CHAPTER - 1

INTRODUCTION

1.1. Need of the study
1.2. The study and the objectives
1.3. Scope of the study
1.4. Background and Issues of Pharma Sector
1.5. Data and methodology
1.6. Chapter scheme
Chapter 1

INTRODUCTION

1.1. Need of the study

The pharmaceutical industry particularly in a country of India's dimension is directly concerned with multitude of health related problems, besides playing an important economic and social role. It is a science based industry and augers to the expansion of scientific and technological, knowledge, offers employment opportunities to various levels of population and has a significant contribution to the overall growth of India's industries. Over the years, Indian pharmaceutical industries have emerged as producer of almost all classes of medicines for domestic use and minimized imports from developed nations. (Kiran Vallecha, 2008) The pharmaceutical industry has grown at 1.5-1.6 times the growth of the economy over the past couple of years. India with its inherent competitive advantages has now become one of the most preferred destinations for Contract Research and Manufacturing Services (CRAMS) at present. (Kiran Vallecha, 2008) The global manufacturing and outsourcing opportunity is estimated at USD 20 billion and is expected to reach USD 31 billion by 2010. (Kiran Vallecha, 2008) Recognizing its crucial roles Indian planners have included the industry in the core sector aided by various measures enacted by government and due to enterprising attitude the pharmaceutical industry has grown at the phenomenal pace during last two and half decades.

The present work proposes a study of the performance and prospects of pharmaceutical industries in consideration for its phenomenal growth and future
expectations. The historical aspects, demand and supply factors affecting the pharmaceutical industry, drug prices, policies regulations, trends towards Research and Development and some outsourcing challenges have been studied considering the growing relevance of these aspects in the country as well as at the global level. Following aspects are emphasized in the present study.

i.) Some economic aspects and a quantitative growth of the pharmaceutical industry: "As per McKinsey study (2007), the Pharmaceutical Industry in Asia is projected as high as USD 25 billion by 2010 whereas the domestic Indian market is likely to be more than triple to USD 20 billion by 2015 to become one of the leading pharmaceutical markets in the next decade" (BVS Prasad & K Gowri Shankar, 2007). It is important to note that, during the last three decades, the Indian pharmaceutical industry has undergone spectacular structural changes along with quantitative changes. From mere processing industry, today it has become an industry possessing sophisticated and advanced manufacturing technology, modern equipments and stringent quality control. It has also made significant progress in terms of infrastructure development, as well as producing wide range of products.

As mentioned above, we intend to study both micro as well as macro economic aspects of this industry such as demand, supply, price behavior, employment etc. which is useful from the point of view of policy makers and researchers. Some other aspects which are also important and discussed by us are as follows.

ii.) Discovery, development and distribution aspects of the pharmaceutical industry: The pharmaceutical industry is the world's largest industry due to worldwide revenues of approximately USD 2.8 trillion. Pharmaceutical industry has
seen major changes in the recent years that place new demands on payers, providers and manufacturers. Customers now demand the same choice and convenience from pharmaceutical industry that they find in other segment. (Saurabh Kumar Saxena, 2005)

Indian Pharmaceutical Industry is poised for high consistent growth over the next few years, driven by a multitude of factors- Unresolved issues of intellectual property rights, stringent regulatory environment with growing awareness among consumers and the threat from the biopharma sector.

The pharmaceutical industry is a knowledge driven industry and is heavily dependent on Research and Development for new products and growth. However, basic research (discovering new molecules) is a time consuming and expensive process and is thus, dominated by large global multinationals. (Saurabh Kumar Saxena , 2005)

Due to high cost of innovations in developing newer molecules, the Indian pharmaceutical industry is rather hesitant to approach this area .However, some of the tropical diseases which are dominant in developing countries are not looked into by developed countries as they are not profit generating. Hence the developing country like India has to spend money for R and D for such diseases Our study highlights issues and aspects relating to drug development process, nature of drug research and Indian as well as global status of Research and Development.

iii.) Cost Benefit aspects of the industry: It may be pointed out at the outset that measurement of the benefits produced for society by such an industry raises a number
of complications which is therefore beyond the scope of the present study. The benefits can be social, economic or a mixture of both which require detailed estimation process and methodology of benefits. Also there could be variety of costs. They may well be the resultants of costs other than those required to purchase the manufacture of existing drugs or the discovery of new ones. Any attempt to measure the benefits is hampered because the identification and estimation of benefits are challenging tasks and having identified the benefits, it may be impossible to ascertain what proportion of them results from the pharmaceutical industry's operations. We are therefore, neither estimating costs, nor benefits of this huge industry. However we do touch upon some important related aspects which may be able to give some direction in future to the researchers and the future corporate investors if they intend to take up the task of estimating costs and benefits of this industry let us therefore try to enlist objectives of the proposed study.

1.2. The Study and the Objectives:

The purpose of the present study is to look into the performance of the Pharmaceutical Industry in India during pre reform and post reform years and the likely trend in future. Through the analysis of data of the pharmaceutical industry, it has been possible to know the movement of the market, the new and emerging companies in this industry and expenditure and profit ability of the industry. The analysis of such data gives direction to monitor the market conditions which in turn may facilitate future investment decisions. Furthermore this also helps in keeping track of various developments relating to certain diseases such as cardio vascular, anti allergy, etc. Moreover the analysis throws light on the legal aspect (patent laws) and requirements pertaining to this industry.
The study also proposes to discuss the specific segments of the pharmaceutical industry, namely, the therapeutic segments. Thus the proposed study includes the generally accepted pharmaceutical manufacturing activities that are currently used, including the bulk drug industry, formulations and major therapeutic segments. The researcher presents an overview of India's pharmaceutical industry and its evolution from almost non existent to one of the world's suppliers of generic drugs. Thus the principle objectives of the study can be summarized as below.

The principal objectives of this study are to:

- Throw light upon global industry development including forecast of growth. Study demand, supply, cost, marketing and structural aspects of this industry in India.
- Understand how the fundamental drivers of growth in Indian economy will affect affordability, accessibility and acceptability of pharmaceutical products. An attempt has been made to compare India's market with those of other emerging markets.
- Infer the key implications of such changes for the policy makers, researchers and corporate sector in the context of pharmaceutical industry.
- Give some idea about the differentiated strategies, study of market structure and marketing capabilities of this industry.
- Analyze the current situation, major challenges and the future prospects of the pharmaceutical industry.
• Determine the relative position of the Indian pharmaceutical companies in the global pharmaceutical industry, as well as to reveal opportunities for further strengthening of their positions.

• Identify major players of the global pharmaceutical industry and make a comparative analysis of their business practices

1.3. Scope of the Study

The present study covers briefly the historical aspects of pharmaceutical industries since its inception to present day. The entire period is divided into pre-reform and post reform periods. The main areas covered are marketing, diversification of activities leading to further growth, mergers between different concerns for further growth and specializations. Quality and process control activities, this also stresses the roles played by various government regulations.

The study traces the evolution of Indian pharmaceutical industry, its growth over the years and its position in the international market. The period from 1970 to 2007 is covered and depending on the availability, the data are analyzed for some variables.

Further, the discussion regarding the Act and its implication has been included. Indian Research and Development (R & D) activities and Indian government efforts has also been emphasized. The global challenges faced by Indian firms and the competition have been examined too. A growth opportunity available for the Indian firms and its comparison with the global market has been made. The study also mentions few aspects of India’s globally competitive strategy policy and pricing framework, industry partnership and alliances, clinical trials etc. We have provided a few tables.
relating to states but on the whole we focus on this industry at all India level only.

1.4. Background and Issues of Pharma-Sector

Review of some earlier studies suggest that the aspects like demand, supply, marketing, discovery processes and other related issues have acquired great importance in studies on this industry namely pharmaceutical industry. The pharmaceutical industry is praised as one of the nation's leading industrial sectors. The fruits of its extensive research and development are sold worldwide and have improved the length and quality of life of countless individuals. At the same time, however, the industry is criticized for its marketing and pricing practices and even for its research and development priorities (Comanor, 1986 and Kane, 1997) suggests that it is the industry's consistently high profits and large expenditures on research and development as well as on marketing that foster scrutiny and criticism. (Schweitzer and Comanor, 2001) point out that lower insurance coverage for drugs than that for other health services, coupled with the increased likelihood that people will incur catastrophic costs due to prescribed drugs, increases people's resentment toward the industry.

Another factor responsible for the criticism of this industry is the occasional revelation that there are dangers in prescribed drugs that were not earlier evident. The most recent example is the risks of the COX-2 arthritis medications such as Vioxx and Celebrex. People feel confused because it is not clear whether the fault lies with the manufacturer or with the Food and Drug Administration (FDA), which approved the product for marketing in the first place. How is it that an industry can be both praised and criticized at the same time? The answer lies in the conflicting roles and responsibilities the industry faces.
The market for Pharmaceuticals that differentiate it from other markets creates this sense of ambivalence toward the industry. Unfortunately we could not access a large number of studies relating to this industry but some important ones are referred to often by us we find that in such studies the approach taken by several scholars is that of a standard economic inquiry. Their studies deal with the supply of pharmaceuticals, looking at the many components of the industry and its various functions, including research and development, production, and marketing along with demand side of the marketplace. On the demand side not one but four parties are involved in the consumption decision: the physician, the patient, the pharmacist and, increasingly, the insurer. Market performance includes the pricing of drugs and the multinational character of the market. Regulatory issues that differentiate the pharmaceutical market from other markets are also examined by different studies, which raise some crucial questions. These questions illustrate the role of economic analysis in formulating policies regarding the pharmaceutical sector. (National Centre for Health Statistics, 2005)

The foundation of the pharmaceutical industry is its research and development (R&D). Pharmaceuticals are one of the technology and economic success stories of the twentieth century. The programs subsidizing non commercially viable research also suggest a model whereby R&D could be directed to problems of developing countries, where incidence and prevalence of diseases infrequently seen in industrialized countries, such as malaria, may be enormous, but incomes of those afflicted are so low that the commercial market is small.
The pharmaceutical industry is also differentiated from other industries by its marketing efforts. Marketing prescription pharmaceuticals is unlike marketing most other products because of the peculiar consumer-agent relationship characterizing health care demand. Traditionally, prescribed drugs have been selected by physicians on behalf of their patients, whose role in product selection is passive. By definition, purchase of prescription drugs by patients must be authorized by a physician. Firms compete heavily in many of the more popular therapeutic markets, such as those for cardiovascular, analgesic, and digestive system drugs. Historically, this marketing has taken the form of advertising in medical journals and magazines and visits by sales representatives to physician offices and hospitals. Physicians frequently report that their primary source of information about new drugs is pharmaceutical company representatives (Bowman, 1992). But there is considerable concern as to whether this drug marketing has been in the best interests of patients.

In recent years, another type of drug marketing has appeared: advertisements aimed directly at the end-user, the patient. This is called direct-to-consumer (DTC) advertising. These advertisements, in the press and on television, urge patients to tell their physicians that they would like to try a particular product. Are consumers responsive to such advertising? Do physicians feel unduly pressured to prescribe drugs that they feel are inappropriate? We present direct evidence on the extent to which DTC advertising leads to an increase in unnecessary use of new and expensive drugs as well as a decrease in the number of patients not receiving appropriate drugs. (Schweitzer O Stuart, 2007)
1.4.1. Issues related to demand and pricing

The demand for pharmaceuticals derives from the demand for health. While most markets have two participants, the producer and the consumer, demand for health care is also determined by so-called third-party intermediaries, the insurers or other players who stand behind the patient ready to pay for whatever he or she decides to purchase. But the picture for health care is even more complicated because the physician frequently has two roles as decision maker: as a provider of care and as the consumer's agent. This "agency relationship," in which the professional acts in the consumer's best interest, has been the subject of intense debate for decades, primarily because of the incentives built into fee-for-service medical care, still the predominant form of physician payment. Fee-for-service payment rewards the practitioner for performing each specific service.

The inherent conflict of interest facing a physician who is paid according to the quantity of services performed is disquieting. Of course there are many other areas of our lives in which our expertise as consumers is so limited that we must trust others to make decisions for us. We trust our accountant to advise us regarding tax regulations, and we rely similarly on our architect and contractor when we contemplate a construction project. Most of us also rely on the advice of our auto mechanic. And then there are our professors, who set the curricula, teach the courses, and may even write and recommend the textbooks. Health insurance creates an odd division between professional advice, service delivery, consumption, and payment. Health services are traditionally selected by the physician who neither consumes the service nor pays for it.
1.4.2. Arguments for Product differentiation and price discrimination

Pricing of pharmaceuticals is perhaps the most controversial aspect of the industry. Consumers and their elected legislative representatives are highly attuned to drug prices. To understand how drug prices are set, one must return to the structure of the industry. Perhaps its most differentiating characteristic is that it is particularly intensive in fixed costs. A study for U.S.A. suggests that the cost of bringing a new drug to market were about USD 359 million in the early 1990s (U.S. Congress, OTA 1993) and are as high as USD1.7 billion today (Landers, 2003). Once those fixed costs are expended, the remaining costs of drug marketing, manufacturing, and distribution, while far from insignificant, are relatively small.

The costs in developing country like India is small because we do not spend much on Research and Development (R and D) but buy the patent for the drugs invented in the developed countries. The model of price setting in a perfectly competitive market suggests that prices are based on marginal costs. But this model obviously does not apply for pharmaceuticals, for if they were priced according to their marginal costs, they would be very inexpensive, but in the long run no expenditures on R&D would be made. A more applicable model allows either buyer or seller to act as an imperfect competitor or oligopolist, with some control over price. Such markets allow prices to exceed marginal cost in the long run. Indeed, there are relatively few markets within the pharmaceutical industry that are close to satisfying the conditions of perfect competition. This result is in part the objective of many institutional arrangements whose purpose is to reward innovation through protection of intellectual property.
Many pharmaceutical markets are highly competitive. Even new drugs, which enjoy full patent protection, often compete with other products in the same drug class and with older drugs that have a favorable reputation and product loyalty. A useful question to address will be the degree of competitiveness in the pharmaceutical industry. Obviously the answer to this vexing question goes beyond the total number of pharmaceuticals in the marketplace or the number of pharmaceutical manufacturers, either domestic or foreign. (Schweitzer O Stuart, 2007)

Product differentiation among competing drugs highlights the role of consumer tastes and preferences in price determination for competing drugs. Both of these factors underscore the importance of demand in pharmaceutical price determination. This is counterintuitive at first because the cost of drug development, a supply-side variable, is so often blamed for high costs. This argument is heard not only from industry critics but also from the industry itself.

It is observed that Price variation is extremely high in the industry, with some classes of buyers paying much more for the same drug than other classes do. The buyers who are best able to negotiate substantial discounts from list prices are NGOs or government organizations because they are able to control prescribing decisions by their participating physicians. Retail pharmacies, which are passive in the product selection decision, are unable to obtain the same discounts. Economic theory describes this phenomenon as price discrimination. We know that profit-maximizing sellers will attempt to charge different purchasers different prices, depending on their demand elasticity. Purchasers whose demand is particularly price sensitive (e.g., NGO or Government) will receive a lower price than those whose demand is less price
sensitive (e.g., retail pharmacies). Price discrimination is not unique to pharmaceuticals, of course, as the same behavior is observed with respect to airlines, telephone companies, and even health services, where purchasers who can readily switch among sellers according to price pay less than buyers whose demand cannot be switched. Thus drug prices are substantially determined by purchaser demand elasticity, another demand factor.

The studies and observations of some scholars suggest that in this industry prices are largely determined by what consumers are willing to pay rather than by the cost of research or production. That is price is largely determined by demand factors in the industry. While industry spokes persons and even its critics generally argue that the cost of investment determines price, and acknowledge that price determines demand, the evidence is quite different, suggesting that it is demand that determines price, and it is price (and profit) that determine subsequent investment.

Rather than investment being exogenous, determining price and hence demand, some scholars suggest that a more realistic model is that demand determines price, and the ability of a drug to earn a substantial rate of return stimulates subsequent investment. The evidence shows that price and investment are correlated, but the explanation is that firms that spend large amounts developing new drugs must in the long run recover these expenses through sales revenue or else they will not survive in the market. The important point is that firms believe that costly drugs are good enough to command high prices, not the other way around. Firms cannot charge high prices merely because development costs are high. The inherent attributes of the product must warrant high prices. (Lu and Comanor, 1996)
1.4.3. Liberalization of Pharmaceutical Industries

There are a few industries as multinational pharmaceuticals. Even though pharmaceuticals are ubiquitous and sold worldwide, the largest producers are based in relatively few countries, most notably the United States, Switzerland, the United Kingdom, Japan, France, Germany, and Sweden. However, each of the major firms has substantial operations in many countries, and it is often difficult to tell where a firm's R&D, manufacturing, or even strategic planning for a particular product occurred. Thus describing the nationality of a firm or product by the nation in which the corporate headquarters is located fails to identify such important concerns as employment generated or the relevant governmental regulatory jurisdiction. (Schweitzer O Stuart, 2007)

An area of concern to multinational organizations such as the World Health Organization (WHO) or the United Nations International Children's Emergency Fund (UNICEF) is the imbalance in response to health needs of developed and developing countries by the pharmaceutical industry. For much of their pharmaceutical supply, the poorer countries of the world are dependent on drug manufacturers located primarily in the wealthy countries—the United States, Western Europe, and Japan. These firms seek markets primarily in the developed world because patients in poor countries have only a limited ability to pay for drugs. It is therefore not surprising that R&D efforts are devoted to health problems of the developed world and not those of poor countries. As firms export to developing countries there is often a gap between the importing country's health needs and the selection and price of products offered for sale. The problem is so serious that the
WHO has recently suggested the possibility of focusing multilateral aid into supporting R&D specifically to diseases prevalent in developing countries, and then supporting the purchase of these drugs. (Schweitzer O Stuart, 2007)

However it is happy to note that during post reform era this industry is doing wonderful in India. Indian pharma companies are growing strong and going global. Earlier the Indian pharma market was dominated by foreign MNCs. From a stage of being nowhere, Indian pharma companies today are not only dominating the domestic market but have also begun to dominate some of the world markets. (Schweitzer O Stuart, 2007)

One of the main reasons for Indian pharma companies' success is the support from the Government. Without the Government intervention Indian pharma companies would not have grown to this great level. Various policies followed by the Indian Government initially sowed the seed of development of the Indian pharma industry. The Indian Patent Act, 1970, allowed pharma companies to reverse-engineer the already available product i.e., the act recognized process patents and not the product patents unlike in the western world. This enabled Indian companies to flourish, and at the same time demotivated foreign companies from doing business in India. (Schweitzer O Stuart, 2007)

Liberalization of Indian economy to some extent motivated foreign companies to enter India. When the foreign MNCs entered India, Indian companies established technical and marketing alliances and learnt expertise in those areas from foreign MNCs. Relaxation of limits in overseas foreign direct investment motivated Indian companies to go global. Even though Indian companies began to internationalize
during 1960s, it gained significant momentum only during 1990s. Today, Indian pharma companies are going global through exports, joint venture, mergers & acquisitions, Contract Research and Manufacturing service (CRAMS) and out-licensing. Many Indian players are using these strategies according to their needs. For example, most of the Indian companies prefer the acquisition strategy to enter Europe and the Greenfield Investment strategy to enter the US market. The strategic reason behind this is that the valuation of European companies is lower than that of US companies. Moreover, by acquiring European firms they can also establish their presence in the US market because most of the European firms have a good presence in the US market too. Also, many more pharmaceutical companies are available for acquisition in Europe than in the US. (Schweitzer O Stuart, 2007)

Indian companies are not only targeting developed and regulated markets like the US, Europe and Japan but have also begun to exploit the opportunities in developing markets like South Africa, Mexico and China. (Carey, 2006)

One of the main reasons behind the success of Indian companies both in the domestic and international markets is that India offers many advantages to Indian firms. India has a larger number of US FDA approved plants compared to any other country in the world. India has 75 US FDA approved plants, Italy has 55 and China is lagging behind with 27 plants. India also has a large pool of scientific talent with cheaper cost that puts Indian companies ahead of their competitors. (Schweitzer O Stuart, 2007)

Even though going global offers many advantages for Indian firms, it is not without challenges. Indian companies have had to tackle many challenges in going global. Political challenges, cultural challenges and integration challenges are
faced by Indian pharmaceutical, but these challenges are common to companies in every sector. The unique challenges faced by pharmaceutical companies are litigation challenges. Most Indian companies are generic players and they have many productions in the pipeline. So, litigation will be one of the biggest challenges for Indian pharmaceutical companies. In order to become successful in the highly competitive pharmaceutical market, Indian companies have to invest more on R&D and come out with innovative products. Even though none of the Indian companies is in the list of 50 global majors, they will become strong contenders globally if they innovate.

1.5. Data and Methodology

The study is based upon some selected secondary data relating to Indian pharmaceutical industry. Most of the useful data have been provided by the reports of Centre for Monitoring Indian Economy (CMIE) published on a regular basis. Other secondary sources such as research publication, reports and journals are used for the study. The major sources of data are:

- Various CMIE reports monthly, annual and soft reports.
- Growth Strategies of Indian Pharma Companies (ICFAI publication)
- Indian Health Care Industry, a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis (FICCI 2002) and others.
Various issues of the Economic and political weekly (EPW).

Relevant websites to support the existing reports or papers.

Annual reports of certain selected pharmaceutical firms

Data in regards to profitability, investment, balance of trade etc were collected at regular intervals. Average values were taken and statistical methods like standard deviation as well as percentage calculation were used to tabulate and analyze the data. Wherever necessary, use of charts, graphs and diagrams has been made. We have not carried out any sophisticated regression analysis or other econometric modeling due to data constraints on one hand and larger selected range of aspects on the other. However we have used a useful management tool - namely, SWOT (a strategic planning method used to evaluate the Strengths, Weaknesses, Opportunities, and Threats involved in a project or in a business venture) analysis to identify the growth of exports in this sector, an insight into the investment infusion structure currently prevalent in the industry and the further opportunity areas, the major contributors in the industry and analyze various other aspects of pharmaceutical industry.

1.6. Chapter Scheme

The proposed thesis will cover issues related to performance and prospects concerning pharmaceutical industry in India. The Seven Chapters in the thesis cover the issues as follows:

Chapter I entitled “Introduction” deals with objectives, nature and scope of the study, literature survey, limitations, sources and kind of data used and methodology used for the study. Chapter II is entitled “The Historical Perspectives Based on the Literature
Review” traces the evolution of Indian pharmaceutical industry, its growth over the years, Stages of growth. It also discusses about the structure of Indian pharmaceutical sector and its growth in exports. The chapter also highlights the Indian and World scenario in respect to post and pre reform periods. Chapter III entitled “Demand and Supply for Pharmaceuticals”- describes demand factors for a drug. The demand is governed by several special factors like number of patients, doctors, insurers, physicians. Even demand for Indian pharmaceutical as a market place, market segmentation and global pharmaceutical market place has been discussed. The supply conditions, pharmaceutical market structure and segmentation have been discussed in the chapter. The Indian and global pharmaceutical market comparison has also been made. It also discusses about the pharmaceutical industry, the market environment, and the challenges it faces. Chapter IV entitled “Price, Policies and Regulations” provides an overview of the pharmaceutical system of regulation. It includes the aspects like the drug prices, policies and regulations and its impact on Indian pharmaceutical companies. It describes government industrial policy and intellectual property rights (IPR) issues to further stimulate growth in the industry. It also illustrates the regulatory issues raised in the earlier sections. Lastly impact of globalization on the drug industry is also discussed. Chapter V entitled “Research and Development “is included to provide an analytically-based overview of the mechanisms of the drug discovery process, development and nature of drug research. The modern pharmaceutical company faces numerous challenges in its efforts to improve productivity and to strengthen the product portfolio. A thorough market analysis of the global as well as Indian pharmaceutical industry, including the challenges faced by pharmaceutical manufacturers and the technological developments currently affecting innovation has been focused. Chapter VI
"Outsourcing Strategy of the pharmaceutical industry" establishes a relationship with external firms to conduct some of the tasks necessary to bring a drug product to market like New Drug delivery Systems. Trends in outsourcing, contract research and manufacturing as well as clinical trials has been discussed. Advantages of Outsourcing in India have been highlighted and it draws attention towards outsourcing models. The last Chapter VII "Opportunities and Challenges" aims to conclude the study showing the core issues most of drug companies are facing namely the problem of declining productivity. It also covers aspects of in-house R & D, patent expiration of number of block buster drugs, increasing legal and regulatory concern, and pricing issue causing shifting of larger pharmaceutical companies to new business model with greater outsourcing of discovery services, clinical research and manufacturing. Such issues have been discussed in this chapter.

Now in the second chapter we will give the historical perspective of the development and growth of pharmaceutical industry in India.