CHAPTER 1
INTRODUCTION

1.1 AN OVERVIEW OF THE STUDY

The Indian pharmaceutical industry has expanded drastically in the last three decades. The Pharmaceutical industry in India is an extremely fragmented market with severe price competition and government price control. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and inventible. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India. The Indian pharmaceutical industry, which had little technological capabilities to manufacture modern drugs locally in the 1950s, has emerged technically as the most dynamic manufacturing segment in the Indian economy in the 1990s. When the product patents on Pharmaceutical products were abolished in India in 1972, the Indian industry was not a significant player either in the domestic or the overseas market. It was largely confining its activities to reverse engineering and thriving on developing new processes for the existing products and catered mostly to the domestic market. In the last two decades, the Pharmaceutical companies have gained a firm footing in the market; their share of the domestic market
has risen from 10 per cent in the early 1970s to over 80 per cent now. India has also emerged as a major supplier of drugs to the international markets, particularly over the past decade. A major factor that contributed to the rapid growth of the Pharmaceutical industry is that through skilful innovations in production processes, the Indian companies could make cheap copies of patented drugs and sell them at very low prices compared to anywhere else in the world. However, this favorable business environment will now undergo a change to favor drug MNCs because of their size and heavy R&D budgets. Under the new IPR regime, the challenge for Indian small pharmaceutical firms is to remain innovative as they were under the earlier regime. Three Amendments in March 1999, June 2002 and April 2005 on the Patent Act 1970 had been carried out to bring Indian patent regime in harmony with the requirements of TRIPS. These new policies have a number of implications for the survival and growth of small pharmaceutical firms’ today. This new IPR regime had extended patent protection to products in drugs, food and chemicals sectors, besides increasing the duration of patent term to 20 years. The burden of proof has been reversed in the case of a process patent and patent owner may not produce the product locally. This growth will be driven by the expanding economy and increasing per capita GDP. In 2008, India's middle class constituted 13% of
the population, according to the National Council of Applied Economic Research (NCAER-2008). While this remains a fairly small proportion of the total population, it represents a substantial increase from a mere 3% in 1995 (NCAER-2006). If the economy continues to grow faster than those of the developed world and the literacy rate keeps rising, around a third of the population (34%) is expected to join the middle class in the near future. While these consumers still earn substantially less than their US or European counterparts, they are rapidly acquiring the buying power necessary to afford modern healthcare, particularly if purchasing power parity is considered.

India's federal Government currently mandates price controls on essential drugs; however, these are under review. Price controls are carried out on certain drugs by virtue of the Drugs Price Control Order (DPCO), supervised by the National Pharmaceutical Pricing Authority (NPPA). The 347 price-controlled drugs included in 1979 were reduced to 143 in 1987 (OPPI 2008). The Government's draft pharmaceutical policy in 2006 sought to expand the scope of essential drugs and evoked a sharp reaction from the industry. They argued that it would adversely affect R&D activities in India, as companies would stay away from investing in new drugs. To date, no further action on the proposed policy changes had been taken and it currently looks unlikely that the DPCO will be expanded.
Some multinational pharmaceutical companies are already taking measures to reach a larger patient population by reducing drug prices and increasing affordability. One example: Merck & Co. has launched differential pricing through Januvia, its anti-diabetic drug, which is priced at approximately US$1 per dose in India - a fifth of its price in the US (Harachand 2008). Indian companies like Biocon have also followed a similar pricing strategy. Biocon has launched its monoclonal antibody BIOMAb EGFR at one-fourth of its price in the global markets (www.pharmexcil.com 2011). It's also likely that India will require different types of drugs in the future. Like almost every other emerging economy, India is experiencing epidemiological changes.

1.2 BACKGROUND AND IMPORTANCE OF THE STUDY

From being almost non-existent before 1970 to a prominent provider of healthcare products, meeting 95% of the country’s pharmaceuticals needs, the Indian pharmaceutical industry has come a long way. The industry has increased from US$ 4 bn in 1970-71 to US$ 26 bn in 2012, at a compound annual growth rate of 19.8% per annum. The total Indian production constitutes about 1.3% of the world market in value terms and 8% in volume terms. Increasing generic penetration, intense competition, fragmentation of the industry has negatively impacted overall value growth of the domestic
market. In this scenario, to grow in the domestic market, companies are looking at introducing value added new products, innovation, product life cycle management and increasing their market reach. Indian pharmaceutical Industry is moving up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented industry with a global presence, providing wide range of value added quality products and services. The industry is a net exporter and manufactures over 350 APIs (Active Pharmaceutical Ingredients). More than 60 Indian manufacturing facilities are approved by some of the toughest Regulatory Agencies such as US FDA, UK MCA, Australian TGA, WHO etc. Globally, pharmaceutical industry in India ranks 4th in volume term and 13th in value (largely because of very low prices). The industry is highly fragmented with about 15,000 plus registered units with only about 300 in the organized sector. The industry manufactures a wide range of drugs (over 100,000 - which includes vitamins, anti-biotics, anti-bacterials, cardio-vascular drugs etc.) Nearly 80% of the manufacturers have sales less than Rs. 1bn. Of the 300 manufacturing and formulation units in the organized sector; the market is concentrated at the top with the top 30 players controlling about 70% of the market share.
As the growth opportunities in the domestic market are on a decline, the Indian Companies are focusing on exports for higher growth and improved margins. Exports of pharmaceuticals consist of basic drugs (bulk), intermediaries & fine chemicals and finished formulations. The industry has been able to build a strong export market for Indian pharmaceuticals in the face of fierce competition from manufacturers in foreign countries with a long record of technology growth.

**Indian Pharmaceutical Industry till 1970**

Till 1970, the size of the Indian pharmaceutical industry was very small in terms of number of firms as well as production capacities. Bengal Chemicals and Pharmaceutical Works in Kolkata and Alembic Chemicals in Baroda, set up around 1910 were the first two Indian firms to start pharmaceutical production. The market was dominated mainly by multinational companies (MNCs) through their subsidiaries, who imported bulk drugs into India from the country of their origin, which were later processed into formulations. During this period, the patent regime, based on The Indian Patents and Designs Act, 1911, recognized both product and process patents. This acted as major entry barrier for Indian firms to enter pharmaceutical manufacturing. Between 1947-57, 99% of the drugs and pharmaceutical patents in India were held by foreign MNCs. During this period, due to the
monopoly status enjoyed by the foreign companies, the drug prices in India were at very high level. Given the high drug prices and low technical base of the domestic companies, the Government decided to directly intervene in the drug production. A major Government initiative in this regard was to set up two public sector drug companies, viz., a) Hindustan Antibiotic Ltd. (HAL) established in 1954, with the help of WHO and UNICEF; and b) The Indian Drugs and Pharmaceutical Limited (IDPL), in 1961. The Government received technical support from countries like Russia to set up and start pharmaceutical manufacturing. These two companies played an important role in producing critical drugs for domestic market including penicillin. The Government has also encouraged MNCs to set up manufacturing base in India. However, during this period, FDI in drugs and pharmaceuticals industry was minimal and the country was totally dependent on imported bulk drugs.

**Indian Pharmaceutical Industry in Post-1970 Period**

Before 1970, patent protection served to encourage foreign inventors and foreign R&D. MNCs patented their inventions in India, but did not produce locally, using the patents to establish a protected foreign market in the country. This not only denied the spillovers of technologies developed by MNCs to the local innovation system, but also did not help develop local
technological capabilities. The need for a system that encouraged technology acquisition, transfer, development, diffusion and incremental innovation was obvious. Patent Law was used as a tool to establish this system in India. It was The Indian Patents Act, 1970, that laid the foundation of the local industry. In the 1970s, India introduced complex laws and policies to regulate the pharmaceutical industry, to counteract monopoly abuses by multinationals and to promote local industry. The reforms included changes to foreign exchange regulations, price controls, industrial licensing and, most important of all, and the non-recognition of pharmaceutical product patents. The Patents Act, 1970, which came into effect in 1972, represented a significant change in the legal and technological regime and had an enormous impact on the technological evolution of the pharmaceutical industry in India.

A lot of research works were done on Indian pharmaceutical industry to know the developments and future prospects but the study on issues like increasing span of price control, price erosion in generics, low research and development productivity etc and challenges like growing export, expanding presence in regulated market, rise in new product launches etc in this respect was neglected. Indian companies need to attain the right product mix for sustain future growth. Core competencies will play an important role in
determining the future of many Indian pharmaceutical companies in the post product patent regime after 2005. Indian companies in an effort to consolidate their position will have to increasingly look at merger acquisition options of either companies or product. This would help them to offset loss of new product options, improve their research and development efforts and improve distribution to penetrate markets. Research and development has always taken the back seat amongst Indian pharmaceutical companies. In order to stay competitive in the future, Indian companies will have to refocus and invest heavily in Research and development. That is why researcher is also interested to know the factors behind the issues and challenges in Indian pharmaceutical industry. In our present research work we have consider the issues and challenges in Indian pharmaceutical industry, since 1991 to the present day. The proposed research is intended to survey the factors behind the issues and challenges in Indian pharmaceutical industry.

1.3 OBJECTIVES OF THE STUDY

The basic objective of the study is to analyze in a comprehensive manner the issues like increase span of price control, price erosion in generics, low research and development and challenges like growth in the field of sales, export, patenting and new product development faced by Indian
pharmaceutical industries during the post liberalization era. To be specific the study intends to:

i) To analyze the sales growth over the years, role in export of raw materials, active pharma ingredients and generic drug formulation of the Indian pharmaceutical industries.

ii) To explain the role of patenting and clinical trials adapted by the Pharmaceutical Industries of India.

iii) To disclose the emerging trends of Research and Development in the Indian pharmaceutical industry.

iv) To show the paradigm changes of pharmaceutical marketing in India and success of Indian pharmaceutical companies.

1.4 RESEARCH METHODOLOGY

Research in common parlance refers to a search for knowledge. Once can also define research as a scientific and systematic search for pertinent information on a specific topic. In fact, research is an art of scientific investigation.

Redman and Mory define research as a “systematized effort to gain new knowledge.” Some people consider research as a movement, a movement from the known to the unknown. It is actually a voyage of discovery. We all possess the vital instinct of inquisitiveness for, when the unknown confronts
us, we wonder and our inquisitiveness makes us probe and attain full and fuller understanding of the unknown. This inquisitiveness is the mother of all knowledge and the method, which man employs for obtaining the knowledge of whatever the unknown, can be termed as research. Research is an academic activity and as such the term should be used in a technical sense.

Research is, thus, an original contribution to the existing stock of knowledge making for its advancement. It is the pursuit of truth with the help of study, observation, comparison and experiment. In short, the search for knowledge through objective and systematic method of finding solution to a problem is research. The systematic approach concerning generalization and the formulation of a theory is also research. As such the term ‘research’ refers to the systematic method consisting of enunciating the problem, formulating a hypothesis, collecting the facts or data, analyzing the facts and reaching certain conclusions either in the form of solutions towards the concerned problem or in certain generalizations for some theoretical formulation.

**TYPES OF RESEARCH**

The basic types of research are as follows:

i) **Descriptive vs. Analytical**: Descriptive research includes surveys and fact-finding enquiries of different kinds. The major purpose of descriptive
research is description of the state of affairs as it exists at present. In social science and business research we quite often use the term Ex post facto research for descriptive research studies. The methods of research utilized in descriptive research are survey methods of all kinds, including comparative and correlation methods. In analytical research, on the other hand, the researcher has to use facts or information already available, and analyze these to make a critical evaluation of the material.

(ii) Applied vs. Fundamental: Research can either be applied (or action) research or fundamental (to basic or pure) research. Applied research aims at finding a solution for an immediate problem facing a society or an industrial/business organization, whereas fundamental research is mainly concerned with generalizations and with the formulation of a theory. “Gathering knowledge for knowledge’s sake is termed ‘pure’ or ‘basic’ research.” Research concerning some natural phenomenon or relating to pure mathematics are examples of fundamental research.

(iii) Quantitative vs. Qualitative: Quantitative research is based on the measurement of quantity or amount. It is applicable to phenomena that can be expressed in terms of quantity. Qualitative research, on the other hand, is concerned with qualitative phenomenon, i.e., phenomena relating to or involving quality or kind.
(iv) **Conceptual vs. Empirical**: Conceptual research is that related to some abstract idea or theory. It is generally used by philosophers and thinkers to develop new concepts or to reinterpret existing ones. On the other hand, empirical research relies on experience or observation alone, often without due regard for system and theory. It is data-based research, coming up with conclusions which are capable of being verified by observation or experiment. We can also call it as experimental type of research. In such a research it is necessary to get at facts firsthand, at their source, and actively to go about doing certain things to stimulate the production of desired information. Evidence gathered through experiments or empirical studies is today considered to be the most powerful support possible for a given hypothesis.

(v) **Some Other Types of Research**: All other types of research are variations of one or more of the above stated approaches, based on either the purpose of research, or the time required to accomplish research, on the environment in which research is done, or on the basis of some other similar factor.

**Data source and sampling design:**

The present study is based on secondary data obtain from CMIE and respective company data base. In the presence study purposive sampling has
been used to represent the universe. We have selected fourteen pharmaceutical companies originated from India. The secondary sources of data collection include published materials such as extract from relevant journals, books and periodicals covering the present area of study. Literature are reviewed from annual reports of the department of pharmaceutical, the ministry of commerce and industry, parliamentary reports and reports published by individual organizations and authors. In addition industry journals, conference proceedings and industry association publications are also referred to.

Period of study:
We have used six to ten years data (based on availability of data) Starting from 2004-2005 to 2013-2014.

Tools used:
In the course of analysis, accounting and statistical tools have been used. Accounting tools include the absolute value of sales, profit and R &D and statistical tools include descriptive statistics linear trend, exponential trend and cumulative growth rate have been used. We have used R software for statistical output like value of adjusted R squared which indicates that the model is perfectly fitted or not for the computation of sales variation and result of fitted trend value of sales. After that we have plotted the ‘observed
sales’ and the ‘fitted sales’ values in the graph to graphically understand how close fitted and observed values of sales are by this way we can see the sales trend over the year and we have done trend indices which indicates the future tendency of the data and it also predicts the expected value that will provide effectiveness or ineffectiveness of the series.

Model specification:

Trend analysis: Trend analysis is based on least square method of trend equation, that is \( Y=A+Bt \) (where \( Y=\text{sales}, A=\text{intercept}, B=\text{trend coefficient}, t=\text{time} \)) that indicates \( Y \) will be transformed with the change of time.

Trend indices: Trend indices are the trend percentage between current year and base year’s data. Trend indicates the future tendency of the data. It predicts the expected value that will provide effectiveness or ineffectiveness of the series.

\[ \text{Trend indices} = \frac{\text{Current year value}}{\text{Base year value}} \times 100 \]

1.4 PLAN OF THE WORK

The present study has been divided into following eight chapters viz.

**Chapter 1** of the study deals with the framework of the study including the overview, background, importance, objectives, research methodology adopted for the research work. Overview of the study indicates the paradigm changes of Indian pharmaceutical industries of last three decades.
Background of the study explains the scenario of the pharmaceutical industries from 1970 to present times.

**Chapter 2** the purpose of this chapter is to report on the review of the literature made by us relevant to the present study. It helps to identify the areas where lies the scope of further research and to find out the answers of the unsolved questions. Further it facilitates comparison of the findings from the current study with the result of the previous studies.

**Chapter 3** provides the detailed review of the Pharmaceutical market at a glance. Overall growth outlook for the Indian drugs and pharmaceutical market are also described here. We have also highlighted the key drivers of the growth in the below mentioned points like low cost operations, research-based processes, improvements in API and availability of skilled manpower in Indian Pharmaceutical Industries.

**Chapter 4** describes various policy measures taken by the Government in recent past, and qualitative research and development (R&D) activities implemented by major Indian Pharmaceutical Companies. Brief write-up about at 14 leading Indian pharma companies which are into new drug discovery and some of them have also increased their R&D spending by over 5 per cent of their respective sales turnover.
Chapter 5 denotes a study on Issues (increasing span of price control, price erosion in generics, low research and development productivity etc) in Indian pharmaceutical industry. The details of policy reforms aimed at boosting the pharmaceutical R&D include liberalization of foreign investment and foreign technology collaborations, exemptions from tax obligations, exemptions from drug price regulation and product patent rights to pharmaceutical innovations are also touched in here.

Chapter 6 describes a study on challenges (patenting, growth in the field of export, expanding presence in regulated market, rise in new product launches etc) in Indian pharmaceutical industry.

Chapter 7 is an empirical study on the Indian Pharmaceutical industry and the various findings from the study, this involves paradigm changes from post liberalization period to present times. In this chapter, we have taken data of fourteen leading Indian pharmaceutical companies for analytical purpose.

Chapter 8 concludes the study mentioning the summary, limitation, recommendation and scope of the future research work. We also touched key points like sample size, impact of practical issues and challenges, qualitative response from respondents and sustainable future model of successful Indian pharmaceutical companies are elaborated in this chapter.