1.4 THE PHARMA INDUSTRY – AN INTRODUCTION

The **Pharmaceutical Industry** develops, produces, and markets drugs licensed for use as medications. For this they have a well equipped R&D department. Pharmaceutical companies are allowed to deal in generic and/or brand medications and medical devices. They are subject to a variety of laws and regulations of the government regarding the patenting, testing, pricing and ensuring safety and efficacy and marketing of drugs.

The **Indian Pharmaceutical industry** is the second-largest in the world by volume and is leading the manufacturing sector of India [1]. The Indian bio-tech industry has achieved a growth rate of 17 percent and has gained revenues of Rs.137 billion ($3 billion) in the 2009-10. Bio-Pharmaceutical was the biggest contributor generating 60 percent of the industry's growth at Rs.8, 829 crore, followed by bio-services at Rs.2, 639 crore and bio-agriculture at Rs.1, 936 crore. The first pharmaceutical company was Bengal Chemicals and Pharmaceutical Works, which still exists today as one of 5 government-owned drug manufacturers, in Calcutta in the year 1930. For the next 60 years, most of the drugs in India were imported by multinationals either in fully formulated or bulk form. The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and due to the Patents Act in 1970, the industry got an opportunity to grow. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The lack of patent protection made the Indian market undesirable to the multinational companies who had dominated the market, and while they streamed out, Indian companies started to take their places. The multinationals were market leaders at that time because of their superior technology. As a result of this, they had gained expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken small steps towards drug innovation, the industry as a whole has been following this business model until the present.
Research and Development

**Drug discovery** is the process by which the required drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions. All this requires constant innovation and research by either the traditional or modern methods, or a combination of both.

**Drug development** refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate Formulation and Dosing, as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The amount of capital required for late stage development has made it a historical strength of the larger pharmaceutical companies. *(Suggested citation: Tufts Center for the Study of Drug Development, Annual Impact Report, http://csdd.tufts.edu/)*

Often, large multinational corporations contribute in a broad range of drug discovery and development, manufacturing and quality control, marketing, sales, and distribution. On the other hand, smaller organizations lay emphasis on a specific aspect such as discovering drug candidates or developing formulations. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to discover any probability of new drug.

1.4.1 **HISTORICAL BACKGROUND OF PHARMA INDUSTRY**

The origin of the earlier drugstores goes back to the middle Ages. The first known drugstore was opened by Arabian pharmacists in Baghdad in 754,[2] and it gave way to many more, which soon started operating throughout the medieval Islamic world and eventually medieval Europe. Many of the drugstores in Europe and North America had gradually developed into larger pharmaceutical companies by the 19th century.
The late 19th and early 20th centuries gave birth too many of today's major pharmaceutical companies. The discoveries of the 1920s and 1930s, such as insulin and penicillin, became the mass-manufactured and distributed drug of that time. Switzerland, Germany and Italy were among the front runners in these industries, with the UK, US, Belgium and the Netherlands following them.

In 1910s the pharmaceutical production began in India with the establishment of Bengal Chemical and Pharmaceutical Works in Calcutta and Alembic Chemicals in Baroda privately. With British initiatives pharmaceutical research institutes for tropical diseases like King Institute of Preventive Medicine, Chennai (in Tamil Nadu), Central Drug Research Institute, Kasauli (in Himachal Pradesh), Pastures Institute, Coonoor (in Tamil Nadu), etc was setup. In its early stages the industry received a setbacks during the post World War II period, as a result of which a new therapeutic developments in the Western countries had started.

Natural elimination of the older drugs gave way to the newer drug like sulpha, antibiotics, vitamin, hormones, antihistamine etc. This resulted in the elimination of local drugs using indigenous materials and now the industry was forced to import bulk drugs meant for processing them into formulations and for selling in the domestic market.

The Stages of Growth

The Indian pharmaceutical industry had four stages of growth. In the first stage during 1950s–60s, the industry was largely dominated by foreign companies and it was dependent on imported bulk drugs. Foreign firms, were enjoying a strong patent protection under the Patent and Design Act 1911, this had an adverse effect on the local production. Given the inadequate capabilities of the domestic sector to start local production of bulk drugs and hesitation of foreign firms to do so, the government decided to intervene by starting public sector enterprises. This led to the establishment of the Indian Drugs and Pharmaceuticals Ltd. (IDPL) plants at Rishikesh and Hyderabad in 1961 and the Hindustan Antibiotics at Pimpri, Pune, in 1954 to manufacture penicillin. The starting of the public sector enterprises has been an important feature in the evolution of the pharmaceutical industry and has
revolutionary importance in the history of the Indian Pharmaceutical company. As these public sector industries took initiatives in producing bulk drugs indigenously and motivated the private domestic sector.

The second growth stage of the industry took place in the year 1970s. The enactment of the Indian Patent Act (IPA) 1970 and the New Drug Policy (NDP) 1978 during this stage are important milestones in the history of the pharmaceutical industry in India. The IPA reduced the scope of patenting to only processes and non-pharmaceutical products. It also reduced the period from sixteen to seven years. This brought in a number of changes in patent system. Compulsory licensing after three years of the patent was also recognized. The enactment of the process patent significantly lead to the local technological development via adaptation, reverse engineering and new process development. As there are many ways to produce a drug, the domestic companies were able to find out ways of producing less costly and quality drugs for supply in the domestic market. This led to the growth and development of the domestic firms in the market. Pressure was mounted on foreign companies to locally manufacture bulk drugs and that too from the basic stage. Firms producing high technology drugs were allowed foreign ownership up to 74 per cent under the Foreign Exchange Regulation Act (FERA) 1973 under it only those Foreign firms that are simply producing formulations based on imported bulk drugs were required to start local production from the basic stage within a two year period. Otherwise were required to reduce their foreign ownership holding to 40 per cent. New foreign investments were to be permitted only when the production involves high technology bulk drugs and formulations thereon. The soft patent policy and policies of the government against foreign firms affected the industry and leaded strong growth impetus to the domestic sector during 1980s.
In the third stage of its development, near self-sufficiency was achieved in the technology and production of domestic enterprises based on large scale reverse engineering and process innovation. This was for production of bulk drugs and have developed manufacturing technique for all forms like tablets, capsules, liquids, orals and Injectable and so on. This gave a competitive edge to the domestic firms in the national and international markets. In 1991, domestic firms have emerged large in the market having about 70 and 80 per cent of the market shares in the case of bulk drugs and formulations respectively (Lanjouw, 1998).

Source: Stage classification is based on the Report of the Pharmaceutical Research and Development Committee (PRDC) November 1999. Production data is from Organization of Pharmaceutical Producers of India and the Department of Chemicals and Petrochemicals, Annual Reports, various years.
The industry with more than 30 per cent of its production being exported to foreign markets made it one of the most export oriented industry of India (Kumar and Pradhan, 2003). In terms of trade, the deficits which was experienced in the seventies was replaced by trade surpluses during 1980s.

The growth momentum which started in the third stage continued in the fourth stage of the evolution of the industry during 1990s. The production and formulations of bulk drugs rose new heights and the share of bulk drugs in total production from a low of 11 per cent in the year 1955-56 has gone up to 19 per cent in the year 1999-2000. This stage has also witnessed dramatic changes in the strategic policy of the pharmaceutical industry. Under this the licensing requirement for drugs was abolished, 100 per cent foreign investment was permitted under automatic route, and minimum restrictions were imposed on price control. After the three Amendments carried out in March 1999, June 2002 and April 2005 on the Patent Act 1970, the Indian patent regime was brought in harmony with the WTO agreement related to Trade Related Intellectual Property Rights (TRIPs). The third and the final one, known as the Patents (Amendment) Act, 2005 came into force on 4th April 2005 and it also introduced product patents in drugs, food and chemicals sectors. The term of patenting was increased to 20 years period. With these changes in the patent policy regime in the 1990s, started a new era in the history of Indian pharmaceutical industry where the trade patterns and industrial performance was determined by the various features such as free imports, foreign investment and technological superiority. The Indian pharmaceutical industry is looking at this era of globalization as both an opportunity and a challenge. (Pharmaceutical Policy 2002, Press Information Bureau Releases, February 15, 2002, available at http://www.nppaindia.nic.in/ceiling/policy.htm)

1.4.2 THE INDIAN PHARMACEUTICAL INDUSTRY- SOME FACTS

PHARMACEUTICAL INDUSTRY: the annual turnover of the Indian Pharmaceutical industry is estimated to be about US$ 21.73 billion (Rs. 1, 04, 209 crore) during the year 2009-10. The share of export of Drugs, Pharmaceutical & Fine Chemicals is around Rs. 42,154 crore. The industry now produces bulk drugs belonging to all major therapeutics
groups requiring complicated manufacturing process and also has developed good GMP; in fact the prices of bulk drugs have also grown in last three years. Growth in Bulk drug Prices in India is shown in below given table:

**Table 1.1 Growth in Bulk drug Prices in India**

*Source: Annual Report 2010-11, Department of Pharmaceutics, Government of India*

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<tr>
<td>No. of Bulk Drugs Where Price Increased</td>
<td>9</td>
<td>22</td>
<td>15</td>
<td>8</td>
<td>131</td>
</tr>
<tr>
<td>No. of Bulk Drugs Where Price decreased</td>
<td>50</td>
<td>9</td>
<td>10</td>
<td>5</td>
<td>340</td>
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<tr>
<td>No. of Bulk Drugs Where price fixed For First Time</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>No change</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>65</td>
<td>31</td>
<td>28</td>
<td>16</td>
<td>496</td>
</tr>
</tbody>
</table>

**Table 1.2 Formulation Packs for past three years**

*Source: Annual Report 2010-11, Department of Pharmaceutics, Government of India*

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<tbody>
<tr>
<td>No. of Packs Approved</td>
<td>2012</td>
<td>1577</td>
<td>1824</td>
<td>455</td>
<td>10795</td>
</tr>
<tr>
<td>Price Increased</td>
<td>78</td>
<td>190</td>
<td>184</td>
<td>118</td>
<td>1427</td>
</tr>
<tr>
<td>Price Decreased</td>
<td>422</td>
<td>89</td>
<td>450</td>
<td>51</td>
<td>3350</td>
</tr>
<tr>
<td>Price fixed for first time</td>
<td>1429</td>
<td>1256</td>
<td>1155</td>
<td>247</td>
<td>5699</td>
</tr>
<tr>
<td>No change in prices</td>
<td>83</td>
<td>42</td>
<td>35</td>
<td>39</td>
<td>280</td>
</tr>
<tr>
<td>Total</td>
<td>2012</td>
<td>1577</td>
<td>1737</td>
<td>455</td>
<td>10795</td>
</tr>
</tbody>
</table>

**Table 1.3 Performance of Enforcement Division Up till 2010**

*Source: Annual Report 2010-11, Department of Pharmaceutics, Government of India*
The concentration of pharmaceutical manufactures in various states of India has been depicted in the chart below.

**Fig 3: Concentration of Pharmaceutical Manufacturing Units in India**

*Source: Annual Report 2010-11, Department of Pharmaceutics, Government of India*
Introduction to Pharma Industry

**Patents and generics**

Depending on a number of considerations, a company may apply for and be granted a patent for the drug, or the process of producing the drug, granting exclusivity rights typically for about 20 years. However, for seeking permission for marketing and selling drugs a company requires government only after rigorous study and testing, which takes 10 to 15 years on average. Patent protection helps the owner of the patent to regain the costs of research and development due to high profit margins of the branded drug. In a situation where the patent protection for the drug expires, a generic drug is usually developed and sold by the company. The reason behind this is that the development and approval of generics is not that costly, which enables them to be sold at a much lower price than the patent drug. To get him launched in the generic market usually the owner of the branded drug introduces it before the patent expires. Companies failed to launch a new product to replace the older one necessitated restructuring exercises.

The British colonial masters, enacted in 1911 were still practiced at the time of Indian independence. This secured the Indian market for the British industry. Prior to 1970, the domestic production was very less, the major player at this time were the multinational companies with a share of 85 percent. Section 83 of the Patents Act 1970 states "that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent and not to enable patentees to enjoy a monopoly for the importation". At the turn of the century, the share of multinationals had declined to 40 percent of the India’s market, including a major share of local processing by multinationals. The "architect" of the patent law of 1970, S. Vedaraman, then director of the Indian Patent Office, summarizes the spirit of the law as follows: "We are not against patents. And we are prepared to pay decent license fees. But we in India cannot afford monopolies." Since then, the product patents for pharmaceutics was removed in India, with the exception of production processes which may be patented for seven years. In addition, the law allowed for compulsory licenses may be granted to the patent holder by the state, in the case of a patent holder not granting voluntary licenses on fair conditions. India had a large section of well-qualified experts who made good use of the new opportunities and contributed to the success story of the pharmaceutical industry.
Through patents was only developed in the last 30 years in many other industrial countries. To imitate foreign drugs, such as Aspirin at the end of the 19th century the enactment of a patent law was fought by many industries especially Swiss pharmaceutical industries. The Product patents for medical drugs started only in 1978 in Switzerland. Those countries which exports technology earns profit from patent protection, which protect them from low-cost competition. Most of the developing countries who imports technology want to avoid patent protection for gaining technical innovations as freely and at low cost. The economic development of Japan, Korea and Taiwan was possible due to the absence of patents, which proved very beneficial to them.

The Cipla chief objective has for decades been to promote the principle of relying on one’s own strength. "For India, this means striving for a high degree of self-sufficiency in vital areas of health and nutrition, and for our business practice, it means aiming for the fulfillment of the needs of the Indian population, the use of indigenous raw materials and of local personnel", says Cipla managing director Y.K. Hamied. All this and with Cipla technical superiority promoted the Indian Council for Medical Research suggested to Cipla in 1990 that the AIDS drug Zidovudine be locally manufactured. With limited financial support from the state government, the market of this drug was small. With a yearly turnover of approximately US$ 2 million for AIDS drugs in India, 80 percent is shared by Cipla.

1.4.3 INDIAN PHARMACEUTICAL INDUSTRY: SWOT ANALYSIS

It is often said that the success story of the pharmaceutical sector has no cyclical factor attached to it; it is growing and growing very fast. Usually it is believed that the demand for drugs is likely to vary over the period whether the economy is experiencing a downturn or in an upturn. True in some sense as the demand for drugs especially the life saving drugs comes under the category of necessity commodities which have an inelastic demand. Here are the various perspectives of the Indian pharma industry by carrying out a SWOT analysis (Strength, Weakness, Opportunity, and Threat).

Before we start the analysis let’s look a little back into the industry’s performance. The Industry is a largely fragmented and highly competitive with a large number of players having interest in it.
Introduction to Pharma Industry

The SWOT analysis of the industry reveals the position of the Indian pharma industry in respect to its internal and external environment.

**Strengths:**

1. Indian with a population of over a billion is a largely untapped market. In fact the use of modern medicine is less than 30% in India. The per capita expenditure on health care in India is US$ 93 while the same for countries like Brazil is US$ 453 and Malaysia US$189.
2. The rapid growth of middle class in India has contributed in the changing lifestyles in urban areas. This forms the very bases of a huge market for drugs, in which the share of the domestic producers is very less.
3. The cost of production of the Indian manufacturers is the lowest cost among the drug producers in the world. With a huge labor force, India can manufacture drugs 40% to 50% cheaper than rest of the world. In some cases, this cost is as low as 90%.
4. With excellence in chemistry and process reengineering skills the Indian pharmaceutical industry gives an added competitive advantage to the Indian companies. This also helps the industry to develop techniques which are cost effective.

**Weakness:**

1. The pricing regulation is proving to be the biggest obstacle in way of rapid growth of the industry. Over a period of time, this regulation has reduced the pricing ability of companies. The NPPA (National Pharmaceutical Pricing Authority) is the regulating authority of the pharmaceutical companies. Its job is to decide the various pricing parameters, sets prices of different drugs etc, all these leads to lower profitability of the companies. The companies, which produces at lower cost are at advantage while those whose cost of production is high are left with no other, option that to stop production or bear losses.
2. There is lack of product patenting in the Indian pharmaceutical sector which prevents global pharmaceutical companies to introduce new drugs in the country and also discourages innovation and drug discovery.
3. Indian pharmaceutical market is very less exploited in the world. The growth of the domestic producers and drugs consumption has been slow. Due to this the big Indian Manufacturers have to still depend on exports. To put things in to perspective, India accounts for almost 16% of the world population while the total size of industry is just 1% of the global pharma industry.

4. Due to very low barriers to entry, Indian pharmaceutical industry is facing competition with about 300 large manufacturing units and about 18,000 small units spread across the country. The industry witnesses price competition, which reduces the growth of the industry in value term. To put things in perspective, in the year 2003, the industry actually grew by 10.4% but due to price competition, the growth in value terms was 8.2% (prices actually declined by 2.2%)

Opportunities

1. The transformation into a product patent based regime is likely to give a stimulus to the industry. It will not only encourage research and developmental activities of the domestic companies but will also increase the profitability of MNC pharmaceutical companies. This transformation may also lead to consolidation of the fragmented pharmaceutical industry. Very small players might not be able to survive the stiff competition and may be taken over by the giants.

2. Large number of drugs was not patented in Europe and in the US between 2005 to 2009 which gave big opportunity to the Indian companies to take over the European and US markets. Indian producers have the competitive advantage in producing the generic drugs, because there cost of production is the lowest in the world as it is easily available in India.

3. The expansion of the health care industry due to opening up of health insurance sector and the expected growth in per capita income also is a major health indicator. The Pharmaceutical industry being an integral part of it had an opportunity to grow at the same time.

4. Being the lowest cost producer combined with FDA approved plants; Indian companies may be a global outsourcing hub for pharmaceutical products.
Threats:

1. The political instability in India is a major concern for the pharmaceutical industry, as patent act might be changed by the new government and the new provisions might not be in the interest of the pharmaceutical industry.
2. Threats from other the low cost countries like China and Israel may be a threat to the pharmaceutical industry. However, India enjoys the reputation of providing better the quality drug, than to China.
3. Another Short term threat for pharmaceutical industry is the uncertainty regarding the changing policies of the Government.

1.5 CHAPTER SCHEME OF STUDY

The process of globalization has put heavy pressure on Pharmaceutical industry to be competitive. The impact of these pressures is all pervasive and long term survival of business is dependent on its ability to improve continuously. Organizations have to gear up with new and innovative HR Practices to survive and flourish in today’s hyper competitive business environment. In this scenario, HR is expected to play a vital role in helping organizations to overcome these challenges.

Chapter II: “REVIEW OF LITERATURE” critically explores the existing wealth of literature available on the dimensions underlying the elements of the topic of research i.e. HR Practices, Job Satisfaction and Organizational Commitment in Global and Indian context.

Chapter III: It will provide details regarding the “RESEARCH METHODOLOGY” adopted for this study. The need and relevance of the study, its scope, its objectives, Hypothesis, Sources of data collection i.e. both primary and secondary, its analysis will be stated.

Chapter IV: It discusses and compares the “HR PRACTICES IN PHARMACEUTICALS COMPANIES” under study. It will include a comparative analysis of the prevalent HR practices in the Pharmaceutical companies in and around Jaipur under study and it will be analyzed also.
Chapter V: In this chapter the focus will be on the “IMPACT OF HR PRACTICES ON THE JOB SATISFACTION” of employees at managerial level in the Pharmaceutical units under study. It will include factors of Job Satisfaction, company wise analysis of Job Satisfaction, there analysis, Correlation between factors of HR Practices and Factors of Job Satisfaction.

Chapter VI: It is concerned with the “IMPACT OF HR PRACTICES ON ORGANISATIONAL COMMITMENT” of employees at managerial level in the Pharmaceutical units’ understudy. It will include measures of organization commitment, its company wise comparison, its analysis, analysis of correlation between factors of HR practices and Organization commitment.

Chapter VII: It presents a pertinent “CONCLUSIONS AND RECOMMENDATIONS” of the entire body of research. Recommendations, limitation and scope of future studies based on the findings will be included.