1.1 INTRODUCTION

Man focuses his knowledge intensely towards some specific industries that are highly "Knowledge-Driven". Pharmaceutical industry is one such industry as it is continuously in a state of dynamic transition. This industry is a lifeline industry; it comprises a complex matrix of processes, operations and organizations involved in the discovery, development and manufacture of various drugs and medications. A nation with a strong pharmaceutical industry has a healthy and strong population. Therefore, pharmaceutical industry plays a very important role in providing a nation with a strong human capital. Indian pharmaceutical industry is an ideal example of a highly growth-oriented industry, which is enhancing its value in the process. From being a pure reverse engineering industry focused on domestic market, the Indian pharmaceutical industry is moving towards basic, research-driven, export-oriented global presence, providing in the process a gamut of value added quality products and services.

1.2 MEANING OF PHARMACEUTICAL COMPANY

A pharmaceutical company is a commercial business house, which may focus either on research, manufacturing, marketing and/or distribution of medicine, drugs, and chemicals mostly in the context of healthcare. All the pharmaceutical companies involved in working in these different categories are collectively termed as pharmaceutical industry.

1.3 HISTORY AND DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

The roots of pharmaceutical firms can be traced back to 754 B.C. and were known as 'drugstores' in Arabian countries. Arabian pharmacists opened the first known drugstore in 754 BC in Baghdad. In those times, drugstores were famous in medieval Islamic world, Europe and North America. After discovering insulin and penicillin in the 1920s and 1930s, the drugstores were converted into major pharmaceutical firms. Mass-manufactured and distributed pharmaceutical firms made entry into Switzerland,
Germany, Italy, the UK, the US, Belgium and the Netherlands in those times. Towards the end of 1950s, most of the sophisticated drug manufacturing techniques came into existence as a result of developing systematic scientific approaches, understanding human biology (including DNA). This development made it necessary to enact legislations to test and approve drugs. Prescription and non-prescription drugs became legally distinguished from one another even as the pharmaceutical industry matured.

Numerous new drugs were developed to control Cortisone, blood pressure and other heart diseases towards the end of 1960. Production of numerous new drugs increased the need for regulatory environment and also to limit the financial risk of the pharmaceutical companies. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and which demanded the subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies are required to prove efficacy in clinical trials before marketing drugs. The year 1970 stands out because Cancer drugs were discovered in that year. From 1978, India took over as the primary center of pharmaceutical production without patent protection.

Pharmaceutical markets worldwide can be classified as – Regulated, Semi-regulated and Non-Regulated markets. Regulated Markets are those that have stringent laws in order to ensure availability of quality drugs; developed countries comprise these markets. To enter into US pharmaceutical market, the companies must get authorization from the US Food and Drug Administration (USFDA). The main characteristic of the US market is – strict regulations are not there on the pricing front; hence, innovative new products enjoy higher prices and exclusive production rights during the patented time period. This market accounts for the largest size and controls 88 per cent of the global pharmaceutical market. North America (47%) is the largest market. Europe comes second and Japan is the third largest market.
The markets are termed as semi-regulated and non-regulated markets because regulations and laws made to ensure availability of quality drugs are low. The market in developing countries like the Asian, African, Australian and Latin American markets are semi-regulated and non-regulated markets. However, the size of these markets is relatively small and the margins are lower. In the year 2008, these markets registered a double-digit growth, which highlight the tremendous market potential of these regions; and they also have some strict price control regulations on essential drugs, which restrict higher margins. As these markets are easier to access, competition is also intense and the profits these markets make have low margins. Overall, the global pharmaceutical market reached US$748 billion in the year 2008; however, the growth rate moderated from 6.4% in 2007 to 5.10% in 2008. (Refer Table 1.1 and figure 1.1). The Pharmaceuticals market had to contend with a number of forces including decline in new product approvals and the global economic recession, marked in particular by a sharp downturn in the world’s largest economies – the USA and the EU. However, the pharmaceutical market scenario was also characterized by a growth in the emerging markets. The global pharmaceutical industry has grown at a compounded annual growth rate (CAGR) of 10.7 per cent for the period 2002-08. However, global pharmaceutical sales are expected to grow at around 5% p.a to exceed $810 billion in 2009.

Table 1.1
GLOBAL PHARMACEUTICAL MARKET SIZE & GROWTH RATES

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total World market (Current US$)</td>
<td>365</td>
<td>392</td>
<td>428</td>
<td>499</td>
<td>560</td>
<td>605</td>
<td>649</td>
<td>712</td>
<td>748</td>
</tr>
<tr>
<td>Growth Over Previous year (Constant US$ Growth)</td>
<td>11.50%</td>
<td>11.80%</td>
<td>9.50%</td>
<td>10.30%</td>
<td>8.00%</td>
<td>7.30%</td>
<td>7.10%</td>
<td>6.40%</td>
<td>5.10%</td>
</tr>
</tbody>
</table>

Source: IMS Health Market Prognosis (includes IMS Audited and Unaudited markets)
1.4 INDUSTRY SEGMENTS

Pharmaceutical industry manufactures products that may be broadly classified based on various parameters. The classification of pharmaceutical industry too is based on various factors such as follows:

Source: Table 1.1

FIGURE 1.2
SEGMENTS OF PHARMACEUTICAL INDUSTRY
a) Therapy based classification: On the basis of therapy, pharmaceutical industry can be classified as – Allopathic, Ayurvedic, and Nutraceutical.

- **Allopathic**: Formulation developed out of chemical entities.

- **Ayurvedic/Herbal (AYUSH)**: Formulations are developed out of herbs like Chinese traditional herbs, traditional Indian medication or ayurvedic herbs/other traditional medicines like Unani system/Siddha system/Homoeopathic system.

- **Nutraceutical/Cosmeceutical**: Formulations based on Alternate system of medicine largely Herbal. It consists Food Supplements, Nutritional supplements, Dietary Supplements etc.

b) Classification based on Sales Mode:

- **Ethical**: Sales generated out of Doctor’s prescription. Advertisement is strictly not allowed.

- **Over the Counter (OTC)**: Sales generated from products, which do not require prescription from Doctor. The Drug Laws freely allow these to be dispensed either at the chemist’s counter or stores. Advertisement is allowed.

c) Form Based Classification

- **Bulk Drug**: Bulk drugs are the active pharmaceutical ingredients (APIs) with medicinal properties, which are used to manufacture formulations. APIs cannot be administered directly to the patient, and necessarily require other substances called “excipients” to be added to stabilize the mixture.

- **Formulation**: Formulations are the end products of the medicine manufacturing process, and can take the form of tablets, capsules, injectables or syrups, and can be administered directly to patients.
d) Therapeutic Application based:

- **Anti-infective:** Antibiotic (penicillin, sulphonamides, aminoglycosides, tetracyclines, macrolides, cephalosporins, quinolones, etc.), anti-parasitic (anti/protozoa, anti-malarial, anti-fungal, antihelmintic, etc.), and vaccines.

**Cough & Cold Drugs**

- **Pain Management:** Anti-pyretic and analgesics, NSAIDs and anti-rheumatics.

- **Cardiovascular (CVS) Drugs:** Cardiac therapy, anti-hypertensives and anti-hypotensives.

- **Central Nervous System (CNS) Drugs:** Analgesics, anti-psychotics, anti-epilepsy, tranquilizers and sedatives, and anti-Parkinson’s disease.

- **Gastro-intestinal:** Antacids, anti-ulcerants, anti-helmintics, anti-flatulents and anti-diarrhoeals.

- **Corticosteroids:** Topical corticosteroids, and systemic corticosteroids.

- **Genito-urinary:** Gynaecological preparations, sex hormones and stimulants.

- **Respiratory Drugs:** Cough and cold preparations, anti-asthmatics, anti-histamines, rubs, and anti-tuberculosis.

- **Vitamins:** Plain vitamins and combinations.

- **Anti-diabetics:** Insulin, oral anti-diabetics.

- **Other Drugs:** General nutrients, minerals, anti-anaemia, and blood plasma.
e) **Dosage Based:**

- Tablet
- Capsule
- Caplet
- Injectables including Dry Powder
- Syrup
- Dry Suspension
- New Drug Delivery Systems (Once a Day Therapy/Sustained Release/Delayed release/
- Effervescent Tablets etc
- Ointments/ Cream

The main segments of products of the pharmaceutical industry are formulations (finished dosages) and bulk drugs (Active Pharmaceutical Ingredients).

i. **Bulk Drug:** Bulk drugs are the Active Pharmaceutical Ingredients (APIs) with medicinal properties, which are used for manufacturing formulations. Bulk drugs are Active Pharmaceutical Ingredients (API) or compounds that show specific medicinal properties. Bulk drugs and drug intermediates consist chemicals and solvents; these are the raw materials for the production of drug formulations, which are ultimately sold to the customers. Indian bulk drugs industry registered impressive growth over the past few decades which is very encouraging. India is among the top five bulk drugs producers, producing around 400 different drugs. About 60% of bulk drugs are exported and the balance is sold to domestic formulators.
ii. **Formulation:** Formulations are the end-products of the medicine manufacturing process, and can take the form of tablets, capsules, injectables or syrups, which are ultimately consumed by customers. Formulations constituted nearly 78% (FY08) of the Indian Pharmaceutical industry’s sales, and the remaining accounted for bulk drugs. Out of the formulation sales, about 68% are domestic sales and the rest are exports.

The key therapeutic segments include anti infectives, gastro intestinal, central nervous related, anti diabetes, gynaecology, respiratory, analgesics, dermatology, vitamins/food, cardio vascular surgery. Anti infectives is the major contributing segment with 14.7% of total pharmaceutical market in India followed by Gastro intestinal with 13.8%. The figure 1.3 presents the Industry segments.

**FIGURE 1.3**

**SHARE OF INDUSTRY SEGMENTS**
iii. **Antibiotics/anti-infective** – It comprises the largest part of the drugs sold. In India, the nature of ailments suggests that antibiotics are likely to be the most commonly prescribed drugs for long. Competition is intense which drives down the prices of older molecules. It is likely to dominate the pharmaceutical market in the foreseeable future.

iv. **Respiratory** – Chronic exposure of the lungs to inhaled particles and gases released can have deleterious effects on the respiratory system. It is estimated that 100 million people suffer from asthma worldwide. The management of respiratory disease remains a major healthcare challenge. With ever increasing pollution and stress in India as elsewhere, the incidence of asthma, bronchitis, and other lung diseases is also growing at an alarming pace.

v. **Life style drugs** – Lifestyle drugs like cardiovascular, anti diabetes, CNS are the new favorites among the pharmaceutical companies as their sales are fast rising. These drugs are so named because urbanization and associated Lifestyles among other things are believed to trigger the related ailments.

### 1.5 INDIAN PHARMACEUTICAL INDUSTRY

Among the developing countries, India has the largest Pharmaceutical Industry. It provides essential drugs at affordable prices to its vast population, and also provides employment to millions. Indian Pharmaceutical Industry has attained wide-ranging capabilities in the complex field of drug manufacture and technology. From simple painkillers to sophisticated antibiotics and complex cardiac compounds, almost every type of drug is now made indigenously. Pharmaceutical industry first took root in India in 1930 in Calcutta (Kolkata), West Bengal when the Bengal Chemicals and Pharmaceutical Works was set up in government sector. In India, up to 1960s, multinational companies (MNCs) imported most of the pharmaceutical products either in fully formulated or bulk form. The MNCs held a dominant position until the
government intervention. These firms imported most of the bulk drugs (the active pharmaceutical ingredients) from their parent companies abroad and sold the end products in the form of tablets and capsules, syrups etc. at prices unaffordable for a majority of the Indian population. This led to a revision of Government of India's (GOI) policy towards this industry. In the early 1960s, the GOI started encouraging the growth of Indian companies that were into manufacturing drugs. With GOI’s support and with the Patents Act in 1970, the industry was able to become what it is today. The Patents Act dissipated the dominance of MNCs and the Indian pharmaceutical companies occupied that place. They carved a niche in both the Indian and world markets with their expertise in reverse-engineering and new processes for manufacturing drugs at low costs.

The growth of Indian pharmaceutical Industry may be divided into five phases. The first phase was up to 1970, where foreign companies dominated the market share with very few recognized Indian Companies in existence. The period from 1970-80 comprised the second phase, where drug prices were controlled. The Government of India passed Indian Patent Act, 1970 and domestic pharma companies began to tap the market. The third phase was characterized by pharmaceutical production infrastructure creation, and announcement of export initiatives to domestic pharma companies. The duration of the third phase was from 1980-90. The fourth phase began in 1990 and ended with 2000. During this phase, Indian pharmaceutical companies expanded their businesses in India and outside India very rapidly. In this phase, research orientation production was started. The fifth phase began in the year 2000. Innovation and Research is the chief characteristic of this phase. The Patent Act, 2005 was introduced during this phase, which gave Indian companies the strength to rise to International standards.
At present, the Indian pharmaceutical industry can be broadly segmented to (i) bulk drugs (APIs) and (ii) formulations with very few companies risking investing in primary research aimed at developing and patenting new drugs. The bulk drug business is essentially a commodity business, whereas the formulation business is primarily a market-driven and brand-oriented business. This industry meets about 90% of the country's bulk drug requirement.

1.5.1 Growth & Market Size

The Indian Pharmaceutical industry grew from a mere US$0.3 billion turnover in 1980 to about $19 billion of which local market is worth US$10.76 billion and international market is worth US$ 8.24 billion in 2008. It accounts for nearly 2% of the global market in terms of value and 10% in terms of volume. The Indian Pharmaceutical industry is now ranked 4th in terms of volume of production and 13th in terms of domestic consumption. One reason for lower value share is the lower cost of drugs in India ranging from 5% to 50% less as compared to developed countries. The industry grew at a CAGR of 13 per cent from 2002 to 2008. The industry registered 6.78 per cent growth rate in the year 2009 and India's pharmaceuticals market is expected to grow by about 12-13 per cent in 2010 and will grow at a CAGR of 10% in 2011-15. The slope of Indian pharmaceutical industry growth rate is presented in the figure 1.4. Rising disposable income and rising health consciousness resulted in a positive impact on the pharmaceutical industry. The industry is likely to become one among the top ten in the market in the next decade. It is also playing a crucial social role by distributing quality medicines to society. The industry is poised to usher in a new era showing a tremendous growth in infrastructure development, technology base creation with wide range of production. The industry is self-sufficient and is a low cost producer of high quality bulk drugs & formulations.
Indian Pharmaceutical Industry employs over 42 lakhs people directly and indirectly. It contributes nearly 1% to the India's GDP. Indian Pharmaceutical Industry meets 40% of the world's bulk drug requirement. The Exports value of bulk actives and dosage makes it to occupy the 17th rank position. Presently, the Indian pharmaceutical industry meets 90% of the country's pharmaceutical needs and imports the remaining 10% drug requirements from other countries. Indian pharma industry exports to more than 200 countries with a sizeable share in the advanced regulated markets of US and Western Europe. Pharmaceutical industry has shown commendable export performance, the trade balance being positive throughout the years. During the period between 2003-04 and 2008-09, the Compounded Annual Growth Rate (CAGR) of exports was 17.8 per cent (Refer Tables & figure 1.2 & 1.5).
TABLE 1.2
INDIA’S TRADE IN PHARMACEUTICAL PRODUCTS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Exports of Drugs, pharmaceuticals &amp; fine chemicals (Rs. in Crore)</td>
<td>15,213.24</td>
<td>17,857.80</td>
<td>22,115.72</td>
<td>26,895.18</td>
<td>30,760.57</td>
<td>38,433</td>
<td>17.8</td>
</tr>
<tr>
<td>Imports of Medicinal &amp; pharmaceutical products (Rs. in Crore)</td>
<td>2,958.04</td>
<td>3,169.33</td>
<td>4,550.87</td>
<td>5,851.64</td>
<td>6,679.87</td>
<td>7,946.37</td>
<td>18.4</td>
</tr>
<tr>
<td>Exports Growth Rate (%)</td>
<td>18.61</td>
<td>17.38</td>
<td>23.84</td>
<td>21.61</td>
<td>14.37</td>
<td>24.94</td>
<td></td>
</tr>
<tr>
<td>Imports Growth Rate (%)</td>
<td>3.24</td>
<td>7.14</td>
<td>43.59</td>
<td>28.58</td>
<td>14.15</td>
<td>18.96</td>
<td></td>
</tr>
</tbody>
</table>

Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata

FIGURE 1.5
INDIA’S TRADE IN PHARMACEUTICAL PRODUCTS

Source: Table 1.2
According to Ministry of Commerce, domestic investment in the pharmaceutical sector is estimated at US$ 6.31 billion. The Government of India allowed Foreign Direct Investment upto 100 per cent in pharmaceutical industry. This sector was able to attract FDI worth US$ 1.43 billion from April 2000 to December 2008 and US$ 0.46 billion during the period from April, 2008 to April, 2009.

1.5.2 Rural Market

The rural market accounts for 21 per cent of the country's pharmaceuticals market. In 2007-08, the rural Indian pharmaceuticals market was estimated at around US$ 1.9 billion, growing at about 40 per cent from its previous year.

1.5.3 Pharmaceutical Retail

India has 5.5 million chemists and druggists, the organized retail market accounts for just 2 percent of the industry but is posting a year-on-year growth of 30-40 percent. The country's pharmaceutical retail market is expected to cross the US$ 10 billion mark in 2010 and be worth an estimated US$ 12 billion- US$ 13 billion by 2012.

India has the capability to become a global pharmaceutical hub by exporting domestically produced generic products and positioning itself as an off shoring destination for clinical and pre-clinical research and other support services. There is tremendous potential in the Indian pharmaceutical market itself. Consumer spending on healthcare went up from 4 percent of Gross Domestic Product (GDP) in 1995 to 7 per cent in 2008. That number is expected to rise to 13 percent of GDP by 2015. Consumers' expenditure on health as % of GDP in various countries is presented in the figure 1.6.
1.6 MARKET STRUCTURE OF THE PHARMACEUTICAL INDUSTRY IN INDIA

Indian Drug & Pharmaceutical industry is highly regulated in public interest. The Central Drug Standard Control Organization is the enforcing body at the central level while each state has a Food and Drug Administration Department to regulate at the state level. The National Pharma Pricing Authority (NPPA) is an organization of the Government of India, which was established, inter alia, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. In this industry, at present, there are over 20,000 licensed drug companies producing over 500 bulk drugs and 50,000 formulations. Out of these, nearly 330 are large and moderate size companies. This structure causes intense competition, especially in the bulk drug markets, with profitability falling as demand expands.
For value purposes, drugs in India are generally classified into two categories—bulk drugs and formulations. Due to India's low overhead costs, bulk drugs comprise the largest sector in the country's pharmaceutical market. Drug intermediates are used as raw materials for the production of bulk drugs, which are either sold directly or retained by companies for the production of formulations. Formulations can be subdivided into generic drugs and branded or "ethical" drugs, the latter of which are made under process patent and sold under a separate brand name. The expected short-term growth for the two types of drugs has been 20% for bulk drugs and 15% for formulations. 

1.6.1 H Index

**H Index (The Herfindahl-Hirschman Index):** H index stands for Herfindahl-Hirschman index, which is used to calculate the concentration of market share held by a particular company in the industry. The H index is the sum of squares of the percentages of the market shares held by a particular company in the industry. It is computed by using the formula:

\[ HI = \sum (\text{Market Share of each player})^2 \]

The computation of H Index for pharmaceutical industry is done and presented in Table 1.3:

<table>
<thead>
<tr>
<th>Name of the company</th>
<th>Net Sales (Rs. Crore)</th>
<th>(Share %)^2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cipla</td>
<td>5,234.29</td>
<td>323.69</td>
</tr>
<tr>
<td>Ranbaxy Labs</td>
<td>4,652.04</td>
<td>255.68</td>
</tr>
<tr>
<td>Dr Reddys Labs</td>
<td>3,999.50</td>
<td>188.98</td>
</tr>
<tr>
<td>Lupin</td>
<td>2,954.70</td>
<td>103.14</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>2,774.65</td>
<td>90.96</td>
</tr>
<tr>
<td>Piramal Health</td>
<td>2,321.91</td>
<td>63.70</td>
</tr>
<tr>
<td>Aurobindo Pharm</td>
<td>2,234.63</td>
<td>59.00</td>
</tr>
<tr>
<td>Cadila Health</td>
<td>1,743.40</td>
<td>35.91</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>1,676.36</td>
<td>33.20</td>
</tr>
<tr>
<td>Matrix Lab</td>
<td>1,501.77</td>
<td>26.65</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>29,093.25</strong></td>
<td></td>
</tr>
</tbody>
</table>
From Table 1.3, it can be concluded that Cipla Ltd., Ranbaxy Laboratories Ltd., Dr. Reddy’s Laboratories Ltd., and Lupin Ltd., are the main players in Indian Pharmaceutical industry and occupy the Lion’s share in the market.

1.6.2 Competitive Analysis

The competitiveness of Indian pharmaceutical industry is explained by using Michael Porter analysis in the following lines. Michael Porter Analysis uses concepts developed from the structure of Indian pharmaceutical industry to derive five forces that determine the competitive intensity and therefore attractiveness of the market.

FIGURE 1.7
MICHAEL PORTER'S FIVE FORCES MODEL FOR INDUSTRY ANALYSIS

Source: http://www.brs-inc.com/porter.asp
**Threat of Entry:**

The industry is largely fragmented with many organized and unorganized players. The entry barriers are low for the unorganized players because they mostly sell bulk drugs; however, for the organized players, the entry barriers are moderate, as huge capital outlay faces many regulatory issues.

**Bargaining Power of Suppliers:**

With more than 20,000 players exist in the industry, the bargaining power of suppliers is low.

**Bargaining Power of Buyers:**

The prices of many drugs are regulated and hence the consumer has very low bargaining power. Moreover, the final consumer has little choice on medicines and treatments. Medical doctors, general practitioners and pharmacists usually act as agents to final consumers. Hence the bargaining power of buyers is low.

**Threat of Substitutes:**

The only substitutes for allopathic medicine could be homeopathic or ayurvedic medicine. Therefore, one may conclude that there are hardly a few substitutes for allopathic medicine.

**Competition:**

The competition is very high in the industry from domestic players as well as from multinational companies (MNCs). Indian companies cannot give tough competition to MNCs in New Drug Discovery Research and in commercializing molecules on a worldwide basis.
1.7 SWOT ANALYSIS FOR THE PHARMACEUTICAL INDUSTRY

The strengths, weaknesses, opportunities and threats for the Indian pharmaceutical industry are presented below.

STRENGTHS

i. India has skilled scientists/technicians/management personnel at affordable cost leading to low cost of innovation/ manufacturing and high quality documentation and process understanding.

ii. India is regarded as having an edge over China in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system.

iii. The country has well developed chemistry capabilities R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high tech manufacturing facilities and regulatory compliance.

iv. The healthy domestic market with rising per capita expenditure is another significant strength enabling achievement of economies of scale.

v. India is considered a desirable destination for off shoring of data management functions for clinical trials and also due to its rich biodiversity and strength in Chemistry which are essential for drug discovery.

vi. The country has significant ability to circumvent API Patents. India has filed a number of non-infringing process patents. The country has a recent success track record in circumventing formulation patents. Proven Legal skills to evaluate IP and commercial strategies are available at least in select top companies.
Weaknesses:

i. Low investments in innovative R&D continue to be a major weakness of Indian pharmaceutical industry.

ii. Diffused nature of the Indian pharmaceutical industry means that only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained exports to and compliance with entry regulations of the developed markets.

iii. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis due to lack of resources.

iv. Strong linkages between industry and academia which are essential for growth of the industry are lacking in India.

v. Comparatively small domestic market size due to low medical and healthcare expenditure in the country.

vi. The country has at times shown inadequate regulatory framework or compliance and enforcement regime, reflected in occurrences such a production of spurious or low quality drugs.

vii. Competency in API/Formulation, intellectual property creation, facility design and maintenance, global regulatory affairs, legal intricacies, and managing international work force is limited to a few players among the big players.

Opportunities:

i. India has significant export opportunities.

ii. Due to the cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage.
iii. Licensing deals with MNCs for NCEs (New Chemical Entities) and NDDS (New Drug Delivery Systems) offer new opportunities for Indian manufacturers.

iv. Marketing alliances for MNC products in domestic and international market is another emerging opportunity.

v. India has a very high potential for developing as a centre for international clinical trials due to its rich diversity.

Threats:

i. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

ii. R&D efforts of Indian pharmaceutical companies are hampered by lack of enabling regulatory requirement.

iii. Drug Price Control Order puts unrealistic ceilings on product prices and profitability.

iv. Export effort is hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad.

v. Mergers and acquisitions by foreign companies particularly multinational corporations of a few Indian generic leaders may completely change the direction of India's pharmaceutical movement neutralizing its thrust on generics and cost competitiveness.
1.8 PHARMACEUTICAL INDUSTRY'S PROBLEMS

i. Weakness in domestic markets

Fierce price competition has become the order of the day for the domestic pharmaceutical industry, and this factor restricts the ability of the domestic pharmaceutical market to grow in value terms. Also, its highly fragmented structure has largely curtailed the pricing power of the players. The Indian markets have traditionally been and continue to remain price sensitive and premium pricing of products is extremely difficult to maintain.

ii. Impact of the patent regime

The Patent Act, 2005, promises a lot for the industry in India; but it might not be good for the smaller players in the industry, as they will not be able to survive in the industry. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

iii. High excise duty

Indian Pharmaceutical industry has to pay 16% excise duties; however, this duty is not there in the tax-free zones. Companies have long been lobbying to lower the excise duty to 8% when it is levied on MRP.

iv. Challenging generics environment

As Indian Companies deployed a low investment in innovative R&D activities, they are facing more problems in the US and European generics market, which has intensified in the past couple of years on the back of increased competition leading to brutal price erosion. While the product flow is set to increase in the coming couple of years, pricing pressure is expected to continue. Generic players also have to contend with a host of other challenges such as increased difficulty in securing Para IV wins,
presence of authorized generics and making the right acquisition to acquire scale, and effectively compete in the market.

v. Lower end of value chain

Indian companies are cost competitive in manufacturing bulk drugs, which has made them an outsourcing destination for the global majors. But this is the lower end of the pharmaceutical industry value chain and is basically a commodity making skill due to low entry barriers. Also, the Indian industry still lacks facilities and resources to develop a molecule, conduct clinical trials and then launch the product. Indian companies will thus have to depend on their international peers to undertake the more expensive clinical trials and product launches.

vi. Multiple indirect taxes

Pharmaceutical industry in India is facing multiple indirect taxes like customs duty on import of goods, excise duty on manufacture of goods, VAT and CST on sale of goods.

vii. High cost of R&D

In order to compete with the global players, Indian pharmaceutical companies need to spend huge amount on R&D. Rising interest rate further makes the borrowings very expensive and hence difficult to compete. Indian companies have to face lot of litigation related to infringement of intellectual property rights.

viii. Rupee Impact

The appreciating rupee against US dollar is badly affecting exports margin of the companies. However, its impact may be off set to some extent for those companies, which are importing their raw material from outside.
ix. **Low turnover ratios**

The raw material turnover ratio, the finished goods turnover ratio, and working capital turnover ratio of the Indian pharmaceutical industry are very low. It means these companies have to maintain high inventory levels. The pharmaceutical companies have to incur more and more amounts on inventories. Raw material cost accounts for 35 percent of total sales value. The length of net working capital cycle is also more in the industry.

It is necessary to manage current assets i.e., raw materials, and finished goods in significant manner to yield more profits. Hence the liquidity decisions, working capital management and credit policy of the pharmaceutical company are crucial for the success and survival of the pharmaceutical companies.

1.9 **GROWTH DRIVERS OF INDIAN PHARMACEUTICAL INDUSTRY**

Indian pharma industry is expected to grow at a CAGR of 14% over 2007-2011. The major growth drivers are:

- Research and Development
- CRAMs
- Government Support
- Changing Demographics & Life style Diseases
- Increasing population and Competitive position

i. **Research and Development**

Indian pharmaceutical companies have realized the importance of drug efficacy, safety, and stability; their focus is therefore more on research and development, which helps the companies to grow at a rapid pace. Indian manufacturers are one of the lowest
cost producers of drugs in the world. Indian pharmaceutical industry possesses excellent chemistry and engineering skills. This adds to the competitive advantage to develop processes that are cost effective. The major R&D expense is incurred mainly on New Chemical Entities (NCEs). The R&D cost on NCEs over the years has increased sharply against NCEs approvals. In 2008, the cost in bringing up an NCE is around US$1,000 million.

ii. CRAMs

Contract Research and Manufacturing Services (CRAMS) has become a promising medium for the Indian pharmaceutical industry, with India increasingly being viewed as the global hub for CRAMS. Over the last five years the CRAMS has been contributing close to 8 percent of the total Indian pharmaceutical operations. Developed countries are expected to further propel the CRAMS industry to grow at a CAGR of nearly 34 per cent from 2006 to 2013 as India offers global pharmaceutical companies both quality and cost advantage. India has the largest number of US Food and Drug Administration (US FDA)-approved plants outside the US, with over 100 facilities. And now, even small and medium scale pharmaceutical companies are setting up new and upgraded high quality manufacturing plants to take part in this growing segment. The Boston Consulting Group estimates that the contract manufacturing market for global companies in India would touch US$900 million\(^{10}\) by 2010.

iii. Government Support

To encourage R&D activities in the Pharmaceutical industry, the government is extending support through tax exemptions on clinical research & trials services, and innovative funding models. One of the positive measures in 2008-09 annual budget is reduction of excise duty from 16 per cent to 8 per cent. The government of India is also focus on strengthening of the National Rural Health Mission as the leading reform to
address the health needs of the poor, including extension to an Urban Rural Health Mission.

iv. Changing Demographics & Life style Diseases

Ageing population in India is on the rise leading to more consumption of Drugs. Moreover, the disease profile is changing from infectious to life style related diseases like heart disease & stroke, diabetes, and obesity. Life style related drugs are higher value drugs that further driving the sales of pharmaceutical companies. Increasing health awareness and rising real income has also led to the growth of Pharmaceutical companies.

v. Increasing population and competitive position

India’s population, which is over one billion, is expected to rise to 1.6 billion by 2050 and 189 million Indians will be in the above 60 years age group. The demand for drugs therefore would increase in future.
REFERENCES

1. www.ibef.org


5. "The Indian Pharmaceutical Industry" ICRA Industry watch series, ICRA Limited, 2002


7. www.cygnusindia.com

8. Article from Pharma Times “National drug policy and quality control of drugs” by Geer M. Ishaq, M. Y. Shah, Department of Pharmaceutical Sciences, University of Kashmir, Srinagar, India

9. New Trends in India's Pharmaceutical Market By Ames Gross Published by Pacific Bridge, Inc