CHAPTER 1

THE PHARMACEUTICAL INDUSTRY AND MARKETS IN INDIA

1.1 INTRODUCTION

The Indian pharmaceutical industry currently tops the chart amongst India’s science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian pharmaceutical industry is estimated to be worth $6 billion, growing at 8-9% annually. It ranks very high amongst all the third world countries, in terms of technology, quality, and the vast range of medicines that are manufactured. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds; almost every type of medicine is now produced in the Indian pharmaceutical industry.

The Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in last two decades. The pharmaceutical and chemical industry in India is extremely fragmented market with severe market competition and government price control. The pharmaceutical industry in India meets around 70% of the country’s demand for bulk drugs, drug intermediaries, drug formulations, chemicals, capsules, tablets, oral and injectibles.

Going forward, the large domestic companies will face strong competition on both sides. On one hand, smaller players can maintain their trajectory if they continue to pioneer market creation. On the other, multinational firms can gain share through the launch of patented products depending upon the level of regulatory and infrastructural support. In such a competitive environment, top-tier
domestic players will find it a challenge to maintain or improve their market share performance.

Hence the priorities are likely to differ for the three groups of industry players. For leading domestic companies, the case for action is underpinned by the need to counter the threat to their market leadership. For midsized and small domestic players, the challenge lies replicating past success and coping with increasing scale and complexity. For multinational firms, the imperative is to build businesses of scale in the new patent regime and be relevant in this high growth market.

1.2 CHAPTER SCHEME

The study is structured into Six chapters. To ensure easy readability of the report even while addressing technical issues and to maintain a flow in the study, the chapters are divided in a problem solution mode.

This introductory chapter (Chapter I) titled “The Pharmaceutical Industry and Markets in India”. It is divided into two parts. The first part of chapter primarily elaborates upon the industry and the market structure and has made an attempt to identify possible anticompetitive practices in the pharmaceutical industry and markets in India. Here both desktop and field research has been included. It includes a brief history of the pharmaceutical industry; current structure of the pharmaceutical industry; exports-imports and balance of trade; market shares and net-worth of leading firms; inward and outward foreign direct investments; mergers, acquisitions and alliances; emerging trends and patterns in the pharmaceutical industry in India; innovation, R&D and patents; introduction to pharmaceutical market in India and the structure of pharmaceutical distribution network; drug promotion and advertising; flagging the relationship between various actors in the pharmaceutical supply chain- with emphasis on hospital pharmacy practices; pricing practices in the pharmaceutical industry in India; drug pricing, availability and
affordability and its interaction with health care concerns- with emphasis on geriatric medicines; drug procurement systems and concerns for competition; The chapter briefly concludes with conclusions and recapitulation.

The Second part provides a brief introduction to the report, with stated objectives, structure and chapterisation and methodology. Here details concerning the use of CAF framework and its limitations are discussed, the same includes structure of interviews (structured and unstructured). This section also provides the scope of the study along with its limitations. The second part briefly introduces the reader to the development dimension of competition law and policy, and relevance to the pharmaceutical industry. It also visits some basic economic analysis, concepts, functions and emphasizes on the welfare effects of competition law for consumers and its usefulness for maintaining a competitive industry framework in the pharmaceutical sector. It briefly introduces the reader to issues concerning the pharmaceutical sector in India that are addressed in this paper. Here a brief conceptual backdrop is provided highlighting the tension points that this report has attempted to address. The third part provides details about the methodology used for the study.

Chapter II is titled as “Literature Review”.

This chapter primarily aims as to examine the relevant literature on the subject of present study. The methodology and results are critically examined. The chapter tries to identify the gaps in the existing literature and summarise by providing a conceptual frame work for undertaking this study.

Chapter III is titled as “Research Methodology”.

The research implements a multiple approach. Both quantitative and qualitative approaches are applied in this research. This research adopts the hybrid approach of combining qualitative and quantitative methods in a two stages research design. Quantitative method is applied to first to deal with comparative figures and then a qualitative method is used to try to find out the key matters. The
design of the multiple approaches includes three phase’s data collection, analysis and reporting.

**Chapter IV is titled as “Research Analysis”**.

This chapter covers the complete analysis of the research conducted by the researcher. The different testing approaches are applied to find the best result from the analysis.

**Chapter V is titled as “Hypothesis Testing and Research Findings”**.

This chapter gives the detail idea about the hypothesis which is set for the research. Hypothesis is tested and checked through the economic models.

**Chapter VI entitled as “Conclusion”**.

This chapter identifies some of the potential areas for future research and also the gaps that remained unaddressed in this study.

### 1.3 INDIAN PHARMA INDUSTRY- CURRENT SCENARIO

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually.

The “organized” sector of India’s pharmaceutical industry consists of 250 to 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75 percent of India’s demand for medicines is met by local manufacturing. India’s potential to further boost its already-leading role in global generics production, as
well as an offshore location of choice for multinational drug manufacturers seeking to curb the increasing costs of their manufacturing, R&D and other support services, presents an opportunity worth an estimated $48 billion in 2008.

The pharmaceutical industry in India has made a phenomenal progress in the past 10 years. With over $ 8 billion in domestic sales and another $ 5 billion in exports in the year 2006, both growing at double digit, it has acquired its place in the sun. It has also started making global footprints and over $ 2.5 billion worth of acquisitions were made overseas in past couple of years. Undoubtedly, the major inflexion point in the history of Indian pharma industry is the passage of product patent law in 2005. This has resulted in many pharma majors almost doubling their R&D investment and it is likely that New Chemical Entities (NCEs) will start trickling down from Indian R&D labs, in few years time. However, before we start patting ourselves on the back for these commendable achievements, we must remember that India contributes less than two percent of the global pharmaceutical sales of about $ 650 billion. While McKinsey has projected a domestic sale of $ 20 billion by the year 2015, we need to identify key strategic drivers for growth and use these levers to accelerate the pace. While robust economy with eight-nine percent GDP growth will certainly give right business environment, there are other internal factors which will act as catalysts. These are Intellectual Property Rights (IPR), government pricing policies, regulatory reforms, scientific and technical manpower and capital funding.

The Indian Pharmaceutical industry is currently the largest amongst the developing nations and one of the flagship sectors of the Indian economy. Indian pharmaceutical companies continue to move to the center stage of the global pharmaceutical market. There is a worldwide structural trend evolving in pharmaceuticals and Indians companies play a key role in this framework, driven by their superior biotech and drug synthesis skills, high quality and vertically integrated manufacturing assets, differentiate business models and significant cost advantages. The pharmaceutical industry in India has emerged, as a prominent maker of healthcare products, currently meeting almost 95% of the domestic healthcare
needs. From a modest beginning in 1970, today the total Indian pharmaceutical sector is valued at US $ 8.8 billion with a growth rate of 8%. The Indian pharmaceutical industry is a net exporter of bulk drugs and generics and ranks 17th in the world in terms of bulk drug and formulation exports. In 2004-05 the net pharmaceutical export was more than US $ 3.75 billion, formulations accounted for 55% while the remaining 45% came from bulk drugs. US, Germany, Russia, the UK and China are the top five export destination for the Indian pharmaceutical sector.

![Share of MNC's and Indian Pharmaceutical Companies](image)

**Figure 1.3.1 Share of MNC & Indian Pharmaceutical Companies**

An analysis of the pharmaceutical sector’s performance is a complex task due to the convergence of often conflicting social and health goals on the one hand and industrial goals on the other. While innovation and access are usually welcome by all stakeholders, high prices and growing expenditure are bad news from a payer’s perspective (consumers and health insurers), but a desirable outcome for suppliers, since it translates into higher revenues and profits for them. A global pharmaceutical policy necessarily has to make trade-offs between these conflicting goals.

The Indian pharmaceutical industry today is leading India’s science-based industry with wide ranging capabilities in the complex field of drug manufacture and technology. The Indian Pharma Industry has grown consistently at 9.5 percent CAGR
in last five years and is presently estimated to be worth a little over $ 5.7 billion and expected to reach $ 9.48 billion mark by 2010.

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share</th>
<th>Sales (in Rs. Crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy Laboratories Ltd</td>
<td>14.49</td>
<td>7,609.23</td>
</tr>
<tr>
<td>Cipla Ltd</td>
<td>11.78</td>
<td>6,183.87</td>
</tr>
<tr>
<td>Dr Reddys Laboratories Ltd</td>
<td>10.17</td>
<td>5,340.10</td>
</tr>
<tr>
<td>Lupin Ltd</td>
<td>8.63</td>
<td>4,530.23</td>
</tr>
<tr>
<td>Aurobindo Pharma Ltd</td>
<td>8.06</td>
<td>4,229.99</td>
</tr>
<tr>
<td>Sun Pharmaceuticals Industries Ltd</td>
<td>6.01</td>
<td>3,157.36</td>
</tr>
<tr>
<td>Cadila Healthcare Ltd</td>
<td>5.63</td>
<td>2,955.40</td>
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<tr>
<td>Matrix Laboratories Ltd</td>
<td>5.48</td>
<td>2,877.73</td>
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<tr>
<td>Glaxosmithkline Pharma Ltd</td>
<td>4.56</td>
<td>2,391.73</td>
</tr>
<tr>
<td>Jubilant Life Sciences Ltd</td>
<td>4.34</td>
<td>2,277.70</td>
</tr>
</tbody>
</table>

Source: Capitaline Database
As the Indian Pharma Industry grows more and more, bigger players gear up to bring global blockbusters in the Indian market, the competition is definitely going to heat up. Many of these MNCs are collaborating with Indian companies, which often offer as much as 30% to 50% savings in total drug discovery and development costs. Recent amendments to India’s patent laws have also made India more attractive as a drug discovery destination. In 2005, India amended its patent laws to comply with the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international treaty mandating minimum standards for trade and intellectual property protection. These amendments allowed, for the first time, patent protection in India for pharmaceutical products. The earlier law provided patent protection only for the process of making the drug, not for the drug itself.

**Figure 1.3.2** Market Share of Top 10 Pharmaceutical Companies in India
Companies in India offer two types of opportunities for drug discovery and development: outsourcing and true collaborations. The outsourcing model entails an alliance between one or more entities to perform discrete tasks or specific operations and processes previously done in-house. In this model, the company soliciting the research typically maintains control over the technology and related assets, including intellectual property.

More recently, a growing number of MNCs have entered into more collaborative ventures with Indian pharmaceutical companies and contract research organizations, extending well beyond task-driven outsourcing. These transactions involve more complex intellectual property considerations.

A recent Price Waterhouse Coopers report indicates that India could well become one of the top 10 global pharmaceutical markets by the year 2020. Thus, any pharmaceutical company doing research and development in India will likely choose to patent its technology in India and, therefore, will need to be familiar with Indian Patentability standards.

1.4 Indian Pharma Industry: Scenario- 2020

The pharmaceutical industry in India is expected to grow from $5.5 billion now to $25 billion by 2010 and $75 billion USD by the year 2020. By 2020, global integration of most sectors in the world economy would be much more pronounced, and the pharma industry will not be an exception. In fact the Indian pharma industry, which currently has strong linkages with the global pharma market, will become even more strongly integrated. Globally the pharma market is undergoing a transformation led by change in demand patterns, realignment of supply chains, and global regulatory shifts. In order to predict the state of the Indian pharma market in 2020, it is useful to understand the current global environment of the pharma
market and its key trends and analyze the implications that these factors will have on the global as well as on the domestic pharma market. **Key trends of global pharma industry are declining R&D productivity, increasing spread of generics and increasing outsourcing.**

India is expected to host 30% of the world’s contract research within the next 10-15 years, driven by the attractions of low cost and high quality standards, says the India Brand Equity Foundation, IBEF. The IBEF quotes a McKinsey forecast for the value of pharmaceutical clinical trial outsourcing in India at $1.23 billion by 2010. This would represent 7% of the total world market, projected by Biopharm at $18.5 billion in 2010.

India offers a huge cost advantage in clinical trials compared with Western countries. A multinational company moving R&D to India could save as much as 30-50%, IBEF says. Indian companies can conduct clinical trials at less than one-tenth of US costs.

The Indian Pharma Industry is entering an era where the value chain components are reassessed and redesigned to realize optimum value. **While the cost of doing business is increasing, the customers are demanding more innovative pharmaceutical products at more competitive prices. The change in patent regime has also become heralded a change in the industry dynamics. On one hand, patents on blockbuster drugs are expiring and on the other hand, there are insufficient drugs in the pipeline. The changing industry dynamics both at the domestic level as well as the international level has forced the pharma players to rethink their traditional business strategies.**

**1.5 CONCLUSION**

The Indian market has some unique advantages. India has a 60-year-old thriving democracy. It has an educated work force and English is a business
language. It has a solid legal framework and strong financial markets. There is already an established international industry and business community. It has a good network of world-class educational institutions and established strengths in information technology. The country is now committed to an open economy and globalisation. Above all, it has about 200 million middle class market, which is continuously growing. Over time the international pharmaceutical industry has been finding great opportunities in India.

The Indian pharmaceutical industry players in the future can continue to look forward with confidence. There are immense opportunities for pharmaceutical players both at the domestic as well as the global level, but along with opportunities, there are challenges which need to be overcome in order to achieve sustainable growth in the future. The future will be extremely promising with many more milestones to come in the journey of the Indian pharma industry.

1.6 Market Structure

It is widely recognised that the Indian pharmaceutical industry, known for its technical prowess in generic production, has grown out of favourable policy choices adopted since 1970’s (later discussed in detail). Health concerns were central to the policies articulated and adopted during this period. However, there are critical challenges presented by the reversal of many of such policies on the Indian generic industry and for the access to medicines situations in India. The recent years have witnessed a host of reports, studies and analysis conducted by the academia, industry, technocrats and policy makers on issues concerning the pharmaceutical industry in India. Some reports have highlighted the pertinent threat presented by introduction of product patent regime and consequent change in the market structure, while others have dealt with opportunities presented in the post-2005 regime. While some authors are sceptical about the future of the generic industry, many others would argue that increasing consolidation in the industry would lead to
emerging survival strategies and help the industry to grow. We would briefly visit some studies here under.

Many studies have noted that the strength of the Indian industry lies in offering price based competition to the global pharmaceutical industry by producing generic version of patented drugs (Gelh Sampath, 2006; Chaudhuri, 2005). They also point out that another interesting facet- the current maturing of the industry in to an innovation based one, which could possibly repeat the success of the global majors located in the developed countries. (Gelh Sampath, 2006).

Even considering that the industry is maturing and moving up the value chain, some studies have pointed out to several inherent limitations of Indian firms to mature in to global firms due to low R&D intensity (Pradhan, 2006). However, they suggest that a host of competitive strategies like greenfield direct investment, overseas acquisitions, strategic alliances and contract manufacturing have emerged as favourites to Indian pharmaceutical firms recently and these may be an opportunity to mature from mere survival techniques. (Pradhan, 2006).

Others have provided for mixed reactions, and some have even gone to the extent of emphasizing that the future of the generic pharmaceutical industry looks bleak. A SWOT analysis of the Indian Pharmaceutical Industry in new WTO regime conducted in the year 2002 reveals that the “much acclaimed expertise in process development skills” of the Indian pharmaceutical were made possible by the amendments made to the Indian Patents Act 1970 (Narayanan, 2002). Another study highlighting the historical development of the Indian pharmaceutical industry and envisaging trends in the light of post-2005 regime also concludes that the current expertise in reverse engineering and process skills were possible only due to the conscious and strategic industrial policy with reference to patent laws and regulation of foreign participation. (Chaudhuri, 2005); (Pradhan, 2006).

Some commentators argue that such strength should be utilized maximum to benefit from opportunities that arise from vertical disintegration of research, clinical
trials and manufacturing by the multinationals entering post 2005. (Narayanan, 2002). Studies also point out to weaknesses that such opportunities will be limited to a few firms in this sector. IPI faces threats in the form of competition from other Asian giants particularly China which has similar expertise in process development and reverse engineering Narayanan, 2002). They further argue that considering new patent regime being a reality, various strategies like producing off patented products, new patented products by acquiring compulsory licensing or cross licensing, collaboration with multinationals not only in R&D and manufacturing but also in marketing new patented products and improving the standards of production to widen the export market (Narayanan, 2002). However, they also warn that unless efforts are geared towards improving the domestic R&D and increasing the FDI in R&D, optimal benefits may not accrue. Even on the issue of processing quality FDI, they remark such investments do not result in increasing the FDI per say but contributes to improving technology (Narayanan, 2002).

From a competitiveness perspective, a review of evidence shows that the Indian pharmaceutical industry is at a crucial crossroad. Certain practices within the industry which were hitherto regarded as within the routine activities of working of the pharmaceutical industry may need a comprehensive re-look. Practices within the industry and distribution networks can substantially undermine effective competition and thus reduce consumer welfare. Further, since the advent of the product patent system in developing countries, coupled by poor health infrastructure and lack of social security, it can push significant population in to poverty. This presents immense challenge in maintaining an essential competitive framework for growth of R&D based industry with adequate generic competition within the pharmaceutical industry in India.

1.7 STUDY MOTIVE

The difficulty in finding reliable information on medicine prices and availability –and therefore in analysing their components – hinders governments in
constructing sound medicine pricing policies or evaluating their impact. It also makes it difficult for them to evaluate whether their expenditure on medicines is comparable to that of other countries at a similar stage of development. Moreover, those responsible for purchasing medicines cannot negotiate cheaper deals because they have no sound basis from which to start their negotiation. Even in countries where consumers and patients have greater purchasing power, governments, insurance funds and hospitals often find it difficult to decide on the selection of medicines because they lack information.

Prices of the same medicines frequently vary between firms and countries; some commonly used medicines have been found to be more expensive in developing countries than in industrialized ones; and many studies have shown that affordability is unrelated to purchasing power. The ex-manufacturer prices to countries – in particular for the private sector – are often confidential. Medicine price indicator guides provide the sales prices from large wholesalers of generically equivalent medicines to governments. However, they do not give the price patients must pay in either the public or private sectors and often do not include new, essential but patented medicines. A few countries have publicly available prices, but the information’s use is obstructed by the country-specifics that apply and language barriers.

The manufacturer chooses the price such that the cost of producing and selling an additional unit of the product is lower than the revenue from a sale. This single price would imply that some markets and consumers would not be served by the manufacturer’s price.

Recent trends, however, are prompting the pharmaceutical industry to pay more attention to differential pricing, such as economic and demographic growth in some low and middle-income markets, which has increased the potential market size of many low and middle income countries; greater recognition by the pharmaceutical manufacturers and their investors of the social responsibilities; stronger global advocacy for access to medicines, and growing competition from
generic manufacturers in emerging markets. Differential pricing allows pharmaceutical companies to signal that their pricing policies are socially responsible and consistent with their obligations to society and not just geared towards maximizing profits. In addition, differential pricing on select drugs opens opportunities to serve low and middle-income markets and creates economies of scope for pharmaceutical companies.

A review of the existing literature on differential pricing and analysis of successful and unsuccessful examples of such pricing reveal that it may lead to overall welfare benefits only when the overall sales increase as a result. Whether the benefits of differential pricing accrue more to the pharmaceutical company or to the patient/payer depends on the elasticity of demand and the market structure.

Despite some evidence that differential pricing of pharmaceuticals can benefit manufacturers and developing countries without adversely affecting higher income countries, the widespread and systematic use of such pricing has been limited to vaccines, contraceptives, and antiretroviral (ARVs) mostly in developing countries.

Differential pricing of ARVs between high, middle and low-income markets, however, has raised complicated economic, legal, and supply chain challenges. The lure of getting prices paid by low income countries has raised substantial legal and political tensions between pharmaceutical companies, middle income country governments and non-governmental organizations.

1.8 RATIONALE

Having identified technological change as a major source of growth in the developed country context, the process of technological change has been subjected to intense study. There are studies that try to examine the nature of the process by which economic resources are transformed into technological advancement. Related
issues of whether such a process exhibits increasing, decreasing or constant returns to scale and the involvement of significant spill over effects and pricing behaviour of firms are also addressed.

Determining the most conducive market environment for innovative activity also has become the subject of interest ever since the pioneering work of Schumpeter (1942). Schumpeter hypothesizes that firm size and market concentration induce innovative activity. Since then, the hypothesis has been tested exhaustively in the developed country context. Kamien and Schwartz (1982) summarize some important issues of concern on market structure and technological change for developed country economists, as follows:

What is the nature of the market for technical advances? Will the competitive marketplace allocate resources so that the mix and timing of the technological advances will be efficient? Is there a market structure most conducive for pricing? If so, is it sustainable? What is the effect of pricing behaviour on market structure?

In the Indian context, studies relating to market structure and innovative activity attained importance only in the 1970s. Since then, there have been numerous attempts to empirically verify the Schumpeterian hypothesis in India. Most of these studies, however, pertain to the import-substituting policy environment. Moreover, these studies generally conceptualize innovative activity only in terms of in-house R&D. Given the liberal policy environment, it is important that innovative activity is understood in terms of both technology imports and in-house R&D. In addition to conceptual issues, there are a number of methodological issues that need to be taken care of. In this context, there arise a number of issues in terms of the relationship between firm size, market structure and innovative activity. How do dynamic policy changes in the economy during liberalization affect the market structure/innovative activity relationship? How have the firm-specific, industry-specific and product-specific characteristics of firms influenced innovative activity? What factors in a liberal environment affect the decision to engage in innovative activity or determine its intensity? Another important issue for analysis is
the need to examine whether in the post-liberalization period there are significant inter-industry differences in the relationship between market structure and pricing behavior.

Based on the above issues, the current study tries to look at the relationship between firm size, market concentration and pricing for the pharmaceutical firms. **The specific objectives of the current study are to analyse:**

i) The firm-level relationship between market concentration, firm size and the decision to do innovative activity, and

ii) The factors influencing the intensity of changing prices at the firm level.

High drug prices could mean two things; first, cost price of drugs is high due to high research and production cost and second, high mark-up of the retail prices due to lack of competition or cartel behaviour. In other words, drug prices can be kept under check through fast and less expensive research and creation of settings that charge less mark-up. High mark-up is an important phenomenon in India particularly after the partial withdrawal of drug price control in recent times. Given this context, this paper analyses the price differentials across various market/ownership settings.

Due to the interaction between income and prices elasticity, price margins tend to be higher for drugs demanded by the rich and vice versa. That is the reason why the producers tend to produce the rich persons’ drugs first. Second, the market for drugs is imperfect in the sense that there exists entry cost. Since the drug sellers enjoy some form of ‘protection’ from other entries into the market, they have the ‘liberty’ to fix a higher mark-up when they decide their retail price.

**The proposed research will identify the behavior of entrepreneurs or managers of the pharmaceutical firms towards pricing of their products within a given structure of Indian pharmaceutical market and industry.**
1.9 **Implications of the Study**

This study will help researcher and other theoreticians to know the behavior of firm towards strategic decision with special context to the pricing, in Indian context.

This study will help to the policy makers to review the recommendations to review the changes in the competition policy or we need separate competition policy for the particular industry.

The survey has been developed for use by governments, civil society groups, international agencies, researchers and health professional organizations. A survey manager coordinates the survey management. The survey manager is the primary audience for this manual, though the commissioning organization should also be thoroughly familiar with the survey procedures. An advisory committee should always be established to provide support and expertise throughout the survey and to initiate policy discussions based on the findings. The inclusion of prominent and respected stakeholders will enhance the credibility of the study, report and recommendations.

1.10 **Objective of the Study**

The survey’s objective is to generate reliable information on the price, availability and affordability of selected important medicines and price components in the supply chain, with the ultimate goal of improving access to affordable medicines for all.

The medicine price and availability study focuses on a limited number of medicines and enables their prices and availability to be investigated across health-care sectors within individual countries and also between countries. It is designed to measure medicine prices and availability at a certain point in time, but can also be
used to monitor them over a period of time. The methodology facilitates rapid and reliable data collection and is easily replicable.

The survey identifies issues related to procurement price efficiency, public and private sector availability and prices, price structure and mark-ups, and crucially, the affordability of treatments for people with lower incomes. It is a useful tool for policy-makers and others concerned about access to medicines, and serves as an important basis for more in-depth analysis of various issues that might be identified, policy considerations and interventions.

The survey enables to identify the following objectives:

1. To present an overview of Indian Pharmaceutical Industry and markets and to strategize means to identify anti-competitive activities prevalent in the pharmaceutical market.
2. Propose areas of advocacy and identifies possible strategies.
3. To know the behaviour of the mangers for pricing decision
4. To know the behavior of manager towards the competitive structure.
5. Review situation for the firm whether it is price leader / price follower in the industry.
6. To identify pricing strategies adopted by the firms.

1.11 HYPOTHESIS

Hypothesis 1 – Profit of the firm depends upon sale, price and the market share of the firm.

Hypothesis 2 – Prices of the firm are influenced by sales, firm size, market concentration and experience of the firm in the market.

Hypothesis 3 – Prices are influenced by the cost and revenue of the firm.

Hypothesis 4 – There is no significant difference between sales turnover and cost of production of firms over past three years (2009 – 2011).
1.12 Methodology

The study is based on the operational framework provided by DFID’s “Competition Assessment framework (CAF): An Operational Guide for Identifying Barriers to Competition in Developing Countries”, published in 2008. The CAF provides a flexible diagnostic tool that poses sets of questions that are grouped by theme. The nature of questions will depend on the particular sector taken up for assessment. It then follows with steps to analyse the state of competition in the selected sector. It includes: identifying the markets and competitors, examining the market structure, looking for barriers to entry, looking for anticompetitive conduct, considering vested interests and the principal beneficiaries, and identifying government policies or institutions that limit competition.

In the survey, data are collected on the availability and pharmaceutical firms from the public, private and other sectors (e.g. NGOs) of a country. Data on medicine prices, but not availability, are also collected for government procurement; these data are usually collected at the central level (e.g. government procurement office). As survey is at national level, the methodology is applied at the state or provincial level or that the number of regions surveyed is increased. Sampling is done in a systematic way to ensure that the findings are representative of the country or state/province in which the survey is being conducted.

A range of semi–structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to firstly, help clarify the structure and content of the study framework and secondly, to refine and provide content validation to the survey questionnaire.

Based on the Primary research and semi-structured interviews, a structured questionnaire was completed. A background report on the Indian pharmaceutical
industry and emerging prospects and strategies from 2005 onwards was prepared to assist in identifying the main issues. The 181 firms that participated in the survey were chosen using a purposive probability sampling technique, from a list of companies’ generated for purposes of this study using major Indian databases like the India Info line and Pharmabiz (export potential, R&D investments and total sales were used as the three main parameters to arrive at the ranking for the list generated for the survey).

The questionnaire consisted of five main parts: firm demographics, R&D issues and emerging strategies for process and product technologies, collaboration and inter-linkages, finance, and lastly, emerging marketing and business strategies. These sections were designed with the aim of generating as much information as possible on:

(a) Firm demographics, such as net sales turnover, focus of pharmaceutical activities, ownership structure of the firm and main firm policies on various issues such as pricing;

(b) Emerging R&D and business strategies amongst firms in response to a transition towards increased intellectual property protection in India, especially the introduction of product patents; and,

(c) Firm views regarding the viability of compulsory licensing as a supply mechanism for least developed countries, and the circumstances under which they would consider this option as contained in the Indian Patent (Amendments) Act of 2005.

1.13 DATA COLLECTION AND RESEARCH INPUTS

The study uses data on the pharmaceutical industry from various sources such as CMIE- Prowess, existing studies and reports. The legal and policy framework is studied by collecting texts and materials from Westlaw, Hein Online for study in
comparative jurisdictions. Online web resources, websites of comparative competition authorities. The report has used structure and non-structured interviews to flag the relationship between pharmaceutical industry and health service providers and the anticompetitive practices prevalent in the pharmaceutical market. In order to understand the views and opinion of the various stakeholders, different media sources are used. As part of field study, interviews with key stakeholders are also conducted. However, the study presents quantitative analysis.

1.14 **Scope of the Study and Limitations**

The study examines all possible issues that underline the objectives framed above. However, this study is scoped in at least four levels.

a) First, the objective of the study is limited to pharmaceutical industry/sector and not to the healthcare industry/sector in general. Hence issues of competition in relation to hospitals and other service based segments of the pharmaceutical industry are not a part of this study.

b) Second, the pharmaceutical industry comprises allopathic medicines and other forms of traditional and alternative medicines like Ayurveda, Unani, Homeopathy, Siddha, Naturopathy and Yoga. This study is specifically concerned with the use of allopathic treatment (both organic and inorganic chemistry) where concerns of competition and its interaction with healthcare are paramount. This is also because of wider acceptability and standardization of allopathic treatment as being universal to modern health care.

c) Third, pharmaceutical products/processes can be divided into therapeutics (drugs), diagnostics, vaccines and prophylactics (preventive technologies-products/methods). Since the scope of examining all such product/process categories is prohibitively outsized, the study has examined only
therapeutics. This is also because the medicines are directly consumed by people and the large amount of consumer and competition law and policy concerns emerge in this product range, primarily in relation how drugs are innovated and patented, generic availability and pricing practices and nature of interactions in the pharmaceutical distribution markets. However, it is not to suggest that the markets for vaccines, diagnostics and prophylactics do not carry any competition concerns- which can definitely be a distinct stand alone study.

d) Fourth, the therapeutics markets can be divided into over the counter drugs (OTC) and prescription drugs. OTC drugs are directly sold to consumers and hence consumers have a choice for making brand preferences. Hence to some extent it can be said that demand and supply factors work in a competitive market environment. There is an increasing tendency to get more drugs out of the prescription ambit. There are both advantages and disadvantages to this issue. It is not to suggest that OTC drug market present no competition concerns in an increasingly drug advertising driven market where information asymmetries and lack of effective consumer drug information forms the perverse genesis of this market. Even while the study refers to OTC drugs in pharmaceutical market overview, the major focus of this study is in relation to prescription drugs or what is generally called as “ethical drugs”. It is a known fact that prescription drugs are chosen by the doctors- who are generally price insensitive due to a variety of reasons, including perverse incentives– but purchased by patients (consumers). Hence consumer and competition concerns are more in ethical drug market, which the study rightly focuses in its entirety.

While the study examines the pharmaceutical sector and market positions of companies their strategies and practices, it does not specifically point to practices of one particular company or firm or any particular.
However, general practices have been identified. With reference to pricing, while pricing practices of companies have been highlighted, it is not to suggest that any one company/enterprise is prima-facie in violation of any law. As mentioned earlier, this study does not warrant a quantitative analysis of anticompetitive practices prevailing in the market. However, the study has provided good amount of updated data on various aspects of the pharmaceutical sector. But some data on certain fronts has been lacking due to unavailability. This is especially in the area of mergers and acquisitions. Hence the study extensively relies on empirical evidence already provided in different studies.

The chapter VI make some recommendations, but where issues concern suitable amendment in the law, no particular wording for any amendment has been suggested. It would be beyond the scope of this study to engage in any such exercise.