional decline of 26% in brand prices.

The single study comprised of index pricing (**Brekke et al, 2003**) confirmed that generic and branded drugs prices were declined. There was not statistically major decline in brand drug prices. Me-too drug prices declined (comparatively) more than branded drugs. Long-term consequences were some what higher than short-term consequences (-5.3% v/s -4.0% for me-too drugs; -1.1% v/s -0.8% for branded drugs).

(King & kanavos, 2002) conducted a study with the aim of "reviewing the policies instigated in Canada, Denmark, Germany, the Netherlands, the UK, and the USA". The outcomes of this study are;

- a) Reserves in countries studied are grasped by upsurges in volume of me-too medicines used and variances in price b/w me-too and innovator drugs.
- b) Me-too drug advertising regulation enables market entrance right after patent termination; reference pricing that is pricing of innovator products; and extent of price rivalry in pharmaceutical markets are considered as key supply-side policies.
- c) Persuading prescribing and dispensing arrays and copayments are included in demand-side policies.
- d) A prerequisite for all other measures to take effect is the quality of generic medicines.
- e) In order to have supreme impact in interim countries, policies employed in developed countries must be acclimated and local conditions should also be considered.

(Simoens, 2005) conducted a study with the aim of "discussing the Belgian pharmaceutical policy pertaining to generic drugs and analyzing the Belgian drug market evolution following the commencement of a reference pricing scheme in 2001". The outcomes of this study are;

a) Following the commencement of reference pricing, the market portion held by generic drugs in Belgium augmented. 2.05% was the average market fraction from 01-1998 to 06-2001) which is enhanced to 6.11% from 07-2001 to 12-2003.

- b) Reserves of 1.8% of pharmaceutical spending by third-party financiers in 2001 and 2.1% in 2002 is due to the launch of the reference pricing proposal.
- c) The authors states that the concurrent policy considering the part that physicians and pharmacists can perform in encouraging the use of generic drug. They foresee that establishment of enticements for physicians tore commend while pharmacists to distribute the generic medicines may perform the pivotal role in future expansion of the Belgian generic drug market.

## 2.4. Health Technology Assessment (HTA) Review:

(Anis & Gagnon, 2000) conducted a study with the aim of "assessing the amenability of pharmacoeconomic studies presented to Pharmacoeconomic Initiative of British Columbia, Canada and assessing the procedural quality of individual submission sand to exhibit importance of presentingguidelines-compliant evaluates. 88 submissions were reviewed". The outcomes of this study are;

- a) Cost-comparison of twenty five investigates, fourteen cost effectiveness, eleven cost-minimization, nine cost-utility, and twenty nine budget impression investigates.
- b) "65 out of 88" (74%) of investigates/analyses failed to conform with the guidelines.
- c) 80% non-compliant investigates were cost-comparison or budget impression investigates.
- d) "74% of all analyses" were not suggested for recording as a provincial drug plan profit.
- e) "80% of non-compliant" analyses were not suggested.
- f) "Out of 64 only 13 (20%) of non-compliant investigates" were suggested for reporting while 10 out of 24 (42%) of compliant investigates obtained a positive suggestion.

g) p = 0.03 is the correlation/association found between type of recommendation and type of analysis. Things which were less likely to be suggested are cost comparison and budget impact investigates.

Drummond et al (2011) (116) conducted a study with the aim of "comparing the utilization of reference pricing and HTA for pricing and repayment status of drugs in Germany, the Netherlands, Sweden, and the UK. Number/type of studies are not pertinent". The outcomes of this study are;

- a) If there are great dissimilarities in prices of drugs in given assemblage or cluster, the influence of reference pricing is only ample.
- b) Reference pricing can have a huge influence when one of the drugs in an assemblage/cluster turn in to generic.
- c) No clear relationship of HTA's influence on prices could be governed.
- d) Establishing the repayment level for the group is the core of reference pricing; however, it is uncertain how this level is fixed if a generic does not exist. In juxtapose, repayment may be restricted or constrained to few signs of drug or evident patient sub-groups with HTA.
- e) Authors determined that for gaining value for currency from pharmaceuticals reference pricing lonely does not signify a practical policy, and a much better attitude is represented by HTA, given bonus for novelty and worth for money. A twin policy may be evolving in which prime policy for getting worth of money from new drugs is grounded on HTA, reinforced by RP pricing or another tactic.

Chapter 03

**Methodology and Data Sources** 

The objectives of this study are; help the policy makers to control pharmaceutical prices

at the reasonable price and lead such course of actions linked with the national objectives and

according to the Pakistani Healthcare System. These objectives will be accomplished with the

context of 'concurrent embedded strategy', a type of 'concurrent mixed method' which will be

explained in methodology.

The conclusion of quantitative data and experience or recommendations of the expert

stakeholders composed through qualitative method (semi-structured interview) will act as

baseline for recommendation of this study. This section will elaborate the data sources and

methodological framework to achieve the above-mentioned objectives.

**3.1. Methodology:** MIXED METHODS RESEARCH

**Type:** Concurrent Mixed Method

**Strategy:** Concurrent Embedded Strategy

**Philosophical Approach:** The Pragmatic Worldview

3.2. Mixed Methods Research Concept:

Mixed methods research is a methodology to review that conjoins or unites both

qualitative and quantitative forms. It involves theoretical suppositions, the use of qualitative and

quantitative methods, and the interspersing of both methods in a study. Hence, it is not as simple

as merely gathering and analyzing both kinds of data, rather to augment the complete strength of

29

a study than either quantitative or qualitative research, it utilizes both approaches in tandem (Cresswell & Plano Clark, 2007).

## **Importance:**

For many reasons this mixed methods model is alluring. Two types of data can be collected concurrently by a researcher during a single data collection phase. Beneath its of both quantitative and qualitative data are provided in a study. In addition, a researcher can obtain view points from the various types of data or from diverse levels within the study by using the two separate methods in this approach.

### **Mixed Methods Strategies:**

In comparison to either the quantitative or qualitative methods, mixed methods strategies are not well known. Campbell and Fisk utilized multi methods to investigate validity of psychological characters since then the idea of mixing different methods was originated in 1959. They inspired others to study multiple approaches of data collection and to utilize their multi method matrix. This encouraged others to merge methods, and quickly methodologies associated with field techniques, such as opinions and interviews (qualitative data), were conjoined with conventional surveys (quantitative data; Sieber, 1973). Researchers recognized that there are limitations of all methods, they felt that partialities integralin any single method could counter balance or revoke the partialities of other methods. Triangulating data bases-a way for pursuing conjunction across qualitative and quantitative methods-was innate (Jick, 1979).

The idea of mixing shifted from pursuing conjunction to essentially assimilating or linking the quantitative and qualitative data by the early 1990s. For example, one can recognize participants to search or set questions to ask for the other method with the help of results from

one method (Tashakkori& Teddlie, 1998). Alternatively, one can merge the qualitative and quantitative data into one big database or to strengthen each other, the results can be used side by side (e.g., qualitative estimates support statistical results; Creswell & Plano Clark, 2007). Or to encourage sidelined groups, such as women, ethnic/racial factions, members of gay and lesbian groups, people within capacities, and those who are poor, these methods can perform a larger, transformative resolve (Mertens, 2003). Writers across the globe are led by these reasons for mixing methods to elaborate procedures for mixed methods approaches of inquiry, and in the literature abundant terms are found, such as *multimethod*, *convergence*, *integrated*, and *combined* (Creswell & Plano Clark, 2007), and these reasons also helped to sculpt procedures for research (Tashakkori& Teddlie, 2003).

#### **Concurrent Mixed Methods:**

The procedures in which the researcher congregates or combines quantitative and qualitative data to provide a complete analysis of the research challenge are called **concurrent mixed methods**. In this approach, both forms of data are collected at the same time by the investigator and then in the analysis of the overall results researcher integrates the information. Also, in this design, to investigate different types of questions the investigator may insert one lesser form of data than another bigger data collection.

#### **Concurrent Embedded Strategy:**

Utilization of single data collection phase through both quantitative and qualitative data are gathered at the same time can help identify the **concurrent embedded** strategy of mixed methods. In concurrent embedded approach the project is guided by a primary method and auxiliary role in the procedures is provided by a secondary database. The principal method

(qualitative or quantitative), given more priority within which the secondary method (quantitative or qualitative) is embedded, or entrenched. This embedding may signify that a different question is addressed by the secondary method than the principle method (e.g., in an experiment, the results anticipated from the treatments are addressed by the quantitative data while the processes faced by participants in the treatment groups are explored the qualitative data) or it may signify that secondary method obtains information at a distinctive level of analysis (in hypothesizing these levels, the analogy to classified analysis in quantitative research is helpful) (Tashakkori and Teddlie, 1998). Frequently to assimilate the information and link one data source with the other, the blending of the data from the two methods is done, typically achieved in a discussion segment of a study. However, to present an overall merged assessment of the problem, the data may also not be matched but remains side by side as two different pictures.

The concurrent embedded model may be utilized to fulfill a variety of purposes. Usually in contrast of utilizing the predominant method alone, this model is utilized so that an investigator can obtain wider perspectives because of using the different methods. For example, Morse (1991) observed that to augment the description of the sample contributors a chiefly qualitative design could entrench some quantitative data.

#### **Visual Model:**



### Factors consider in selection of methodology type:

- a. Timing.
- **b.** Weighting.
- **c.** Mixing.
- **d.** Theorizing and Transforming Perspectives.

#### DATA ANALYSIS AND VALIDATION PROCEDURES

The quantitative and qualitative data assemblage may be exhibited in separate sections, but the analysis and understanding of results syndicates the two forms of data to pursue convergence or resemblances among the results in a concurrent study. No clear difference between the quantitative and qualitative phases can be made by the organization of this type of mixed methods study.

#### The Pragmatic Worldview:

Pragmatism, as a worldview ascends out of activities, situations and outcomes rather than precursor conditions (as a post positivism). There is a disquiet with the functions, what works and answers to the problems (Patton, 1990). Investigators highlight the research problem instead of centering on methods and use all the methods available to comprehend the problem (Rossman & Wilson, 1985).

3.3. Qualitative Method: (Priority Data)

**Importance:** 

The investigator keeps emphasis on finding the meaning that the contributors hold about

the problem or issue, not the sense that the investigators bring to the research or authors express

in the literature, in the whole qualitative research process.

**Study Design:** Interpretive Qualitative Research and Emergent.

A form of interpretive review in which investigators make an elucidation of what they

see, hear, and comprehend is called Interpretive Qualitative Research. Their elucidations cannot

be detached from their own backgrounds, past, contexts, and previous understandings.

For qualitative researchers, the research process is developing. This signifies that the

principal plan for research cannot be firmly prescribed, and after the investigator enters the field

and starts to gather data, all stages of the process may change or altered. For example, the forms

of data assemblage may change, the questions may be altered, and the participants studied, and

the places visited may be modified revised. To understand the problem or matter from

participants and to deal with the research to gain that information is the key concept behind

qualitative research.

**Data Collection Method:** Interviews (semi-structured)

Face to face, one to one, in person interview.

**Sample:** Resolutely selected participants (7-10)

Participants will be included from;

34

- a) Health Ministries, (M/o NHSR & C)
- b) Drug Regulatory Authority of Pakistan (DRAP).
- c) Planning Commission of Pakistan (Islamabad).
- d) Pharmaceutical Companies located in Rawalpindi and Islamabad.
- e) NGOs/ Stakeholders located in Rawalpindi and Islamabad.

#### **Data Record Procedure:**

Conduct a semi-structured interview and take notes.

#### **Interview Protocols:**

- I. Guidelines for the interviewer to follow to ensure that standard procedures are obeyed from one interview to another.
- II. The questions (usually an ice-breaker query in the start followed by 4-5 queries that are often the sub-questions in a qualitative research plan, tailed by some closing statement or a question, such as, "Who should I visit with to learn more about my questions?
- III. Reviews for the 4-5 questions, to follow up and inquire individuals to describe their ideas in more detail or to expound what they have said.
- IV. Space between the questions to record responses.
- V. A finishing thank-you statement to recognize the time the interviewee expended during the interview.

## 3.4. Quantitative Method: (Supporting/Secondary Data)

Study Design: Cross sectional

**Data Collection Method:** Structured Record Review (Secondary Data)

Drug Prices Data.

Sample: Random Sample (systematic/probabilistic sample).

Then, divided the sample in following categories/intervals.

- 1. Drug Prices ranges between 50-500 PKR.
- 2. Drug Prices ranges between 500-12000 PKR.
- 3. Drug Prices ranges between 2000-4000 PKR.
- 4. Drug Prices ranges above 4000 PKR.

## **Questions to Study:**

- 1. Impact of fixed tax ratio as markup component on above price ranges.
- 2. Impact of fixed manufacturer profit as markup component on above price ranges.
- 3. Impact of fixed marketing expenses as markup component on above price ranges.
- 4.Impact of fixed distribution expenses and discount as markup component on above prices ranges.

# 3.5. Limitations of the Study:

The limitations of this study are;

- i) No study available specific to Pakistan.
- ii) Unavailability of resources.
- iii) No feedback on the efficacy/effects of the drugs by the patients/end user.

## Chapter 04

# **Qualitative (Priority Data) Study Findings:**

This chapter presents the findings of the qualitative study regarding Drug Pricing Policy and the Reference Pricing Mechanism adopted by Drug Regulatory Authority of Pakistan from Interviewees perspective. The qualitative study was conducted with the purpose of getting the insight about Drug Pricing Policy and missing information in quantitative: however to a great extent, the findings of the qualitative study regarding Drug Pricing Policy and mechanism endorsing of the arguments given in the study and are in the introduction chapter. However, as stated earlier in the section of thesis methodology, key policy makers were interviewed from both public and private sectors.

The main questions to be asked are;

- 1. Should Pakistan use price control measures to manage medicines prices?
- 2. Should Pakistan Adopt measures to control add on costs in the supply chain?
- 3. Should Pakistan promote the use of quality assured generic medicines as a strategy to manage prices?

Details of questions are indicated in Annexure at page no. 115.

## 4.1. Discussion and Key findings:

After extensive brainstorming sessions with the respondents, following are the key findings of these interviews;

When the interviewees were asked about Drug Pricing Mechanism of Pakistan , one of the respondent who served in Ministry of Health for almost 30 years on key positions discussed about the Background of the Drug Pricing for better understanding. The respondent highlighted that in past, prices under section 12 of the Drug Act, 1976 were fixed for each drug on the basis of required data supplied by the manufacturer since the start of the registration of the drug. The general formula applied for fixation of MRP was Prime cost (cost of raw materials + cost of packaging material+ direct cost) + 75% mark up for all dosage forms would and 115% on injectables which was practices for more than a decade.

In 1991, Economic Coordination Committee (ECC) allowed general price increase of 10% on all products and six categories of drugs were decontrolled subject to an automatic annual increase of 10%. From 1991 to 1993, process increases were allowed in certain hardship cases on individual basis. Despite strict price control by the government, the growth rate of Pharma sector in Pakistan was estimated to be about 20-25% per annum in these years.

The respondent further added that Pharma industry was not satisfied with the strict price control and they a singed a "Gentleman's Agreement" with the government for partial control on the plea that due to free market economy and healthy competition, the prices of drugs were come down and will not increase. Some 861 so called essential drugs were put under price control while, rest (great majority) were out of control

On June 12, 1993 when the government announced the partial de-regulation of price control, the prices of most of the drugs kept continuously on rise in spite of the Pharma manufacturer's assurance to the Ministry of Health that they would continuously increase the prices which

would not be increased more than 20% during the first 03 months after de-regulation. But, in reality more than 20 companies increased their prices more than 50% during first 12 days.

Another respondent who currently serving in Planning Commission said that A comparison of process with neighbouring countries will show that many medicines be already sold at high prices in our country compared to remaining "South Asian" countries. Prices of "17" out of "21" frequently consumed drugs be higher in "Pakistan than in India, Nepal and Bangladesh".

According to W.H.O. findings, "life saving drugs in Pakistan are four to twelve times expensive than in India "because of failure of develop indigenous basic raw materials manufacturing base. It is surprising to note that Pharma Industry is pressurizing the government to decontrol all drugs (Except W.H.O. list of essential drugs) and let the Pharma Industry make some gains on its investment so that they can generate funding of investment at the cost of health of the people. It may be emphasized that the prices of drugs are constitutionally controlled globally in the interest of Public Health which is the basic right of the public.

One of the respondent added that, Pharmaceutical companies are providing drugs to the market at higher prices than those at which the same medicines were offered to hospitals thus making huge profit, at the cost of immense burden on the consumers.

Another respondent from academics background, added that basic manufacture of raw materials in Pakistan according to a report published in the proceedings of international seminar on polices, management and quality assurance of Pharmaceuticals 1985, 14 leading pharmaceutical companies committed to set up manufacturing plant of some life saving imported drugs from 1960 to 1964 against some incentives given to them but all of them failed to do so even after getting the incentives.

One respondent said that Pakistan should use price control measures and highlighted key factors which directly influence the drug prices;

- a) High Prices of the raw materials both active and non-active (additives) (transfer pricing) as compared to competitive international prices.
- b) Aggressive sale promotion.
- c) High Profitability.

The respondents when asked specific about External Reference Pricing (ERP), the strategy adopted by DRAP, most of the respondents are not satisfied with this strategy and highlighted the loopholes associated with this strategy.

One respondent from pharmaceutical consultancy stated that, the major factor which causes drastic increase in drug prices is Transfer Pricing (over invoicing) which unfortunately not handled in this strategy.

A commonly used transfer pricing definition is "the price charged by one member of multinational organization to another member of the same organization for the provision of goods or services or the use of a property, including intangible property".

"In other words, transfer pricing relates to the price applied to intercompany transactions.

These transactions can include the sales of products, the provision of a service, the lending of money and the use of (intangible) assets".

## **Example for understanding:**

- Company A manufactures automobiles in Japan that are ultimately to be sold to customers in Germany.
- The automobiles are sold by Company A to its distribution subsidiary in Germany, Company B. Company B resells the automobiles to independent dealers.
- ➤ The automobiles cost € 10,000 per unit to develop and build.
- $\triangleright$  The customers pay € 20,000 for the automobiles at retail.
- The independent dealers earn gross profit of 15% of the end sale price or € 3,000 per automobile. That is, they buy automobiles from Company B at a price of € 17,000 per unit.
- ➤ That leaves € 7,000 (20,000 3,000 10,000) to cover freight, selling / marketing costs, and overhead costs, to fund development of new car models and technology, and to provide profit for Company A and Company B.

Below table shows how the impact of prices on finished products made out of this price inflated raw materials. Take ketotifen as example, Multinational Company (MNC) purchased this raw material at the cost of 60, 000 \$/Kg while the same raw material was purchased at 3,072 \$/Kg which is 1953 times lower than the MNC raw material.

**Table 4.1. Transfer Pricing of RAW Materials and Impact on Finished Products** 

Sr.	Raw Materials \$/Kg				Finished Product			
no								
		M.N.C	Others	%age	Dosage	M.N.C	Others	%age
					Forms			
1	Ketotifen	60,000	3,072	1953	Syrup	61.37	30-	204
							40.70	
					Tablets	174.9	21.9-	794
							120	
2.	Diclofenic Na	165	15	1100	Tablets	125.58	42.00	299
	Diclofenic K	1397	35	3991	Tablets	125.58	58.00	216
3.	Famitidine	8,250	90-450	3210	Tablets	293	69-200	218
4.	Ofloxacin	2,350	158-	1382	Tablets	329.78	100-265	180
			185					
5.	Doxycycline	700	58-71	1076	Tablets	6.14	2.86-	150
							5.36	
6.	Pizotifen	67,000	8,000	837	Tablets			
7.	Amlodipine	30,000	1650	1830				
8.	Phulphenazine	16000	2500	540				
	Decon							
9.	Phlphenazine	14000	1850	762				
	HCL							
L	M/ NHCD C				1			

Source: M/o NHSR&C

One respondent stated that, it is interesting to note that the import policy order issued by the Ministry of Commerce states, "No import shall be made except at the most competitive rates" which order has never implemented and caused variation and increase in drug prices.

The respondent further highlighted about transfer pricing that, it not only involve pricing but also payments made through discrepancies towards the effective and declared quality and quantity of the goods and services exchanged. Moreover, transfer pricing practices of Multi-nationals occur at all stages of production. He referred to a study that carried out in early 1984 about transfer pricing in respect of 7 Raw materials only, revealed that foreign exchange savings could have been to the tune of about \$ 6.5 millions (Rs. 100 million) per annum if these were imported from sources offering next lower price. The items under study are;

Table 4.2. Remittance in U.S \$ Through Transfer Pricing in Year 1984-85

Sr.no	Name of Raw Material	Extra Remittance
1.	Trimethoprim	
2.	Sulfamethoxazole	
3.	Chloremphenicol	
4.	Dipyron	6.5 Million U.S \$
5.	Ampicillin Trihydrate	
6.	Doxycycline	
7.	Erythromycin	

Source: M/o NHSR&C

If the money remitted abroad through transfer pricing in case of these 7 items was reflected in profits, national exchequer would have been benefited to the tune of \$ 1.6 million ( 2.5 crores)

in the form of taxes. The total impact of savings in case of all the imported 'over priced' raw materials, if calculated, would run into over several million dollars annually. He stated that, the plea put forward in favour of 'over priced' raw materials is their 'better quality' or Bioavailability' but scientifically there are no two standards of quality in pharmaceuticals-the drug must confirm to established quality control specifications to be standard quality otherwise it is sub-standard. Bioavailability is certainly an important factor in drug formulations but it has no relevance in raw materials so any attempt to justify many fold higher than the international market prices has no validity on scientific grounds except for minor variations which may be due to economics of scale, over head charges etc. furthermore, most of the international sources of supply of raw materials are F.D.A. approved and are collaborators of many Transnational firms. The respondent further highlighted that, another implication of transfer pricing is that not only the multinationals are able to make enormous remittance abroad but also manage to get higher prices in respect of dosage forms based on the over-priced raw materials. If we consider the dosage forms produced from the above 7 over priced raw materials having 60 to 90% of the total market share, not only these manufacturers make extra profits but the poor public is faced to use

Table 4.3. Remittance in U.S \$ Through Transfer Pricing in Year 1987

most expensive brands of a given formulation.

Name of RAW Materials	Extra Remittance
29 RAW Materials	20.0 Million U.S \$

Source: M/o NHSR&C

 Table 4.4. Remittance in U.S \$ Through Transfer Pricing in Year 1994-95

Sr.no	Name of Raw Material	Extra Remittance
1.	Xylometazoline	
2.	Piroxicam	
3.	Pizotifen	
4.	Diazepam	
5.	Ampicillin Trihydrate	6.648 Million U.S \$
6.	Pindolol	
7.	Dydroxyprogesterone	
8.	Nandrolone Decanate	
9.	Mefenamic Acid	
10.	Bromocriptine	
11.	Metamizole	
12.	Pizotifen	

Source: M/o NHSR&C

Table 4.5. Remittance in U.S \$ Through Transfer Pricing in Year 1999

Sr.no	Name of Raw	Price of	Price of	Difference	Quantity	Extra
	Material	Import/Kg	imports/Kg		Imported	Remittance
		M.N.C US \$	Others US			US\$
			\$			
1.	Ketotifen	58333	3702	54631	15 kg	874096
2.	Pizotifen	63650	8000	55650	16 kg	890400
3.	Diclofenic Na	85	15	70	1168 kg	81760
4.	Diclofenic K	85	35	50	787 kg	39350
5.	Ofloxacin	7200	158-185	2040	660 kg	1346400
6.	Famotidine	7425	90-450	7335	40 kg	293400
7.	Amlodipine	30000	1650	28350	65 kg	1842750
8.	Fluphenazine	14000	1850	12150	2 kg	24300
9.	Doxycycline	595	58-71	535	2500 kg	1337500
Total:			1	<u> </u>		6.73 M

Source: M/o NHSR&C

Note: The date quoted above is old but the situation has not changed much.

The respondent from Ministry of Commerce pointed out that the drug prices goes down after the expiry of their patent rights which have been expired in most of the case of imported raw materials. He shared a table which shows the decrease in prices of few essential drug raw materials but the price of drugs based on these raw materials have never shown any decrease.

Table 4.6. Reduction in Prices of Some Raw Materials Over the Years

Sr.no	Raw Material	CIF Price \$/Kg			
		1996	1999	%age Reduction	
1.	Erythromycin	140	65	53	
2.	Rifampacin	122	60	51	
3.	Linocomycin	131	65	50	
4.	Cefaclor	1000	430	57	
5.	Captopril	172	87	49	
6.	Diltiazem	385	120	69	
7.	Norfloxacin	65	24	63	

Source: DRAP

The respondents when asked about cost plus pricing strategy and fixed mark ups, most of the respondents disagree with the division of fixed mark up. One respondent stated that, Rule 33 ( L.R & A Rules 1976) says, 'No person shall spend more than 5% of his turnover on advertisements, sampling and other promotional activities in respect of drugs (including salaries of medical representatives, seminars, foreign tours of doctors, gift items etc). This rule has never

been implemented. A study will reveal many times more spending than 5% on advertisements which add up to the cost of drugs.

The respondents when asked about control of add on costs in the supply chain and exemption of medicines from taxes/or tariffs, all respondents agreed that government should take steps regarding supply chain management for large masses. One respondent stated that there is a huge difference in prices of drugs offered by the pharmaceutical companies to the hospitals and other institutions which highlights the importance of profits management which needs to be fixed keeping in view the prices offered to hospitals, bonuses, discounts and the pricing data supplied by the firms and their audit reports. Below table is explaining the differences between the prices of same drug sold in Retail Pharmacies and quoted for institution orders.

Table 4.7. Prices of Drugs Quoted to Provincial Governments Versus Fixed Trade Prices by the Governments

Sr.no	Drug	Manufacturer	Trade Price	<b>Quoted Price</b>
1.	Metronidazole inj.	S.Ejazudin Co	51.0 Rs for 100	18.00 for 100 ml
			ml	
2.	Ampicillin inj, 500	Sami	29.75/vial	6.47/vial
	mg			
3.	Disprin Tab.300 mg	Reckitt & Colman	255.00 for 600	137.00 for 600
			Tab	Tab
4.	Dopamine Inj. 200	Abbott	76.33/5 ml	23.30/ 5ml
	mg			
5.	Famotidine Tab. 40	Bosch	7.65/Tab	1.8/Tab

	mg			
6.	Gentamycin Inj. 80	Bosch	93.50/ 5 Amp	27.0/ 5 Amp
	mg			
7.	Ibuprofen Tab. 400	PDH	244.32 for 250	100.00 for 250
	mg		Tab	Tab
8.	Chloroquinine Tab	Pharmacare	374.00 for 1000	304.44 for 1000
	250 mg		Tab	Tab
9.	Nifedipine cap. 10	Akhai Pharma	106.74 for 30 cap	61.44 for 30 cap
	mg			
10.	Doxycycline Cap	Ethical	2.50 Each	0.60 Each
11.	Diclofenic Na Inj.	Siza	48.75/ 5 Amp	9.95/5Amp
12.	Ceftriaxone	Bosch	331.50 each	100 each Amp
			Amp	
13.	Captopril Tab. 25	Zafa	55.25 for 20 Tab	21.98 for 20 Tab
	mg			
14.	Pentazocine Inj. 30	Indus	10.30/Amp	7.25/Amp
	mg/ ml			
15.	Cimetidine Inj	Indus Pharma	83.30 for 20	64.00 for Amp
			Amp	

Source: Drug Court (Islamabad)

All respondents aggress on the promotion of quality assured generic medicines but subject to the proper pricing policy strategy and its implementation. The respondents also endorsed the

importance of academic participation in determination of cost, price, quality and distribution of medicines.

## 4.2. Summary:

Following is the summary of the findings by the respondents and interviews conducted;

- A comparison of process with neighbouring countries will show that many medicines be already sold at high prices in our country compared to remaining "South Asian" countries.
- ➤ Prices of "17" out of "21" frequently consumed drugs be higher in "Pakistan than in India, Nepal and Bangladesh".
- According to W.H.O. findings, "life saving drugs in Pakistan are four to twelve times expensive than in India "because of failure of develop indigenous basic raw materials manufacturing base.
- ➤ Pharmaceutical companies are providing drugs to market at high prices than those by which the identical medicines were offered to hospitals thus making huge profit, at the cost of immense burden on the consumers.
- ➤ In 1985,14 leading pharmaceutical companies committed to set up manufacturing plant of some life saving imported drugs from 1960 to 1964 against some incentives given to them but all of them failed to do so even after getting the incentives.
- ➤ High prices of raw materials, aggressive sales promotion and high profitability are the key factors which directly influence the drug prices.

- ➤ The major factor which causes drastic increase in drug prices is Transfer Pricing (over invoicing).
- ➤ No import shall be made except at the most competitive rates.
- ➤ Implication of transfer pricing is that not only the multinationals are able to make enormous remittance abroad but also manage to get higher prices in respect of dosage forms based on the over-priced raw materials.
- The drug prices goes down after the expiry of their patent rights which have been expired in most of the case of imported raw materials.
- No person shall spend more than 5% of his turnover on advertisements, sampling and other promotional activities in respect of drugs (including salaries of medical representatives, seminars, foreign tours of doctors, gift items etc). This rule has never been implemented. A study will reveal many times more spending than 5% on advertisements which add up to the cost of drugs.
- There is a huge difference in prices of drugs offered by the pharmaceutical companies to the hospitals and other institutions which highlights the importance of profits management which needs to be fixed keeping in view the prices offered to hospitals, bonuses, discounts and the pricing data supplied by the firms and their audit reports.

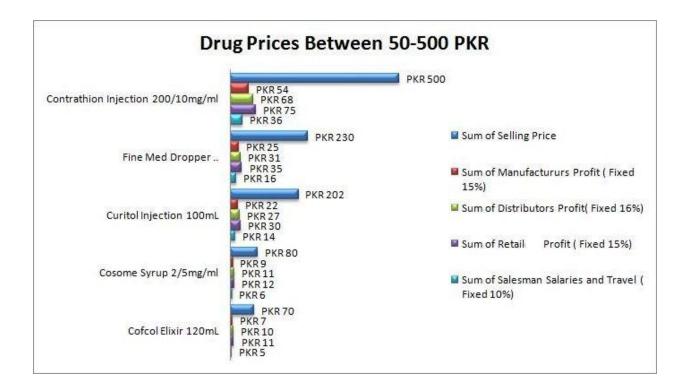
## Chapter 05

# **Quantitative (Supporting Data) Study Findings:**

This chapter presents the findings of the quantitative study on the impact of fixed mark-ups of i) Manufacturer's Profit, ii) Distributor's Profit, iii) Retailer's Profit and iv) Salesman Salaries and Travel. The quantitative study is supporting data in this study. The comparison of profits in the tables will help in finding the impact of these fixed mark-ups in different pricing ranges and shows the burden which faced by the end consumer. This chapter will also present the less assumed fixed mark-ups impact on final pricing for the sensitization of the concept. I selected four components from the fixed mark-up for the understanding of the subject. These four components cause major increase in drug prices.

5.1. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges between 50-500 PKR.

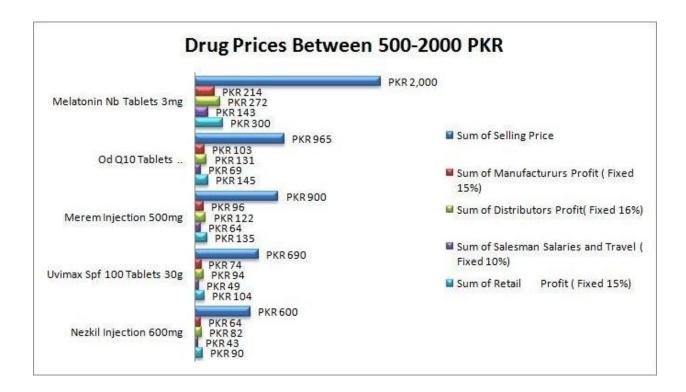
Figure 5.1. Drug Prices Between 50-500 PKR



"A mark-up represents the additional charges and costs that are applied to the price of a commodity in order to cover overhead costs, distribution charges, and profits". It is clear from above figure, the impact of fixed mark-up of drug prices ranges between 50-500 PKR. Lets take Conthrathion injection 200/10mg/ml as example. The selling price of this drug, purchased by the patients/consumers form pharmacies is 500 PKR. The manufacturer, distributor and retailer and salesman's salaries fixed profits are 54, 68, 75 and 36 PKR respectively which increases the drug prices significantly and ultimately cause out of pocket expenditures (OOPS). The sum of these four is 233 PKR. The reason behind implementation of fixed mark ups is that this strategy is technically less complex to implement than other policy options as it requires relatively limited information about cost of goods and the supply chain, and some enforcement capacity.

# 5.2. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges between 500-2000 PKR.



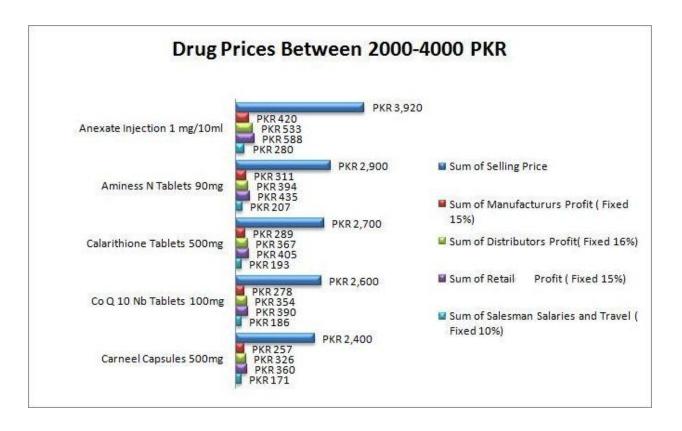


The above figure of table ranging drug prices between 500-2000 PKR are also showing the similar case discussed above. The main point that requires attention is when we apply the fixed mar-up profits on costly drugs, the margin of profits increases many folds and cause poor consumers in extreme trouble and ultimately drugs becomes unreachable from their access. This statement is also supported by a study that conducted on "Regressive mark-up" (i.e. a lower markup for high priced products). The regressive mark-up strategy is made in countries such as "Tunisia, Syria and Labanon". This leads to improved outcomes than fixed profit mark ups

during their influence lying on financial incentives. Though, fixed markups can significantly increase the value of otherwise less cost medicines.

# 5.3. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges between 2000-4000 PKR.

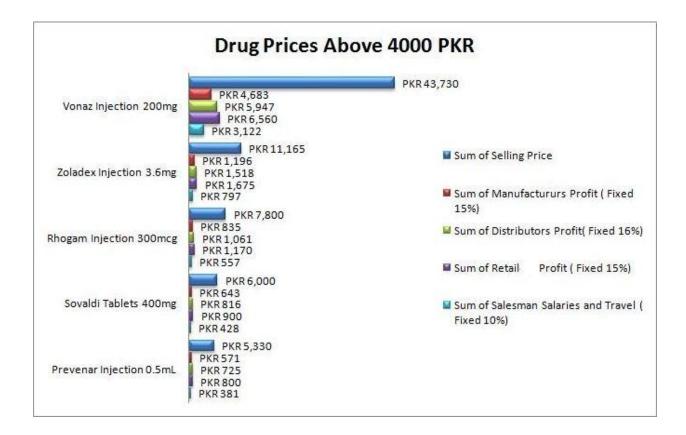
Figure 5.3. Drug Prices Between 2000-4000 PKR



This drug price ranges also showing the similar results citied above. More the Price, more the margin of profits.

# 5.4. Impact of fixed manufacturer, distributor, retailer and salesman salaries on drug prices ranges Above 4000 PKR.





The above mentioned figure of drug prices above 4000 PKR showing extreme inequality in fixed mark-up profits . Take Vonaz injection 200 mg as example , a anti-fungal agent and used for the treatment of fungal infections of lungs, mouth and throat. The selling price of this drug in market is 43, 730 PKR . if we calculate the profits of only 4 components discussed in table, the total profit on a single product becomes 20, 312 PKR. This is a huge amount of profit on a single drug for the third world countries like Pakistan. These drugs are usually produced in a batches , means thousands of injections produced at once, this reduces the production cost, salesman salaries and other costs.

## 5.5. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 50-500 PKR.

For the sake of understanding and sensitization of the subject, lets reduce the fixed mark-ups of distributor, retailer and salesman salaries from 16,15 and 10 to 10, 10 and 5 % respectively. In this case, we are not changing the manufacturer's profit. The below table will show substantial decrease in drug prices by reducing little margin of profits in three components.

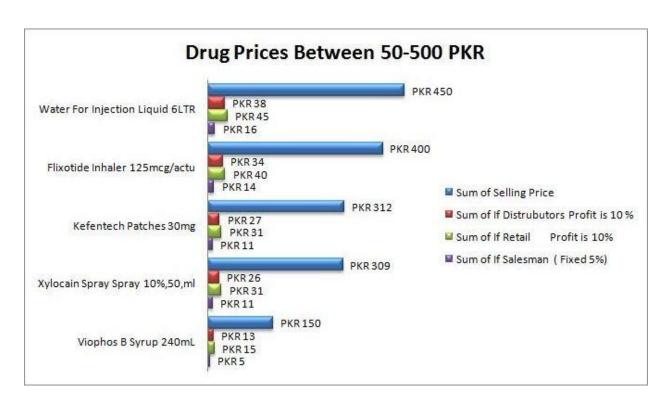
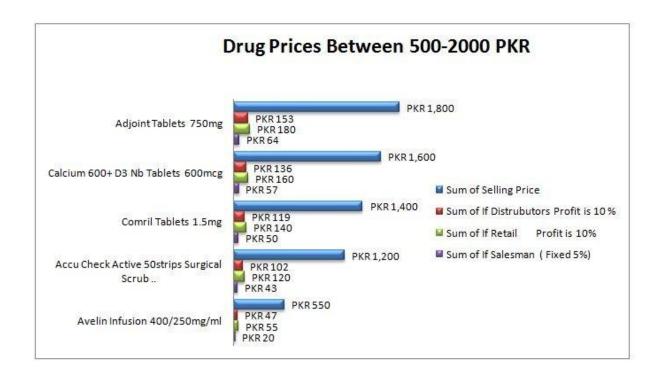


Figure 5.5. Drug Prices Between 50-500 PKR (reduced mark-ups)

5.6. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 500-2000 PKR.

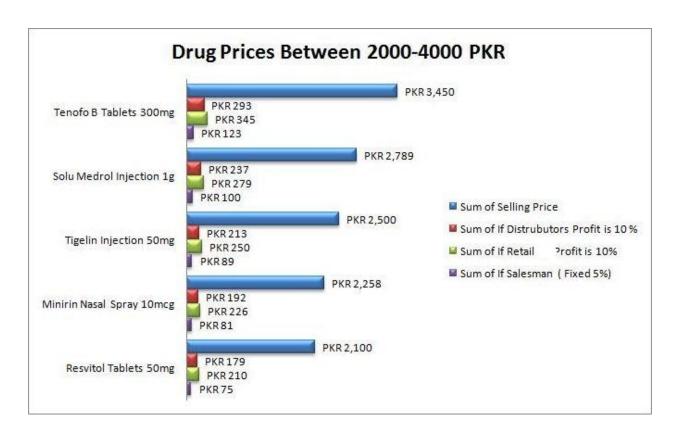
Figure 5.6. Drug Prices Between 500-2000 PKR (reduced mark-ups)



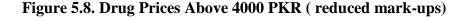
Similar results can be drawn from above figure. The more the price more is the saving.

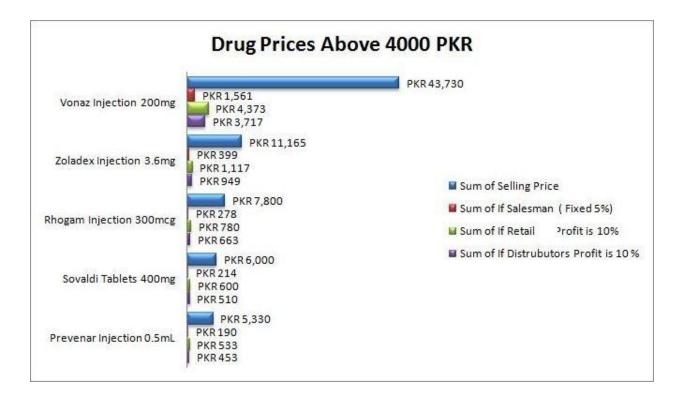
## 5.7. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 2000-4000 PKR.

Figure 5.7. Drug Prices Between 2000-4000 PKR (reduced mark-ups)



5.8. Impact of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges Above 4000 PKR.





## 5.9. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 50-500 PKR.

The below figures of table will show the total savings from the drugs ranging different categories. By reducing the small amount of fixed mark-up, one can reduce the drug prices and make it affordable for the end consumers.

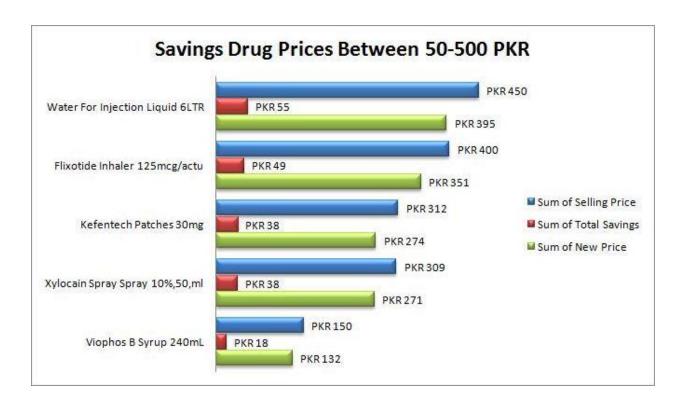
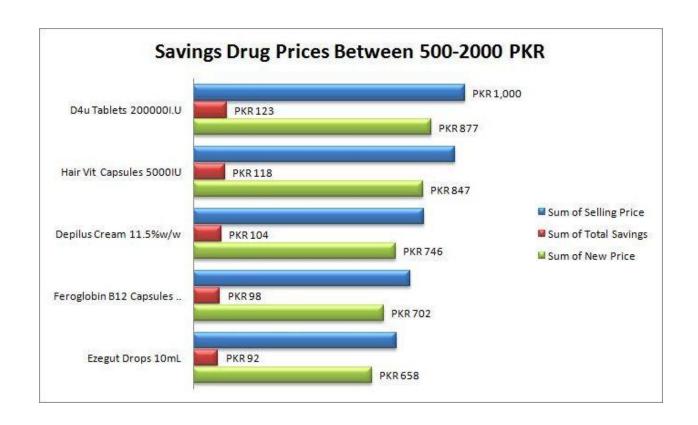


Figure 5.9. Drug Prices Between 50-500 PKR (Total Savings)

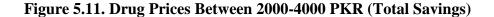
As discussed above, by reducing the half amount of fixed mark ups, one can save smart amount of money from medicines. lets take Flixotide inhaler as example, by cutting the profit margin of 3 component to half, comsumer can save Rs. 49 from a single drug. This drug falls under 500 Rs category.

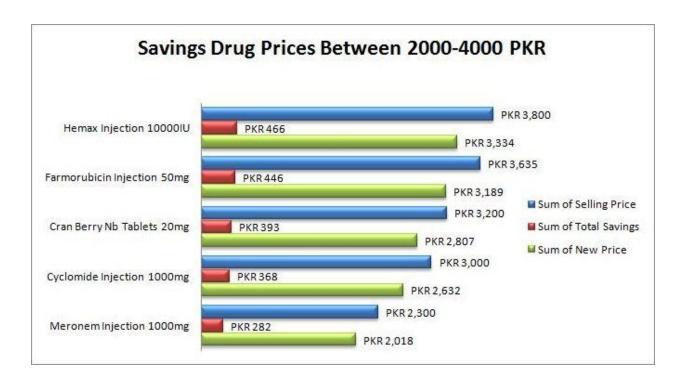
## 5.10. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 500-2000 PKR.

Figure 5.10. Drug Prices Between 500-2000 PKR (Total Savings)



5.11. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges between 2000-4000 PKR.





## 5.12. Impact on Total Savings of Reduced fixed distributor, retailer and salesman salaries on drug prices ranges Above 400 PKR.





The above figure is very alarming for policy makers. If we reduce the mark up of three components to half, one can save Rs. 5365 on Vonaz injection 200 mg, injection which is used to treat variety of fungal infection .The present price of injection in market is Rs. 43730. The new price will become Rs. 38364.

### **5.13. Summary**

Following is the summary of the findings;

- when we apply the fixed mar-up profits on costly drugs, the margin of profits increases many folds and cause poor consumers in extreme trouble and ultimately drugs becomes unreachable from their access.
- The reason behind implementation of fixed mark ups is that this strategy is technically less complex to implement than other policy options as it requires relatively limited information about cost of goods and the supply chain, and some enforcement capacity.
- The regressive mark-up strategy is made in countries such as "Tunisia, Syria and Labanon". This leads to improved outcomes than fixed profit mark ups during their influence lying on financial incentives. Though, fixed markups can significantly increase the value of otherwise less cost medicines.
- ➤ Take Vonaz injection 200 mg as example, a anti-fungal agent and used for the treatment of fungal infections of lungs, mouth and throat. The selling price of this drug in market is 43, 730 PKR. if we calculate the profits of only 4 components discussed in table, the total profit on a single product becomes 20, 312 PKR. This is a huge amount of profit on a single drug for the third world countries like Pakistan. These drugs are usually produced in a batches, means thousands of injections produced at once, this reduces the production cost, salesman salaries and other costs.
- > By reducing the small amount of fixed mark-up, one can reduce the drug prices and make it affordable for the end consumers.

### Chapter 06

## **Conclusions and Policy Recommendations**

#### **6.1. Conclusion:**

According to W.H.O. findings, "life saving drugs in Pakistan are four to twelve times expensive than in India "because of failure of develop indigenous basic raw materials manufacturing base. Findings from both qualitative and quantitative study reveals that current Drug Pricing Policy, 2015 needs revision.

As per our knowledge, this is the first research to examine the impact of fixed markups and transfer pricing on Drug Prices of Pakistan.

We have observed that, Pharmaceutical companies are providing drugs to market at high prices than those by which the identical medicines were offered to hospitals thus making huge profit, at the cost of immense burden on the consumers.

Also implication of transfer pricing is that not only the multinationals are able to make enormous remittance abroad but also manage to get higher prices in respect of dosage forms based on the over-priced raw materials.

There is a huge difference in prices of drugs offered by the pharmaceutical companies to the hospitals and other institutions which highlights the importance of profits management which needs to be fixed keeping in view the prices offered to hospitals, bonuses, discounts and the pricing data supplied by the firms and their audit reports.

The profitability of pharmaceuticals manufacturers can be seen through this example, "As Abbott pharmaceuticals use preferential pricing structure for their products through which African and least developed countries obtain lowest price of \$500 per patient per year, low income and lower middle income countries at \$1000 per patient per year and remaining countries get the regular price". Many multinational pharmaceutical companies now changing their prices in developing to better replicate each markets capacity to pay. For example, "Merck pharmaceuticals launched Januvia®, a drug used in type2 diabetes in India at a price less than US\$ 1 a pill, which is approximately a fifth of its price in the US market. For this, Merck consulted 350 Indian doctors and patients in deciding an India specific price and which so far has been successful in its differential pricing strategy for this particular drug"

The comparison of drug prices among countries is a complicated procedure because the medicine habitually sold in another countries in diverse strengths, pack sizes and even in various mode of administration with different tariffs, taxes and markups for public and private health care system. The solely relying on external price reference with low income countries don't make it inexpensive as further measures are essential such as the number of days the country's lowest paid worker work to pay for the medicine. A measured used in studies conducted by "HAI and WHO".

It would be instructive here to quote Article 38(a) and (d) of the Constitution of Pakistan which says: "The state shall secure the well being of the people, irrespective of sex, caste, creed and race, provide basic necessities of life such as medical relief for all such citizens as are permanently or temporarily unable to earn their livelihood on account of infirmity, sickness or unemployment".

Is the government fulfilling its constitutional obligation? It is true that drug all over the world including the US, have registered a sharp increase. But in Pakistan many additional factors, including ruthless manipulation by market forces, have further complicated things.

Until our government policies do not give better health care facilities, the consumer specially poor will remain vulnerable to poor health because most of them being poor cannot afford high price medicines.

### **6.2. Policy Recommendations:**

In this section, the policy points are written based on the findings of qualitative and quantitative study. The main recommendations are listed below;

- Government of Pakistan should consider using "Regressive mark-ups" (lower mark-up for higher priced products) rather than fixed mark-ups.
- Government of Pakistan should consider exempting 'Essential Medicines' (EM) from taxation.
- Government should make sure any tax reductions otherwise exemptions which result
  in lowered price of medicines to patient/purchaser.
- Government should consider or select comparator countries to use for External
  Reference Pricing (ERP) that must be based one economic status, pharmaceutical
  pricing system in place, the publication of actual versus negotiated or concealed
  prices, exact comparator products supplied, and similar burden of disease.

- Government should formulate their "pricing policies, processes and decisions transparent". If the development and production costs for particular medicines are publically known, patients and the public can more readily identify the most egregious examples of price grouping and demand action. The disclosures can also have a direct effect on drug manufacturers behaviors as manufacturers may avoid pricing drugs at costs what would trigger disclosure requirements.
- Government should implement such policies that support the use of quality guaranteed generic medicines and indigenous manufacturing of raw materials in order to increase access and affordability.
- Government should work in partnership to promote exchange of information about polices, their impacts and pharmaceutical prices.
- Government should develop the infrastructure and expertise required for basic drug manufacturing. It should ensure local production of drugs whose patents have run out to lower the prices if lifesaving products.
- Government should start comprehensive national drug research programme that jointly developed by the universities and research institutes active in this field according to national health priorities to ensure coordination and collaboration in drug research. Incentives e,g, prizes shall be provided for encouraging researchers.

### **6.3.**Potential Beneficiaries and Policy Implementation:

The beneficiaries of this research at national level are political leaders. At second, the beneficiaries are managers and policy makers in the health and population sectors in a country who require evidence and answers for policy change. The other beneficiaries include civil society, non-government organization and international community who are concerned about the non existence of any social health protection for the people of Pakistan as majority of the medicines are purchased by the people from the pharmacies directly, making medicines the largest household expenditure after food. It results in catastrophe due to high cost medicines. This study is first step in this direction and can fill a void in knowledge among policy makers regarding economic insight, importance, issues and needs of drug policy and its load on government exchequer.

### Chapter 07

### **Definitions**

#### 1) Cost-plus Pricing

Adding a standard markup to the cost of the product.

#### 2) Break-even Pricing (target profit pricing)

Setting price to break even on the costs of making and marketing a product or setting price to make a target profit.

#### 3) Value-based Pricing

Setting price based on buyers' perceptions of value rather than on the seller's cost.

#### 4) Value Pricing

Offering just the right combination of quality and good service at a fair price.

#### 5) Competition-based Pricing

Setting prices based on the price that competitors charge for similar products.

#### 6) Market-skimming Pricing

Setting a high price for a new product to skin maximum revenues layer by layer from the segments willing to pay the high price; the company makes fewer but more profitable sales. (Chew, et al., 2000)

#### 7) Market-penetration Pricing

Setting a low price for a new product to attract many buyers and a large market share.

#### 8) Product Line Pricing

Setting the price steps between various products in a product line based on cost differences between the products, customer evaluations of different features, and competitors' prices. (Cockburn & Pit, 1997)

#### 9) Optional-products Pricing

The pricing of optional or accessory products along with a main product.

#### 10) Discount and Allowance Pricing

- A) Cash Discount: A price reduction to buyers who pay their bills promptly.
- **B)** Quantity Discount: A price reduction to buyers who buy large volumes.

#### 11) Segmented Pricing

Selling a product or service at two or more prices, where the difference in prices is not based on differences in costs.(Ahmed & Saeeed, Ethical and non ethical Pharmaceutical marketing practices: Case study of Karachi city., 2002)

#### 12) Psychological Pricing

A pricing approach that considers the psychology of prices and not simply the economics; the price is used to say something about the product.

#### 13) Reference Prices

Prices that buyers carry in their minds and refer to when they look at a given product.

#### **14)** Promotional Pricing

Temporarily pricing products below the list price, and sometimes even below cost, to increase short-run sales.(Duffy & Clark, 2003).

#### 15) Drug Price Reference Index (DPRI)

The DPRI lists the ceiling prices of essential medicines for government bidding and procurement set by the DOH for all National and Local Government Health Facilities and Government Agencies. The DPRI only reflects the acquisition costs including landed cost, packaging, drug content, quality assurance, manufacturing overheads and Food and Drug Administration (FDA) fees. The DPRI excludes other costs such as pharmacy services,

preparation and storage fees, and other reasonable pharmacy mark-ups, which are now being evaluated by the DOH.

#### 16) Universal Health Care:

Universal health care is a system that provides quality medical services to all citizens. The federal government offers it to everyone regardless of their ability to pay.

#### 17) TARIFF

A schedule of duties imposed by a government on imported or in some countries exported goods.

#### 18) Taxation

Taxation is the process by which the government collects money from people to use for government purposes.

#### **19)** Cost

An amount that has to be paid or given up in order to get something. In business, cost is usually a monetary valuation of (1) effort, (2) material, (3) resources, (4) time and utilities consumed, 95) risks incurred, and (6) opportunity forgone in production and delivery of a good or service. All expenses are costs, but not all costs ( such as those incurred in acquisition if an incomegenerating asset) are expenses.

#### 20) Excise Duty:

An excise or excise tax (sometimes called an excise duty) is a type of tax charged on goods produced within the country (as opposed to customs duties, charged on goods from outside the country). It is a tax on the production or sale of a good.

#### 21) Value Added Tax (VAT):

Value added tax or VAT is an indirect tax, which is imposed on goods and services at each stage of production, starting from raw materials to final product. VAT is levied on the value additions at different stages of production.

#### 22) Reimbursement:

The action of repaying a person who has spent or lost money.

#### 23) Semi-Structured Interview:

The semi-structured interview is a qualitative data collection strategy in which the researcher asks informants a series of predetermined but open-ended questions.

### **References**

(2018, 01 25). Retrieved from https://propakistani.pk: https://propakistani.pk/2018/01/25/govt-increases-prices-life-saving-drugs/

Aaserud, M. (2006). Pharmaceutical policies: effects of refernce pricing, other pricing, and purchasing policies. *Cochrane Database of Systematic Review*, (2).

Ahmed, R., & Saeeed, A. (2002). Ethical and non ethical Pharmaceutical marketing practices: Case study of Karachi city. *Interdisciplinary journal of Contemporary Research Business.*, 3(11): 456-475.

Al-Gedadi, N. (2008). A pilot survey on perceptions and knowledge of generics medicines among consumers in Penang, Malaysia. *Pharmacy Practice*, 6(2): 93-97.

Anis, A., & Gagnon, Y. (2000). Using economic evaluations to make formulary coverage decisions. So much for guidelines. *PharmacoEconomics*, 18(1): 55-62.

Bertoldi, A. (2005). Generic drugs in Brazil: known by many, used by few. *Cadernos de Saude Publica*, 21(6):1808-1815.

Chew, I., D, M., O'Young, T., Thomas, K., hazlet, K., Bradley, et al. (2000). A physican Survey of the Effect of Drug Sample Availability on Physicians' Behavior. *J gen Inern Med*, 15:478-483.

Cockburn, J., & Pit, S. (1997). Precribing Behaviour in clinical practice: patients' expectations and doctors preceptions of patients. 315-520.

Cresswell, J. W., & Plano Clark, V. L. (2007). Designing and conducting mixed methods research. Thousand Oaks. *Sage* .

Dowell, J. (1995). Chaning to generic formulary: how one fundholding practice reduced prescribing costs. *British Medical Journal*, 310(6978): 505-508.

Duffy, C., & Clark, M. (2003). Who receives free sample medications? *Journal of General Internal Medicine*, 18:205.

Garcia, M. B. (2011). External referencing and pharmaceutical price negotiation. Health Economics.

Hakonsen, H. (2009). Price control as a strategy for pharmaceutical cost containment- what have been acheived in norway in the period 1994-2004? *Health Policy*.

King, D., & kanavos, P. (2002). Encouraging the use of generic medicines: implications for transition economies. *Croatian Medical Journal*, 28(8): 649-663.

Kola, I., & Landis, J. (2004). Can the pharmaceutical Industry Reduce Attrition Rates? *Nature Review Drug Discovery* .

Sturm H, et al. Pharmaceutical Policies: effects of financial incentives for prescribers. Cochrane Database of Systematic Reviews. 2007 [ Pub Med : 1736851]

Creese A. Working paper 5: Sales taxes on medicines - review series on pharmaceutical pricing policies and interventions. Geneva: world Organization and Health Action International; 2011.

Measuring medicines prices, availability, affordability, and price components: survey reports. Geneva: World Health Organization and Health Action International; [October 2012].

Patouillard E, et al. Retail sector distribution chains for malaria treatment in the developing world: a review of the literature. Malaria Journal. 2010;9;50.

Yu X, et al. Pharmaceutical supply chain in China: current issues and implications for health system reform. Health Policy. 2010;97 (1): 8-15. [ Pub Med : 20307912]

Carasso BS, et al. Availability of essential medicines in Ethopia: an efficiency -equity trade off? Tropical Medicines and International Health. 2009;14(11): 1394-1400.

Levison L, Kimatu S. Price components and essential medicines in Nairobi, Keneya: report to WHO. 2008.

Guimier JM, et al. Why drug prices are high in sub-Saharan Africa. Analysis of price structure: the case of Senegal. Cashiers d'etudes er de recherches francophones/Sante 2005;15 (1): 41-52. [ Pub Med : 15919632]

Mohammad GK. Mark up percentages for drug revolving funds. Feb 27, 2006. [October 2010]. E-Drug discussion forum message.

Battersby A, et al. Improving the supply, distribution and use of anti microbial drugs by the private sector in Tanzania. London: Malaria Consortium; 2003.

Coughlan R, Auton M, Maija A. Supply chain and price components of antimicrobial medicines: Uganda 2007. Geneva: Medicines for Malaria Venture; 2008.

Caves R. et al. Patent expiration, entry and competition in the U.S. pharmaceutical industry. Brookings Papers: Microeconomics, 1991.

Penvick N. Do pharmaceutical prices respond to potential patient out-of-pocket expenses? Rand J Econ. 2002; 33 (3): 469-487. [ Pub Med : 12585303]

Bardey D, et al. Retail price regulation and innovation: reference pricing in the pharmaceutical industry. Journal of Health Economics. 2010; 29(2): 303-316.

Puig -Junoy J, Moreno- Torres I. Do generic firms and the spanish public purchaser respond to consumer price difference of generics under reference pricing? Health Policy. 2010; 98 (2-3): 186-194.

Mendis, S., Fukino, K., Cameron, A., Laing, R., Filipe, J., Khatib, O., et al. (2007). The availability and affordability of selected essential medicines for chronic diseases in the six low and middle income countries. *WHO*.

Naryan, S. (2007). Price controls on pharmaceutical products in India. Institutte of South Asian Studies.

(2005). OECD Health Data.

OECD. (2008). Pharmaceutical pricing policy in a Global Market. Corrigenda.

Olcay, M., & Laing, R. (2005). Pharmaceutical tarrifs: what is their effect on prices, protection of local industry and revenue generation? *WHO* .

(2012). Pharaceutical pricing policy. Management sciences for Health.

Pollack, A. (2002). Despite Billions for Discoveries, Pipeline of Drugs is Far from Full. The New York Times.

Richter, A. (2008). Assessing the impact of global price interdependcies . PharmacoEconomics .

S. Lee, K., Shahidullah, A., T.R. Zaidi, S., P.Patel, R., C.Ming, L., H.Tariq, M., et al. (2017). The crux of the medicine prices' controversy in Pakitan. *Frontiers in Pharmacology*.

Simoens, S. (2005). Pharmaceutical policy regarding geenric drugs in Belgium. *PharmacoEconomics*, 23(8): 755-766.

Snell, B. (2003, 01 09). www.essentialdrugs.com/edrug. Retrieved from www.essentialdrugs.com: www.essentialdrugs.com/edrug

Stargardt, T., & Schreyogg, J. (2006). Impact of cross-reference pricing on pharmaceutical prices:manufacturers' pricing strategies and price regulation. *Applied Health Economics and Health Policy.*, 5(4): 235-247.

Valles, J. (2002). Acceptance of generic prescribing in general practice: effect of patient education and refernce prices. *Gaceta Sanitaria*, 16(6): 505-510.

Yadav, P. (2010). *Differential pricing for pharmaceuticals*. U.K department for International Development (DFID).

Zaidi, S. B., M, A., & A, R. (2013). Access to essential medicines in Pakistan: policy and health system research concerns.

## **Appendices**

## 1.1. Domestic tax rates on medicines in selected low- and middle-income countries ( Appendix - I)

<b>Country and survey</b>	VAT or sales tax	Other taxes on	Total
year	VIII of sales tax	medicines	domestic tax
Armenia, 2001a	20%	20%	
Plurinational State of Bolivia, 2008	13%	13%	
Brazil, 2001a	18%	6% state tax	24%
Chad 2004	2% statistical tax  (public & private sectors), 0.9%  purchase verification tax (private sector)	2.9%	
China, 2004 & 2006	17%	3% regional sales tax	20%
Congo, 2007	18% (unclear whether medicines exempt)	1% community tax	19%
Democratic Republic of the Congo, 2007	0%	17% turnover + other taxes	17%
El Salvador, 2006	13%	13%	

	15% + national health		
Ghana, 2004		15%	
	insurance levy		
	Was 6.5–9.8% sales		
	vv as 0.3-7.0% sales	5–16% state excise	
	tax,		
India 2002 0 2004	overently 50/ MAT -	duty	12 240/
India, 2003 & 2004	currently 5% VAT on	3% national education	13–24%
	most		
	di ain aa	"cess"	
	medicines		
Indonesia, 2004	10%	10%	
Lordon 2007	40/ soles to:	40/	
Jordan, 2007	4% sales tax	4%	
Kyrgyzstan, 2005	4% sales tax	4%	
Mal: 2004	00/ towas and face	00/	
Mali, 2004	8% taxes and fees	8%	
		6% stamp duty and	
Mongolia, 2004	15%	other fees	21%
		outer rees	
Morocco, 2004	7% (some exemptions)	7%	
	"Multiple tax regimes"		
	winniple tax regimes		
Nigeria, 2004	>30% other	30%	
	fees		
	1005		
		19% goods &	
	12% (some	services tax + 2%	
Peru, 2005		SOLVICOS tax   2/0	34%
	exceptions)	local	
		tax, some exemptions	
		_	
Philippines, 2008	12%	12%	
South Africa, 2004	14%	14%	
2001	/ •	/ •	

Tajikistan, 2005	20%	1–5% sales tax	21–25%
Tunisia, 2004	6% (locally made)	6%	
Yemen, 2006	5%	5%	
	Approximate		
	average =		
All 23 countries	14.8%		
	Range = 2.9-		
	34%		

a Data from Levison L, Laing R. The hidden costs of essential medicines. *Essential Drugs Monitor*. 2003, (33):20–21.

Source: Creese A. Working paper 5: Sales taxes on medicines – review series on pharmaceutical pricing policies and interventions. Geneva, World Health Organization and Health Action International, 2011.

# 1.2. General Framework/Typology of Reasons for Designing and Conducting Mixed Methods Research: Adapted from Bryman (2006). (Appendix- II)

Component	Reasons
1. Triangulation or greater	Refers to the traditional view that quantitative and qualitative
validity	research might be combined to triangulate findings in order
	that they may be mutually corroborated.
2. Offset	Refers to the suggestion that the research methods associated
	with both qualitative and quantitative research have their

	own strengths and weakness so that combining them allows
	the researcher to offset their weakness to draw on the
	strengths of both.
3. Completeness	Refers to the notion that the researcher can bring together a
	more comprehensive account of the area of inquiry in which
	he or she is interested if both quantitative and qualitative
	research are employed.
4. Process	Refers to when quantitative research provide an account of
	structures in social life but qualitative research provides
	sense of process.
5.Different Research Questions	Refers to the argument that quantitative and qualitative
	research can each answer different research questions.
6. Explanation	Refers to when one used to help explain findings generated
	by the other.
7. Unexpected results	Refers to the suggestion that quantitative and qualitative
	research can be fruitfully combined when one generates
	suprising results that can be understood by employing the
	other.
8. Instrument development	Refers to contexts in which qualitative research is employed
	to develop questionnaire and scale items, for example, so that
	better wording or more comprehensive closed answers can be
	generated.
9. Sampling	Refers to situations in which one approach is used to

	facilitate the sampling of respondents or cases.
10. Credibility	Refers to suggestions that employing both approaches
	enhances the integrity of findings.
11. Context	Refers to cases in which the combination is rationalized in
	terms of qualitative research providing contextual
	understanding coupled with either generalizable, extremely
	valid findings or broad relationships among variables
	uncovered through a survey.
12. Illustration	Refers to the use of qualitative data to illustrate quantitative
	findings, often referred to as putting 'meat on the bones' of
	'dry' quantitative findings.
13.Utility of improving the	Refers to a suggestion, which is more likely to the prominent
usefulness of findings	among articles with an applies focus, that combing the two
	approaches will be more useful to practitioners and others.
14. Confirm and discover	Refers to using qualitative data to generate hypothesis and
	using quantitative research to test them within a single
	project.
15. Diversity of views	Includes two slightly different rationales, namely, combining
	researchers and participants perspectives through quantitative
	and qualitative research respectively and uncovering
	relationships between variables through quantitative research
	while also revealing meaning among research participants
	through qualitative research.

16. Enhancement or building	Entails a reference to making more of or augmenting either
upon quantitative and qualitative	quantitative or qualitative findings by gathering data using a
findings	qualitative or quantitative research approach.

## 1.3. Characteristics to consider in developing a Questionnaire : ( Appendix-III)

Following are the characteristics which are kept in mind in developing a questionnaire.

1	Overall health care system	organization with private actors publicly funded
		organization with private actors privately funded
		• public organization and funding of health care system
2	Primary 'payer'	social health insurance
		• public sector
		• consumers/private households (i.e. direct payment)
		private actuarial insurance
		• government (via finance or taxation)
		• enterprises
3	Regulatory agency	no regulatory agency
		regulatory agency with limited capacity
		stringent regulatory authority
4	Pharmaceutical sector	unregulated with little scope for regulation within
		political environment

		• unregulated but regulation feasible within the political	
		environment	
		• regulated	
5	Pharmaceutical market	primarily locally manufactured medicines	
		primarily imported medicines	
		• mixed – local and imported medicines	
		role of generic medicines in market	
		local research and development	
6	Supply chain and	number and nature of suppliers, wholesalers, and	
	procurement	retailers	
7	Legal enforcement	limited capacity to enforce regulations	
		capacity to enforce regulations	
8	Type of product	on-patent versus off-patent	
		• single-source versus multisource	
		• high-cost	
		• reimbursed	
		essential versus non-essential	
		prescription versus over-the-counter	
9	Sector	• public	
		• private	
		• other	
		• all	
10	Patient contribution	• co-payment	

	• co-sharing

### 1.4. SCHEDULED DRUGS (Appendix- IV)

The following categories of drugs shall fall in the list of scheduled drugs:

- (i) Biologicals, infusions and drugs used for the treatment of Cancer, T.B., Hepatitis, HIV, Thalassamia and Organ Transplant.
- (ii) 160 molecules of public health significance from the Essential Drug List (EDL) of Drug Regulatory Authority of Pakistan.
- (iii) Top 50 molecules in unit terms as per Information Medical Statistics (IMS).
- (iv) New Chemical Entities (NCEs).

The following molecules have been found falling in the above categories of scheduled drugs and all drugs containing a molecule listed in the schedule, either individually or in combination with other non schedule drugs will be deemed to be included in the list of scheduled drugs. Top 50 molecules have been taken from IMS 2Q-2014 data. The list is not exhaustive and is subject to inclusion or exclusion as may be decided by the Policy Board.

S.No.	Molecule	Therapeutic use / Indication
1.	Abacavir	HIV Treatment
2.	Abiciximab	Biologicals / Cancer Treatment
3.	Acetazolamide	Anti-Hypertensive

4.	Acetylcysteine	Endocrine drug
5.	Acetylsalicylic acid	Pain Killer
6.	Actinomycin D	Cancer Treatment
7.	Acyclovir	HIV Treatment
8.	Albendazole	Anti-worms
9.	Alcuronium	Muscle relaxant
10.	Allopurinol	Anti-Gout/Joint pain
11.	Alprazolam	Anti-anxiety

12.	Amifostine	Cancer Treatment
13.	Amikacin	Antibiotic
14.	Amiloride	Anti-Hypertensive
15.	Amino Acid Infusions	Infusion
16.	Aminophylline	Anti-asthma
17.	Amitriptyline	Anti-depressant
18.	Amlodipine	Anti-Hypertensive
19.	Amodiaquine	Anti-malarial
20.	Amoxicillin	Anti-biotic
21.	Amoxicillin + clavulanic acid	Anti-biotic
22.	Amphotericin-B	Anti-biotic
23.	Ampicillin	Anti-biotic
24.	Anastrozole	Cancer Treatment
25.	Anti hepatitis b immunoglobulin	Biological Drug

26.	Anti-D immunoglobulin (human)	Biological Drug
27.	Antitetanus immunoglobulin (human)	Biological Drug
28.	Antivenom immunoglobulin	Biological Drug
29.	Artemether + lumefantrine	Anti-malarial
30.	Artesunate	Anti-malarial
31.	Asparaginase	Cancer Treatment
32.	Atenolol	Anti-Hypertensive
33.	Atorvastatin	Anti-Cholesterol
34.	Atropine	Used in various eye operations
35.	Azathioprine	For organ transplant
36.	Basiliximab	Biologicals / Cancer Treatment
37.	BCG Oncotice	Cancer Treatment
38.	BCG vaccine	Biological Drug
39.	Beclometasone	Steroid
40.	Benzoyl peroxide	Anti-septic /anti-itching
41.	Benzyl benzoate	Anti-scabies
42.	Beractant	Biological
43.	Betamethasone	Steroid
44.	Bevacizumab	Biologicals / Cancer Treatment

45.	Bicalutamide	Cancer Treatment
46.	Bisoprolol	Anti-hypertensive
47.	Bleomycin	Cancer Treatment

48.	Bromazepam	Anti-anxiety
49.	Bupivacaine	Anaesthesia
50.	Busulfan	Cancer Treatment
51.	Calcium folinate	Cancer Treatment
52.	Capecitabine	Cancer Treatment
53.	Capreomycin	Anti-biotic
54.	Carbamazepine	Anti-Epileptic
55.	Carboplatin	Cancer Treatment
56.	Cefazolin	Anti-biotic
57.	Cefixime	Anti-biotic
58.	Cefotaxime	Antibiotic
59.	Ceftazidime	Anti-biotic
60.	Ceftriaxone	Anti-biotic
61.	Cephalexin	Anti-biotic
62.	Cephradine	Anti-biotic
63.	Cetirizine	Anti-allergic
64.	Cetuximab	Cancer Treatment
65.	Chlorambucil	Cancer Treatment
66.	Chloramphenicol	Anti-biotic
67.	Chloroquine	Anti-malarial
68.	Cholera vaccines	Biological Drug
69.	Ciclosporin	For organ transplant
70.	Ciprofloxacin	Anti-biotic

71.	Cisplatin	Cancer Treatment
72.	Clarithromycin	Anti-biotic
73.	Clindamycin	Anti-biotic
74.	Clobetasole	Anti-biotic
75.	Clofazimine	Anti-biotic
76.	Clomifene	Anti-fertility
77.	Clomipramine	Anti-depression
78.	Clotrimazole	Anti-biotic /Antifungal

79.	Cloxacillin	Anti-biotic
80.	Codeine	Used as pain killer
81.	Cyclophosphamide	Cancer Treatment
82.	Cyproterone	Cancer Treatment
83.	Cytarabine	Cancer Treatment
84.	Dacarbazine	Cancer Treatment
85.	Dactinomycin	Cancer Treatment
86.	Dasatinib	Biologicals / Cancer Treatment
87.	Daunorubicin	Cancer Treatment
88.	Deferoxamine	Anti-poisoning
89.	Dexamethasone	Steroid
90.	Diazepam	Anti-anxiety
91.	Diclofenac	Pain Killer
92.	Didanosine	HIV Treatment

93.	Dimercaprol	Anti-poisoning
94.	Dipatheria-tetanus vaccine	Biological Drug
95.	Diphtheria antitoxin	Biological Drug
96.	Diptheria-pertussis tetanus vaccine	Biological Drug
97.	D-methionine	Amino acid
98.	Dobutamine	Anti-Hypertensive
99.	Docetaxel	Cancer Treatment
100.	Domperidone	Anti-vomiting
101.	Dopamine	Anti-Hypertensive
102.	Doxorubicin	Cancer Treatment
103.	Doxycycline	Anti-biotic
104.	Efavirenz	HIV Treatment
105.	Emtricitabine	HIV Treatment
106.	Enalapril	Hypertension
107.	Ephedrine	Used in anaphylactic shock
		Used in anaphylactic shock to
108.	Epinephrine (adrenaline)	improve breathing, respiration
		and blood pressure.
109.	Epirubicin	Cancer Treatment
110.	Eptifibatide	Biological

111.	Ergometrine	Anti-migraine
112.	Erlotinib	Biologicals / Cancer Treatment

113.	Erythromycin	Anti-biotic
114.	Erythropoiten (Alfa & Beta)	Biological
115.	Esomeprazole	Anti-Ulcer
116.	Etanecept	Biological
117.	Ethambutol	Treatment of T.B
118.	Ethionamide	Treatment of T.B
119.	Etoposide	Cancer Treatment
120.	Exemastine	Cancer Treatment
121.	Exenatide	Biological
122.	Factor ix complex (coagulation factors, ii, vii,	Biological Drug
	ix, x) concentrate	
123.	Factor viii concentrate	Biological Drug
124.	Famotidine	Anti-Ulcer
125.	Filgrastim	Biologicals
126.	Flu vaccines	Biological Drug
127.	Flubiprofen	Pain killer
128.	Fluconazole	Anti-biotic
129.	Flucytosine	Anti-fungal
130.	Fludarabine	Cancer Treatment
131.	Fluorouracil	Cancer Treatment
132.	Fluoxetine	Anti-Depression
133.	Flutamide	Cancer Treatment
134.	Folic Acid	Vitamin moiety

135.	Folinic acid	Cancer Treatment
136.	Follicle Stimulating Hormone	Hormone
137.	Furosemide	Anti-Hypertensive
138.	Gefitinib	Cancer Treatment
139.	Gemcitabine	Cancer Treatment
140.	Gentamicin	Anti-biotic
141.	Glibenclamide	Anti-Diabetes
142.	Glimepiride	Anti-diabetes
143.	Glucose	Infusion

144.	Goserelin	Cancer Treatment
145.	Griseofulvin	Anti-biotic
146.	Haemophilus Influenzae type b vaccine	Biological Drug
147.	Halothane	Anaesthesia
148.	Heparin sodium	Blood thinning agent
149.	Hepatitis A vaccine	Biological Drug
150.	Hepatitis B vaccine	Biological Drug
151.	Human normal immunoglobulin	Biological Drug
152.	Human Chorionic Gonadotropin Hormone	Hormone
153.	Human Menopausal Gonadotropin Hormone	Hormone
154.	Hydralazine	Anti-Hypertensive
155.	Hydrochlorothiazide	Anti-Hypertensive
156.	Hydrocortisone	Steroid

157.	Ibuprofen	Pain Killer
158.	Idarubicin	Cancer Treatment
159.	Ifosfamide	Cancer Treatment
160.	Imatinib	Cancer Treatment
161.	Imipenem + cilastatin	Anti-biotic
162.	Indinavir	HIV Treatment
163.	Infliximab	Biologicals / Cancer Treatment
164.	Insulin (all types)	Biological Drug
165.	Insulin analogues (all types)	Biological Drug
166.	Interferons (all types)	Hepatitis C treament
167.	Interleukin (all types)	Anti-cancer
168.	Intraperitoneal dialysis solution (of appropriate composition)	Used for dialysis
169.	Ipratropium bromide	Anti-asthma
170.	Irinotecan	Cancer Treatment
171.	Isoniazid	Treatment of T.B
172.	Isosorbide dinitrate	Anti-Hypertensive
173.	Ivermectin	Anti-worms
174.	Kanamycin	Anti-biotic
175	.Ketamine	Anaesthesia
176.	Lactulose	Anti-flatulence

177.	Lamivudine	HIV Treatment

178.	Lapatinib	Biologicals / Cancer Treatment
179.	Letrozole	Cancer Treatment
180.	Leuprorelin	Biologicals / Cancer Treatment
181.	Levamisole	Anti-worms
182.	Levodopa + carbidopa	Anti-parkinsonism
183.	Levofloxacin	Anti-biotic
184.	Levothyroxine	Thyroid drug
185.	Lidocaine	Anaesthesia
186.	Lincomycin	Anti-biotic
187.	Liraglutide	Biological
188.	Lopinavir	HIV Treatment
189.	Loratadine	Anti-allergic
190.	Mannitol	Infusion
191.	Measles vaccine	Biological Drug
192.	Measles-mumps-rubella vaccine	Biological Drug
193.	Mebendazole	Anti-worms
194.	Mecobalamin	Vitamin
195.	Mefenamic acid	Pain killer
196.	Mefloquine	Anti-malarial
197.	Melphalan	Cancer Treatment
198.	Meningococcal vaccine	Biological Drug
199.	Mercaptopurine	Cancer Treatment
200.	Metformin	Anti-Diabetes

201.	Methadone	Pain killer
202.	Methotrexate	Cancer Treatment
203.	Methyldopa	Anti-Hypertensive
204.	Metoclopramide	Anti-vomiting
205.	Metronidazole	Anti-biotic
206.	Mintomycin	Cancer Treatment
207.	Mitozantrone	Cancer Treatment
208.	Montelukast	Anti-asthma
209.	Morphine	Used as analgesic /pain killer
		drug in severe pain conditions.

210.	Mycophenolate	Cancer Treatment
211.	Nalidixic acid	Anti-biotic
212.	Naloxone	Anti-poisoning
213.	Nelfinavir	HIV Treatment
214.	Neostigmine	Endocrine drug
215.	Nevirapine	HIV Treatment
216.	Niclosamide	Anti-worms
217.	Nifedipine	Anti-Hypertensive
218.	Nilotinib	Biologicals / Cancer Treatment
219.	Nimesulide	Pain Killer
220.	Nitrofurantoin	Anit-infective
221.	Nystatin	Anti-biotic

222.	Octreotide	Cancer Treatment
223.	Ofloxacin	Anti-biotic
224.	Omalizumab	Biologicals / Cancer Treatment
225.	Omeprazole	Anti-ulcer
226.	Oseltamivir	HIV Treatment
227.	Oxaliplatin	Cancer Treatment
228.	Paclitaxel	Cancer Treatment
229.	Papiloma Virus Vaccine	Biological Drug
230.	Paracetamol	Pain Killer
231.	Pazopanib	Biologicals / Cancer Treatment
232.	Pegaptanib	Biologicals / Cancer Treatment
233.	Pemetrexed	Cancer Treatment
234.	Pentavalent vaccines	Biological Drug
235.	Permethrin	Anti-Scabies
236.	Pethidine	Used as analgesic /pain killer
230.	T cumume	drug in severe pain conditions.
237.	Phenobarbital	Anti-epileptic
238.	Phenoxymethylpenicillin	Anti-biotic
239.	Phenytoin	Anti-Epileptic
240.	Phytomenadione	Vitamin-K
241.	Picosulfuric Acid	Anti-constipative
242.	Pilocarpine	Eye diseases

243.	Pirarubicin	Cancer Treatment
244.	Pneumococcal vaccine	Biological Drug
245.	Poliomyelitis vaccine	Biological Drug
246.	Potassium chloride	Infusion
247.	Povidone Iodine	Anti-septic
248.	Primaquine	Anti-malarial
249	.Procainamide	Anaesthesia
250.	Procaine benzylpenicillin	Anti-biotic
251.	Procarbazine	Cancer Treatment
252.	Procyclidine	Endocrine drug
253.	Proguanil	Anti-malarial
254.	Promethazine	Anti-Allergic
255.	Propranolol	Anti-Hypertensive
256.	Propylthiouracil	Cancer Treatment
	Pulmonary surfactant of natural origin 80.0mg	
257.	(corresponding to approx. 74.0 of total	Biological
	phospholipids / Poractant (Curosurf)	
258.	Pyrazinamide	Treatment of T.B
259	.Pyridostigmine	Endocrine drug
260.	Pyrimethamine	Anti-malarial
261.	Quinidine	Anti-malarial
262.	Quinine	Anti-malarial
263.	Rabies immunoglobulin	Biological Drug

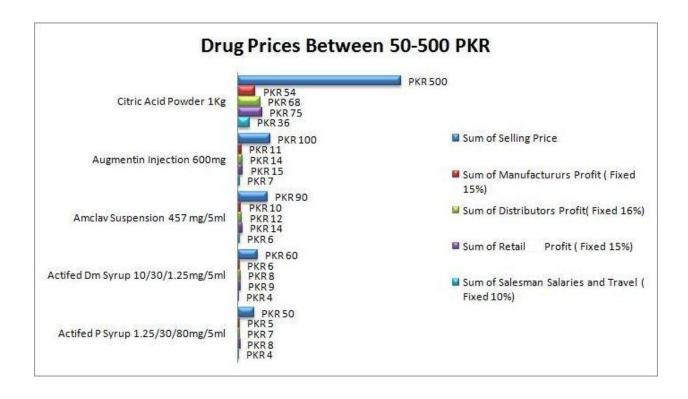
264.	Rabies vaccine	Biological Drug
265.	Ranibizumab	Biologicals / Cancer Treatment
266.	Ranitidine	Anti-ulcer
267.	Reteplase	Heart Attack
268.	Ribavirin	Antibiotic/Antiviral
269.	Rifampicin	Treatment of T.B
270.	Risperidone	Anti-Psychotic
271.	Ritonavir	HIV Treatment
272.	Rituximab	Cancer Treatment
273.	Rosuvustatin	Anti-Cholesterol
274.	Rota virus vaccine	Biological Drug

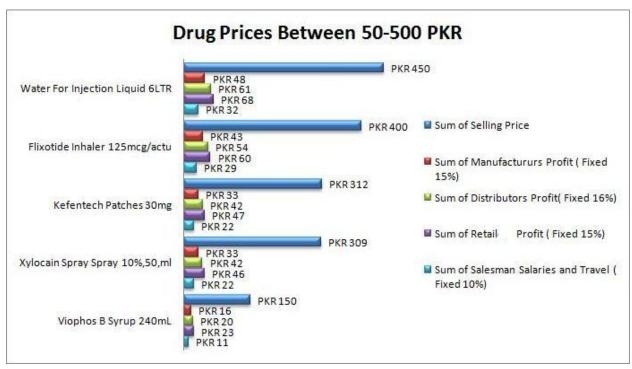
Rubella vaccine	Biological Drug
Salbutamol	Asthma
Salicylic acid	Anti-warts
Saquinavir	HIV Treatment
Silver sulfadiazine	Anti-biotic
Simvastatin	Anti-Cholesterol
Sodium calcium edetate	Anti-poisoning
Sodium chloride	Infusion
Sodium hydrogen carbonate	Infusion
Sodium lactate, compound solution	Infusion
Sodium nitroprusside	Used in cardiology
	Salbutamol Salicylic acid Saquinavir Silver sulfadiazine Simvastatin Sodium calcium edetate Sodium chloride Sodium hydrogen carbonate Sodium lactate, compound solution

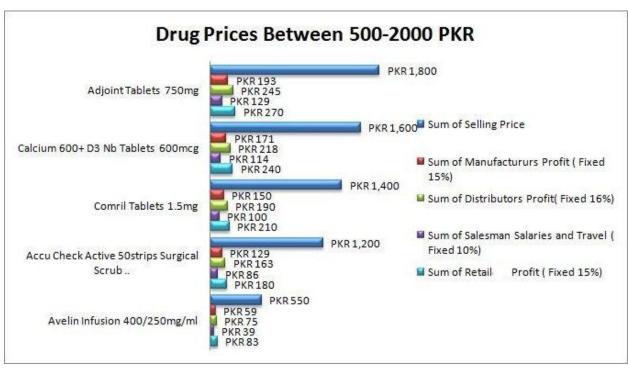
286.	Sodium stibogluconate (s)	Anti-Lishmeniasis
287.	Sofosbuvir	Anti-Hepatitis C
288.	Somatotropin	Growth Hormone
289.	Sorafenib	Cancer Treatment
290.	Spectinomycin	Anti-biotic
291.	Spironolactone	Anti-Hypertensive
292.	Stavudine	HIV Treatment
293.	Streptokinase	Cardiac enzyme used in the
		treatment of heat attack.
294.	Streptomycin	Anti-biotic
295.	Sulfadiazine	Anti-biotic
296.	Sulfadoxine + pyrimethamine	Anti-biotic
297.	Sulfamethoxazole + trimethoprim	Anti-biotic
298.	Sulfasalazine	Anti-biotic
299.	Sunitinib	Cancer Treatment
300	.Suxamethonium / Succinylcholine	Endocrine drug
301.	Tamoxifen	Cancer Treatment
302.	Tenofovir Disoproxil Fumarate	HIV Treatment
303.	Terbutaline	Anti-Asthmatic
304.	Testosterone	Male hormone
305.	Tetanus vaccine	Biological Drug
306.	Tetracaine	Anaesthesia
307.	Tetracycline	Anti-biotic

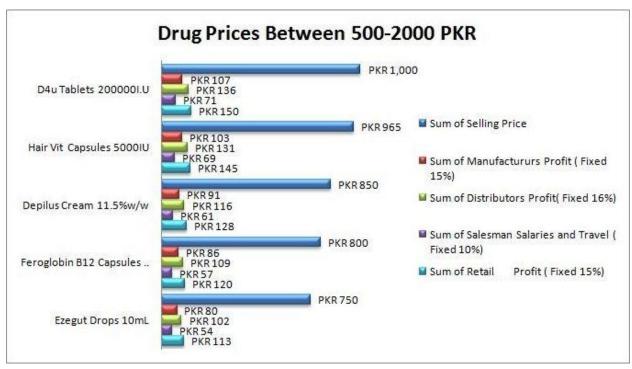
308.	Theophylline	Anti-asthma
309.	Thiopental	Anaesthesia
310.	Timolol	Eye diseases
311.	Tocilizumab	Biologicals / Cancer Treatment
312.	Topotecan	Cancer Treatment
313.	Tranexamic acid	Abnormal hemorrhages
314.	Trastuzumab	Biologicals / Cancer Treatment
315.	Typhoid vaccines	Biological Drug
316.	Valproic acid / Sodium Valproate / Divalproic Acid Sodium	Anti-Epileptic
317.	Vecuronium	Muscle relaxant
318.	Verapamil	Anti-Hypertensive
319.	Vinblastine	Cancer Treatment
320.	Vincristine	Cancer Treatment
321.	Vinorelbine	Cancer Treatment
322.	Yellow Fever Vaccine	Yellow Fever
323.	Zinc sulfate	Zinc Supplement

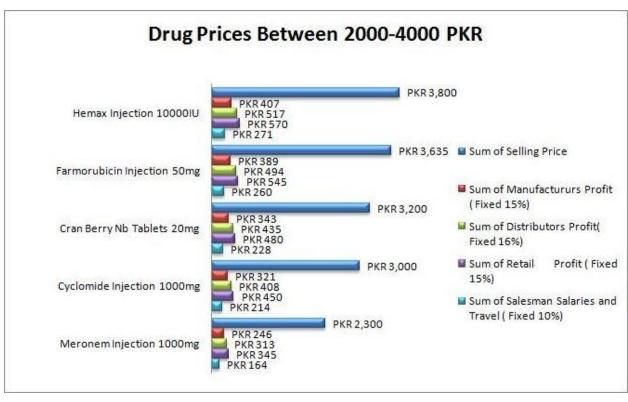
## 1.5. Effect of Fixed Mark-ups on Drug Prices.

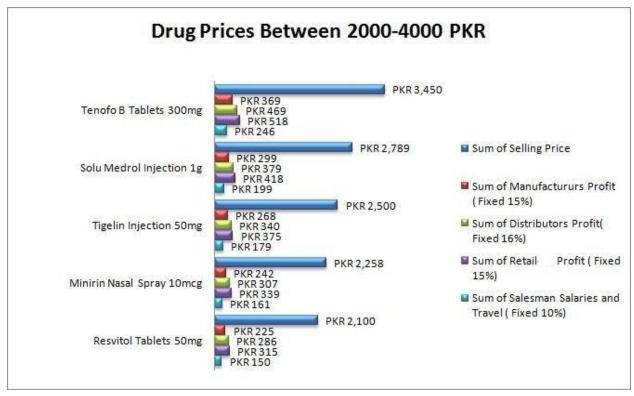


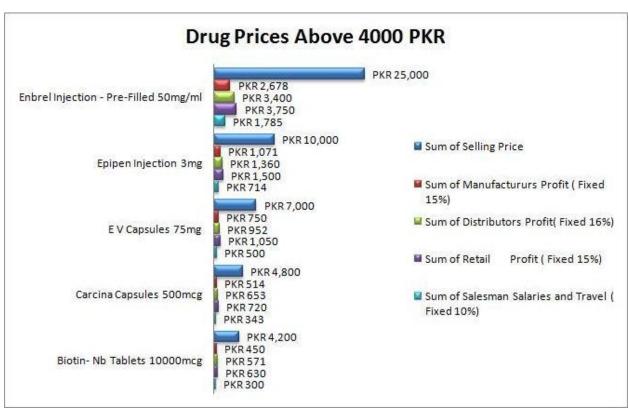


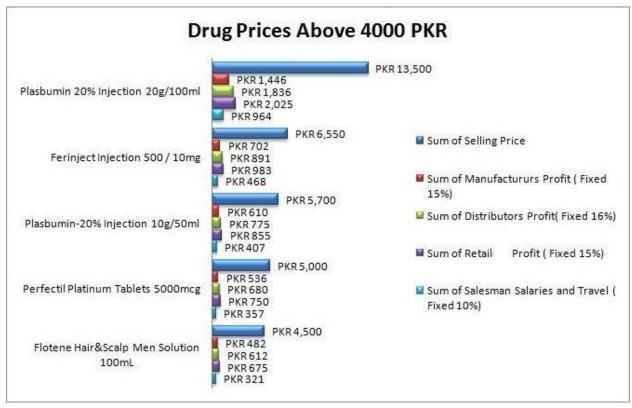


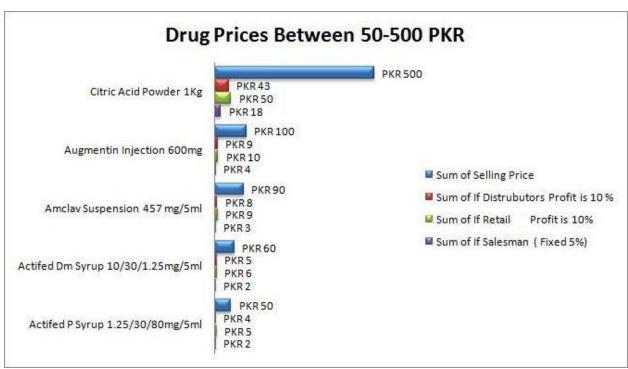


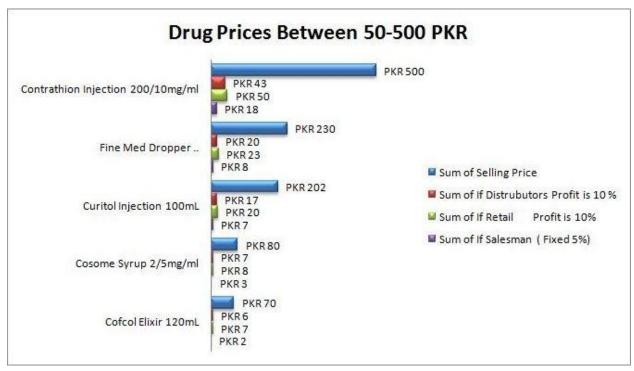


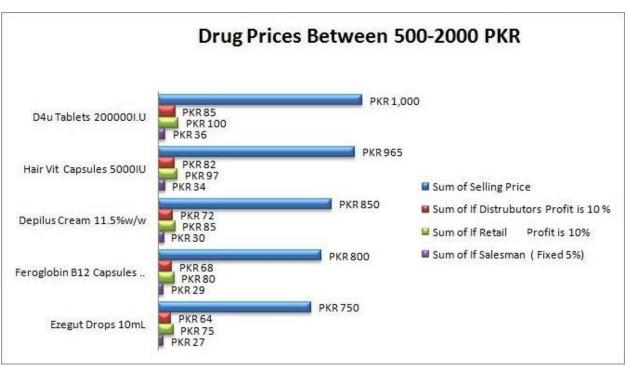




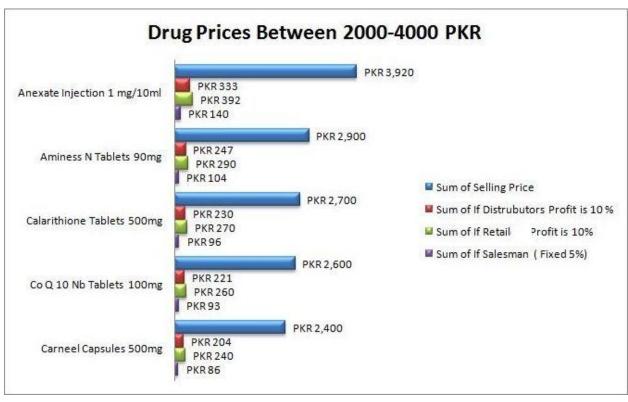


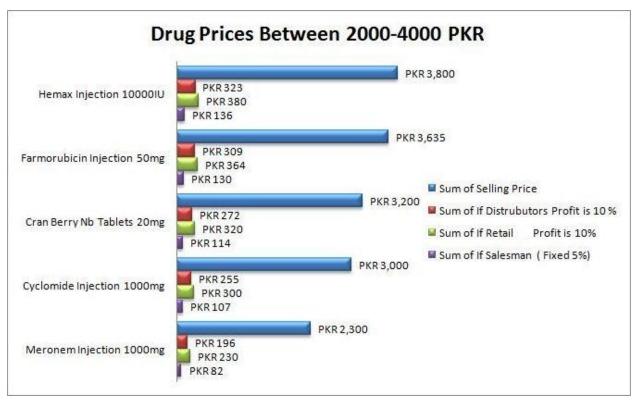


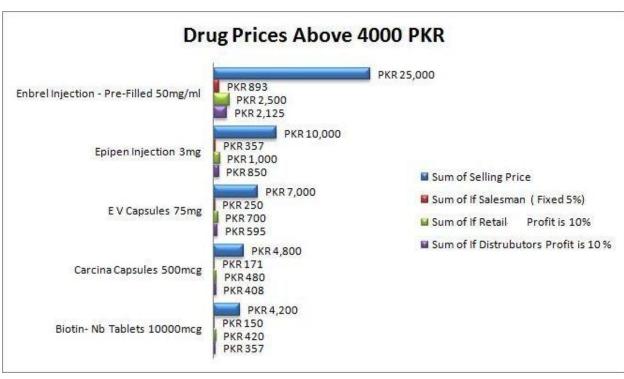


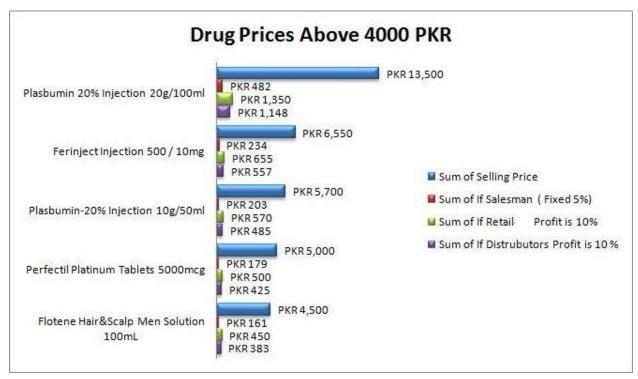


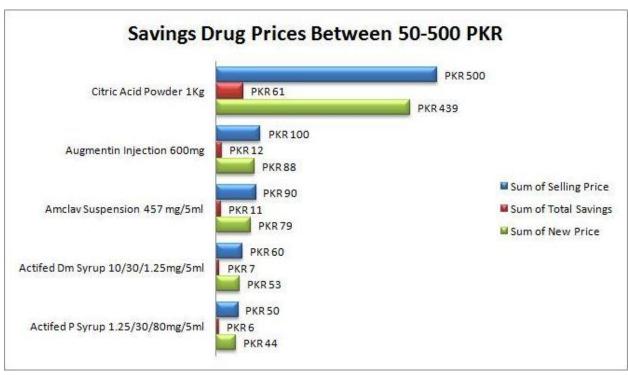


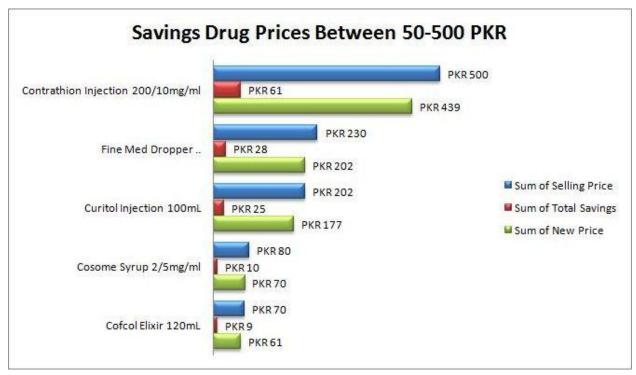


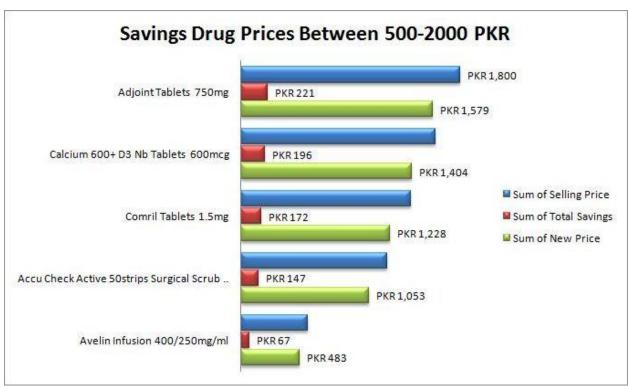


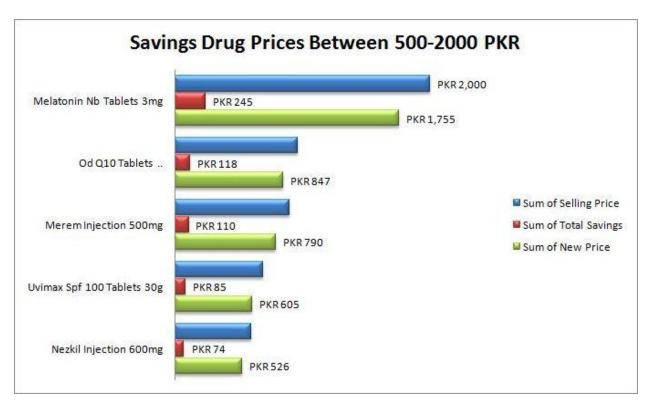


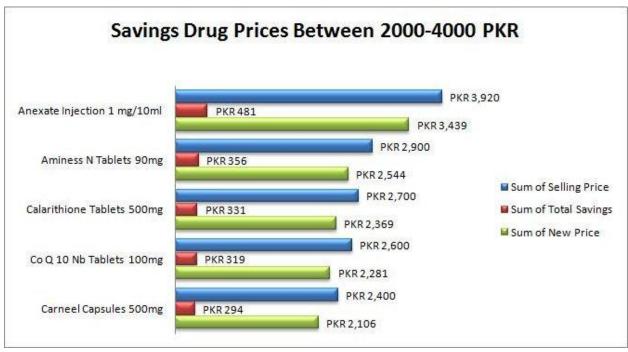


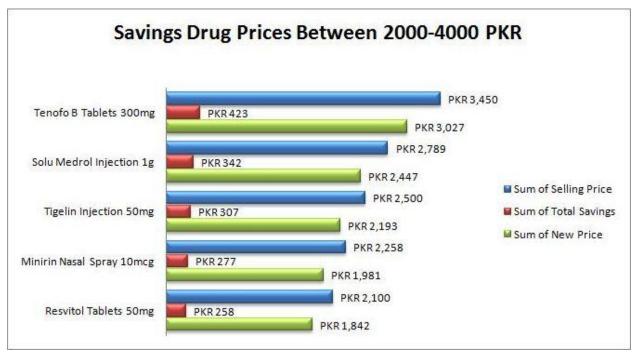
















## Questionnaire

Interviewee Name:
Designation/Department:
Experience:
Thesis Title: Economic Insight of Drug Pricing Policy of Pakistan.
Questionnaire for Decision Making Framework.
Question # 01: Are you/ Have you been ever involved in to assist Decision Making Process in
Pricing/control regulation/ such dimensions ?

Question # 02: Should Pakistan use price control measures to manage medicine prices? If yes

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

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

Question # 02: Should Pakistan adopt measures to control add on costs in the supply chain? If yes

Sub Questions		Supporting Questions
A) Should wholesaler and retail markups	If yes, then	i) Under what conditions should
be controlled in Pakistan?		controlling the mark ups of supply

		chain agents be considered?
		ii) How can 'reasonable' mark ups be
		estimated?
		iii) What best practices should be
		followed in controlling supply chain
		mark ups( flat, regressive, regressive
		but not applies across the total
		procurement price) etc ?
		&
		What are the potential positive
		outcomes of each strategy and what
		are the risks?
B) Should medicines be exempt from	If yes, then	i) What mechanisms are needed to
taxes/or tariffs?		ensure that cost savings obtained
		through exemption are passed on to
		patients ?

Question # 03: Should Pakistan promote the use of quality assured generic medicines as a strategy to manage medicine prices? If yes

Sub Questions	Supporting Questions

A) What prerequisites are needed to		
promote increased use of generic		
medicines?		
B) Should optional/mandatory generic	If yes, then	i) Under what conditions should it be
substitution by dispenser/pharmacist be		considered for use?
used to promote increased use of generic		ii) What are the potential positive
medicines?		outcomes of using this strategy and
		what are the risks?
		iii) What best practices should be
		followed?
		iv) What are the resources and skills
		required for effective
		implementation?
C) What is the role of ( generic)	If yes, then	i) Under what conditions should it be
competition in the pharmaceutical		considered for use?
market as part of a strategy for managing		ii) What are the potential positive
prices?		outcomes of using this strategy and
		what are the risks?
		iii) What best practices should be
		followed?
		iv) What are the resources and skills
		required for effective
		implementation?
D) Should internal reference pricing (by	If yes, then	i) Under what conditions should it be

product or therapeutic group) be used to		considered for use?
promote increased use of generic		ii) What are the potential positive
medicines?		outcomes of using this strategy and
		what are the risks?
		iii) What best practices should be
		followed?
		iv) What are the resources and skills
		required for effective
		implementation?
E) Should strategies be adopted to	If yes, then	i) What strategies should be
encourage the use of generic/lower cost		considered for use ( e.g payment
products among providers ( prescribers		structure, financial incentive to
and dispensers)?		encourage prescribing and dispensing
		lower cost products, education
		strategies) etc?
		ii) Under what conditions should it be
		considered for use?
		iii) What are the potential positive
		outcomes of using this strategy and
		what are the risks?
		iv) What best practices should be
		followed?
		v) What are the resources and skills
		required for effective

	implementation?
If yes, then	i) What strategies should be
	considered for use (e.g. generic
	restrictions and substitution
	requirements, education strategies)
	etc?
	ii) Under what conditions should it be
	considered for use?
	iii) What are the potential positive
	outcomes of using this strategy and
	what are the risks?
	iv) What best practices should be
	followed?
	v) What are the resources and skills
	required for effective
	implementation?
	If yes, then

Question # 04 : Importance of Academic participation in determination of cost, price, quality and distribution of the medicines?

Question # 05: Any further guidelines/recommendations for data collection/Interviews?

## **Inform Consent**

Thesis Title: Economic Insight of Drug Pricing Policy of Pakistan.

Consent to take part in research

I...... voluntarily agree to participate in this research study.

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

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

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

I understand that I will not benefit directly from participating in this research.

I agree to my interview being audio-recorded/field notes.

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

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

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

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

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

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

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

Signature of research participant	Date:
Signature of researcher	Date: