

The National Drug Policy 2005 and Government's Role in Monitoring the Pharmaceutical Market: A Critical Analysis

A Dissertation

Submitted to the **Institute of Governance Studies**, BRAC University, Dhaka
in partial fulfillment of the requirements of the degree of

MA in Governance and Development

By

MOHAMMAD MOZAMMEL HOSSAIN KHAN

Student ID No: 07272020

Session: 2007-2008



Institute of Governance Studies
BRAC University, Dhaka, Bangladesh
December 2009



The National Drug Policy 2005 and Government's Role in Monitoring the Pharmaceutical Market: A Critical Analysis

A Dissertation

Submitted to the *Institute of Governance Studies*, BRAC University, Dhaka
in partial fulfillment of the requirements of the degree of

MA in Governance and Development

By

MOHAMMAD MOZAMMEL HOSSAIN KHAN

Student ID No: 07272020

Session: 2007-2008

Approved as to style and content by

Dr. Rizwan Khair

Academic Coordinator

&

Supervisor



**Institute of Governance Studies
BRAC University, Dhaka, Bangladesh
December 2009**



ACKNOWLEDGMENTS

At the very outset, I would like to convey my heartfelt thanks and gratitude to Ministry of Establishment for permitting me to attend the course and BRAC, Royal Dutch Government and World Bank for financing the course and IGS, BRAC universality to arrange the course in a successful manner.

I, whole-heartedly acknowledges the sincerest gratitude, respects and indebtedness to Dr. Rizwan Khair, my supervisor and Academic Coordinator, MAGD 2nd batch for his inspiration to chose the topic and successively his wise and eager supervision, timely instruction to complete this dissertation.

This study would not have been possible without the cooperation of Dr. Md.Shah Amran, Assistant Professor, Department of Pharmaceutical Chemistry, University of Dhaka. I am deeply indebted to Professor Dr. Habibur Rahman, Chairman, Department of Pharmacy, University of Dhaka and Ex Director of Directorate of Drug Administration Dhaka, Professor A B M Faroque, President Bangladesh Pharmaceutical Society for sharing their experiences and knowledge.

I am grateful to all the officials of Directorate of Drug administration and the association of Bangladesh Pharmaceutical Industries, Bangladesh Pharmaceutical Society. Moreover, special thanks are given to Mohammaed Rafiqul Islams, Senior Assistant Secretary to the Government for his suggestions and support.

Finally, I would like to thank all officers and staffs of IGS, BPATC, BRAC TARC, Savar and BCDM, Rajendrapur for their support.

Mohammad Mozammel Hossain Khan

Declaration

I hereby declare that I am the sole author of this thesis.

I authorize the Institute of Governance Studies (IGS) and BRAC University to lend this thesis to other Institutions or individuals for the purpose of scholarly research only.

I further authorize the IGS and BRAC University to reproduce this thesis by photocopying or by other means, in total or in part, at the request of other institutions for the purpose of scholarly research.

Mohammad Mozammel Hossain Khan
Student ID No. 07272020
MAGD Batch II
IGS, BRAC University

LIST OF ABBREVIATIONS

API	Active Pharmaceutical Ingredient
BAPI	Bangladesh Association of Pharmaceutical Industries
BCSIR	Bangladesh Council for Scientific and Industrial Research
BMA	Bangladesh Medical Association
cGMP	Current Good Manufacturing Practice
CPD	Center for Policy Dialogue
DCO	Drug (Control) Ordinance 1982
DDA	Directorate of Drug Administration
DTL	Drug Testing Laboratory
FBCCI	Federation of Bangladesh Chamber of Commerce and Industries
GDP	Gross Domestic Product
GMP	Gross Manufacturing Practice
GOB	Government of Bangladesh
ICDDR	International Center for Diarrhoeal Disease Research Bangladesh
IMS	Information Management System
LDC	Least Developed Country
MNC	Multinational Corporation
MOF	Ministry of Finance
NDP	National Drug Policy
NGO	Non-Governmental Organization
R&D	Research and Development
QA	Quality Assurance
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
USA	United States of America
USFDA	United States Food and Drug Administration
WHO	World Health Organization

LIST OF TABLES

Serial No	Title of the Table	Page No
Table 1	Number of pharmaceutical production units, registered brands and number of pharmacies	14
Table 2	Total pharmaceutical production in Bangladesh, production by local companies and rate of increase upto 2000	14
Table 2.1	Total pharmaceutical production in Bangladesh and increase rate up to 2009	15
Table 3	Total sale and market share of the leading companies	16
Table 4	The mostly consumed drug molecules:	17
Table 5	Export earnings in pharmaceuticals	20
Table 6	State of Imported Raw Materials, Packaging Materials & Finished Products	21
Table 7	Implementation status of the National Drug Policy 2005	37
Table 8	Manpower status of the DDA	49

List of figures

Serial No	Name of the Figure	Page No
1	Relationship among different actors and institutions involved in DP 2005 implementation	27
2	Retail price fixing formula adopted by most pharmaceutical companies	44
3	Influence of different policy actors/ institutions in implementation success of the Drug Ordinance 1982	58
4	Influence of different policy actors/ institutions in implementation the Drug Policy 2005	62
5	Supply pattern of pharmaceutical market in Bangladesh	70

ABSTRACT

Bangladesh has a thriving pharmaceutical sector. Over the last 27 years this sector has been making development every year. Bangladesh pharmaceutical industry is mainly dominated by domestic manufacturers. The local manufacturers hold 97 percent of the total markets. The country also has been showing great potentiality in exporting pharmaceuticals to a number of countries. These have made Bangladesh's base for pharmaceutical manufacturing strong. It is certain that the positive impacts of the National Drug Policy 1982 and the successive The Drug (Control) Ordinance 1982 made the development of the pharmaceutical sector in this country. But due to the changed socio economic scenario, global pharmaceutical market demand, WTO perspectives a new revised Drug policy was essential. To meet this demand of the time The National Drug Policy 2005 was approved by the Government in 2005 setting new objectives.

Four years have been passed. How much the objectives of the NDP 2005 has been achieved. Moreover recent *Paracetamol tragedy* that took lives of 25 innocent children severely raised the issue of Governments monitoring role and capability over the pharmaceutical market. This study has been carried out to find the answers.

In the beginning of this research the history of success made by the pharmaceutical sector and the present market scenario have been illustrated. Theories and the context of the NDP 2005 and various analytical frameworks for the policy implementation have been widely discussed.. Analytical framework given by Grindle (1980) has been selected to be tested in

aiming to find out a policy implementation framework in regard to implementation process of NDP 2005 in respect to enabling Government's monitoring role. The implementation success of the DCA 1982 was critically analyzed too. The study depended on the secondary data. Personal observation, interview with different groups of people like working pharmacists, doctors, academicians, medical representatives, consumers, retail sellers and so on. The findings of this research revealed some policy outcomes and policy failures. But the policy failure is more prominent. It has been found the major policy actors, the politicians and the proprietors of pharmaceutical manufacturing companies can play the pivotal role to make success and failure of the NDP. The study ends up with some workable recommendations that will enable the Government's regulatory body to exert monitoring role which is a must for the sustainable growth of this promising pharmaceutical sector as well as ensuring safe, effective drugs for the consumers.

TABLE OF CONTENTS

	Page
Acknowledgement	III
Abbreviation	V
List of Tables	VI
List of Figures	VII
Abstract	VIII

Chapter 1

1.1	Introduction	1
1.2	Indication of problem Area	3
1.3	Objective of the study	4
1.4	Importance of the study	5
1.5	Limitation of the study	6
1.6	Study Design and Research Methodology	6
1.7	Chapter Outline	6

Chapter 2 Pharmaceutical Market in Bangladesh,

The development history and present scenario

2.1	Introduction	8
2.2	Pharmaceutical sector in pre independence period (Before 1971)	9
2.3	Pharmaceutical sector in Post independence period (After 1971)	9
2.3.1	Before 1982	
2.3.2	Development after 1982	11

2.4	Pharmaceutical Export from Bangladesh	19
2.5	Pharmaceutical import by Bangladesh	20
2.6	Conclusion	22

Chapter 3 Conceptual framework for the National Drug Policy 2005

3.1	Introduction	23
3.2	Rationale of formulation of the Drug Policy 2005	23
3.3	A brief analysis of DP 2005	24
	3.3.1 Policy Model of Drug policy 2005	
3.4	Actors and institutions involved in DP 2005	26
3.5	Policy instrument needed in implementation of DP 2005	28
3.6	Different Policy styles and the DP 2005	29
3.7	Conclusion	34

Chapter Four Learning from the study

4.1	Introduction	35
4.2	Structure of this chapter	35
4.3	Implementation status of the NDP 2005	36
4.4	Government's monitoring role over pharmaceutical market	40
	4.4.1 Ensuring <i>Accessibility</i>	
	4.4.1.1 Price control of drugs	40
	4.4.1.2 Distribution of drugs	46
	4.4.1.3 Retail sale of the pharmaceuticals	47
4.4.2	Ensuring <i>Quality and safety of drugs</i>	48
4.4.3	Ensuring Rational Use of drugs	53

4.4.4	Traditional gift items	54
-------	------------------------	----

4.5	Conclusion	55
-----	------------	----

Chapter 5 Findings and Analysis

5.1	Introduction	56
-----	--------------	----

5.2	Implementation state of the DP 2005	56
-----	-------------------------------------	----

5.3	Comparison between NDP 2005 and DP 1982	57
-----	---	----

5.4	Pharmaceutical market structure and supervision of the Government	58
-----	--	----

5.5	Conclusion	72
-----	------------	----

Chapter 6 Conclusion and Recommendations

6.1	Conclusion	73
-----	------------	----

6.2	Recommendations	77
-----	-----------------	----

6.3	Further scope of the study	81
-----	----------------------------	----

6.4	Concluding remarks	82
-----	--------------------	----

REFERENCES

ANNEXURES

CHAPTER 1

Introduction

1.1 Introduction

Pharmaceutical sector one of the sectors for which Bangladesh can be proud of. This sector is the second largest contributor to the government exchequer. There are about 246 pharmaceutical companies in this sector and the approximate total market size is about Taka 30,000 million per year. Good thing is that about 97 percent of the total requirement of medicines of the country is produced by the local companies and the rest 3 percent is imported. The imported drugs mainly comprise of the cancer drugs, vaccines or viral diseases. There are about 1032 generics registered in Bangladesh and the brand product number is 18792(*The Directorate of Drug Administration*).

In Bangladesh pharmaceutical sector is now one of the fastest growing sectors. In 2004, the total size of the pharmaceutical market was estimated to be Taka 28, 416 million. According to a June 2009 Businesses Monitor International (BMI) report in 2008 the domestic pharmaceutical market worth 59, 330.7 million (US \$ 858 million). Besides meeting the local demand, some leading pharmaceutical companies have started export to various countries and earning a lot of foreign currency. Pharmaceutical industry is the second largest contributor to the national exchequer after garments.

The story of development in this sector is not a long one. In 1970s the situation was not in control by the Government. In some aspects the situation was even terrible. The local drug market was governed by the giant multinational companies. There was no

control of government against substandard and banned products. In order to remedy the deplorable situation that existed in the drug and health sector of the country and to ensure adequate supply and availability of good quality essential drugs at affordable prices, a radical and far-reaching National Drug Policy (NDP) was formulated in 1982. Later on in the same year a Drug (Control) Ordinance was promulgated. These two national documents which were highly applauded all over the world's, and produced tremendous positive effects on rapid development of the local pharmaceuticals.

The National Drug Policy of 1982 brought about revolutionary changes in this sector. Local production of allopathic, traditional and complimentary alternative drugs increased substantially. Local production increased from Taka 1,730 million in 1981 to about Taka 41,000 million in 2002, and their share of production increased from 30 percent in 1970 to more than 95 percent at present. During this time Bangladesh also made significant achievements in production of standard drugs. The proportion of substandard drugs fell from 36 percent in 1970 to only about 2 percent in 2002. (Government of Bangladesh 2005)

While these spectacular achievements of the Drug Policy and Drug (Control) Ordinance of 1982 were well appreciated, these documents of national pride were not reviewed or updated regularly to keep pace with time and the remarkable developments that were taking place in the medicine world. Besides changes in socio economic sectors nationally and internationally, challenges on account of liberalization, the globalization of world economy and WTO issues made it imperative to review and update the Drug Policy 1982.

In 2001, the Ministry of Health and Family Welfare started the process of reviewing the policy. A National Drug Policy Committee with members from all relevant sectors. The committee took two years for detailed analysis and finally proposed for a updated drug policy. And finally in 18 April 2005 the new amended Drug Policy 2005 was notified.

1.2 Indication of Problem Area

The Drug Policy 2005 had been formulated to meet the requirements of the changing needs of the country. It was an updated version of the National Drug Policy 1982. It was formulated with a view to make drug policy more applicable, effective and adaptive to the remarkable technological achievements that have been made in the pharmaceutical industry. Moreover, the policy was aimed at making the country a producer and exporter of good quality drugs in the world. The Policy has 18 objectives. The most important objectives are to ensure that the people have easy access of useful, effective, safe and good quality essential and other drugs at affordable prices. In pursuance of it the National Drug Policy (NDP) sets the objectives to update the criteria for drug registration, and for regulating the pharmaceutical market stressed on strengthening of the vital agency the Directorate of Drug Administration. Moreover objectives are there to update the existing acts, rules and such other regulatory legal instruments by making necessary amendments. Other objectives are to strengthen the pharmaceutical base of the country by offering incentives to companies in production of finished drugs and also Active Pharmaceutical Raw Materials.

After adopting the Drug Policy in 2005, already three years have passed. This has created a scope of studying the achievements of the policy and the implementation status

of the policy. The WHO Expert Committee on National Drug Policies sets guidelines that the national drug policy of a country should be periodically evaluated, preferably every two or three years. In particular it is necessary to investigate Government's control over the drug market, the monitoring systems and also Government's role to facilitate the development of this sector. How far the policy objectives of Drug Policy in 2005 related to these have been achieved has created a scope of study. This study will thus try to uncover those questions.

1.3 Objectives of the Study

Therefore the focus of the study is to evaluate the implementation and challenges of the National Drug Policy (DP) 2005 and trace out the both institutional and procedural challenges that the Government faces in controlling and monitoring the pharmaceutical sector. It will also try to evaluate the governments' role in attaining the targets set by the policy. Thus, particular objectives of the study are as follows-

- To find out the achievements and bottlenecks of the Drug Policy 2005 in controlling and regulating the market to ensure the accessibility of safe drugs.
- To find out the institutional capacity of the government in regulating this sector.

1.4 Importance of the Study

The huge demand of the people for safe drug of a developing country has been satisfactorily met by the local companies. There are about 246 pharmaceutical industries here. But many companies are producing sub standard drugs and marketing those. Our laboratory testing facilities are not adequate to test all the new manufactured drugs. So along the good products many sub standard products are entering market in a large amount. Again patients are prescribed to take such drugs. This in turn poses great threat to the national health security. The very recent Paracetamol syrup tragedy rocked the entire nation once again. In 2009 it took lives of 25 innocent children of age from 1 to 5 years and has shaken the entire nation. Using toxic chemical diethylene glycol instead of costlier propylene glycol as solvent in Paracetamol syrup has caused catastrophe. It shows the inefficiency of the government's regulatory body to ensure safety of the drugs.

Many companies are manufacturing substandard drugs and thus the Government has to play supervisory role over all these issues. Thus, this certainly is a governance issue of the country. But does the Government have institutional capacity to monitor and put control over the entire drug market? How far the Government can play its role efficiently? What are the main impediments in this process? There are some objectives in the DP regarding these issues. How far these objectives have been achieved is a matter to be analyzed.

1.5 Limitations of the Study

The Drug Policy 2005 covers a wide area. So the success and failure of it is a too vast an area to cover in a single dissertation. Moreover, Government offices do not have sufficient data regarding these. Again the pharmaceutical industries are not that interested to share data and their existing facilities, and also plans for future development. There was also lack of time, resource and spatial constraints.

1.6 Study Design and Research Methodology

The present study is based on both primary and secondary data. Primary data was collected with the help of discussions and personal interviews with the selected respondents, while secondary data was collected from books, articles, reports and newspapers.

- ◆ Content analysis: The secondary data was mostly collected from the Directorate of Drug Administration, Ministry of Health and Family Planning, Export Promotion Bureau, Bangladesh Pharmacy Council.
- ◆ Interview method- Interview with expert personnel in this field, entrepreneurs in this sector and policy makers.

1.7 Chapter Outline

The whole thesis is organized into six chapters. It starts with Introduction Chapter. The second Chapter will discuss the pharmaceutical sector in Bangladesh. In this Chapter

the whole picture of pharmaceutical market, development history and all other issues will be narrated. Data will be presented to show the import, export trends, markets share and other related issues. Most of the data has been collected from the Directorate of Drug Administration.

The third Chapter will discuss context and rationale of the Drug Policy (DP) 2005. This Chapter will be mainly covering the theoretical aspects of a public policy. The DP will be analyzed in light of theoretical framework. Theories related to policy implementation with some analytical frameworks will also be discussed at the end of the chapter.

In the fourth Chapter, achievements and challenges of DP 2005 will be analyzed on the basis of secondary data analysis, interview with professionals, policy makers, entrepreneurs and so on. A survey will be conducted in 3 markets. Two will be from the capital city. The Mitford market- the biggest whole sale market of pharmaceutical raw material, packaging materials and also finished drugs will be one study area. The Aziz super market adjacent to the BSMMU and a local market in Gazipur district are two other places where the survey will be carried out. The objective of the survey will be to find out the role of the Government in monitoring the pharmaceutical market of the country and also the awareness of the people about the National Drug Policies.

Attempts will made to analyze the extent of policy implementation of DP will be shown in Chapter five with the help of exploring the findings of the study. The role of different policy actors and institutions will be narrated here. In the final chapter there will be conclusion and recommendations.

CHAPTER 2

Pharmaceutical Market in Bangladesh: The development history and present scenario

2.1 Introduction

Although Bangladesh has a long history of pharmaceutical manufacturing and marketing, during the last couple of decades this industry has made a significant progress. Now a large number of pharmaceutical firms are manufacturing pharmaceutical products of international standard. After the promulgation of the Drug (Control) Ordinance of 1982 (DCO 1982) the local manufacturing companies have been enjoying the benefits of a '*protected*' market. The congenial atmosphere, incentives offered by the Government enabled the country to move forward towards achieving self sufficiency in the production of finished pharmaceutical products. Yet there is poor development made in the area of manufacturing the pharmaceutical raw material known as Active Pharmaceutical Ingredient (API)and this is a matter to great concern. In this chapter the background history of development in this sector will be illustrated as well as the present market scenario will be shown.

If we summarize the development history we find 2 different stages. These are

- 1) Pre independence period (before 1971)
- 2) Post Independence phase- it can again be divided into two sub-phases
 - 2.1 Before 1982
 - 2.2 After 1982

2.2 Pharmaceutical sector in pre independence period (Before 1971)

The pharmaceutical industry, however, like all other sectors in Bangladesh, was much neglected during Pakistan regime. Most multinational companies had their production facilities in West Pakistan. Considering the volume of the market multinational companies started to come to West Pakistan for marketing their drugs. In 1952 Globe Pharmaceuticals was set up at Tejgaon area in Dhaka and it was the largest pharmaceutical manufacturing unit in the then East Pakistan. Then came Glaxo Pharmaceuticals for marketing purpose and later set up a manufacturing plant in Chittagong. In the meantime some very small local pharmaceutical companies started operations. Before 1971 the following companies were established and ran operation:

1952:	Globe Pharmaceuticals
1954:	ACME Laboratories
1956:	Opsonin Pharmaceuticals
1956:	Jayson Pharmaceuticals
1958:	Square Pharmaceuticals
1964:	Orion Pharmaceuticals
1964:	Nuvista Pharmaceuticals

2.3 Pharmaceutical sector in Post independence period (After 1971)

2.3.1 Before 1982

With the emergence of Bangladesh in 1971, the country inherited a poor base of pharmaceutical industry. For several years after liberation, the government could not increase budgetary allocations for the health sector. Millions of people had little access to essential life saving medicines. The local companies were suffering from proper

infrastructure, modern equipments, and technology. They did not have effective marketing strategies. Moreover there was lack of proper regulatory authority. The multinational companies set the price of medicine according to their will and also marketed some drugs that later proved to be harmful and ineffective to human health.

During that period some local companies were newly established like Beximco Pharmaceuticals Ltd in 1976, Ambee Pharmaceutical in 1976. But the market was governed by drugs produced and marketed by multinational companies. This situation continued for several years. Gradually people become more and more educated and health conscious. There was also growing consciousness about the safe drugs at reasonable prices among policy makers.

According to Banglapedia: *the National Encyclopedia of Bangladesh*

In 1981 there were 166 licensed pharmaceutical manufacturers in the country, but local production was dominated by only eight multinational companies (MNCs) which manufactured about 75percent of the products available in the market. There were 25 medium sized local companies which manufactured 15percent of the products. The remaining 10 percent were produced by other 133 local small companies. All these companies were engaged mainly in formulation out of imported raw materials involving an expenditure of Taka 600 million in foreign exchange. In spite of having 166 local pharmaceutical production units, the country had to spend nearly Taka 300 million in importing finished medicinal products.

2.3.2 Development after 1982

This situation continued until 1982 when the government promulgated an ordinance to put control over the pharmaceutical market and also facilitate the growing of local manufacturers. This ordinance named as The Drug (Control) Ordinance 1982 prevented some multinational companies from marketing ineffective and in some cases harmful drugs from the local market. Consequently they started to lose the market share. A basic rule was adopted in that policy. The pricing policy determined the price for the packing and the raw materials plus the mark up. Provision was that if it is the same drug, regardless of who makes it, it should be sold at same price. It could be less, but not more. As a result national companies were benefited. As their manufacturing cost was not that high. Moreover incentives were offered to the local companies by the Government in various ways. Multinational companies were prohibited to manufacture drugs that needed simple manufacturing technology. Vitamins, antacids, pain killers all had good market share. But as multinational companies (MNCs) couldn't manufacture those small molecules, local companies got the opportunities to capture the market.

Restrictions were also there in case of import of drugs. So ultimately the market changed into a '*protected market*' for the local pharmaceuticals. Some multinational companies were compelled to sell their shares to the local authorities. Some of the companies even stopped their operation in Bangladesh. This is why the *Pfizer* sold its share in 1993 and *Renata Bangladesh Ltd.* started operation, and ICI converted into ACI in 1992. Our local manufacturing companies kept on operation with a new endeavor trying to catch the market lost by the giant multinational companies.

Before 1982 there was abundance of substandard¹ and counterfeit² drugs but with the promulgation of the DCO many drugs considered harmful, useless and unnecessary got removed from the market. In the DCO there were provisions about not allowing the manufacturers to produce and market any new molecule which had been derived from slight chemical structural alteration of an existing molecule but possessed similar pharmacological actions. These restricted provisions forced withdrawal of 864 brands of medicines from the market. Gradually this facilitated availability of the essential drugs to increase at all levels of the healthcare system. Increased competition among the local manufactures helped maintain prices of selected essential drugs at the minimum and affordable level.

The most significant positive impact of the DCO was that the limited available foreign currency was exclusively utilised for import of pharmaceutical raw materials and finished drugs, which were not produced in the country. Moreover this ordinance enabled rapid development of local manufacturing capability of drugs of diversified therapeutic classes. Almost all types of possible dosage forms including tablets, capsules, oral and external liquids (solutions, suspensions, emulsions), ointments, creams, injections (small volume ampoules/ dry fill vials/ suspensions and large volume Intravenous fluids), and aerosol inhalers are now being produced in the country.

Bangladesh pharmaceutical firms focus primarily on branded generic final formulations. Most of the basic components, known as APIs, used in this process are

¹ *Substandard medicines* are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient.

² *A Counterfeit drug* is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.

being imported from several countries mostly from China and India. About 80 percent of the drugs sold here are generics and 20 percent are patented drugs. About 450 generic drugs, 5300 registered brands which have 18792 different forms of dosage and strengths are available in the market. These include a wide range of products from anti-ulcerants, flouroquinolones, anti-rheumatic, non-steroid drugs, non-narcotic analgesics, antihistamines, and oral anti-diabetic drugs. And this number is increasing every year. Some larger firms have also started to produce anti-cancer and anti-retroviral drugs. (Sampath 2007)

About 95 percent medicines required every year in Bangladesh are manufactured in the country. Bangladeshi firms produce 82 percent of the pharmaceuticals, locally based MNCs manufacture 13 percent, and the remaining 5 percent is imported. Among the registered 246 registered pharmaceutical companies in Bangladesh, only about 90 are actively producing drugs. The top 30 to 40 companies dominate almost the entire market share (Chowdhury 2006) while, the top 20 companies hold 85 percent of the domestic markets share. In 2006 the top 10 Japanese firms generated approximately 45 percent of the domestic industry revenue, in case of UK it was about 53 percent, for Germany 60 percent (IMS Health 2006), but in case of Bangladesh it was about 70 percent. At present this figure exceeds 85 percent. The table 1 below shows the present scenario of the pharmaceutical market:

Table 1 : Number of pharmaceutical production units, registered brands and number of pharmacies

Systems	No. of Production Units	No. of Registered Brands	No of pharmacies
Allopathic	246	18687	79902
Unani	261	1320	37
Ayurvedic	161	3150	162
Homoeopathic	77	750	299

(Source: Directorate of Drug Administration, Bangladesh)

Table 2: Total pharmaceutical production in Bangladesh, production by local companies and rate of increase upto 2000

Year	Total production	Production by local companies	Increase rate (%)
1982	216	84.2	39
1983	226	116	51.3
1985	328.3	186.4	56.8
1990	530	342.9	64.7
1995	1168	759.3	65
2000	1792.2	1308.3	73

(Source: Directorate of Drug Administration, Bangladesh)

In 2000, the size of the Bangladeshi pharmaceutical market was about \$180 million in terms of production, In 2005 the production was about \$500 million. This sector kept on

increasing the production at an upward trend. Recent years there was sharp rise especially from in the fiscal year 2008-2009.

Table 2.1

Total pharmaceutical production in Bangladesh and increase rate up to 2009:

Year	Total production (in crore taka)	Increase rate (%)
July 2006- June 2007	4174.64	7.01
July 2007- June 2008	4339.93	3.96
July 2008- June 2009	5126.59	18.13

(Source: Directorate of Drug Administration, Bangladesh)

From the above tables we find that the local companies are tapping the market. The competition level in the market is escalating both in terms of quality and prices primarily due to the adoption of the *state-of-the-art* technologies by most of the local companies to occupy the market share. Square takes the lead among the manufactures. It has been found that only Square Pharmaceuticals Ltd holds one fifth of the entire market share. It has more than 700 brand products. Next comes the Incepts Pharmaceuticals. The sharp rise of this new pharmaceutical company is stunning. Aggressive marketing strategy has picked up Incepta to the present situation within only few years. The annual sale of leading 10 companies and also respective market share has been shown in the Table 3

Table 3: Total sale and market share of the leading companies:

Name of the company	Sale in 2Q(MAT) 2009 in crore taka	Share (%)
Square	1019.85	19.89
Incepta Pharmaceuticals	402.24	7.85
Beximco	389.56	7.6
ACME	258.64	5.05
A.C.I	239.6	4.67
Eskayef	238.17	4.65
Opsonin	236.97	4.62
Renata	222.86	4.35
Aristopharma	215.12	4.2
Drug International	178.29	3.48

Source IMS 2009 (Q2)

There are three public sector drug manufacturing units. Two of them are the Dhaka and Bogra units of Essential Drug Company Ltd (EDCL) which is functioning as a public limited company under the Ministry of Health and Family Affairs. There are separate vaccines and Intra venous (IV) fluids production units under the Institute of Public Health (IPH). The production of both EDCL and IPH are mostly used in government hospitals and institutions.

Most of the medicines produced here are small molecules and need not sophisticated technology. Still leading pharmaceutical companies also have been successful to manufacture medicines that need high-tech technology. Over the years some

companies made huge investment to improve the infrastructure as well as the analytical laboratories to meet international standards. In October 2009, the Health Minister announced that Government was planning to launch various initiatives to support local vaccine production to serve the country's Extended Programmes on Immunization. The country recently received a license from the WHO to develop vaccines locally. Manufacturing of vaccines need sophisticated technology and some of the local companies have already achieved the capability of manufacture such type of drugs. In Bangladesh mostly, Over the Counter Drugs are widely needed by the consumers. Drugs used for peptic ulcer, vitamins, antibiotics, analgesics are widely demanded by the people here.

Table 4 : The top 10 molecules that take the leading market share has been shown in the table (in crore taka)

Name of the molecule	July 2008- June 2009	July 2007- June 2008	July 2006- June 2007
Omeprazole	293	255	212
Ranitidine	215	210	211
Calcium	192	165	148
Colecalciferol	182	161	130
Ciprofloxacin	179	158	161
Ascorbic Acid	178	161	155
Cefixime	164	112	113
Paracetamol	147.96	101	115
Vitamin E	145	143	121

Source IMS 2009 (Q2)

From the table above it is found that *Antiulcerant*³ drugs, holding 13 percent market share, have been mostly consumed by the consumers. Besides Azithromycin holds 2.78 percent, Cefradine 2.50 percent, Amoxicillin 2.26 percent and Diclofenac 1.75 percent of the total market share. Among the antibiotics Ciprofloxacin holds the leading position whereas Vitamin D among the vitamins. Every year about multivitamin products¹ worth about 120 crore taka is sold in the country.

Besides manufacturing the finished products, local companies have also made significant success in producing raw material and also packing materials. At present at least 21 companies produce 41 active raw material that is called API.. The leading raw material manufacturers are:

Square Pharmaceuticals Ltd.

Drug International Ltd.

Gonoshasthaya

Globe Drugs Ltd

Bangladesh Antibiotic Industries Ltd (Beximco)

Pharmatek Chemical

For sustainable development of this sector much more initiatives must be taken to manufacture more and more APIs. Bangladesh imports 80 percent of its pharmaceutical raw materials. Every year the country has to spend huge money in importing APIs. Considering the increasing demand the Government has taken initiatives to set up a new Industrial Park in Munshiganj. This 30 billion dollar project will certainly inject fresh momentum to the industry. Bangladesh can save at least 70 percent of expenditure on raw

³ *Antiulcerant drugs* are highly effective in relieving peptic ulcer diseases and cures disorders linked with gastric hyper acidity

material when the API project goes into production. Moreover this API project is expected to transform the industry as a major export earner of the country with the potential to export pharmaceutical products. (Alam 2009)

2.4 Pharmaceutical Export from Bangladesh:

Bangladesh started export from late at '80s. At that time one or two manufactures at their own initiatives exported few products to some less regulated overseas markets like Vietnam, Sri Lanka, Nepal and Myanmar. There was no support from the Government. Successful export to these markets encouraged some more manufacturers to take initiatives to explore some other moderately regulated markets like Russia, Georgia, Ukraine and Singapore early '90s. Gradually more and more companies started to export. Usually the overseas market can be divided into 3 categories

- highly regulated - USA, UK
- moderately regulated - Russia, Singapore
- less regulated - Myanmar, Sri Lanka, Nepal, Kenya, Yemen

Bangladesh now exports medicines to as many as 72 countries. The list of the countries importing medicines from Bangladesh has been shown in Annexure 3. Being a least developed country Bangladesh has been enjoying the patent waiver facility under the TRIPS of the WTO. This has facilitated expansion of pharmaceutical market in the international arena. Bangladesh exports a wide range of pharmaceutical products covering all major therapeutic classes and dosage forms. High-tech specialized products like inhalers, suppositories, nasal sprays, injectables and infusions are in the export list.

The following tables show the trend of export earning

Table 5: Export earnings in pharmaceuticals

Fiscal Year	Export earning (in million)
2002-2003	\$9.05
2003-2004	\$12.69
2004-2005	\$21.26
2006-2007	\$35.00

(Source: Export Promotion Bureau, Bangladesh)

The leading exporting manufacturers are :

- ◆ Novartis Bangladesh Ltd.
- ◆ Square Pharmaceuticals Ltd.
- ◆ Beximco Pharmaceuticals Ltd.
- ◆ Incepta Pharmaceuticals Ltd.
- ◆ The Acme Laboratories Ltd.
- ◆ Aritopharma Ltd.
- ◆ Eskayef Bangladesh Ltd.
- ◆ Opsonin Pharma Ltd.

2.5 Pharmaceutical import by Bangladesh

Bangladesh needs to import raw material, packing material and also some finished products every year. Currently the local manufacturers have been meeting the 97 percent demand of the consumer market. The rest 3 percent needs to be imported. The DCA 1982 discouraged import of unnecessary drugs. The NDP 2005 to some extent relaxed the barrier. So in the last few years import of drugs has been increased. The tendencies of the

leading companies to introduce new molecules every year also resulted in increased import of raw materials and also lucrative packing materials to attract the consumers. The following table illustrates the trends of import in Bangladesh:

Table 6: State of Imported Raw Materials, Packaging Materials & Finished Products (in million taka)

Year	Import		
	Raw Materials	Packing Materials	Finished Product
2003	7927.70	904.10	2050.00
2004	5419.00	475.00	1866.00
2005	6503.00	594.00	2451.00
2006	6643.00	630.00	2637.00
2007	7143.09	640.09	2824.00

(Source: Directorate of Drug Administration, Bangladesh)

Previously Bangladesh imported most of its required ingredients from India. At one stage about 70 percent imported materials came from India and the rest amount came from China, England, Switzerland, Germany and Malaysia. But recently China has become potential exporter of APIs. As Bangladesh has been enjoying *patent exemption* in case of exporting materials up to 2016, she needs to utilize this opportunities maximally. Still a lot of foreign currency is spent in importing APIs. As time goes on prices of raw materials will and that will eventually increase the prices of finished medicines. So the raw material

producing countries will certainly reap the benefits and others will lose the market. Bangladesh needs to address this problem immediately.

2.6 Conclusion

From the above tables it is found that pharmaceutical sector has been making tremendous improvement since 1982. Incentives by the Government, protected market encouraged many new entrepreneurs to invest in this sector. Eventually the number of manufacturing companies kept on increasing. But the leading 20 companies hold most of the market share. So the rest of the companies are always in struggle to survive by taking space in the market. This resulted in adopting unhealthy competition among the small companies. On one hand the number of companies, brands of products kept on rising, on the other hand Government's regulatory capability became faded over the years. This made the entire pharmaceutical market not fully safe. The recent Ridz tragedy shows the fragility of the market safety. To cast more control over the market with a view to ensure safe, effective medicines to the patients at affordable price the Government adopted the long demanded the National Drug Policy in 2005. The following chapters will illustrate different objectives set in the NDP and also extent of implementation. The factors behind the market expansion with fragility will also be analyzed.

3.3 A Brief Analysis of DP 2005

Public policy is whatever government chooses to do or not to do (Dye 1981, p.1)

The main objective of this study is to reveal the achievements and challenges of DP 2005 in some narrow defined field (government's monitoring role over the pharmaceutical market). Policy analysis is relevant to study the extent of achievement during implementation of the policy. The actors, institutions, and strategies all things should be considered. Analysis of DP 2005 is done here.

3.3.1 Policy Model of Drug Policy 2005

The conceptual models are used in studying the public policy with a view to simplify and clarify our thinking about public policy, identify important aspects of policy process and suggest explanations for public policies and predict its consequences. Dye used eight models to examine the public policy. These are;

(1) Institutional model (2) Process model (3) Group model (4) Elite model (5) Rational model (6) Incremental model (7) Theory model (8) Systems model. None of the models is the best to focus all the aspects and features of a public policy. Rather most policies are a combination of rational planning, instrumentalism, interest group activity, elite preferences, systemic forces, game playing, public choice, political processes and institutional influences.

If we try to analyze DP 2005 we find that like many other public policies in Bangladesh, the National Drug Policy 2005 follow the Institutional model firstly. The institutional model implies that Government institutions give legitimacy, universality and coercion. Policy is thus considered as institutional output. In the Drug Policy 2005

Government institutions like the Directorate of Drug Administration (DDA), Ministry of Health and Family Affairs, Health Directorates, hospitals, and so on play significant role in policy process. Structure, institutional capacity, organizations, duties, and functions largely affect the policy success and policy consequences. Dye says particular change of institutional structure would bring about changes in public policy. Increase in institutional capacity of a single Government institution DDA can largely make impact on successful policy outcome.

But only the Institutional model does not focus all the salient features of the Drug Policy 2005. Rather a combination of institutional and incremental model can best examine it. The incremental model views public policy as a combination of past government activities with any incremental modifications. Policymakers generally accept the legitimacy of established programs and totally agree to continue previous processes. The National Drug Policy 1982 was highly applauded all over the world. It produced tremendous effects on the rapid development of the local pharmaceutical industries. The National Drug Policy 2005 was formulated to meet the requirements demanded by the changing world scenario. But the then government did not make much amendment in objectives and other aspects of the previous policy made by a Martial Law ruler in 1982. The overwhelming positive impacts, legitimacy of that policy made the democratic BNP Government make only incremental changes often termed as *Normal Change*⁴ not a paradigmatic policy change.⁵

⁴ Normal policy change implies minor tinkering with policy instruments in the existing policies, so the new policies remain as a continuation of past policies

⁵ Paradigmatic policy changes are changes which are significant and made to make a paradigm shift in terms of overall policy goals, understanding public problems, solutions for them, and policy instruments used to put policies into effect.

3.4 Actors and Institutions involved in DP 2005

Both actors and institutions play a crucial role in the policy process, even though one may be more important than the other in specific instances. (Lundquist: 1987). Policy institutions and actors come from within society at large. It is believed that groups of actors who together form policy sub-systems which play a key role in policy formulation in each policy area. The policy subs-system is a space where relevant actors discuss policy issues and persuade and bargain in pursuance of their interests. These interactions, however, occur in the context of various institutional arrangements surrounding the policy process, which affect how the actors pursue their interests and ideas and the extent to which their efforts succeed.

In case of DP 2005 the policy actors are

- ◆ *Elected officials:* cabinet and legislature (Local MPs, UP Chairmen , parliamentary standing committees)
- ◆ *Appointed officials :* bureaucrats- Secretaries of MHFP, Commerce, Finance, Agriculture, DG Health, other public agency managers and the concerned technocrats (Bhuyan 2005)
- ◆ *Interested groups:* Drug manufacturers' association, FBCCI, BMA, PGA, BPS, Bangladesh Chemists and Druggist association, Financial Institutions, labour.
- ◆ *Research organizations ;* CPD, TIB, IGS
- ◆ *Media ;* print and electronic media

The institutions that have greater role in policy process are DDA, Ministries, BCSIC, and Drug Testing Laboratories. Besides Board of Investment, Board of Revenue, Customs and Excise department pay the role of policy influencing institutions. Relationship between Policy actor and institutions are vital in policy process. Successful implementation of DP will largely depend on the harmonious interdependent relationship among different actors with each other and also with different institutions at national and supra-national level. A diagram showing the relationship among different actors and institutions involved in DP 2005 is shown in the figure below

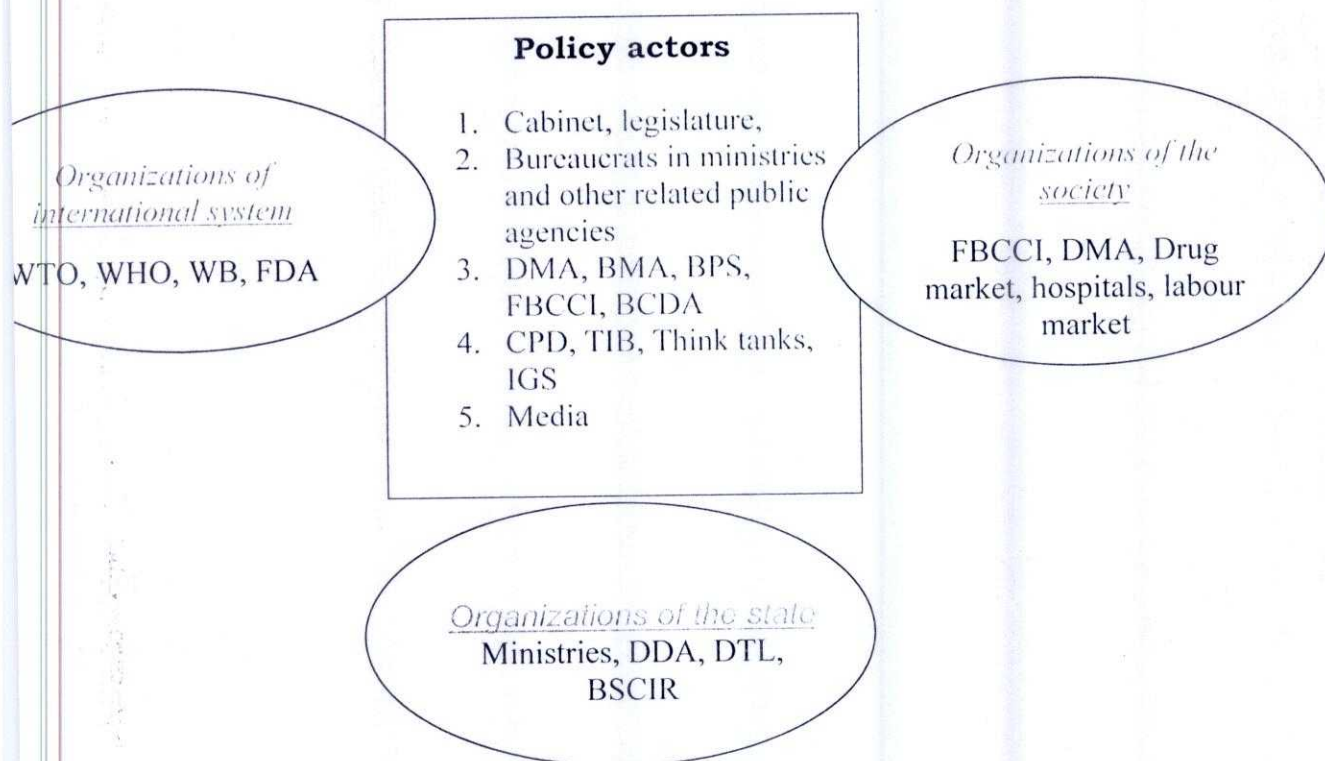


Figure 1: Relationship among different Actors and Institutions involved in DP 2005 implementation

3.5 Policy Instrument needed in implementation of DP 2005

Policy instruments also called as policy tools or governing instruments that Governments use to put policies into effect. Policy instruments are the actual means or devices Government has at their disposal for implementing policies and among which they must select in formulating policy. (Howlett: 2003) Christopher Hood (1986a) proposed that all policy tools used one or four broad categories of Government resources like *nodality* (use of information in their possession as a central policy actor, authority that is their legal powers), treasure (money) or organization (the formal organizations available to them). Government can use these policy instruments to manipulate the policy process.

In case of implementation of the DP 2005 we find different types policy instruments that can be used

- Organization based instruments- the ministries and the DDA can be the best instrument for implementation of the policy process. The National Board of Revenue, Bangladesh Bank, State owned financial institutions; the hospitals are also effective instruments.
- Authority based instruments can be Act, Rules, Ordinances Public-private partnership, custom laws, export and import policies CIP awards,
- Treasure based instruments can be subsidy on pharmaceutical API import, Loan, Tax rebate, Duty free import policy, VAT policy, export incentives, special budgetary allocation, Privatization,

- Nodality of information based instruments- government control over advertising drugs, campaigns, publications on dangers of Drug abuse, free flow of information in electronic and print media.

3.6 Different Policy Styles and the DP 2005

Richardson, Gustafson and Jordan (1982:13) developed the concept and definition of Policy Style. They termed policy style as “the interaction between

1. The Government approach to problem solving and
2. The relationship between Government and other actors in the policy process

Howlett and Ramesh (1995, pp.184-193) describes that there are four types of policy styles: (i) reactionary, (ii) consensus seeking, (iii) domineering and (iv) anticipatory.

Policies adopted in third world countries may be categorized as one of the aforesaid types or combination of two on the basis of how policy shift occurs. There may be various type of combination like:

- a) anticipatory and consensus styles;
- b) reactionary and consensus styles
- c) reactionary and domineering styles
- d) anticipatory and domineering styles

In the preamble of the National Drug Policy it is stated that “there have been spectacular changes in the socio economic sectors nationally and internationally. To keep pace with the changed circumstances, it has become imperative to modernise and expand our pharmaceutical sector aiming beyond national horizon to the international export markets and also to attract the foreign investment in this sector. The aforesaid perspectives have made it inevitable to update and modernize the present national drug policy.”

From the stated preamble it can be said that the National Drug Policy 2005 was a demand of times. The Government formed a 'National drug Policy Review Committee' with members from all relevant sectors. That committee took long two years to review all the aspects of the Drug Policy of 1982 and finally came up with useful recommendations. Those recommendations were the basis of the Drug Policy 2005. So it is evident that the National Drug Policy 2005 was made following the *reactionary and consensus styles*. Besides it can be said that the policy also followed the *anticipatory and consensus seeking styles*.

The National Drug Policy 2005 was an updated version of the National Drug Policy of 1982. It was formulated to

- ◆ make it more applicable, effective and adaptive to the remarkable technological advancements that have been made in the medicine world
- ◆ to guide the Drug Sector of the country to perform better in the competitive world market
- ◆ to make the country a producer and exporter of good quality drugs in the world.

According to WHO the main objective of a National Drug policy should be to promote equity and sustainability of the pharmaceutical sector of a country. WHO draws the general objectives should be set to ensure

- ◆ **Access :** equitable availability and affordability of essential drugs.
- ◆ **Quality:** the quality, safety and efficacy of all medicines
- ◆ **Rational use:** the promotion of therapeutically sound and cost effective drug

The NDP 2005 was formulated considering these key objectives into policy content. Moreover additional objectives were set to safeguard the ongoing development trends of the local pharmaceutical industries. The key objective of the NDP is stated ensure safe, efficacious and useful drugs in the country at affordable prices. There are 18 objectives described in NDP 2005. Government has vital role in fulfilling the objectives at different stages like import of APIs, production stage monitoring specially monitoring the compliances of Current Good Manufacturing Practice (cGMP) by all manufacturing units of pharmaceuticals, export and so on.

The present study is analyzing the NDP in ensuring the extent of Government's role in monitoring the pharmaceutical market. This paper will largely focus on finished products marketing, distribution, storage, trends of consumers' acceptability, awareness, rather than the production procedure itself. Government's regulatory measures will be analyzed in respect of the corresponding objectives in NDP 2005. Among the 18 objectives of the NDP the relevant objectives for this study are as follows

- to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable prices.
- to strengthen the Directorate of Drug administration by raising its status to that of a Directorate General of Drug administration with corresponding increase in its manpower and infra-structure facilities to make it more effective as a Drug Regulatory Authority (DRA)
- to update, from time to time, the criteria of registration for import of all systems of medicines in line with the quality guidelines followed in developed countries to ensure safety, efficacy and usefulness of such medicines.

- to exercise government control over advertisement so that common people are not hood-winked by commercial advertisement on drugs and health matters.
- to ban the manufacture, sale and distribution of counterfeit, adulterated and sub-standard drugs and to award exemplary punishment to persons guilty of such actions.
- to strengthen the system of procurement, storage and distribution of drugs and medicines so that these are accessible to people in all areas of the country.
- to allow manufacturers to manufacture, distribute and sell drugs by their Generic⁶ or Formulary names and Trade or Brand names (except in Homeopathic medicines) as appropriate for best identity of that product
- To continue the current system of controlling prices of the commonly used essential drugs as listed and updated from time to time by the Government
- to ensure rational use of drugs (RUD) by proper counseling and motivation of both the prescriber and the end-users.
- to ensure proper monitoring of Adverse Drug reactions (ADR) in the country by motivating the physician and the patients to report cases of adverse reactions of drugs.

The DP 2005 covered 11 broad areas. Those can be summarized as follows:

- *Laws and Regulations* : relevant laws and regulations regulating the registration, manufacture, distribution, sale, import, export of drugs should be amended

- *Drug Regulatory Authority* : should be strengthen by upgrading its status and capabilities
- *Drug Registration* : registration criteria should be revised to ensure safe, efficacious medicines in the market
- *Drug production*: ensure maintaining international standards like cGMP during production process
- *Drug procurement* : encourage procurement from local companies
- *Drug distribution, sale and storage* : encouraging public-private partnership to ensure availability of safe drug in market
- *Drug Pricing* : provisions for rational pricing to ensure affordable prices for users
- *Quality assurance of Drugs and Pharmaceuticals* : SOP must be maintained in plants, qualified personnel, infrastructure should be ensured
- *Manpower and manufacturing units* : should be staffed adequately with trained personnel
- *Drug Information and Monitoring* : provisions for consumers' awareness building
- *Essential drugs*: provision for making an Essential Drug list in line with the current list of Essential Drugs of the WHO.

From the objectives, elements and policy areas described in NDP 2005, it is obvious that the policy goals were mainly to ensure safe, efficacious medicines for the consumers at affordable prices. Moreover the pharmaceutical market has been supposed to run under strong regulatory framework of Government. Unlike many other policies the National Drug Policy document was not taken to the parliament for legislative approval.

serves as a basis of implementation plans. There are three categories of policies such as:

- ◆ *Distributive*- designed to ensure that Government decisions benefit specific clientele like labour, business, agriculture

- ◆ *Regulatory* – designed with a view to pass laws and delegate power to other agencies. It gives bureaucratic agencies broad discretion to implement laws as they use fit. Such types of policies maintain ongoing relationship among different actors.

- ◆ *Redistributive*- designed to exert impact to sizeable sectors of society who get more from the Government than they put in as for example welfare programmes.

Here little discretion is left to the bureaucrats.

3.6 Conclusion

The Drug Policy 2005 has provisions to control the production, distribution of pharmaceutical products with a view to ensure safe drugs to the mass people. Analyzing the policy content, the NDP 2005 can be termed as a *Regulatory* type policy. Significant discretionary power has been entrusted upon the bureaucracy. After the formulation of a policy then comes the vital thing-policy implementation. In this stage all the actors, institutions, regulatory affairs and all other issues must be well tuned.

The following chapter will analyze the extent of implementation of the NDP 2005 considering the existing scenario prevailing in pharmaceutical market.

CHAPTER 4

Learning from the Study

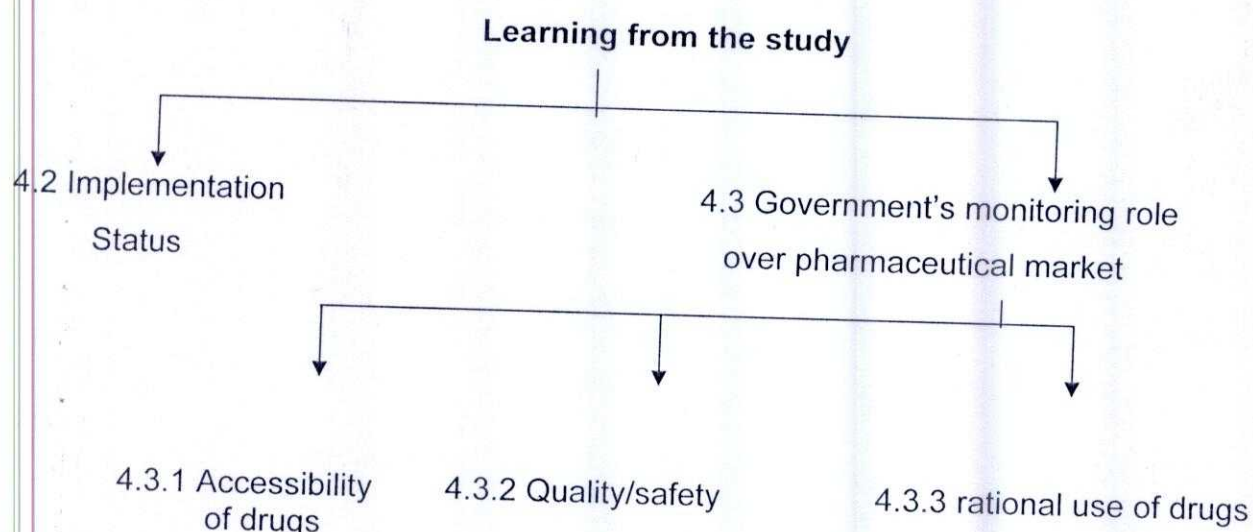
4.1 Introduction

The previous chapter described the theoretical aspects of a public policy and also the conceptual framework of the National Drug Policy 2005. Policy objectives of the NDP 2005 and also different policy areas were also narrated shortly. In this chapter the learning from practical experience will be described. The policy outcome, implementation prospect in respect to the monitoring role of the Government over the pharmaceutical market will be described based on practical experiences. In the first part of the chapter the implementation state will be checked out. Later part will cover the outcome of this study in respect to the objectives of this study. In the upcoming chapter attempt will be made to analyze the real scenario. This chapter will be divided into two broad parts. Two case studies has been designed to show the extent of Government's monitoring role will be presented here.

4.2 Structure of this chapter

This chapter will be in two parts. First part will show the present implementation status considering corresponding policy objectives described in the policy. It will be shown in tabular form. Second part experience from study will be described. One case study reflecting the Government's regulatory role to ensure safe drug and another over price control of essential drugs will be presented.

So the structure of this chapter will be as follows:



4.3 Implementation status of the NDP 2005

After the objectives of a policy have been set, workable programmes and strategies need to be adopted. Reviewing the NDP 2005 the following plans or programmes that are supposed to be implemented by the policy actors through utilizing the policy instruments have been identified. This study is focused narrowly on monitoring role of the Government over the drug market. And also the supervisory role to ensure a safe, effective drug at affordable prices will also be analyzed. That will ensure a secured public health. So if we consider respective objectives and try to draw the present implementation status after three years of adopting the said policy we find the some developments. Table 7 will illustrate the implementation status of NDP 2005.

Table 7: The implementation status of the National Drug Policy 2005

Sl. no	Objectives	Implementation status
1	to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable prices	No specific effective programme has been taken yet
2	to strengthen the Directorate of Drug administration by raising its status to that of a Directorate General of Drug administration with corresponding increase in its manpower and infra-structure facilities to make it more effective as a Drug Regulatory Authority (DRA)	A draft proposal regarding up gradation of DDA to a Directorate General office with increase of manpower has been approved by the Committee of Secretaries. It is under process. In few months it will be implemented
3	to update, from time to time, the criteria of registration	No development has been made yet. The previously set criteria still exists

Sl. no	Objectives	Implementation status
4	to exercise Government control over advertisement so that common people are not hood-winked by commercial advertisement on drugs and health matters.	This is being implemented satisfactorily
5	to ban the manufacture, sale and distribution of counterfeit, adulterated and sub-standard drugs and to award exemplary punishment to persons guilty of such actions.	No structured framework to implement this has not been designed yet, in most cases punitive action is reactionary not preventive
6	to ensure rational use of drugs (RUD) by proper counseling and motivation of both the prescriber and the end-users.	No initiative apparently found
7	to ensure proper monitoring of Adverse Drug reactions (ADR) in the country by motivating the physician and the patients to report cases of adverse reactions of drugs.	No initiative apparently found

Sl. no	Objectives	Implementation status
8	Relevant laws and regulations regulating the registration, manufacture, distribution, sale, import, export of drugs should be amended	No initiative taken yet.
9	Provision for making an Essential Drug list in line with the current list of Essential Drugs of the WHO.	An Essential Drug List has been published by the Government in 2008 in consultation with WHO, but no implementation plan has been taken yet to make it effective for betterment of the consumers

These observations have been made based on content analysis, interviews with officials working in different Government agencies, physicians, some retail sellers and also some professional think tanks. Representatives from different segments which can be regarded as policy actors were interviewed open questionnaire. From the table above it is found that the implementation status of the NDP has not been satisfactory. In the last 3 years there has been no significant progress has been made to achieve the objectives of the drug policy. In the next chapter critical analysis will be made why the implementation

has not got momentum in 3 years. Now the real life scenario will be depicted on the basis of the data, opinion that was found in the study.

In the third world countries public agencies are the main policy instruments. The success of a public policy will therefore largely depend on the institutional capacities, leadership efficiencies, and harmonious coordination with other policy actors. As the general objectives of a National Drug Policy are to ensure equitable availability and affordability of essential drugs⁷, quality, safety and efficacy of all drugs consumed by the people and also rational use of drugs. Government's role over in attaining these objectives will in turn reflect the overall role on the pharmaceutical market as a whole. Now what was found in this study regarding this has been described as follows:

4.4 Government's monitoring role over pharmaceutical market

4.4.1 Ensuring Accessibility

4.4.1.1 Price control of drugs

Government's main duty is to ensure easy access of essential drugs at affordable prices to the mass population specially the poor segment. WHO terms an *Essential Drugs List* as a core component of a National Drug Policy. In the Drug Policy of 1982, 150 drugs were selected as essential drugs and were in practice for quite a long time. But there have been spectacular changes in the socio-economic sectors and pattern of prevailing

⁷ The essential drug lists consists of drugs for a wide variety of therapeutic ranges from symptomatic relief to critical care and all the medicines are considered as the essential needs for national health care system and intended to be available with assured quality and at a price the individual and the community can afford.

diseases. Modernization of therapeutic agents also took place. Newer drugs become available and some drugs become imperative obsoletes.

To keep pace with the changed circumstances, there was an urgency to revise the essential drugs list. But in the NDP 2005 there was no clear guideline about this burning issue. And this has been termed as "*a vital weakness*" of the DP. After the declaration of DP 1982, there was a drastic change in the pharmaceutical market. Strict implementation of the policy enforced about 850 brands of medicines to get out of market. In 1995 the Government, by another circular, revised the essential drugs list 117 from 150. The prices of those drugs were controlled by the Government.

As the prices were controlled, most of the leading companies were losing interest to manufacture those type of drugs due to fewer profit margins. Rather the companies have been more interested to manufacture the drugs out of that list as the prices can be set by the respective company. Consequently use of widely prescribed drugs got diminished. Doctors used to prescribe Amoxicillin once for treatment of bacterial infections. Amoxicillin is *First Generation Antibiotic* and regarded as a safe drug as there is least incidence of drug resistance⁸ in the body. Amoxicillin is in the Essential Drug List, so the price is controlled. This makes most of the companies less interested to manufacture it. Rather companies are investing in manufacturing antibiotics and other medicines in which they can apply *Indicative Price*. Comprehensive marketing has enabled new drugs take major share in the market. Now a day's physicians prescribe antibiotics starting from *broad-*

⁸ *Drug resistance* is the ability of bacteria and other microorganisms to withstand a drug to which they were once sensitive and were once slowed in growth or killed outright

*spectrum antibiotic*⁹ like Ciprofloxacin, Azithromycin and so on. This way many widely prescribed essential drugs are not available in the market.

In NDP 2005 no objectives were set to ensure the availability of such essential drugs. Rather in the last part of the policy document it is mentioned that "there shall be an Essential Drug List for Bangladesh. The Directorate of Drug Administration, in consultation with the experts committee formed by the Government, shall update from time to time and maintain the list of essential drugs in line with the current list of Essential Drugs of the WHO." In December 2007 an 11-member expert committee was headed by the Director, The Directorate of Drug Administration, constituted by the Ministry of Health & Family Welfare to prepare an essential drug list in light of the WHO model list. A Technical Sub-committee was formed comprising the experts from different groups to review the therapeutic needs of various groups of medicines in context of various diseases patterns. Several factors like local demography, pattern of prevalent diseases, financial resources, local availability of the pharmaceutical products and environmental conditions. The committee also considered essential drug list of the neighboring countries, recommendations from local think tanks and WHO model list of essential medicines during up gradation of the existing list. Finally on 8 April, 2008 the Updated Essential Drug list containing 209 items was approved by the ministry. This list was published in Bangladesh Gazette on May 22, 2008. This list is presented as Annexure 4

It was a significant job made by the Government. But this list has not been widely circulated. In this study a survey was carried out among conscious people like

⁹ *Broad-spectrum antibiotic* refers to an antibiotic with activity against a wide range of disease-causing bacteria

academicians, physicians. It is found that only 6 people out of 30 know about the latest drug list. But none has seen the list in person. In fact it is found that the list was published by the Government in gazette only but it was not circulated widely throughout the country to build awareness among the common people. So there is no further positive impact of this list. Government has not yet taken any initiatives to make essential drugs more available than the drugs outside the list. Motivation is badly needed so that the physicians prescribe common medicine, not new variety of drugs at different times and thereby justify the companies' initiative to introduce new drugs everyday and make the people guinea pigs.

To analyze the Government's control over the price of essential drug a case study was carried out.

(I) Case Study: Ciprofloxacin

Ciprofloxacin (INN¹⁰) is a widely prescribed second generation flouroquinolones antibiotic used in the treatment of urinary tract infections, lower respiratory tract infections, skin infections, bone and joint infections, infectious diarrhoea (enteric fever) caused by *Salmonella Typhi* and so on. As it is a broad spectrum antibiotic¹¹ physicians feel confident to prescribe it. Even it has been found that Ciprofloxacin is given by the sellers in the pharmacies without any prescription. Often people especially in the countryside and rural areas go to the pharmacies and describe the symptoms and seek medicine for ailment. The sellers have the tendency to push medicines that can give him large profit margin.

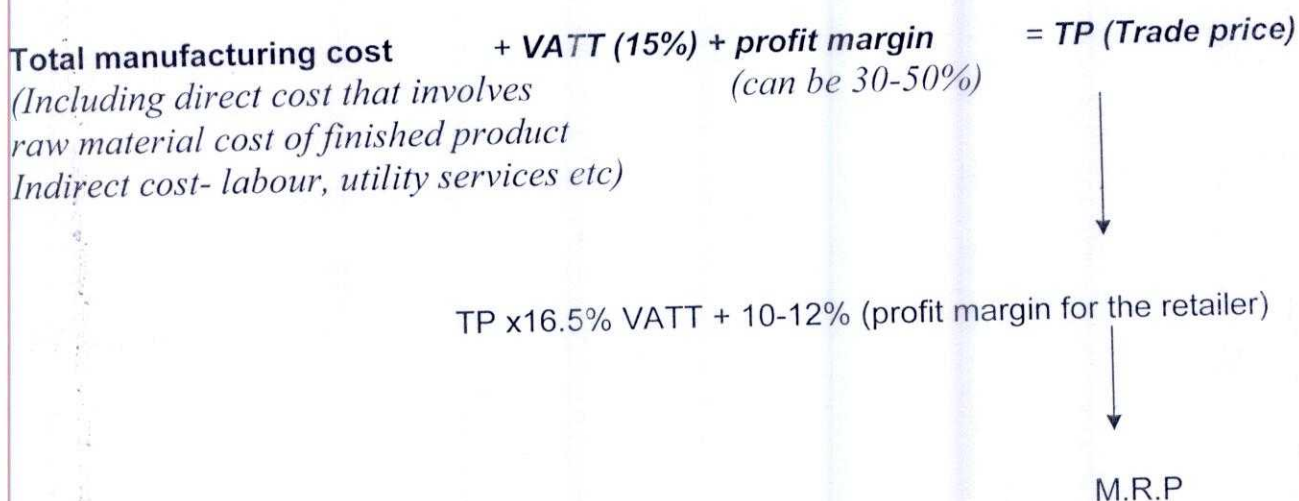
¹⁰ INN stands for International Nonproprietary Name and refers to the official non-proprietary or generic name given to a pharmaceutical substance, as designated by the WHO.

¹¹ The term broad-spectrum antibiotic refers to an antibiotic with activity against a wide range of disease-causing bacteria. It acts against both Gram positive and Gram negative bacteria.

In this study attempts have been made to examine the market price of this widely used antibiotic. Several years ago when Ciprofloxacin was first introduced in Bangladesh the price of API Ciprofloxacin Hydrochloride was costly in the world market. That time the raw material was 120\$ per kg and a Ciprofloxacin 500mg tablet was 14 taka. Ciprofloxacin tablet is available in 250mg and 500mg dosage form. But now the price of the raw material has fallen manifold. The price ranges from 21-22\$ / kg.

Now let us see how the M.R.P (maximum retail price) is fixed by the companies. Different pharmaceutical companies adopt different methods to fix up the M.R.P. The following figure represents an well accepted price fixing policy followed by most companies.

Figure 2: Retail price fixing formula adopted by most pharmaceutical companies



In other way for simplification, $TP \times 1.325 = M.R.P$

For Ciprofloxacin

Price of API Ciprofloxacin HCL = 22\$ per kg (China or Indian origin)

For one Ciprofloxacin 500 mg tablet: (*Considering 1\$=68 taka*)

$$\text{The price of active raw material is} = \frac{22 \times 500}{1000 \times 1000} = 0.011\$ \times 68 = 0.75 \text{ taka}$$

Prices of all other excipients¹², printing, packaging materials = 0.60 taka

Total price of materials (*direct cost*) = 1.35 taka

Indirect cost = 0.50 taka (can differ from company to company)

So, the Trade price for 1 Tablet is = $1.85 \times 15\% \text{ VATT} + 40\% \text{ profit}$
= 2.98 taka

M.R.P would be = 2.98×1.325
= **3.95 taka**

This M.R.P setting technique varies largely among different companies. But it is obvious that the maximum price of a Ciprofloxacin 500mg tablet is below 4 taka. Even in the market, some company supply the product even 2.50 to 3.00 taka. Popular brands are sold from 10 to 14 taka. As the real manufacturing cost is much less, some financially sick companies manufacture this antibiotic at even low cost and make push sells to the pharmacies. On the other hand a pharmacy gets 25-30 percent profit if they keep popular

¹² An excipient is an inactive substance used as a carrier for the active ingredients of a medication.

brands of good local companies which strictly follow cGMP during every step of production. Suppose, in case of brands manufactured by Square, Beximco, ACI pharmaceuticals, the retail sellers get 30-35% profit margin. But if an unknown company gives 200% profit margin, the retailers will be more interested to keep them and sell to the poorly conscious consumers who go to them without prescription. Even from the study it has been found that the retailers try to insist the customers to buy the unknown poor quality brands.

Government has no control over the price control of such essential medicines. As Ciprofloxacin was not in the *Essential Drugs* list before 2008, Government had no control over price setting. The Indicative price set by the company was ultimately approved by the Price Control Committee. Few years ago DDA tried hard to include Ciprofloxacin in the Essential Drugs List to make some control over it. But all efforts were in vain as there were strong resistance from the local companies and also the Druggist and Chemist Association¹³. Finally in the last Essential Drugs List Ciprofloxacin has been included, but still today no control has been implemented by the Government over its price. The pressure group still makes hindrance to take control by the Government.

This inability of the regulatory authority to control price making some good companies make big margin profit by selling good quality brands on one side, while letting some mischievous people earn huge money selling counterfeit drugs and making money overnight. In both cases the distressed consumers are the ultimate loser as they do not

¹³ Interview with Dr. Saiful Islam, Chairman, Department of Clinical Pharmacy and Pharmacology, University of Dhaka and former member of the Parliamentary Standing Committee relating Pharmaceuticals

know what they are administering inside, how much effective the medicines are, how much safe those are for their body.

4.4.1.2 Distribution of Drugs

Drug distribution is an important part in ensuring accessibility by the common people at any corner of the country.. To restrict adulterated or substandard drugs from getting entry in the market, there should be a well-framed distribution channel. The private pharmaceutical companies have their own supply system. The well reputed companies have their own storage facilities in local level. There are some private distribution companies which carry out distribution part of a company. These companies have own transport vehicles, warehouses in different local levels. Small independent pharmacies are the main component of the distribution system. . The Mitford market located in the old Dhaka city plays an important role in marketing of pharmaceuticals. That wholesale market supplies almost all types of pharmaceutical products, raw materials, packing materials. Government has no role in this supply channel run by private firms. Government has no role in these supply chains.

4.4.1.3 Retail sale of the Pharmaceuticals

The number of registered pharmacies all over the country is about 80,000. But in reality approximately 2, 50,000 private pharmacies are in business.¹⁴ in the country So the rest pharmacies are illegal. In Indonesia the total population is about 210 million, there are

¹⁴ Interview with representative from Bangladesh Chemist and Druggist Association

only about 8000 pharmacies all over the country, while in Bangladesh population is 150 million, but about 2, 50,000 pharmacies are in business.¹⁵

Most of the pharmacies in rural areas even in some urban areas do not have any license. Usually pharmacies are individual shops in the market places. As the country is burdened with a huge number of unemployed people, the policy makers, local elites even the administration cannot be very strict against them. Here starting a pharmacy business is very easy. Anybody can start business, with some cash taking permission from the local administration. As there is no regulatory supervision, most of the pharmacies do not have educated well trained pharmacists as staff. Many pharmacies in urban areas have staff having higher education level. But in rural areas this scenario is alarming. Drugs must be dispensed by trained pharmacists. But in case of Bangladesh anybody can start this business as like as other petty business. Consequently this huge drug market has become a resort of counterfeit, banned drugs alongside the quality and safe drugs. Government has very poor supervisory role to monitor. Only 24 Superintendent of Drugs have been working all over the country. So it is quite impossible for them to monitor such a huge market. The Drug Policy 2005 does not mention anything regarding the control over such matter.

4.4.2 Ensuring Quality and safety of drugs

One of the main objectives of the National Drug Policy is to ensure quality, safety and efficacy of all medicines. As medicines are needed for treating the sick people, there is no question of compromising with quality. While some Bangladeshi pharmaceutical

¹⁵ Interview with Professor, Habibur Rahman, former Director of DDA

products on the market are of world-class standards, others are less so. Firms that have invested minimally in quality continue to sell drugs alongside those that have invested substantially. So there is a significant difference in quality aspects available in the market. The medical professionals, pharmacists and also the consumers speak high of quality of drugs manufactured by some top ranked companies in the country. These top 50/60 firms have invested in production of quality raw materials, manufacturing processes and manufacturing environment, and modern technical know-hows. So they manufacture quality medicines. But sufficient data has not been found anywhere about the production of the rest of the firms whether they produce safe medicine or not.

The Drug Directorate Administration (DDA) has been charged with ensuring the safety, efficacy, and quality of drugs in Bangladesh as well as the relevance and accuracy of product information (Ratanawijitrasin 2002). But the DDA is significantly under-resourced. The existing manpower of DDA has been shown in the following table

Table 8: Manpower status of the DDA

Type	Working	Vacant
1 st class	59	22
2 nd class	13	6
3 rd class	91	30
4 th class	57	12
Total	220	70

(Source: Directorate of Drug Administration, Bangladesh)

In 64 districts of Bangladesh there are only 29 superintendents, whereas in every district there must be at least one Superintendent of Drugs. Among 29, 14 working in Dhaka, only 15 working in the field level for 63 districts. Every year one or two Superintendent of Drugs are going to retirement. With this poor manpower the entire pharmaceutical market is nearly impossible to monitor effectively. This is an alarming situation. The other poorly resourced agencies are directly involved in ensuring a safe market are the drug testing laboratories.

Drug testing is the most expensive tool in the drug regulatory process. There are only two drug testing laboratories in Bangladesh, each reporting to different parts of the government. The one in Dhaka reports to the Director of Public Health in the Ministry of Health. The other is in Chittagong and this reports to the DDA. Both the laboratories lack proper equipment, machines and reagents. The staffing is inadequate. The Dhaka laboratory under the Health directorate has no legal capability to independently collect samples from manufacturers. It receives drug samples from DDA inspectors, police raids. If a drug fails its tests, the laboratory reports to the DDA and has no involvement to make further follow up. The laboratory does compile statistics on quality trends but has no knowledge of the reasons why a drug passes or fails, since it is not involved in sample collection.

Now in market about 16000 brand medicines are there. If all the companies on an average manufacture 4 batches of each brand all over the year then there would be $16000 \times 5 = 80,000$ batches. If through random sampling 12000 samples are collected for analytical tests then in one month 1000 samples need to be tested. Then everyday at least

50 sample must be tested. In some cases analytical tests require two or more days. Antibiotics require microbial tests too. For this huge task more than 100 analysts and same number of technical assistants are required. But the laboratories have only 24 staffs working there. Every year two laboratories have the capacities to analyze at best 4000 samples, but it needs to test 12,000 samples. One major problem is in testing such a big amount of samples, there is need of reagents, chemicals. Some reagents are too expensive. The Government does not allocate sufficient budget. So performing analytical tests with this poorly equipped laboratories, scarce manpower and budget and poor logistic support is near to impossible. So many batches of drugs are entering the market without getting pass from the Government authority. It has been found in many cases the authority DDA is permitting the drug in the market depending on the analytical results submitted by the respective companies.

The drug superintendent needs sufficient amount of medicines for testing and he needs to collect that from one shop. Sometimes the medicine is a bit expensive. If the inspector withdraws 40 tablets randomly costing 15 taka each, it will take 600 taka. DDA does not get enough budget to be dispersed among the drug inspectors to do this job. At present WHO is running a project of post marketing surveillance. In this project some allocations have been made to make the survey. On an average a superintendent gets eight to nine thousand taka every year for sample collection from the market. They cannot make surveillance effectively. And this poor supervision can be fatal sometimes. The recent paracetamol tragedy is a citable example.

(II) Case Study: Paracetamol Tragedy

Since independence the country faced Paracetamol tragedy for 2 times. About 2000 children died by toxic paracetamol between 1980 and 1992. Earlier in 1992 a total of 339 children had died after taking Paracetamol syrup of 5 companies- Adflame Pharmaceuticals Limited, BC laboratories, Polychem Laboratories, Rex pharmaceuticals, and Pan Asia Pharmaceuticals Ltd. The 5 companies were shut down by the Government afterwards. After extensive investigation it was found that those syrups contained toxic Diethylene Glycol instead of Propylene Glycol as solvent. Diethylene Glycol solvents usually used in plastic rubber, textile and leather dyeing industries. It is less expensive and can be bought only at taka 200 per liter, while the appropriate solvent Propylene Glycol is 1100 taka per liter. The unscrupulous business people mix diethylene glycol to make profit.

Weak regulatory role of the Government once again brought about Paracetamol tragedy. And this time Rid Pharmaceuticals was the culprit. Rid Pharmaceuticals started operation back in 2005. During that time there was an order that "no new Pharmaceutical company would be allowed to start operation unless it had an investment to make injectables" But Rid pharmaceuticals had no Injectable plants. Still then the company got the license to start operation. Illegal political pressure was behind this¹⁶. The company was established in the BSCIC Industrial Area at Nandanpur in Brahmanbaria. It had license to manufacture paracetamol suspension but not syrup. But the company manufactured paracetamol syrup named 'Temset' incorporating toxic Diethylene Glycol. Upon taking this toxic syrup 25 children were dead from renal failure back in June 2009. 34 children with acute renal complication were admitted to Dhaka Shishu Hospital and BSMMU hospital from June to August 2009. The children were suffering from acute fever, oedema and

¹⁶ Interview with Prof. ABM Farouque, Department of Pharmaceutical Technology, University of Dhaka

suppression of urine. Government ordered to withdraw Rid Pharmaceuticals products from the market on July 22, 2009. 4 cases have been filed by the DDA in the Drug court under provisions of the Drug (Control) Ordinance, 1982. The Managing Director of that company was arrested. The case is under trial although a writ petition has been filed in the High Court division in favour of the accused Managing Director of that company.

The Rid pharmaceuticals tragedy shows the weak supervisory role of the concerned authority DDA. The efficiency of that agency have been going under criticism. The DDA always tries to say that lack of manpower makes the agency inefficient. But the question was raised if the DDA cannot monitor the market efficiently then why it gives permission for launching newer brands frequently. Corruption, unethical service delivery have always defamed the agency.

4.4.3 Ensuring Rational Use of drugs

According to WHO, "The rational use of drugs means that patient receive medicines appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest possible cost to them and their community." Rational use is essential as irrational use can make negative effect not only by making potential risk to health, but also incurs financial loss. Besides the profit seeking pharmaceutical companies physicians can play important role in ensuring rational use of drugs.

Physicians play vital role in shaping the pharmaceutical market. Pharmaceutical companies always try to convince physicians so that they prescribe the brands

manufactured by that company. The *Medical Representatives* (MRs) often termed as *Medical Promotion Officers* are the main field force of a pharmaceutical company. Their main job is to inform doctors about their products. MRs act as promoters of products. As there are good number of pharmaceutical companies that manufacture quality products, so there is always a huge competitions among the companies to take the lion share of the market. And the only way is to achieve is that to convince the doctors more and more. For this companies adopt unique strategies. From the study it has been found that a variety of gift packages are offered for the doctors to convince them. The different gifts that are offered are as follows:

4.4.4 Traditional gift items

Pen, pen holder, desk calendar, glass, tissue box, toiletries and so on were the traditional gift items given to doctors by drug companies to promote certain drugs. But now a day the pattern of offering gifts has been changed. If a renowned senior professor writes any brand, it will surely take major market share. In pursue of that companies do not hesitate to invest more money as gifts to that doctor. Suppose in case of patients suffering from diabetes, hypertension he has to take medicine throughout his rest of life. So what the brand doctor prescribes and if the patient feels by better intake of that drug he will never change the brand until the doctor changes it in next time. So this means one brand gets the lion share. From the study it has been found that doctors in BIRDEM and Heart Foundation gets maximum gifts from companies. The company makes some unique gifts to promote their products, so gifts are as follows:

- Monthly cash (can be 5000 – 100000 taka)
- Plane fare (for attending any international seminar, conference)
- Car
- Children's tuition fees
- Apartment, Land
- Clothes on special occasions (shirt, trouser, Punjabi, sari etc)
- Animals for sacrificing during Eid-ul-Azha
- Variety of food items

In fact there is no restriction for making gifts. Innovative ideas are always in practice just to attract the doctors. In rare cases it has been found that some unethical demands are also met by the companies. In all cases MR plays the role of the media. Company also gets the reward. The doctors are then obliged to accommodate different medicines and thus the prescription become larger. The tendency to write Vitamin tablets arise from this binding of doctors. And the patients have to buy unnecessary medicines quite often.

4.5 Conclusion

In Bangladesh it is very easy to register a new drug. This way every month new generic products, brand products are entering in the market. And there are so many similar type generic drugs in the market that often the physicians get confused. While in Saudi Arabia there is strict restriction of registering INN products, in Bangladesh every year quite a good number of INN brands are swelling the market. Leading companies have tendencies to introduce new drugs. This has made our market flooded with medicines. And the consumers have become guinea pigs. The NDP 2005 has not addressed this issue.

Strict control is needed to make the pharmaceutical market abundant with only necessary drugs. From the study it has been found that the NDP 2005 could not make any positive impact in terms of Government's efficiency to control the market. Still the private sector, business entrepreneurs hold the rein of the market. In the next chapter the findings of this study will be described elaborately along with critical analysis.

CHAPTER 5

Findings and Analysis

5.1 Introduction

In the previous chapter achievements, implementation gaps and also the nature of pharmaceutical market have been identified. This chapter will show what factors influence NDP 2005 implementation process. In doing this, the success factors of the previous programs will also be analyzed. Comparison between the Drug Ordinance 1982 and the NDP 2005 will enable to get the answer. In the later part of the chapter the complex market structure will be discussed along with scrutinizing the Government's monitoring role over the market. Finally causes of major policy failure will be shown. Efforts will be made to fit these factors and causes with the theoretical framework discussed in the third chapter.

5.2 Implementation State of the DP 2005

Implementation represents the conscious conversation of policy plans into reality. Policy success depends on how well bureaucratic structures implement government's decision. Policy execution inevitably depends upon the components of public policy that precede it. If we try to analyze the NDP 2005 in light of the framework proposed by *Gerston (1997)* we find:

➤ **Sufficient resources of entity to carry out the implementation tasks-**

In case of NDP 2005, no additional budget was allocated to implement the policy in the last 3 years.

➤ **Capability of agency to translate goals into an operational framework-**

The agencies involved in implementation process have not yet been capable of translating the goals of the DP 2005. The inertness of the political leadership, uncertainty in the political atmosphere in 2007 and 2008 made the agencies sluggish. The DDA, DTL, Ministry of Health and Family Welfare have not yet achieved the institutional capacity to create an operational framework which will propel the implementation process.

➤ **Oversight and accountability**

This is an important requirement for any successful implementation of public policy. There should be a '*structured body*' to oversee the activities of the concerned policy actors, policy instruments as well as the ongoing policy process. For NDP 2005 no such activity has been found. There has been no accountability to no one.

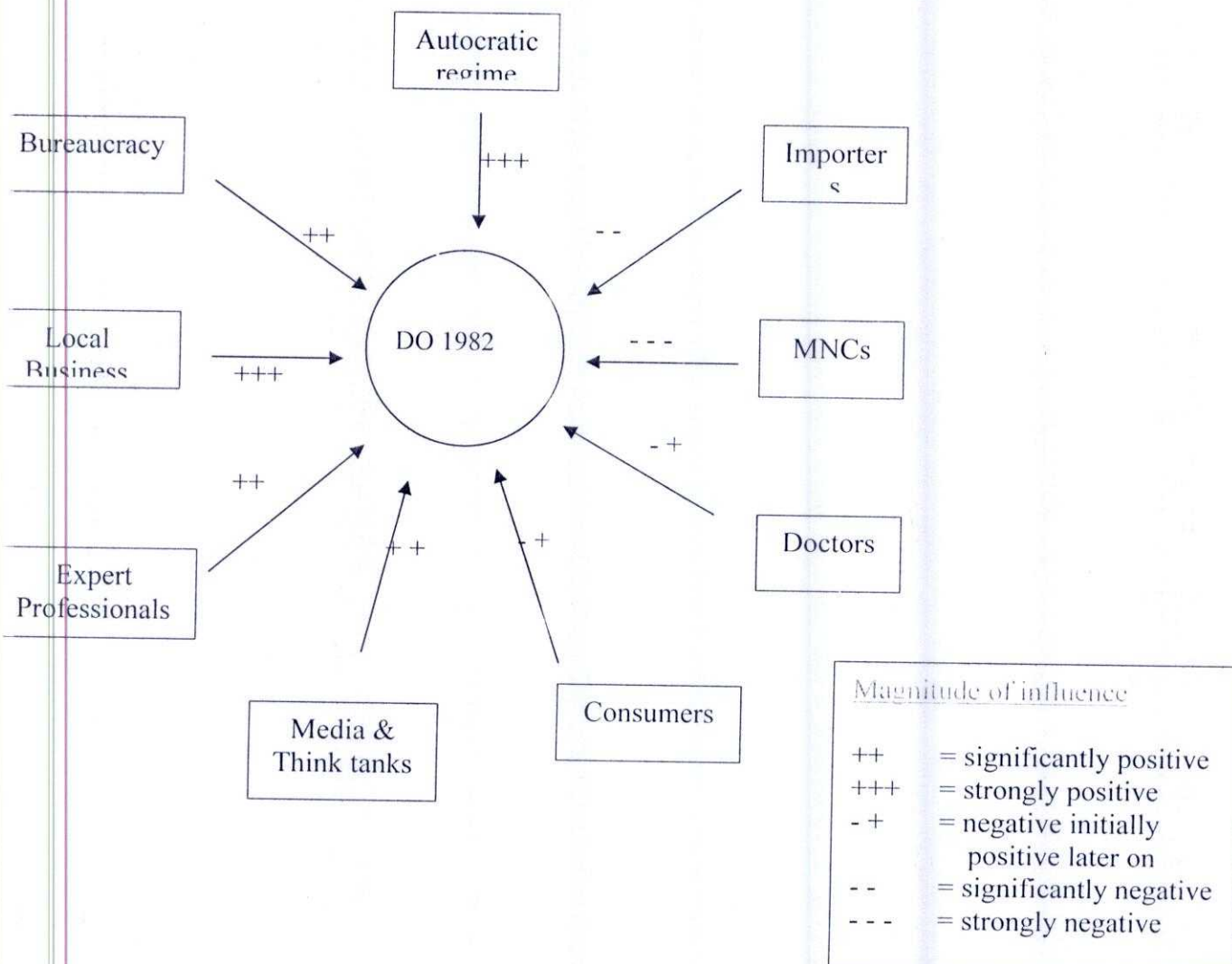
5.3 Comparison between NDP 2005 and DP 1982

The Drug (Control) Ordinance 1982 often termed as the Drug Policy 1982 is considered as a successful public policy. The implementation effect of that policy was exhibited immediately after its promulgation. But implementation of the NDP 2005 is still unsatisfactory. Most of the people do not know about the existence of the policy. It has been found from the survey that 3 educated, conscious people out of 30 know about the policy. On the other hand 24 people know about the Drug Ordinance of 1982. It shows that DO 1982 have been able to create more impact than the latest policy of 2005.

Let us try to analyze why the NDP 2005 fails to bring some impact while DO 1982 has been a successful one.

The content of policy along with the relationships among different policy actors make vital role in implementation success. The actors can be summarized as political parties, bureaucracy, local business entrepreneurs, professionals, media, consumers, doctors, Multi national companies (MNCs), Importers. The following two figures will show influence of different policy actors and institutions in implementation of two policies.

Figure 3: Influence of different policy actors/ institutions in implementation success of the National Drug Ordinance 1982



If we analyze the implementation success of DO 1982 we find the following factors played pivotal role.

- ***Autocratic regime***

Strong autocratic martial law regime played the most significant role in formulation and implementation of the Drug Ordinance 1982 and also the policy. The democratic Government tries to accommodate different views of different pressure groups. As the period was martial law period the Government was able to carry on with most of the implementation steps effectively. That time the Drug (Control) ordinance was passed before any formal policy took shape. This ordinance is widely viewed as Drug Policy 1982¹⁷

- ***Bureaucracy***

As the political regime was committed, the bureaucracy also acted vibrantly in implementation process. The ordinance was formulated to achieve some well accepted objectives like controlling the market, banning of unnecessary harmful products manufactured by multinational companies, and above all development of local entrepreneurship. Need based necessary amendments were made afterwards. The Drugs (Control) (Amendment) Ordinance, 1982, The Drugs (Control) (Amendment) Ordinance, 1984 were made to achieve the goals set in the programme. These initiatives were taken by the bureaucracy then.

¹⁷ Interview with Professor Habibur Rahman, Former Director of DDA

- ***Local business entrepreneurs***

This group played the crucial role as one of the main objectives was to facilitate the growth of local companies. Incentives were offered to local manufacturers. So this community played significant positive role in case of implementation.

- ***Expert professionals***

Expert professionals like pharmacists were in favour as there was a special provision in the ordinance. That is "*No person shall manufacture any drug except under the personal supervision of a pharmacist registered in Register 'A' of the pharmacy council of Bangladesh.*" This was recognition of the pharmacy professional group. They owned the strategies, got chance to apply their talent and professional expertise to improve the pharmaceutical sector in the country

- ***Media, think tanks*** were positive as its objective was for the betterment of the common people and local industries.

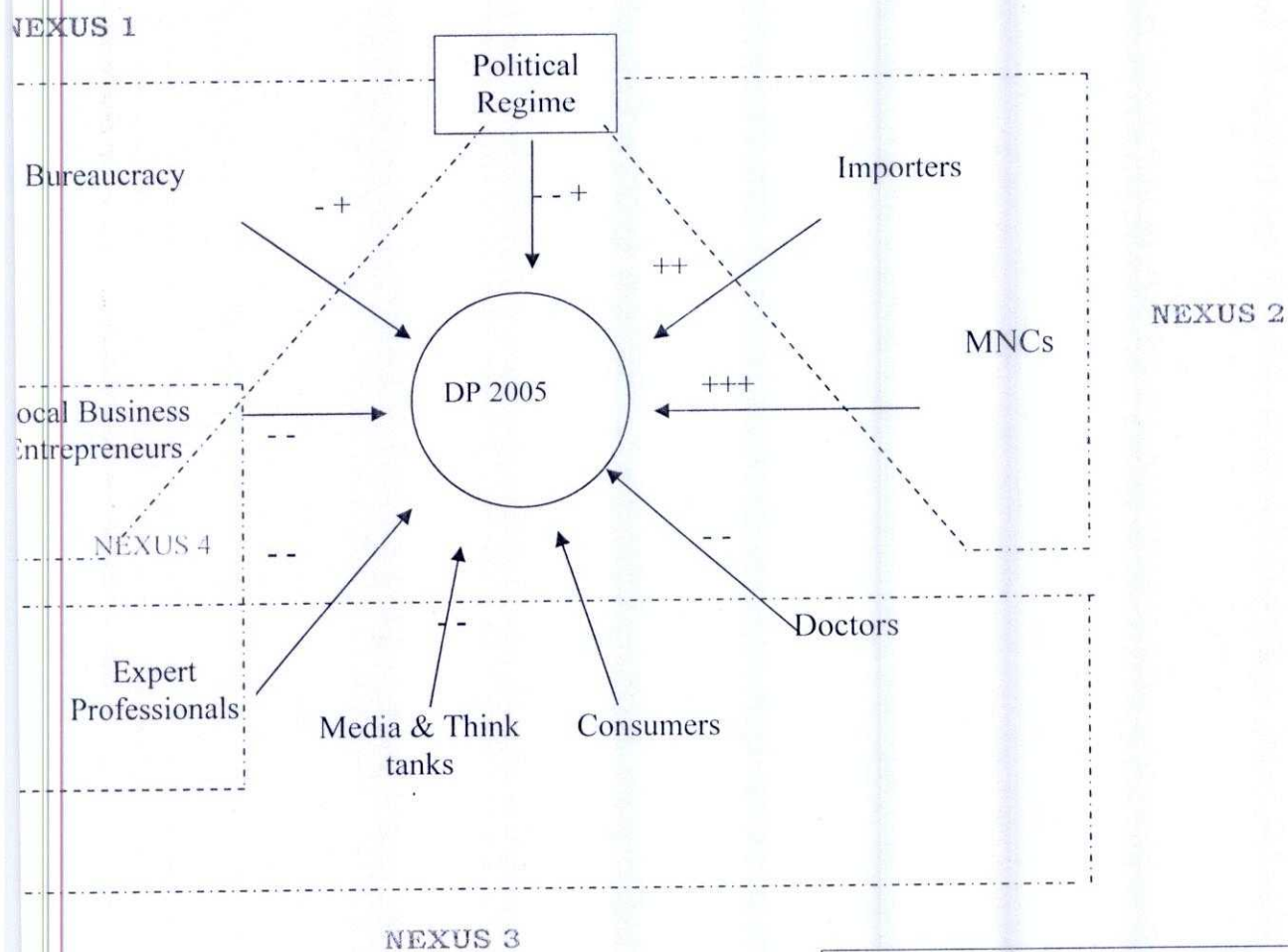
compelled the MNCs to manufacture products that require sophisticated technology and not general technology. Consequently the MNCs started losing their market share to the rising local companies. So the MNCs and the Importer were against the implementation process. The then Government had to bear enough pressure from the international donor community.

- ***Doctors and consumers***

At initial physicians and consumers were confused about the usefulness, safety and efficacy of the products manufactured by local companies as they had long dependency on MNCs' products. But later on confidence was grown among them and they stand alongside the local manufacturers.

Now let us analyze the implementation progress of the National Drug Policy 2005. Since the declaration of the DP 2005, 4 and half years have already passed. Policy outcome is very poor and Government's monitoring over the pharmaceutical market still lacking far behind. Implementation gaps of DP 2005 arise from the failure in making plans and strategies to carry on the above mentioned tasks. If we analyze the role and influence of different actors on DP 2005 we find that the influential actors were not so active like they were in case of DO 1982. Figure 4 below illustrates the salient features that are responsible for making the policy outcome unsatisfactory.

Figure 4: Influence of different policy actors/ institutions in implementation process of the National Drug Policy 2005



Magnitude of influence

- ++ = significant positive
- +++ = strongly positive
- - + = strong negative initially positive later on
- - = significantly negative

◆ **Political regime**

Political regimes exert most significant influence over the policy process. The last 3-4 years Bangladesh has been suffering from fragile political system especially from 2007 and 2008 regime legitimacy was a burning question. The NDP 2005 was formulated in the period of BNP Government. After the declaration of the policy on 18 April 2005, there was a widespread criticism from some segments among the policy actors also. In May, 2005 the DP was slightly amended. Other than this no significant implementation steps were taken in 2005 and 2006 by the Government. Political inertness was mainly responsible for it.¹⁸ In 2007 and 2008 the country experienced anti corruption drive taken by the non-party army backed caretaker government. The uncertainty, illegitimacy, fragility overshadowed the entire political as well as bureaucratic system.

Things were better in 2008 when implementation steps got some momentum. This resulted in preparation of a vital component of NDP 2005, the *Essential Drugs List*. The present Government has started thinking seriously about institutional capacity building of the main public agency related to DP implementation, the DDA. In case of Bangladesh there is no continuity of policy process. Policy formulated by one government is not implemented by the successive government. These tendencies also divert the main policy objectives and lingers the implementation process.

◆ **Bureaucracy**

As the political leadership was inert, the bureaucracy did not take initiative to design short term or long term programs or strategies to implement the policy. In 2007 and 2008

¹⁸ Interview with Professor A B M Faroque, Department of Pharmaceutical Technology, University of Dhaka & Member Secretary, Citizens' Committee for Review of Drug Policies.

this bureaucratic inertia became aggravated. Bureaucrats' 'wait and 'see' motive in those two years made the implementation process slow. The idea of up gradation of DDA from a Directorate to a Director General office with sufficient autonomy has not been well appreciated by some top bureaucrats as they always try to figure out 'who gets what' in new programme. New posting, new authority can be a propelling incentive to make bureaucrats work alongside the implementation track vibrantly.

◆ **Local Business entrepreneurs**

The local pharmaceutical firms have been enjoying '*protected market*' since 1982. There are certain provisions included in the DP 2005 giving some relaxation to the multinational companies and also the importers in respect to import pharmaceuticals from abroad. In Drug Ordinance 1982 special priority was awarded solely to the local companies while in the DP 2005 some provisions have been incorporated to facilitate similar incentives to both local and MNCs. In the objectives it has been stated

"(f) to encourage foreign manufacturers to invest, manufacture and sell drugs in Bangladesh with corresponding assurance of transfer of new technology and technical knowledge in the country."

(k) to ensure that no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh while applying the principles of this policy."

The local business entrepreneurs consider these as potential threats. Moreover they believe that no strict measures have been cited in the policy to restrict import of drugs, rather the policy indirectly encourages import. As imported drugs may take some

portion of the market share, the local firms have not been enthusiastic about the policy success as much as they were so in case of implementation of DO 1982. In case of pharmaceutical market in Bangladesh, the BAPI (Bangladesh association Of Pharmaceutical Industries) is the most influential policy actor. So their opposition has resulted in policy failure up to date

◆ **Expert professionals**

In the DO 1982 there was a section 13 (1)

“no person shall manufacture any drug except under the personal supervision of a pharmacist registered in Register ‘A’ of the Pharmacy Council of Bangladesh.”

None other than the university Pharmacy graduates are eligible to get registration as ‘A’ grade pharmacist. This above rule ensuring the job security and job recognition triggered the pharmacists to render dedicated services and impart knowledge and expertise in the development of pharmaceutical industries in Bangladesh. Today the pharmaceutical sector has become a leading industrial sector in the country. Physicians and also the proprietors of the companies do not hesitate to pay tribute to the ‘pharmacy professional group’ in their contribution of development of this sector.

The inclusion of this section in DO 1982, at one side brought about enthusiasm among pharmacists, on other side experts from other disciplines like Chemistry, Microbiology, Applied Chemistry, Biochemistry were offended as they considered it an attempt to undermine their important roles in the pharmaceutical industries. They, in the shape of BAPC (Bangladesh Association of Pharmaceutical Chemists) exerted pressure

on the policy makers to review and repeal that respective section. So there had been constant tension between Pharmacists and other expert groups.

In the NDP 2005 there have been no directives about recognition, job security, and employment opportunity of different professional groups. So there was wide range of criticism from the professional bodies. Later on 9 February, 2006 parliament passed The Drugs (Control) (Amendment) Act, 2006 in which the respective 13 (1) section has been amended in following way-

“No person shall manufacture –

1. any allopathic drug except under the personal supervision of two personnel, out of whom one shall be a pharmacist registered in Register 'A' of the Pharmacy Council of Bangladesh and another shall be a person having the following academic qualification from any university recognized by the Government
 - Master's degree or Bachelor degree with Honours (4 years curricula) in Chemistry, Biochemistry, Applied Chemistry, Microbiology, Pharmacology or Genetic Engineering; or
 - Bachelor degree in Pharmacy, Medicine or Chemical Engineering.

This amendment created negative attitudes among the most influential expert group in the pharmaceutical sector, the pharmacists' groups as they consider this amendment has curtailed their professional rights. In many of the local and multinational companies pharmacists are holding '*decision making*' and other influential positions, some even have become proprietors of leading companies. There is a NEXUS between this influential

expert group and business entrepreneurs. The inertia created by the 'Nexus' about the policy eventually makes the policy failure.

◆ **Media, think tanks, consumers, doctors**

The DP 2005 was not appreciated by media, think tanks in short the 'Watchdog' of the society. Their observation is that the DP 2005

- ◆ has failed to identify and ban harmful and redundant drugs
- ◆ expresses no effective price control mechanism by the Government
- ◆ has allowed free import from abroad

Besides in the DP there is a provision which says that "*certain drugs, in spite of their known serious side-effects and possibility of being misused may be registered for import, production and sale in limited quantity for restricted use.*" As the Government has poor institutional capacity to supervise the market, it would be impossible to restrict the entrance, supply and use by the consumers of such drugs. The 'watchdog' group criticizes that the policy thereby encouraging the manufacturing firms, importers to do an unethical job within legal framework.¹⁹

◆ **MNCs and Importers**

As there have been certain provisions facilitating MNCs' to spread business in this 'protected market' they are positive about the policy process. Restrictions on imported

¹⁹ Round-table discussions in the National Press Club on 30th June 2006 and 1st August 2006 by 'Doctors for Health and Environment', an organization of doctors and 'Pharmacy Graduates' Association, Bangladesh' an organization of pharmacists.

drugs have been relaxed to some extent in the DP 2005. This also encouraged the 'Importers' to facilitate implementation process.

From the study it is found that there has been different 'Nexus' among different groups. The business group that is BAPI has the most influential role in shaping the pharmaceutical policies. Business society often makes huge donations to the political parties, both in power and in opposition. After the promulgation of DO 1982, the profits made by local companies simply rocketed up. This sharp rise encouraged lot of business people to invest in this sector. This resulted in establishment of so many pharmaceutical companies in short period of time. Pharmaceutical business is regarded as one of the most profitable businesses. As many influential people are involved in this sector, BAPI exercises much influence. They have influence on Drug Control Committee, Price Control Committee and all other committees formed by the Government. This Nexus between pharmaceutical entrepreneurs, political authority and bureaucracy plays the significant role in shaping the implementation process.

5.4 Pharmaceutical market structure and supervision of the Government

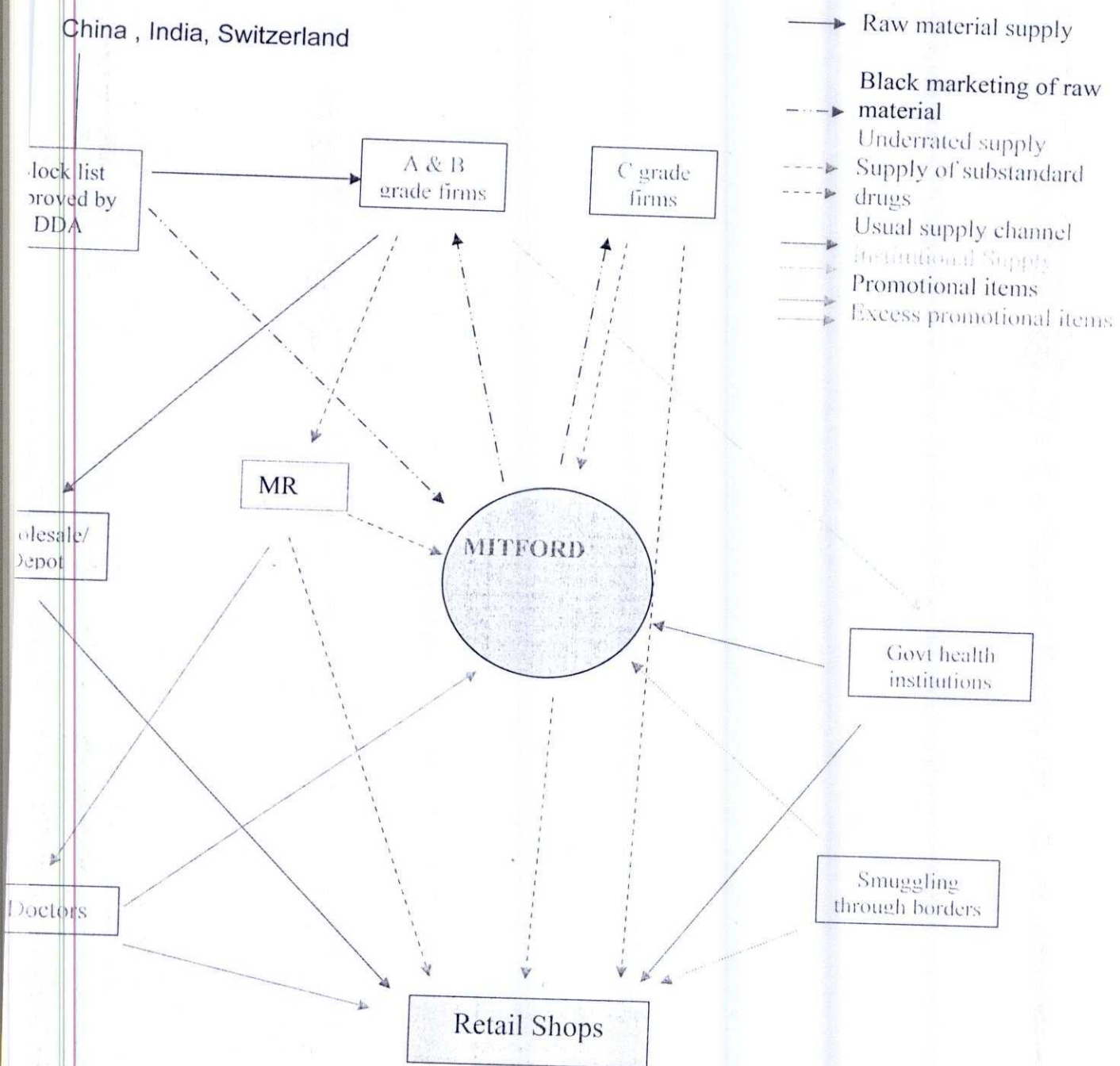
From the previous chapter we have seen Government has poor monitoring role over the pharmaceutical market. We have now analyzed that the policy contents of DP 2005 has failed to strengthen Government's role in broad way. The significant impact created by the DO 1982 enabled the Government to rule over the entire market more efficiently although it is not easy to monitor market full satisfactorily. The open market economy, pressure from different countries to open up the market, unethical business minds, corruption, poor governance, poor institutional capacity have weakened the supervision.

If we try to draw the supply pattern of the existing market we find it is a distorted market having complex structure. Firms submit Block List (annual requirement of raw material, packaging material for import) to DDA. The concerned superintendent or inspector is supposed to evaluate the block list considering annual production capacity of that company, market demand and other aspects before approving the Block list. But in practice, in most cases this is not done by making *Personal inspection* by the inspectors as the DDA has no sufficient manpower. Corruption is another crucial aspect in this issue.

Sometimes some firms do not utilize full lot of the imported raw material; they sell it to Mitford making some profit. Many companies do not feel interested to take the hassle of making Block list, going to DDA day after day to convince the concerned officials and get the list approved. Rather those companies buy necessary raw materials from the black market. Even the leading companies also purchase raw material, packaging materials from Mitford in case of emergency.

In case of distribution of the finished drugs it is found that 'A' and 'B' grade firms have distribution system of their own. Some companies outsourced distribution to other companies. 'C' grade companies market their products mostly in the rural areas through '*push selling*' by agents. From the study it has been found that some unscrupulous business people in Mitford make order to these 'C' grade companies to counterfeit or duplicate the most running brands. The DDA officials admit they have no control over such companies. In some cases even no information becomes available when those companies are in production.

Figure 5: Supply pattern of Pharmaceutical Market in Bangladesh



Some drugs are banned in Bangladesh considering those may exert potential threat to public health as there is chance of drug abuse. But as there is no updated list for the banned drugs. Physicians are often lacking the up dated information. So they prescribe such drugs and upon demand by the patients these types of medicines are entering into the market through borders by illegal way. Considering the risk of 'drug abuse, *Viagra* (active- Sildenafil Citrate) has not yet been permitted to import, manufacture or sale in Bangladesh. But in many countries even in India, it is not banned. Besides *Viagra*, some steroidal drugs like *gynocossides* used as *abortifacient*²⁰ and also intended in the treatment of post-partum haemorrhage are prescribed quite often. Huge amount of such types of drugs are being smuggled from India, China, Myanmar every year. It is not an easy task for the Bangladesh Rifles or other law enforcing agency to check our long border line to restrict smuggling. Airport and sea ports also have been used as smuggling channel. Theses drugs are being sold almost all over the country. As there is demand, *supply* will find its way to take place. The retail sellers use the plea that they do not know about the banned drugs, they keep such drugs in their pharmacies as patients seek those showing prescription.

The Government's health institutions purchase drugs through tender process. Pharmaceutical companies usually supply drugs to such institutions with fewer profit margins. The corrupt employees sell medicines to Mitford at regular basis. In most cases the institution itself has no intention, capacity or any tool to restrict such kind of outward supply.

²⁰ Abortifacient are known as drugs that facilitates miscarriage.

Sometimes the companies even the reputed companies sell several lots of drugs to the Mitford through agents or MRs at lower rates. This '*underrated*' supply is done for implementation of different marketing strategies by that company. Sometime the company wants to increase its liquidity through this kind of transaction. MRs give physicians lots of samples as promotional items every month. A MR of a reputed company can have samples worth of about 30,000-35000 Taka. These samples are also sold to market by the MRs and in some cases the physicians. If a reputed company finds that its popular brand has been duplicated, it will not raise any formal complaint to the regulatory authority. The reason behind it is the fear of losing image of the entire products of that reputed company as a whole. Widespread circulation in dailies will lose patients' confidence on not only that brand but also on that particular company. Consequently other products will lose acceptance to physicians and consumers. This restricts the companies to take any action regarding the duplicated brands. This way the market is cursed with many substandard, counterfeit drugs.

5.5 Conclusion

It is clear that the pharmaceutical market in Bangladesh enjoys complex dynamism. The entire demand-supply network is so critically spread, embedded in the entire market that it is very hard for the regulatory authority to exert control to a significant extent. Government with its limited resources and institutional capacities cannot spread an effective grasp over the entire pharmaceutical market. Without a concerted effort dedicatedly initiated by all the actors involved, institutions engaged, it will be next to impossible to bring the pharmaceutical market of the country within a structured-legal-regulatory framework, which actually needed to ensure welfare for the people of the country.

CHAPTER 6

Conclusion and Recommendations

6.1 Conclusion

Pharmaceutical industry has grown in Bangladesh in the last two decades at a considerable rate. Its healthy growth supports development of other auxiliary industries like glass bottles producing industries, plastic containers, aluminum collapsible tubes, aluminum PP caps, infusion sets, disposable syringes, and corrugated cartons. Printing and packaging industries and even the advertising industries consider pharmaceutical industry as their major clients and a key driving force for their growth. Now the Government needs to support and take pragmatic steps to make this promising market sustainable in this era of globalization, strong competition from the giant multinational companies.

This study has been carried out to analyze the role of the government to develop this pharmaceutical sector. With expansion of this sector, governments monitoring role has become an important question when the matter of public health safety was crucial. From the study we have found the picture of the pharmaceutical market of the country and also the role of the Government in controlling the market. The positive impacts created aftermath of the promulgation of the Drug (Control) Ordinance 1982 which is often well known as the Drug Policy 1982 has been compared with the Drug Policy 2005. The implementation state of the NDP has been critically analyzed in this study.

Since 1982 the pharmaceutical sector has been making development. The political environment, bureaucracy, local business entrepreneurs, civil society members, academicians all the policy actors were brought under same umbrella. This was the greatest success of the Drug Policy 1982. The policy content was designed to give incentives to the development of the local companies to take away market share from the multinational companies. This created a widespread support from all sector of people. But there was always pressure from some corners specially the importers and also the Multi national companies to open up the market and make respective amendments in the policy content of the DCO 1982. Besides there were growing demands to review that policy. The National Drug Policy 2005 was the ultimate result.

According to the World Health Organization a national drug policy of a country should be reviewed in every three years. So there has been a justification to analyze the implementation state of the NDP. The objectives of that policy are to ensure safe, effective drugs to all at affordable prices. On one hand there has been rapid expansion of this sector, on the other side the government's regulatory mechanism has been loosing its efficiency. This study shows that very few steps have been adopted until now to make the regulatory bodies efficient. Consequently most of the policy objectives are still in the document only. Political inertness resulting in bureaucratic sluggishness has been found mostly responsible for making the implementation gape. Moreover policy content has been found to some extent responsible for making the policy itself unworkable.

As the local companies have been enjoying "*protected market*" these pressure group has not been interested about the policy success of NDP accusing that

pharmaceutical import, investment by the giant multinational companies have been encouraged in the policy. So the companies are afraid to lose their market share. Besides weak regulatory environment can encourage many sick companies to manufacture and market substandard, adulterated and counterfeit drugs. We find that until recent past the Government was not enthusiastic in increasing capabilities of different public agencies that can be termed as policy instruments.

The Directorate of Drug Administration is the main public agency to implement the objectives of the policy. But inadequate manpower, budget constraint, poor institutional capacity all has made this agency unworkable. Most of the people consider the agency totally inefficient to monitor the safety, quality of the entire pharmaceutical market. Corruption is another prominent feature. It is believed that with the existing limited resource that agency could perform its duty more efficiently than now if corruption had not been there.

Lack of monitoring of the government agency can be fatal. The country already faced two incidents where many innocent infants had to succumb to death by taking toxic drugs. In the 1980s to early 1990s thousands of infants died of renal failure after being given contaminated paracetamol syrup. At Dhaka *Shishu* Hospital 339 babies have died from taking diethylene glycol-laced paracetamol syrup. At that time the government stopped production of the five accused pharmaceutical companies. But lack of monitoring of the government agency- Drug Administration resulted in history repeating itself in July 2009. This time taking the same toxic tainted paracetamol syrup, produced by Rid pharmaceutical company of Brahmanbaria BSCIC area, 25 children between one and five

died. And this again raised the issue of inefficiency of the government's agencies involved to ensure safe drugs for the consumers.

Upon large criticism Government finally took steps to strengthen the DDA with increased manpower and resources. But the process has been not speedy until now. Moreover from this study it has been shown that maintaining quality cannot be ensured by government only. The huge volume of drugs, imported raw materials (APIs) cannot be tested by the agencies of the government. Private sector needs to be engaged in this arena. Besides quality and safety government has been performing unsatisfactory role to control price of the drugs. The Drug (Control) Ordinance enabled DDA to control prices of the essential drugs at initial stage. Later on there has been some relaxation. The essential drug list and the prices set by the government were needed to be monitored frequently. But this was not done. So the reputed companies gradually lost interest to manufacture such drugs in plea of narrow profit margin. The NDP 2005 admits the necessity of reviewing the *Essential Drugs* list. Finally a new list was published by the Government and it can be considered the most significant implementation success of NDP 2005. But the list needs to be made fruitful. Government has not yet taken any step to review the existing price and set up new prices for the essential drugs.

Being a least developed country Bangladesh has been enjoying the patent waiver facility under the TRIPS of the WTO. The pharmaceutical export in recent years increased satisfactorily. This opportunity will end up in 2016. After that time the local manufacturers would face strong challenges. Even many companies would face the challenge of existence. For that the country needs to take strong steps to ensure sustainability of this

sector. Moreover the recent paracetamol tragedy has largely tainted the reputation of the pharmaceutical products. If this happens again and again, certainly the importing countries will lose trust on Bangladeshi drugs. And this will hamper our export. To solve the existing problems and to face the upcoming challenges In the coming days some recommendations have been drawn through learning from this study. These are as follows

6.2 Recommendations

To safeguard the interests of all people belonging to different strata of the society and in the interest of development of our pharmaceutical industries there should be some amendments in the policy objectives and also policy implementation programmes. The following recommendations are set to meet up the challenges of the policy processes:

- 1) The *Essential Drugs* list should be made effective. Government should review the prices of the essential drugs as it has been fixed in 1994. The *Essential Drug List* should be classified as Drugs used for primary, secondary and tertiary uses.
- 2) A price fixation committee formed by the government must control prices of the drugs and this committee should include drug specialists and representatives of drugs consumers' associations. Once in a year the committee shall review prices of all drugs. It can have a special meeting to consider a written application for enhancement of price, If received from at least 50% of the manufacturing companies on logical grounds.
- 3) The Government must issue instruction to the Essential Drugs Company Ltd (EDCL), a company established with the financial assistance from WHO, to manufacture all the drugs in the Essential Drug List as the price fixed by the Government. The EDCL

must also be given the task for manufacturing life saving antibiotics plus drugs that are less common but used in cases of extreme emergency like those used in Incentive Care Units (ICUs). Availability of these drugs in all hospitals and drug stores all over the country must also be ensured. For this purpose, further extension and development of the EDCL must be undertaken. Incentives must be given to those pharmaceutical companies manufacturing most essential drugs.

4) Some factories in the country are currently producing pharmaceutical raw materials. But in order to meet the ever increasing demands for newer drug molecules, the Government should give all possible assistance to the local entrepreneurs so that they may establish more and more such raw material producing plants.

5) No manufacturing company, local or foreign, should not be given permission to manufacture any drug identified as harmful to human health even it is intended for export purposes only. Because there will always be risk of such drugs getting penetration in the local market.

6) Food and cosmetic items should also be brought under the control of Directorate General of Drug Administration. The regulatory guidelines of WHO should strictly be followed in the activities of the agency which will include inspection of manufacturing plants, storage houses and shops, registration of the retails shops, renewal of licenses, testing of quality of APIs and also finished drugs, employment of personnel and so on.

- 7) The Drug testing laboratories should be modernized. The capacity and manpower should be increased. There should be at least a drug testing laboratory in all divisional headquarters.
- 8) To make successful implementation of the NDP 2005, government must design short term and long term programmes. Besides increasing manpower in DDA, DTL Government must take steps to amend the pertinent existing laws and rules as the punitive measures described in the laws are not effective to punish the ill doers.
- 9) The registration criteria must be changed. To ensure the rational use of drugs the regulatory authority should not allow new drugs to get registration without much supporting data. The tendencies of the pharmaceutical companies to introduce new molecules frequently and in most cases unnecessarily should be restricted.
- 10) The Adverse Drug Reaction Cell belonging to the Drug Administration should be run effectively with the help of the doctors, pharmacists. There must be an information cell in DDA which will dissipate all types of information to the consumers.
- 11) Since a tripartite awareness of the government, doctors and the patients is a prerequisite for ensuring the efficacy and safety of any drug, the government should take all necessary steps in generating this awareness. For this purpose detailed ethical guidelines based on principles of WHO's rational use of drugs should be framed to regulate the marketing strategy of the manufacturers, issue of presentation by the doctors and sale of drugs by the retail shops. All leaflets attached to drugs sold to the users should be written in simple *Bangla* (local language) and in a readable form.

12) Government should take leadership role in adopting a comprehensive national programme to promote rational drug use by health workers and consumers covering both public and private sector. There should be nationally agreed clinical guidelines covering the most common diseases that attack the population here and the complaints raised by the patients in general. Clinical guidelines define the desired prescribing behaviour and constitute the core of all education. In addition they define the selection of essential drugs for the supply system.

13) There should be nationally agreed clinical guidelines covering the most common diseases that attack the population and the complaints raised by the patients in general. This way the most needed essential drug list can be prepared and supply of these drugs can be well monitored by the Government. Drug bulletin providing independent and up-to-date information on selected drugs, their cost of treatment should be published by the Government on regular basis and should be widely circulated. Besides, for success more interactive interventions, such as discussion groups, problem based learning and prescription review can also be helpful.

14) Government should promote Hospital Drugs and Therapeutic committee in some major / big public and private hospitals. Under supervision of the National Committee such committee can develop and coordinate all hospital policies related to pharmaceuticals such as on the selection of standard treatments, hospital formularies and drug budgets. Moreover these committees will also be responsible for adopting the national clinical guidelines and essential drugs list to the needs of the hospital. They should also perform drug utilization studies and prescription reviews and develop educational strategies to improve drug abuse and management.

- 15) One important and sustainable approach is to incorporate some basic information regarding safe use of drugs in school level curriculum as a part of health education
- 16) Pharmaceutical profession or business has always been considered as noble profession. Pharmaceutical companies are working as life saviors in a life crisis moment and are under greater moral obligations than any other company. So people involved in this sector should be morally enlightened to serve the people. Doctors, business entrepreneurs, traders all should be motivated accordingly. Government must take necessary steps to ensure ethical business environment. Corruption at all levels must be eliminated from this sector.
- 17) Government should immediately form a review committee to review the NDP 2005. Representatives from all the stakeholders should be included in the committee. This committee can review the policy content again and recommend necessary amendments.

6.3 Further Scope of the Study

The present study has been carried out to analyze the NDP 2005 in narrow sphere that is only allopathic drug market. Government's monitoring role was also studied on that arena. But the NDP also covers other group of medications namely *Unani*, Ayurvedic and Herbal drugs. These types of drugs specially the *Homeopathic* drugs are also consumed by a large number of people. How much monitoring role the government exercises can be an important research issue. As this study is focused on the finished drugs, the previous steps like manufacturing process, in-process quality control have been unattended. This areas need to be analyzed also.

6.4 Concluding Remarks

Pharmaceutical sector is one of the sectors that has showed the potentials of Bangladesh in hi-tech industrial sector. Today the country has gained self sufficiency in this sector by fulfilling about 97 percent of the local demand. Moreover some leading companies have also been successful to enter and take some share of the overseas market, some even markets of developed countries. Improved technical know how, huge investment, 'state of art' marketing strategy have propelled success for some companies while some other companies have been trying to survive. The Government must facilitate development of this sector. Only promulgation of a policy cannot ensure on one side safe and quality drugs at affordable prices to the consumers and in other hand develop this sector to meet the future challenges. Government needs to sit with all the stakeholders, beneficiaries to design workable programmes to make the National Drug Policy a successful public policy. Unless the stakeholders can not own the policy, there would be no chance for the complete success.

REFERENCES

- Bangladesh Association of Pharmaceutical Industries (2005), *Study on the Pharmaceuticals Sector of Bangladesh*. Jetro, Dhaka Bangladesh.
- Chowdhury, F. (2006). "A Strategy for Establishing the API Park" Consultant Report for the Ministry of Industry, Government of Bangladesh.
- Crosby, Benjamin L (1996) ."Policy Implementation: The Organizational Challenge', *World Development*. Vol. 24, no.9 pp 1403—1415
- Dye, Thomas R (1981) *Understanding Public Policy*. Prentice-Hall, NJ
- Emran, Shah (2009) *Pharmacy Pharmaceutical sector O Shasthaysheba (in Bangla,(in bangla)*, Shova Publications, Dhaka
- Fresie D. Wolfman C (1997) *Public Education in Rational Drug Use*, Geneva: WHO; 1997
- Gerson,Larry (1997) *Implementation: Converting Policy Commitments into Practice* in Larry Gerston's (1997) *Public Policy Making; Processes and Principles*, M,E, Sharpe
- Grindle, Merilee S (1980) *Politics and Policy: Implementation in The Third World*. Princeton University Press, New Jersey
- Horowitz, Donald (1989) 'Is There A Third World Policy Process'. *Policy Sciences* 22:1989
- Howlett, Michael and Ramesh, M (1995) *Studying Public Policy*. Oxford University Press, Ontario
- GOB (1982). *The Drugs (Control) Ordinance* Ministry of Health and Family Welfare, Government of Bangladesh, Dhaka
- GOB (2005). *National Drug Policy*, Ministry of Health and Family Welfare, Government of Bangladesh, Dhaka
- GOB (2006). *The Drugs (Control) (Amendment) Act*, Ministry of Health and Family Welfare Government of Bangladesh, Dhaka

Reich, M.R. (1994)., "Bangladesh Pharmaceutical Policy and Politics. Health Policy and Planning", Harvard School of Public Health, Harvard University, Massachusetts.

Sampath, P. (2007). "Intellectual Property and Innovation in Least Developed Countries: Pharmaceutical, Agro-Processing and Textiles and RMG in Bangladesh", United Nations University-MERIT

The World Bank (2008). Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh. Bangladesh Development Series Paper No. 23. World Bank, Dhaka.

Newspaper reports

The Financial Express 2009. The Paracetamol Syrup Tragedy. *The Financial Express*, 2 August 2009, Dhaka

The Independent 2009, " Paracetamol Tragedy" *The Daily Independent*, 8 August 2009

<http://www.theindependent-bd.com/printversion.php?nid=138347>

Website

' Ridz syrup unauthorized toxic element found', The Daily Star, July 30, 2009

<http://www.thedailystar.net/newDesign/news-details.php?nid=99261> accessed on 7 August 2009 Accessed on 21 September 2009

"Fatal renal failure caused by diethylene glycol in Paracetamol elixir: the Bangladesh epidemic" Accessed on 14 September 2009

<http://www.jstor.org/pss/29728031>

IMS Health (2006). "Patients step up campaign for more generic drugs, Managed Healthcare Executive".2007. Managed Healthcare Executive.

<http://www.managedhealthcareexecutive.com/mhe/article/articleDetail.jsp?id=389268>

“ Pharmaceutical Industry in Bangladesh”

http://en.wikipedia.org/wiki/Pharmaceutical_industry_in_Bangladesh>Accessed on 24 September 2009s

S M Shafiuzzaman “Bangladesh Pharmaceutical Sector A Vision of Success”

<http://www.bapibd.com/articles-president.pdf>> Accessed on 26February 2009

Ferdous Alam “Potential for developing Bangladesh's Pharmaceutical sector”

<http://bangladesheconomy.wordpress.com/2009/12/21/potential-for-developing-bangladeshs-pharmaceutical-sector/>>Accessed on December 26 2009

Shah Amran “TRIPS, Pharmaceuticals and Bangladesh”

<http://www.bangladeshinfo.com/news/special16.php>> Accessed on August 12 2009

Annexure 1

Countries importing medicines from Bangladesh : 67

01.	Afganistan	24.	Iraq	47.	Republic Dominicana
02.	Austria	25.	Italy	48.	Singapore
03.	Australia	26.	Japan	49.	Slovenia
04.	Barkinafaso	27.	Jordan	50.	South Africa
05.	Belgium	28.	Kenya	51.	Spain
06.	Belize	29.	Korea	52.	Sri Lanka
07.	Bhutan	30.	Libya	53.	Sudan
08.	Botswana	31.	Macau	54.	Switzerland
09.	Brazil	32.	Malaysia	55.	Tajikistan
10.	Combodia	33.	Morocco	56.	Tanzania
11.	Columbia	34.	Mauritus	57.	Thailand
12.	Costarica	35.	Mexico	58.	Togo
13.	Denmark	36.	Myanmar	59.	Tunisia
14.	Fiji	37.	Nepal	60.	Turkey
15.	Gambia	38.	Nicaragua	61.	UAE
16.	Germany	39.	The Nederland	62.	UK
17.	Ghana	40.	Nigeria	63.	Ukraine
18.	Guatemala	41.	Pakistan	64.	USA
19.	Honduras	42.	Panama	65.	Venezuela
20.	Hong Kong	43.	Papua New guinea	66.	Vietnam
21.	Hungary	44.	Phillippines	67.	Yeman
22.	India	45.	Poland		
23.	Indonesia	46.	Purtogal		

Annexure 2

Number of Manufacturers Producing Raw Materials : 24

M/s. ACI Ltd.
M/s. Acme Laboratories Ltd.
M/s. Bangladesh Antibiotic Industries Ltd.
M/s. Beximco Pharmaceuticals Ltd.
M/s. Drug International (Chemical Division)
M/s. Drug International Ltd.
M/s. Eskayef Bangladesh Ltd.
M/s. Global Capsule Ltd.
M/s. Global Capsule Ltd. (Gelatin Division)
M/s. Global Heavy Chemicals Ltd.
M/s. Globe Drugs Ltd.
M/s. Gonoshasthya Antibiotics Ltd.

M/s. Gonoshasthya Chemicals Ltd.
M/s. Hydroxide Ltd.
M/s. Jams Pharmaceuticals Ltd.
M/s. Novo Healthcare and Pharma Ltd.
M/s. Opsonin Bulk Drugs Ltd.
M/s. Pharmatek Chemicals Ltd.
M/s. Rahman Chemicals Ltd.
M/s. Remo Chemicals Ltd.
M/s. Renata Ltd.
M/s. Seftchem Ltd.
M/s. Sodical Chemical Ltd.
M/s. Square Pharmaceuticals Ltd., (Chemical Division)

Raw Materials Produced Locally:

01.	Amoxicillin	15.	Diltiazem	29.	Magnesium Hydroxide
02.	Ampicillin	16.	Erythromycin	30.	Magnesium Stearate
03.	Aspirin	17.	Esomeprazole	31.	Magnesium Trisilicate
04.	Azithromycin	18.	Ferrous Fumarate	32.	Omeprazole
05.	Calcium Carbonate	19.	Ferrous Sulphate	33.	Oxytetracycline
06.	Cefixime	20.	Fluconazole	34.	Pentoprazole
7	Celecoxib	21.	Flucloxacillin Sodium	35.	Paracetamol
08.	Cephadrine	22.	Folic Acid	36.	Potassium Chloride
09.	Cephalexin	23.	Gelatin	36.	Potassium Iodide
10.	Cetirizine	24.	Isosorbide Mononitrate	38.	Ranitidine HCl
11.	Ciprofloxacin HCl	25.	Ketoprofen	39.	Riboflavine
12.	Cloxacillin	26.	Lansoprazole	40.	Sodium Chloride
13.	Dextrose	27.	Loratidine	41.	Sodium Citrate
14.	Diclofenac	28.	Empty Hard Gelatin Capsule Shell	42.	Zinc Sulphate Monohydrate

Annexure 4

List of Essential Drugs

Sl.	Name of drugs	S	Name of drugs
1	Abacavir (ABC)	24	Benzyl penicillin
2	Acetazolamide	25	Betametasone
3	Acetylsalicylic acid	26	Bleomycin
4	Aciclovir	27	Bupivacaine
5	Albendazole	28	Calcium gluconate
6	Alløpurinol	29	Carbamazepine
7	Aluminium Hydroxide+Magnesium Hydroxide	30	Charcoal, activated
8	Amitriptyline	31	Chlorambucil
9	Amlodipine Besylate	32	Chloramphenicol
10	Amoxicillin	33	Chlorhexidine
11	Ampicillin	34	Chloroquine
12	Anti-D immunoglobulin (human)	35	Chlorpheniramine
13	Antitetanus immunoglobulin (human)	36	Chlorpromazine
14	Artemether + Lumefantrine	37	Ciprofloxacin
15	Artesunate	38	Cisplatin
16	Ascorbic Acid	39	Clofazimine
17	Atenolol	40	Clotrimazole
18	Atropine	41	Cloxacillin
19	Barium Sulfate	42	Condoms
20	BCG vaccine	43	Cyclophosphamide
21	Benzathine benzylpenicillin	44	Dapsone
22	Benzoic acid + Salicylic acid	45	Dexamethasone
23	Benzyl benzoate	46	Dextran 70

Sl.	Name of drugs	Sl.	Name of drugs
47	Diazepam	73	Furosemide
48	Didanosine (ddl)	74	Gentamycin
49	Diethylcarbamazine	75	Gentamycin+Hydrocortisone
50	Digoxin	76	Glibenclamide
51	Diloxanide	77	Gliclazide
52	Diphtheria antitoxin	78	Glucose
53	Diphtheria vaccine	79	Glucose with sodium chloride
54	Dopamine	80	Glyceryl trinitrate
55	Doxorubicin	81	Griseofulvin
56	Doxycycline	82	Haloperidol
57	DPT vaccine	83	Halothane
58	Efavirenz (EFV or EFZ)	84	Heparin sodium
59	Enalapril	85	Hepatitis B vaccine
60	Epinephrine (adrenaline)	86	Homatropine
61	Ergocalciferol	87	Human normal immunoglobulin
62	Ergometrine	88	Hydrochlorothiazide
63	Erythromycin	89	Hydrocortisone
64	Ethambutol	90	Hyoscine butylbromide
65	Ethinylestradiol + Levonorgestrel	91	Ibuprofen
66	Ferrous salt	92	Indinavir (IDV)
67	Ferrous salt + Folic acid	93	Insulin Injection (Soluble)
68	Fluconazole	94	Isoniazide
69	Fluorescein	95	Isoniazide+Ethambutol
70	Fluorouracil	96	Isosorbide dinitrate
71	Fluphenazine	97	Ketamine
72	Folic acid	98	Lamivudine (3TC)

Sl.	Name of drugs	Sl.	Name of drugs
99	Levamisole	125	Nevirapine(NVP)
100	Levodopa+Carbidopa	126	Nicotinamide
101	Levothyroxine	127	Nifedipine
102	Lidocaine	128	Nitrofurantoin
103	Lithium Carbonate	129	Nitrous oxide
104	Lopinavir+Ritonavir(LVP/r)	130	Nystatin
105	Magnesium hydroxide	131	Omeprazole
106	Magnesium sulfate*	132	Oral rehydration salts
107	Mannitol	133	Oseltamivir
108	Measles vaccine	134	Oxygen
109	Mebendazole	135	Oxytocin
110	Mefloquine	136	Paracetamol
111	Metformin	137	Paromomycin
112	Methotrexate	138	Peritoneal Dialysis Solution
113	Methyldopa	139	Permethrin
114	Methylrosanilinium chloride (gentian violet)	140	Pertussis vaccine
115	Metoclopramide	141	Pethidine hydrochloride
116	Metronidazole	142	Phenobarbital
117	Miconazole	143	Phenoxymethylpenicillin
118	Miltefosine	144	Phenytoin
119	Misoprostol	145	Pilocarpine
120	Morphine	146	Poliomyelitis vaccine
121	Naloxone	147	Polyvalent anti snake venom
122	Nelfinavir(NFV)	148	Potassium chloride
123	Neomycin Sulfate+Bacitracin	149	Povidone Iodine
124	Neostigmine	150	Prednisolone

Sl.	Name of drugs	Sl.	Name of drugs
151	Primaquine	177	Silver sulfadiazine
152	Procainamide	178	Sodium chloride
153	Procaine benzylpenicillin	179	Sodium Chloride 3%
154	Procarbazine	180	Sodium Chloride quartet strength (0.225%)+Dextrose 5%
155	Proguanil	181	Sodium Hydrogen Carbonate
156	Promethazine	182	Sodium Stibogluconate
157	Propranolol	183	Sodium thiosulfate
158	Protamine sulfate	184	Spironolactone
159	Pyrazinamide	185	Stavudine(d4t)
160	Pyridoxine	186	Streptomycin
161	Pyrimethamine	187	Sulfadoxine+Pyrimethamine
162	Quinine	188	Sulfamethoxazole+Trimethoprim
163	Rabies immunoglobulin	189	Suxamethonium
164	Rabies vaccine	190	Tamoxifen
165	Retinol	191	Tenofovir disoproxil fumarate(TDF)
166	Riboflavin	192	Tetanus vaccine
167	Rifampicin	193	Tetracycline
168	Rifampicin+Isoniazid	194	Thiamine
169	Rifampicin+Isoniazid+Ethambutol	195	Thiopental
170	Rifampicin+Isoniazid+Pyrazinamide	196	Trimethoprim
171	Rifampicin+Isoniazid+Pyrazinamide+Ethambutol	197	Tropicamide
172	Ritonavir	198	Tuberculin, purified protein derivative (PPD)
173	Salbutamol	199	Valproic acid
174	Salicylic acid	200	Vecuronium
175	Saquinavir(SQV)	201	Verapamil
176	Senna	202	Vinblastine

Sl.	Name of drugs
203	Vincristine
204	Vitamin B-Complex(Vitamin B1-5 mg+Vitamin B2-2 mg+Vitamin B6-2 mg+Nicotinamide 20 mg)
205	Warfarin
206	Water of Injection
207	Xylometazoline Hydrochloride
208	Zidovudine(ZDV or AZT)
209	Zinc Sulphate

Name of the course : MA in Governance and Development
Institution : Institute of Governance Studies, BRAC University

The National Drug Policy 2005 and Government's role in monitoring the Pharmaceutical market in Bangladesh- A Critical Analysis.

Questionnaire

Opinion Survey

[Note: The present study is an attempt to collect data in search of analyzing extent of Government's monitoring role over the pharmaceutical market in the country. The opinions will be used for research purpose and personal identity of the respondents will never be disclosed. Please help the study by your practical experience. -Researcher]

1. What is the "STRENGTH" of pharmaceutical market in Bangladesh?
2. What are the "Weaknesses" of pharmaceutical market in Bangladesh?
3. What you think about positive and negative aspects of the National Drug Policy 2005?

Positive

Negative

- 1.
- 2.
- 3.
- 4.

4. Was there any short term or long-term programme/ strategy taken by the Government to implement The National drug Policy 2005?

5. Is there any plan to set up new drug testing laboratory in the country? In this area can Public-Private partnership work? How this can be implemented?

6. What is the present status of the proposed "Pharmaceutical Park"?

7. Do you think the list of essential drugs and imported drug list should be revised? In what way-

8. What you think about extent of monitoring role of Government over pharmaceutical market

0 1 2 3 4 5

0 = no control, 1 =poor, 2 =moderate, 3 = good, 4= satisfactory, 5- full control

9. "Government has little monitoring role over the private distribution of medicine, raw material across the country"- how you think this monitoring can be strengthen and effective?

10. What measures Government should take to restrict import, supply of unregistered, banned, substandard medicines?

11. Suggest some ideas how Government can extend its monitoring role over the pharmaceutical market to ensure safe, effective drug at affordable price?

-
-
-
-

Thank you for your valuable comments

Your present Position/ Profession: