CHAPTER-III

PHARMACEUTICAL INDUSTRY
- AN OVERVIEW
Introduction

One of the most successful industries in recent years has been the pharmaceutical industry. Even though most of the largest pharmaceutical firms are old firms founded in the nineteenth century or at the beginning of the twentieth, the industry is a relatively new field to business history. It is distinct industry as it deals with the lives of people. At present, pharmaceutical drugs are the most preferred therapeutic treatments all over the world. The Global Pharmaceutical Industry Survey report provides an overview of the global pharmaceutical industry in terms of size, segments (geography, therapeutics), trends, growth rate and major therapeutic classes and drug products in the last three years. It gives an insight into the major growth drivers, issues and challenges faced by the industry and its impact on the performance, the major and widely-used technologies in drug discovery, drug delivery, manufacturing and marketing and also some of the promising technologies of the future. Outlining the overview of the major markets including the US, Europe, Japan and other emerging markets, the report also profiles the top 10 pharmaceutical companies.

The global pharmaceutical industry is a multinational industry. It is highly regulated, capital-intensive, and is driven by large research and development expenditures. It is primarily privately owned and is technologically sophisticated. 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, market in particular by a sharp downturn in the world’s largest
economies – the USA and 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 No. 3.1

Global Pharmaceutical Market Size & Growth Rates

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Total Global Pharmaceutical market size (Current US$)</td>
<td>365</td>
<td>392</td>
<td>428</td>
<td>499</td>
<td>560</td>
<td>603</td>
<td>649</td>
<td>712</td>
</tr>
<tr>
<td>Growth over previous year (Constant US$ 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>
</tr>
</tbody>
</table>

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

Figure 3.1

AN OVERVIEW OF GLOBAL PHARMACEUTICAL MARKET SIZE
The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, it is estimated to be worth $4.5 billion, growing at about 8 to 9 per cent annually. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. Playing a key role in promoting and sustaining development in the vital field of medicines. The Indian pharmacy industry boasts of quality producers and many units approved by regulatory authorities in the USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical companies control 70% of the market with the market leader holding nearly 7% of the market share. It 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 injectibles. There are about 250 large units and about 8000 Small-scale units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talent and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market.
Indian Scenario

At the time of independence, the drugs and pharmaceutical industry was in an infant stage with a meagre investment of Rs.10 crores, producing very few bulk drugs valued approximately at Rs.26 crores. Most of the bulk drugs and formulations were imported from the developed countries. In line with the objectives of the successive Five Year Plans of the Government of India, Public Sector undertakings (PSU) like Indian Drugs and Pharmaceuticals Ltd., (IDPL) & Hindustan Antibiotics Ltd., (HAL) were established during the 1960s. The PSUs used to produce synthetic drugs as well as products from fermentation processes like antibiotics.

Initiated and catalyzed by the Public Sector Undertakings, a congenial atmosphere was created to establish more drug industries in the country. The pharmaceutical sector made rapid strides by reengineering the sophisticated process technologies and commenced production of a variety of active pharmaceutical ingredients from the 1970s. Entrepreneurs / Technocrats were encouraged to set up units in the country in view of the availability of:-

- skilled technical personnel,
- strong Research & Development (CSIR) activity
- raw materials
- encouragement and support from banks and financial institutions
- pro-active steps taken by State Governments by providing incentives in taxes/electricity etc.,

After the 80s, the Drugs & Pharmaceutical Industry was identified as a thrust area and several companies were established and started production of sophisticated drugs.

After modification of Patent Law in 1971 and the liberalization of policies and de-licencing of the Pharma Sector by the Government of India in 1991, many entrepreneurs including the NRIs also came forward to establish drug companies in the country. These companies started their own units producing most advanced
drugs and also commenced export them to most advanced countries like the USA, Europe, Canada, Japan. There are more than 700 bulk drug industries spread over the country and there are about 70 units which have got accreditation from the USFDA (United States Federal Drug Authority, the most creditable Regulatory Authority in the world), a number that is largest outside the USA. It is pertinent to mention here that Andhra Pradesh alone has 37 units which got accreditation by USFDA. The industry currently produces more than 450 Active Pharmaceutical Ingredients (APIs), meeting 90% of the domestic requirement.

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

**Bulk Drugs:** Bulk drugs are the APIs with medicinal properties, which are used for manufacturing formulations. Bulk drugs are APIs or compounds that show specific medicinal properties. Bulk drugs and drug intermediaries 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 formulations.

**Formulations:** 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.

Our Drugs & Pharmaceutical sector is internationally known for its skills in chemical synthesis and process reengineering on one hand and its commitment to the invention of new molecules on the other hand - it has grown phenomenally in recent years, due to rising consumption levels in the country and strong demand from export markets. The Indian pharmaceutical industry is estimated to be worth about US$ 10 bn, growing at an annual rate of 9%. In world rankings, it stands fourth in terms of volume and 13th in value terms. The ranking in value terms may also be a reflection of the low prices at which medicines are sold in the country.
The pharma industry has seen tremendous progress in terms of infrastructure development, technology base and the wide-range of products manufactured. Demand from the exports market has been growing rapidly due to the capability of Indian players to produce cost-effective drugs with world class manufacturing facilities. Bulk drugs of all major therapeutic groups, requiring complicated manufacturing processes are now being produced in India. Pharma companies today have developed Good Manufacturing Practices (GMP) compliant facilities for the production of different dosage forms.

History of the Indian pharmaceutical industry

The evolution of the Indian pharmaceutical industry can be explained in terms of five broad phases;

The history of Indian medicine can be traced back to 80 B.C. when Ayurveda, the Hindu system of medicine, was part of the Athrva Veda. The treatises by Charaka and Sushruta (500 to 600 A.D) are primarily based on the contents derived from the Vedic period. The Ayurvedic system deals elaborately with the methods of preparation of drugs. It flourished well till the coming of the Unani system, which the Muslims brought with them. In due course, the Unani system also suffered a setback from the western allopathic system, which came with the British. But the fact that despite the widespread use of allopathy, the traditional medical practice is still in use in India, only confirms its vitality the deep roots it has in the country even today. The early pioneers of the Indian pharmaceutical industry were prof. P.C Ray of Calcutta and Rajmitra B.D. Amin of Baroda. It was Prof. Ray who started the first Indian owned drug firm, the Bengal Chemicals & Pharmaceutical works, in Calcutta in 1901. These pioneers had to contend with heavy odds of public prejudices against allopathic medicines, foreign competition, and lack of governmental patronage. It was in the interest of the British, to ship out from India various raw materials such as quinine bark, nux vomica seeds, poppy pods etc., and sell back the finished products.

An important development of that time was Louis Pasteur’s identification of pathogenic bacteria as the cause of many infectious diseases. The discovery led many British medical scientists to India to study the tropical infectious diseases which were taking a heavy toll of their army men. Thus, early government-
sponsored state enterprises for pharmaceutical research—Haffkine Institute, Bombay (1899), King Institute of Preventive Medicine, Madras (1904), the Central Drug Research Institute, Kasauli (1905) and Pasteur Institute, Connor (1907) – came into being.

The Industry received a filling during World War I when the local demand of allopathic medicines increased sharply and imports got almost completely cut off. A number of foreign firms and national residents who had experience in ayurvedic preparations undertook to manufacture easy tonics as cough syrups and other easily preparable tables and capsules. Production of quinine salts in two government factories that had been established earlier in the Darjeeling District and in the Nilgiris Districts in 1890, increased during the war period. A new compound ureastibamine developed by the local R & D effort was found to be highly effective against kala-azar, a scourge of those days. Production of caffeine from tea waste, and surgical dressings was established during this period, which also witnessed increased manufacture of galenicals and other sample’s drugs.

With the resumption of imports of pharmaceutical products immediately after the war, competition sharpened and the native infant industry received a setback. Despite this adverse situation the industry picked up, although slowly, and by 1930 the manufacture of tetanus antitoxin was also taken up for the first time. But on the whole the industry’s progress was slow till 1939, to say the least, as it was catering to only 13 per cent of the country’s medical requirements.

The outbreak of World War II was a blessing in disguise to the industry, which started undertaking the production of a number of drugs in the category of photochemical based on indigenous raw materials and several synthetic and biological drugs. It was during this period that the manufacture of anti-dysentery drugs, iodochlor/diido-hydroxy quinoline, and chemotherapeutic drugs such as arsenicals, antitheric drugs and colloidal preparations of calcium-silver manganese, iodine etc., were taken up along with the production of glandular products like liver extracts, pituitary extracts and adrenaline solutions. However, most of the manufacturing was done on imported raw materials. And since the demand for drugs did not subside after the war, the industry maintained its developmental tempo. The production of drugs and pharmaceutical reached the level of Rs.10 crores in 1947,
the year India attained her independence. Although the need for medicine was huge, the demand was limited because of the low-income levels and the lack of access to medicines. Consequently, the Government had to take certain initiatives to develop this industry.

The initial stage (1947-1970)

From 1947 to 1970, the Indian pharmaceutical industry was small in terms of the number of firms and production capacities. In the 1950s it was mainly based on imported bulk, which was later processed into formulations in India. The Indian government to free gets the industry from dependence on the import of bulk drugs and encouraged indigenous production of new drugs in order to become self-sufficient. The government invested a lot in the pharmaceutical industry and the public sector was a large part of the industry. India received technical assistance and financial means from international organizations, such as the WHO and UNICEF, to set up plants and strengthen the domestic industry. The public unit Hindustan Antibiotics Ltd. was established in 1954 and was provided with technical support, purchasing of equipment and machinery from the WHO and UNICEF. The Indian Drugs and Pharmaceuticals Ltd. (IDPL), another public sector firm, got free access to import technology from overseas and developed more modern manufacturing facilities. Many leading entrepreneurs got their training in public sector units and institutions. For instance, the founder of Dr. Reddy’s, one of the largest pharmaceutical firms in India today, worked at the IDPL, before he took off to start his own firm.

Multinationals are, in addition to the public sector, a part of India’s pharmaceutical foundation. Foreign companies entered the Indian market merely as trading companies with small investments. The new industrial policies emphasized the importance of foreign capital and industrial know-how. The Indian government introduced liberal FDI policies and incentives to invite foreign firms to start manufacturing pharma products in order to get an inflow of know-how in the sector. Leading pharmaceutical companies from the West came to India and established manufacturing facilities. Subsequently, the multinationals brought in technology and international manufacturing practices. Domestic firms were encouraged to tie up with foreign firms, with participation in capital, and there were collaboration agreements in the private sector.
The import substitution stage (1970-1985)

Until 1970, multinational corporations dominated the Indian pharmaceutical industry. During the 1970s, new drug policies were introduced which created an excellent opportunity for Indian domestic firms to grow. Import substitution and self-reliance were the objective in the pharmaceutical industry in the following years. A number of policies and regulations were implemented to expand the domestic pharmaceutical industry in order to make it self-reliant and to keep prices of pharmaceuticals low. The government made a distinction between domestic and foreign firms, where Indian firms were given production incentives the foreign firms faced tighter control. The 1978 drug policy imposed conditions on foreign controlled firms to make sure that they created linkages within the economy. In the present period, the production of both bulk and formulation increased, and the industry more than doubled. The Indian companies took advantage of the new policies and produced molecules that were still under patent elsewhere. They developed better production and marketing skills and consequently the multinationals’ market share started to decline. Despite the tighter controls for foreign firms, they still had a large share of the production in India during this time.

The liberalization stage (1985-1995)

In the 1980s, Indian policy-makers realized that the competitiveness of the pharmaceutical firms suffered from growing technological obsolescence due to the highly protected market. The government therefore laid stress on the importance of modernization of the industry. Another limiting factor for the domestic industry was that the marketing channels were mainly dominated by the multinational corporations. In the mid-1980s, the Indian government to improve efficiency in the industry, introduced a new drug policy in 1986, which was more favourable to foreign firms. Trade barriers were reduced and so was price control. In 1991 supported by the IMF and the World Bank, India started to liberalize its economy. A series of economical reforms were introduced and implemented. Industrial deregulation one of the steps initiated was intended to reduce the role of the government in directing industrial activity where the private sector could operate. The liberalization of Indian economy affected the pharmaceutical industry in several ways. The public units that had a production monopoly in certain drugs were opened
up for competition and privatized. Also, the requirement of a certain ratio in bulk drug production was removed and equity share and approvals of FDI in the industry were relaxed and the number of drugs under price control was relaxed. In thus, a new direction was going to the Indian pharmaceutical industry. In 1995, India joined the WTO TRIPs agreement with enforcement of Intellectual Property Rights (IPR). India was granted a transition period of ten years to implement the new patent laws. The focus among many Indian companies shifted from business and the trend of focusing on R&D commenced. The new patent regime, it is argued, will have a large impact on the future of the Indian pharmaceutical industry.

Table No. 3.2
Growth in Production in Pharma Industry

<table>
<thead>
<tr>
<th>Year</th>
<th>Bulk Drugs</th>
<th>Growth (%)</th>
<th>Formulations</th>
<th>Growth (%)</th>
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<tbody>
<tr>
<td>1985-86</td>
<td>416</td>
<td>10.3</td>
<td>1945</td>
<td>6.5</td>
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<tr>
<td>1986-87</td>
<td>458</td>
<td>10.2</td>
<td>2140</td>
<td>10</td>
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<tr>
<td>1987-88</td>
<td>480</td>
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<td>1988-89</td>
<td>550</td>
<td>14.6</td>
<td>3150</td>
<td>12.5</td>
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<tr>
<td>1989-90</td>
<td>640</td>
<td>16.4</td>
<td>3420</td>
<td>8.6</td>
</tr>
<tr>
<td>1990-91</td>
<td>730</td>
<td>14.1</td>
<td>3840</td>
<td>12.3</td>
</tr>
<tr>
<td>1991-92</td>
<td>900</td>
<td>23.3</td>
<td>4800</td>
<td>25</td>
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<tr>
<td>1992-93</td>
<td>1150</td>
<td>27.8</td>
<td>6000</td>
<td>25</td>
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<tr>
<td>1993-94</td>
<td>1320</td>
<td>14.8</td>
<td>6900</td>
<td>15</td>
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<tr>
<td>1994-95</td>
<td>1518</td>
<td>15</td>
<td>7935</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: www.bdmai.org/statistics

Time period of 1995-1998

In 1995, the Government reduced the number of drugs under Drugs Price Control Order (DPCO) further from 146 to 74. In the same year, the Government also signed the General Agreement on Tariffs and Trade (GATT). As a signatory to the GATT, India was expected to introduce the patent regime and provide legal protection to Trade Related Intellectual Property Rights (TRIPs). The signing of the GATT induced a series of changes in the business strategy of existing
pharmaceutical companies. Their focus shifted and research emerged as the inevitable driver of growth in the long run. Almost all the companies underwent a restructuring exercise and a lot of mergers and acquisitions were witnessed. The move also augmented the interest of the MNCs in India.

Table No. 3.3
Growth in Production in Pharma Industry

<table>
<thead>
<tr>
<th>Year</th>
<th>Bulk Drugs</th>
<th>Growth (%)</th>
<th>Formulations</th>
<th>Growth (%)</th>
</tr>
</thead>
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<tr>
<td>1995-96</td>
<td>1822</td>
<td>20</td>
<td>9125</td>
<td>15</td>
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<tr>
<td>1996-97</td>
<td>2186</td>
<td>20</td>
<td>10494</td>
<td>15</td>
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<tr>
<td>1997-98</td>
<td>2623</td>
<td>20</td>
<td>12068</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: www.bdmai.org/statistics

After 1998

Indian drugs and pharmaceutical industry has advanced perceptibly and is getting ready to withstand global competition, despite the winds of liberalization and turbulence due to the new patent regime. The industry has been expanding at annual rates ranging between 15% and 20% against the global growth rate of 6%. However, the growth in the pharmaceutical market appears to be slowing down, over the last couple of years. According to a study by M C Kinsey, vision 2010, the domestic pharmaceutical industry could attain a size of $25 bn (Rs.1200 bn) by 2010 by focusing on two areas such as innovation-led research, development and new drug discoveries; and information technology-led remote sales and marketing. The prices of Indian drugs are among the lowest in the world. Lower production cost due to reverse engineering and low R & D outlays have been a major factor in keeping the prices under check.

Economic liberalization being underway, the drugs and pharmaceutical sector witnessed initiatives at fresh investment in the sector. Nearly, 1700 investment proposals of the order of as out Rs.150 bn were initiated. As at foreign collaborations proposals were approved with a foreign direct investment (FDI) component of Rs.25 bn. The fund is used for the development and
commercialization of the products and applications, significant improvement in the existing design of products, setting up and expansion of pilot plants, research studies for obtaining regulatory approvals, cost of filing and managing international patent and R & D Centres.

In India, only a few companies had gone into any serious R & D activity. Much of the effort was directed to affordable analogue research. The R & D level in the country was low with even well-placed pharma companies spending less than 2% of the turnover on R & D. The MNCs are known to contribute as much as 10% or more of the turnover to R & D. India would take some more time to develop research and skill for innovation, as infrastructure and mechanisms for technology tie-ups have to be put in place. Overall, the industry is becoming more innovative, more enterprising. It has now a large number of product introductions.

Table No. 3.4

Growth in Production in Pharma Industry

(Rs. In crores)

<table>
<thead>
<tr>
<th>Year</th>
<th>Bulk Drugs</th>
<th>Growth (%)</th>
<th>Formulations</th>
<th>Growth (%)</th>
</tr>
</thead>
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<tr>
<td>1998-99</td>
<td>3148</td>
<td>20</td>
<td>13878</td>
<td>15</td>
</tr>
<tr>
<td>1999-00</td>
<td>3777</td>
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<td>15960</td>
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<td>2000-01</td>
<td>4533</td>
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<td>2002-03</td>
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<td>20</td>
<td>24185</td>
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<td>2003-04</td>
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<td>27692</td>
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<td>2004-05</td>
<td>9034</td>
<td>20</td>
<td>31946</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: www.bdmai.org/statistics

*These figures do not include production from unorganized sector, which is estimated at an additional 35% of the production.
Drug Policy of 1986

1. The Drug Policy of 1986, which was titled "Measures for Rationalization, Quality Control and Growth of Drugs Pharmaceuticals Industry in India" was evolved under the leadership of the late their Prime Minister Rajiv Gandhi. This was done after a detailed examination of the various issues. The main objectives of the Drug Policy, 1986 were:

- ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality.
• strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

• creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs; and,

• Strengthening the indigenous capability for production of drugs.

To meet the requirements of medicines for health needs at reasonable prices and strengthen the indigenous base for the Drugs and pharmaceutical industry the Government has, over the years been guided by the above Policy. Implementation of the main policy provisions has been through the (D&R) Act on Industrial Licensing aspects and through Drugs (Prices Control) Orders under the Essential Commodities Act in regard to the pricing mechanism. The Drug Policy has also given the policy framework in regard to Quality Control and Rational Use of Drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs & Cosmetics Act, which is administered by the Ministry of Health and Family Welfare.

PHARMACEUTICAL POLICY-2002

The basic objectives of the Drug Policy of 1986 still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of the liberalization of Indian economy, globalization of the world economy and new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister’s Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industries, of where the pharmaceutical industry has been identified as one of the most important, which has a comparative advantage.
OBJECTIVES

The main objectives of this policy are:-

a. Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.

b. Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.

c. Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.

d. Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment in R&D in pharmaceuticals in India.

e. Creating an incentive framework for the pharmaceutical industry which promotes new investment in pharmaceutical industry and encourages the introduction of new technologies and new drugs.

NATIONAL PHARMACEUTICALS POLICY 2006

Driven by the knowledge skills, growing enterprise, low costs, improved quality and demand (domestic and international) the pharmaceuticals sector has witnessed a tremendous growth over the past few years - from a turnover of Rs. 5000 crores in 1990 to over Rs. 50,000 crores during 2004-2005. Exports have also grown very significantly to over Rs. 16700 crores during this period. India is today recognized as one of the leading global players in the manufacture of pharmaceuticals - it holds the 4th position in terms of volume and the 13th in terms of value of production. It is also recognized that the cost of drugs produced in India is amongst the lowest in the world. It is estimated that by the year 2010 industry would have the potential to achieve Rs. 1,00,000 crores in formulations with bulk drug production going up from Rs. 8000 crores to Rs. 25,000 crores. India's rich human capital is believed to be the strongest asset for this knowledge-led industry.

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However despite the impressive growth of the sector and low costs there are several concerns which need to be addressed. Some to these concerns are making medicines accessible an affordable to the common man particularly the vast segment of the poor, instituting standards of quality, particularly for units not conforming to the standards of regulated markets, strengthening the fragmented regulatory system, sustaining the growth of generics – the main forte of Indian Industry, meeting the challenge of product patent regime and so on. In order to find the right solutions and the right balance between various viewpoints almost a continuous debate has been going on regarding some of these issues both within and outside Government. As the Drug policy formulated in 2002 could not be implemented due to legal complications involved the policy of 1994 still continued to be in force. Thereafter the present National Pharmaceuticals Policy, 2005 was necessitated due to several developments that had taken place during the last few years as well as to address some of the major concerns highlighted above. Price regulation of the essential medicines is an important component of this policy. However several other matters having a close bearing on the pharmaceuticals sector have also been included in the policy.

Objectives of the policy:

Following are the key objectives of the policy –

(a) To ensure availability at reasonable prices of good quality medicines within the country,

(b) To improve accessibility of essential medicines the common man particularly the poorer sections of the population,

(c) To facilitate higher investment for increased production of good quality medicines,

(d) To promote greater research and development in the pharmaceuticals sector by providing suitable incentives in this regard,

(e) To enable domestic pharma companies to become internationally competitive by implementing GMP, GLP GCP and other established international guidelines, and
To facilitate higher growth in exports of the APIs and formulations by reducing the barriers to internationally trade in the pharmaceuticals sector, to develop India as the preferred global destination for pharma R&D and manufacturing, to facilitate implementation of the Health Policy of the country.

Key issues facing the Pharmaceutical Industry

Some of the issues the domestic industry is facing are as under:

i) Increasing span of price control

The price control as proposed in the Policy is likely to cover at least 50-60% of the domestic market under it. The proposed control on prices is set to impact the industry margin significantly, especially those players having only local operations. However, to secure profitability, firms will have to increase their scale of production.

The number of drugs under price control had come down drastically from nearly 400 in the 1970s to 72 in 1995 and further to 29 in 2002. This decision was however stalled by the Supreme Court, asking the Department of Fertilisers and Chemicals of Government of India to identify the essential and life saving drugs that should continue remaining under price control. The Department listed 354 items that it purchased for its hospitals, called the National List of Essential Medicines (NLEM).

ii) Price erosion in generics

Indian generics market is witnessing a margin pressure in most of the product categories due to two main reasons: the price control likely to be imposed by the Government and the stiff competition among domestic players. In fact, in India the number of players has fast increased over a period of time. Moreover, the expansion of capacities by some leading players has also fuelled competition in certain product categories, which restricts the margins of the smaller players.
The fall in prices of generic drugs is not limited to India only. The US, which is the world’s largest pharmaceutical market, is also experiencing a sharp reduction in prices of generic drugs due to stiff competition. Some other developed countries like the UK and Germany have also have had similar experience. The reduction of in some cases extent of 90%. Indian players, who have been operating in these markets, have also experienced erosion in margins in certain therapeutic segments.

iii) Low R&D productivity

Despite the increasing expenditure on R&D, the introduction of new molecules by the Indian players has been limited. It is, in fact, a hit-and-miss situation in the field of discovery and development of new chemical entities (NCEs), where misses are more than hits. Very few discoveries reach the final stages of approval, and in most of the cases, the claim for patent gets stuck in legal battles. In spite of the rising expenditure on R&D, the level of investment in R&D is still low, on average 4% as compared to the global practice of spending 12-16% of sales on R&D.

The changing global pharmaceutical industry has transformed the prospects of Indian pharmaceutical companies. The leading pharma companies in India have been actively extending the frontiers of scientific knowledge and going global through mergers and acquisitions. In 2005, acquisitions by the Indian pharmaceutical companies were the highest, with 20 buyouts abroad. A similar trend was observed during 2006, which include Dr Reddy’s buyout of Germany’s Betapharm and Ranbaxy’s purchase of Romania’s Terapia. The European generics market has emerged as of a major attraction for acquisitions by Indian companies. According to reports, margin erosion in Europe is much less compared to the US when a drug or formulation becomes generic.

Consolidation is inevitable and is expected to bring in economies of scale and provide access to newer geographies to regional players. The Government has estimated that by year 2010, the industry would have the potential to achieve a size of US$ 28 bn.
STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS OF THE INDIAN PHARMACEUTICAL INDUSTRY

SWOT Analysis

Strengths

- Cost Competitiveness
- Well Developed Industry with Strong Manufacturing Base
- Access to the pool of highly trained scientists, both in India and abroad.
- Strong marketing and distribution network
- Rich Biodiversity
- Competencies in Chemistry and process development.

Weaknesses

- Low investments in innovative R&D and lack of resources to compete with the MNCs for New Drug Discovery Research and to commercialize molecules on a worldwide basis.
- Lack of strong linkages between industry and academia.
- Low medical expenditure on healthcare spent in the country
- The image of the industry at home and abroad tarnished because of production of spur on and low healthy drugs.
- Shortage of medicines containing psychotropic substances. There are 4000 such brands of medicines that fall under the Narcotics Drugs and Psychotropic Substances (NDPS) Act, 1985. Under a clause of this Act, the retailer has to sign the consignment note provided by the stockist. The police check this note regularly so as to prevent these medicines getting diverted to the drug mafia and to arrest the retailer if the signatures are suspect. To protest against this clause, the retailers have stopped stocking these medicines, some of which are life-saving.
Opportunities

- Significant export potential.
- Licensing deals with the MNCs for the NCEs and NDDS,
- Marketing alliances to sell the MNC products in domestic market,
- Contracting manufacturing arrangements with the MNC,
- Potential for developing India as a centre for international clinical trials,
- Niche player in global pharmaceutical R&D,
- Supply of generic drugs to developed markets,

Threats

- Product patent regime poses serious challenge to the domestic industry unless it invests in research and development
- R&D efforts of Indian pharmaceutical companies hampered by a lack of enabling regulatory requirement,
- Drug Price Control Order puts unrealistic ceilings on product prices and profitability and prevents pharmaceutical companies from generating investible surplus.
- Lowering of tariff protection
- The new MRP based excise duty regime threatens the existence of many small-scale pharma units, especially in the states of Andhra Pradesh and Maharashtra, that are involved in contract manufacturing for the larger, established players.

These companies are now shifting their manufacturing from these states to states like J&K where they can enjoy tax holidays.

SME's in the Pharmaceutical Industry

With a large number of medicines expected to go off patent during the next few years and with increasing emphasis on the use of generic medicines in the
The Indian government has been making every attempt to support the SMEs through several incentives. The development of pharmaceutical SEZs can support the growth of SMEs. Around 18 pharmaceutical SEZs have already been identified so far that will focus on the pharmaceutical industry. The advantage of locating them in these zones includes the availability of developed infrastructure, market access, exports, and excise relief.

**Mergers & Acquisitions**

The health-care costs are rising world-wide. Leading companies across the world are merging. Strategic alliances and collaborations are taking place in order to meet the increasing R&D budgetary requirement that exceed billion dollars each for many leading global pharmaceutical players.

The European generics market has emerged as a major attraction for acquisitions by Indian companies. According to reports, margin erosion in Europe is much less compared to the US when a drug or formulation becomes generic.

Indian Drug manufacturers are pursuing foreign acquisitions due to their need to:

- Improve global competitiveness
- Move up the value chain
- Create and enter new markets
- Increase their product offering
- Acquire assets (including research and contract manufacturing firms, in order to further boost their outsourcing capabilities) and new products
- Consolidate their market shares
- Compensate for continued sluggishness in their home market.

Indian firms such as Glenmark, Jubilant Organosys, Nicholas Piramal, Ranbaxy Matrix Labs Aurobindo, Cadila, DRL, Sunpharma, NATCO and a few others have made international acquisitions in areas of generics, marketing, custom synthesis, contract research, pharmacies, manufacturing assets.
Often there is a significant overlap of expenditure in creating manufacturing assets or investing in R&D either in generics or in basic research resulting in wastages at the national level. Consequently corporate have indulged either in acquisitions or mergers to avoid duplication of investments and capture larger market share at global place.

Table No. 3.5

Number of Overseas Acquisitions by Indian Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Acquisitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>1</td>
</tr>
<tr>
<td>1996</td>
<td>-</td>
</tr>
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<td>2003</td>
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<td>2004</td>
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<td>2005</td>
<td>20</td>
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<tr>
<td>2006</td>
<td>14</td>
</tr>
<tr>
<td>2007</td>
<td>14</td>
</tr>
</tbody>
</table>

Source: Exim Bank

R&D Efforts in India

In the medium term the Indian pharmaceutical industry cannot generate adequate revenues to do significant basic R&D. Research in known leads or analogues has produced some success and the country is at a very nascent stage in drug discovery. In the coming years, India needs own products. It has to synergise with government institutions, Universities & industry to develop its own drugs. Such effort needs large balance sheets for companies. Progress in exports, public private initiatives is therefore mandatory. Governments across the world take very serious and at times ruthless initiatives in pharmaceutical matters by forging linkages of
industry, academia and scientific & financial institutions either to guard their current eminence or to protect the health needs of their citizens. There is a need for regulatory reform in India to encourage the leading global players to continue and accelerate the outsourcing of their R&D activities—beginning with discovery research—to the subcontinent. This is particularly urgent in the face of the strong competition from China, where the government has been particularly proactive in encouraging foreign investments in pharmaceuticals and biotechnology. An OECD report on the nature of research funding in India has shown that there are a number of organisations which are engaged in research on biotechnology in India, including, the Department of Scientific and Industrial Research (DSIR), the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Indian Council of Agricultural Research (ICAR) and the Indian Council of Medical Research (ICMR) that have programmes supporting biotechnology and each of them has growing allocations for biotechnology. However apart from the DBT none of these have specific allocations earmarked for areas of research such as biotechnology, etc. This means that in the realm of pharmaceutical research generally and more particularly in the realm of biotechnology based research, there is a great likelihood that research funding is being duplicated i.e. not used to optimal effect. Venture capital has emerged as a major source for funding, but this needs to be encouraged more.

Pharmaceutical Export Promotion Cell

An Export Promotion Cell in the Pharmaceutical Division has been functioning with the objective of boosting pharmaceutical exports and to act as a nodal centre for all queries/issues regarding pharmaceutical exports. The Cell collects statistical data on export and import of pharmaceuticals in the country and provides commercially useful information for developing and increasing drugs and pharmaceutical exports. The Cell also undertakes promotional activities for the acceleration of pharmaceutical exports and considers suggestions for modifications in the EXIM POLICY from the industry. The Cell has also been entrusted with the organization of seminars and workshops on standards, quality control requirements of important countries so as to prepare the domestic companies for exporting their products. Database on the status of pharmaceutical industry in many countries is available in the cell for the benefit of Indian exporters.
Pharma exports touched a level of over Rs. 24942 crores during 2006-07. Exports constitute a substantial part of the total production of Pharmaceuticals in India. Another noteworthy feature of export is more of dosage form export to advanced markets like Europe, the US and Africa etc. The trend of exports is as follows:

Table No. 3.6

Trend of Pharmaceutical Exports

<table>
<thead>
<tr>
<th>YEAR</th>
<th>EXPORTS (Rs. in Crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998-1999</td>
<td>6256.06</td>
</tr>
<tr>
<td>1999-2000</td>
<td>7230.16</td>
</tr>
<tr>
<td>2000-2001</td>
<td>8757.47</td>
</tr>
<tr>
<td>2001-2002</td>
<td>9751.2</td>
</tr>
<tr>
<td>2002-2003</td>
<td>12826.1</td>
</tr>
<tr>
<td>2003-2004</td>
<td>15213.24</td>
</tr>
<tr>
<td>2004-2005</td>
<td>17857.8</td>
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<tr>
<td>2005-2006</td>
<td>22115.72</td>
</tr>
<tr>
<td>2006-2007</td>
<td>26895.18</td>
</tr>
<tr>
<td>2007-2008</td>
<td>30,760.57</td>
</tr>
<tr>
<td>2008-2009</td>
<td>38,433</td>
</tr>
</tbody>
</table>

Source: Directorate General of Commercial Intelligence and Statistics - DGCIS, Kolkata
Growing exports

Exports have been the major growth enabler of the Indian pharmaceutical industry in recent years. India exports pharmaceutical products, APIs and intermediates to more than 200 countries across the world. Traditionally, Russia, Germany, Nigeria and India's neighbouring countries like Sri Lanka, Nepal, and the Middle East were the major markets for Indian pharmaceutical exports. Most of these markets are not highly regulated and are considered to be low-value markets.

Remarkably, the proportion of exports in domestic turnover has been increasing over the years, despite the growing domestic demand. Currently, exports constitute Rs.38433 crores in 2008-09 (53 per cent) of turnover of the industry as compared to 1999-2000 as Rs.7230.16 crores.

Competition

Foreign firms have been a part of the Indian pharmaceutical industry since its initial stage. When the first MNCs entered the Indian market, they had a monopoly in the industry, and thus there were no spillover effects in terms of increased competition. Today, the domestic industry is well-developed, which means that the MNCs and the local firms compete at the same level. In 1992, thirteen companies of the top twenty had foreign origins, but today the number of MNCs at the top has
decreased because of lower profit margins and increased competition from domestic firms. The presence of MNCs in India has a large impact on the competitive environment in the Indian pharmaceutical industry and stimulates the domestic firms to upgrade their technology and investments in marketing. The business environment in the Indian pharmaceutical market is today highly competitive with a large number of players. Features such as costs, research orientation, product portfolio, production capability and marketing and distribution network are important factors for a firm to succeed and be able to compete effectively in the pharmaceutical industry. The MNCs in India are characterized by advantage in many of these factors, while their domestic competitors have an advantage in production capacities and costs. Since the foreign firms do not have cost advantage in production, they invest large sums in marketing and fieldwork to promote drugs. Today the domestic companies seem to have adopted the MNCs’ marketing expertise and strategies to be able to compete. The domestic firms are more or less forced to try to keep up with the MNCs’ marketing abilities and the local firm’s increased market share indicates they have been doing well.

Today, basically all Indian companies are generic firms. Many of the larger domestic firms possess advanced technology and it can be argued that the spillovers from imitation are not as strong as in the past. However, there is still scope for spillover effects through imitation if the MNCs introduce new technology in the Indian industry. With a strong patent regime for protection of intellectual property rights, spillover effects through imitation are less likely to be generated in the future. Adoption of the new patent regime is likely to limit the imitative R&D in India, which might affect the development in the industry in the short run. In the long run however, it is argued, an effective protection of IPR is necessary for the industry to grow further. India has innovative capabilities and increasing numbers of domestic firms are investing in R&D for developing new molecules. Spillover effects through imitation are probably going to decrease but with the establishment of more foreign firms, new technology is entering the country and, through collaboration, demonstration effects can still occur. Furthermore, spillovers from imitation and demonstration effects can also be found in marketing and management practices.
Current Status of Indian pharmaceutical industry

The pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in the early 1990s to Rs.29,139.57 crores by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India were growing at a compounded annual growth rate (CAGR) of 17.8% during the five year period 2003-04 to 2007-08. The total size of the industry is estimated at US$18bn at the end of the year 2007. The Indian domestic pharmaceutical market size is estimated at US$10.76bn in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

Currently, the Indian pharmaceutical industry is one of the world’s largest and most developed, ranking 4th in volume terms and 13th in value terms. The country accounted for 8 per cent of the global production and 2 per cent of the world markets in pharmaceuticals. Most of the domestic pharmaceutical drug requirements are met by the domestic industry. In the segment of Active Pharmaceutical Ingredients (APIs) India ranks third in the world producing about 500 different APIs.

Current Place in the World

India is currently recognised as a high-quality, low-cost skilled producer of pharmaceuticals. It is seen not only as a manufacturing base for the APIs and formulations, but also as an emerging hub for biotechnology, bioinformatics, contract research, clinical data management and clinical trials. The country’s pharmaceutical industry, as evidenced in the paragraphs which follow, has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. India exports full basket of pharmaceutical products comprising intermediates, APIs, Finished Dosage Combinations (FDCs), biopharmaceuticals, vaccines, clinical services, etc., to various parts of the world. The country has achieved the distinction of providing healthcare at very low cost while maintaining profitability.

At present, India is among the top 20 pharmaceutical exporters world-wide and with the largest number of US FDA inspected plants (119 plants), outside the USA. Various other agencies like the MHRA UK, MCA South Africa, the TGA Australia, the HPB Canada have approved scores of plants in India.
India’s Pharmaceutical Export Profile

The Pharmaceutical industry in India has shown commendable export performance, the trade balance being positive through out the years. Over the period 2003-04 to 2008-09 the compounded annual growth rate (CAGR) of exports has been 17.8 per cent.

Table No.3.7

India’s Trade in Pharmaceutical Products (2003-04 to 2007-08)
(figs in Rs. Crores & %)

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports of Drugs, pharmaceuticals &amp; fine chemicals</th>
<th>Imports of Medicinal &amp; pharmaceutical products</th>
<th>Exports Growth Rate</th>
<th>Imports Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-04</td>
<td>15,213.24</td>
<td>2,958.04</td>
<td>18.61</td>
<td>3.24</td>
</tr>
<tr>
<td>2004-05</td>
<td>17,857.80</td>
<td>3,169.35</td>
<td>17.38</td>
<td>7.14</td>
</tr>
<tr>
<td>2005-06</td>
<td>22,115.72</td>
<td>4,551.87</td>
<td>23.84</td>
<td>33.59</td>
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<tr>
<td>2006-07</td>
<td>26,895.18</td>
<td>5,851.64</td>
<td>21.51</td>
<td>28.58</td>
</tr>
<tr>
<td>2007-08</td>
<td>29,139.57</td>
<td>6,679.87</td>
<td>8.34</td>
<td>14.15</td>
</tr>
<tr>
<td>CAGR (2003-04 to 2007-08)</td>
<td>17.8</td>
<td>18.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Directorate General of Commercial Intelligence and Statistics (GCI&S), Kolkata.

Figure 3.4

INDIA’S TRADE IN PHARMACEUTICAL PRODUCTS
Pharmaceutical Industry in Andhra Pradesh

Hyderabad, Andhra Pradesh's capital city, at the centre of the pharmaceutical and bulk drugs industry in the state. It has achieved excellence in the fields of pharmaceuticals, healthcare, biotechnology and IT. Andhra Pradesh's pharmaceuticals sector is internationally known for its skills in chemical synthesis and process engineering on the one hand, and its commitment to the invention of new molecules on the other. The states proximity to ports gives it an advantage for its exports. It has made major improvement in its infrastructure and development in the past four years and is considered as one of the best states in India for investments.

Andhra Pradesh has pioneers in the field of medical/human and animal healthcare. Most of the pharmaceutical companies have set up their R&D facilities in the state, thus, making it the pharmaceutical capital of the country. The major credit for the progress Andhra Pradesh is making in the pharmaceuticals business front goes to the state government, which has given all help to set up the pharma city and other facilities and parks in the state to grow its pharma industry. The pharma players in the state are of the opinion that the pharma city and biotech parks have played a dominant role in changing the pharma landscape in the state. In fact, the biotech park and pharma city have placed the state in a firm position to deliver environment friendly pharma manufacturing with world class standards. Though the pharmaceutical industry in Andhra Pradesh has been slowly but steadily gaining the acceptance of global pharma with its new business strategies, it is nowhere near the expectations placed on it in the early 2000s. It was predicted that Andhra pharma would emerge as the next global hub of pharmaceuticals with a market share of around $8 to $10 billion by 2010. However, with about $2 billion in size, the pharma industry in Andhra Pradesh has a long way to go to live up to the expectations built on it, and also emerge as the next global hub of pharmaceuticals. Regulatory issues related to pollution, which has culminated in the ban on setting up active pharmaceutical ingredients (APIs) infrastructures in five districts of Andhra Pradesh (in and around Hyderabad) and failure to raise enough capital resources have all worked to impede the strides Andhra pharma was making in the early 2000s. Andhra pharma plays a significant role in the country's overall economic development. It performed well during October 2007 - March 2008 with production and sales growing by about 20 per cent over the comparative period in the last fiscal
and exports rising by 10-15 per cent. One finds a bit of slowing down in 2008-09, due to the overall economic situation. However, initiatives such as Jawaharlal Nehru Pharma City would spur the growth of Andhra pharma in days to come as it offers common effluent plants which would fuel the production of bulk drugs. Also, drug makers no more need to waste time on environmental clearance. The state needs several more such initiatives. When Indian pharma industry reaches a size of around $50 to $60 billion, one can expect Andhra Pradesh to hold a market share of $10 billion.

The Pharma industry in the state contributes more than one-third to the country's total production. During 2000-01, the state produced bulk drugs and formulations worth US$ 462 million and US$ 1,150 million against the total production of US$ 1.66 billion and US$ 3.9 billion respectively. The exports from the state stood at US$ 500 million in 2002-03 registering an annual growth rate of more than 20 per cent. The sector accounts for about 18 per cent of the total exports from the state.

The production of bulk drugs in Andhra Pradesh vis-à-vis all India production for the year 2006-07 and projection up to 2010 are given under:

Table No.3.8
Production and Exports from Andhra Pradesh and India
(Rs. in Crores)

<table>
<thead>
<tr>
<th>Year</th>
<th>Andhra Pradesh</th>
<th>India</th>
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<tbody>
<tr>
<td></td>
<td>Production</td>
<td>Exports</td>
</tr>
<tr>
<td>2006-07</td>
<td>11380</td>
<td>6259</td>
</tr>
<tr>
<td>2007-08</td>
<td>13656</td>
<td>7510</td>
</tr>
<tr>
<td>2008-09</td>
<td>16387</td>
<td>9013</td>
</tr>
<tr>
<td>2009-10</td>
<td>19664</td>
<td>10815</td>
</tr>
</tbody>
</table>

Source: Annual Reports, Bulk Drugs Manufacturing Association (BDMA)
Exports : 60% of turnover Annual Growth : 20% – 21%
45% of turnover
Employment : Direct – 3,00,000 Indirect - 6,00,000

101
Figure 3.5
PRODUCTION AND EXPORTS FROM ANDHRA PRADESH

Figure 3.6
PRODUCTION AND EXPORTS FROM INDIA
Problems in Pharmaceutical Industry

The following are the problems facing the pharmaceutical industry:

1) Weakness in domestic markets

Fierce price competition has become the order 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.

2) 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. The product patent regime poses serious challenges to the domestic industry unless it invests in research and development.

3) 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 the MRP.

4) Challenging generics environment

As Indian pharmaceutical companies deploy a low investment in innovative R&D activities, they have been facing many 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, the presence of authorized generics and making the right acquisition to acquire scale, and effectively compete in the market.
5) Lower end of value chain

Indian companies are cost competitive in manufacturing bulk drugs, which has made them an outsourcing destination for global majors. But this is the lower end of 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.

6) Multiple indirect taxes

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

7) 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 competition difficult. Indian companies have to face lot of litigation related to infringement of intellectual property rights.

8) Rupee Impact

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

9) 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 that these companies have to maintain high inventory levels. The pharmaceutical companies have to incur more and more amounts on inventories. The raw material cost accounts for 35 per cent of the total sales value. The length of networking capital cycle is also more in the industry.
It is necessary to manage current assets i.e., raw materials, and finished goods in a significant manner to yield more profits. Hence the liquidity decisions, working capital management and credit policy of the pharmaceutical company are crucial for their success and survival alike.

**Growth drivers of Indian Pharmaceutical Industry**

Indian pharma industry is expected to grow at a CAGR of 14% over 2007-11. The major growth drivers are:

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

**Research and Development**

Indian pharmaceutical companies have realized the importance of drug efficacy, safety, and stability. Their attention is therefore more on research and development, which helps them 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 greater part of R&D expense is incurred mainly on New Chemical Entities (NCEs). The R&D cost on the NCEs over the years has increased sharply against the NCEs approvals. In 2008, the cost in bringing up an NCE was about US$1,000 millions.

**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 the CRAMS. Over the last five years the CRAMS has been contributing close to 8 per cent 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 estimated that the contract manufacturing market for global companies in India would touch US$900 million by 2010.

Government Support

To encourage R&D activities in the Pharmaceutical industry, the government of India is extending support through tax exemptions on clinical research and trails services, and innovative funding models. One of the positive measures in 2008-09 annual budgets was reduction of excise duty from 16 per cent to 8 per cent. The government of India is also keen on strengthening 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.

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 drive the sales of pharmaceutical companies. Increasing health awareness and rising real income have also led to the growth of pharmaceutical companies.

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 60 years and above age group. The demand for drugs by the aged and aging therefore would increase in future and Indian pharmaceutical companies have to equip themselves to meet this prosper effectively.
The majority of pharmaceutical industries in Andhra Pradesh are established in and around Hyderabad, the capital city of Andhra Pradesh and the hub of pharmaceuticals and bulk drugs industry. As all the pharma units among the SMEs cannot be studied, their profiles sample of ten among them are selected to serve as representative samples are present a set of in the following pages. Such a description will serve as a backdrop for the study presented in the ensuing chapters. The following table gives the names of the sample units, which are described thereafter one after another.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Company Name</th>
<th>Industry Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Krebs Bio Chemicals &amp; Industries Ltd</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>2</td>
<td>SMS Pharmaceuticals Ltd</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>3</td>
<td>Avon Organics</td>
<td>Commodity Chemicals</td>
</tr>
<tr>
<td>4</td>
<td>Suven Life Sciences Ltd</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>5</td>
<td>Venkat Pharma</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>6</td>
<td>Vivimed Labs</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>7</td>
<td>Pharmasia</td>
<td>Pharmaceuticals</td>
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<tr>
<td>8</td>
<td>Hindustan Bio Sciences</td>
<td>Biotechnology</td>
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1. KREBS BIO CHEMICALS LTD

Krebs Biochemicals & Industries Limited (KBIL) was established in the year 1991 and is based in Hyderabad, India. It is a Public Limited Company with the main objective of establishing commercially viable biotech processes with applications in Medicine, and Agriculture Industry. The company has pioneered in the fermentation technology over the last decade. The KBIL went into public in March 1994 to part finance its fermentation technology project. It has a strong shareholding community of over 10000 spread over all parts of the country. Its turnover is above hundred crores.
As a biochemical company the KBIL is engaged in manufacture of active pharmaceutical ingredients. The Company's product portfolio comprises Statins (lifestyle drugs), Neutraceuticals and anti-asthmatic groups. The Company has manufacturing units at Ragadichelika, Nellore (Unit I) and Kothapalli Village, Kasimkota Mandal, Visakhapatnam District (Unit II). It produces pseudoephedrine, ephedrine and other salts used in making formulations for respiratory ailments, such as cough and cold.

Krebs Biochemicals & Industries Limited is engaged in the manufacture and sale of active pharmaceutical ingredients and intermediates in India. Its bulk actives include synthetic products comprising lovastatin, simvastatin, L-ephedrochloride, L-ephedrine sulphate, L-ephedrine base (liquid), D-pseudoephedrine hydrochloride, D-pseudoephedrine sulphate, D-pseudoephedrine base, Dl-ephedrine base, n-methyl ephedrine, D-ephedrine bitartarate, vitamin C, and vitamin C (coated); and herbal products that consist of calcium sennosides, garcina combogia powdered extract, and capsacin. The company also offers various intermediates, including crude lovastatin and simvastatin ammonium salt. In addition, its pipeline product includes pravastatin sodium. Further, the company is also involved in the manufacture and sale of potato crisps and sugar.

2. SMS PHARMACEUTICALS LTD

The company was incorporated as S.M.S. Pharmaceuticals Pvt. Ltd. on December 14, 1987 for the manufacture of Bulk Drugs. K G Suggula was the original promoter of the company. It sustained losses till 1990, when the current promoter's viz. Mr. Ramesh Babu Potluri and Mr. T V V S N Murthy acquired it. The reason behind acquiring a loss making company was to avoid all the regulatory formalities to be fulfilled in case of starting up a new unit.

On November 2, 1994 the company was converted into Public Limited Company from a private limited company and its name was changed to S.M.S. Pharmaceuticals Limited. Subsequently on April 12, 2004 for operational convenience the name was changed to SMS Pharmaceuticals Limited from S.M.S. Pharmaceuticals Limited. When the company was in 1990, it had only 20 employees as a single unit and it has only single product Company. It has now grown into a multi-location, multi-product Company with 4 units and 310 employees on its rolls and four Units.
In the year 1991 the company started the manufacturing bulk drugs and the product was called Ranitidine HCL at Unit I situated at IDA Khazipally, Jinnaram Mandal, Medak District, and Andhra Pradesh with a production capacity of 3 metric tonnes per annum and the process consisted of 7 major stages. As of today the installed manufacturing capacity has expanded to 1,440 metric tonnes per annum and the technology has also been upgraded to a 4-stage process, which has enabled the companies to become a competitive seller in the market.

The company acquired a second Unit at Bachipally, Miyapur, Rangareddy District, Andhra Pradesh in 2000 as part of the expansion programme, and started producing Sumatriptan Succinate for which a non-infringing root of synthesis was developed through in-house R&D. Currently Unit II is used to manufacture high value & low volume APIs like Sumatriptan Succinate, Ramipril and Quinapril.

The company in 2003 a Nutraceuticals and health care division (Unit III) as a part of diversification, by launching an OTC product called Fenudiet and Hearty Salt in the consumer market. 'Fenudiet' is a product for diabetics and the company has applied to the Trade Mark Authority to get the brand "Fenudiet" registered. Subsequently the company started manufacturing other products like Alvit, Set Free, De- Mass, and others. However, apart from Fenudiet & Hearty Salt, manufacturing Alvit, Set Free, De- Mass, and others has been discontinued because of high overheads cost on distribution and low margins.

The company also started in 2004 UNIT IV at Gagillapur (Village) Quthbullapur (Mandal Ranga Reddy (Dist) for scaling up the APIs. This unit is to be used as a pilot plant. It has also expanded its R&D activities to have 4 PhD's supported by more than 30 senior chemists. In the year 2004 it started an exclusive basic research facility at Sanath Nagar, Hyderabad. The R&D centre mainly focuses on anti-cancer molecules, anti-migraine molecules, anti-bacterial, anti-ulcer, important intermediates and natural plant extracts. It also has 2 more PhD's who are looking after its production facilities at Unit I and & Unit II.

The company has filed 6 non-infringing process patents and 1 product patent under the PCT and 10 process patent under Indian Patent Laws as detailed under the head 'Intellectual Property' in this Red Herring Prospectus. It has also filed DMFs/CoSs in US, Europe and Canada for 4 products as listed under the head 'Intellectual Property' mentioned in this Red Herring Prospectus. It has also started producing ACE inhibitors Ramipril, Quinapril and anti-cancer drug Gemcitabine.
The company had received in principle approvals from the BSE (vide letter dated December 21, 2004) and (the NSE vide letters dated January 11, 2005, May 31, 2005) and July 12, 2005 and had also received the observation letter from the SEBI dated May 11, 2005 to launch an IPO for financing the same project envisaged in this RHP. However the company did not proceed with the IPO. By the time the observation letter from the SEBI was received its plans had undergone some changes since it perceived a better opportunity in implementing a bigger project with larger capacities, and for the manufacture of a few more products. Hence it was decided not to go ahead with the IPO.

3. AVON ORGANICS

The Company was incorporated on August 03, 1993 as Avon Organics Limited. The Hyderabad based company obtained certificate of commencement of business on July 5, 1994, promoted by Mr. P.R. Agarwal, Mr. Rajesh Agarwal and Dr. G.S. Sidhu. The company manufactures Diketene and derivatives - Mono Methyl Acetoacetamide (MMA) and Methyl Aceto Acetate (MAA). Diketene is the mother chemical and therefore is not sold by itself.

The Company entered into a Tripartite Agreement on 12th October 1994, with Shanghai Machinery & Equipment Import & Export Corporation (SMEC), on behalf of Shanghai Peng Pu Chemical Works (SPCW) for technology transfer and with Xytel Technologies Partnership, USA for the co-ordination and transfer of technology (between the Company and SMEC). The Department of Industrial Development, Secretariat of Industrial Approvals, Ministry of Industry, has gave permission for this agreement vide their letter FC.1II No:90(93)/4/ILF/93 dated April 2nd, 1993. In the year 2000, Avon Organics Ltd. begun the manufacture of chemical intermediates, and it proposes to venture into the area of bio-technology.

The company manufactures and sells fine chemicals for pharmaceuticals, agro, and dyestuff and pigment industries. It offers Diketene, which is the basic unit for derivatives in pesticides, chemicals, pharmaceuticals, and dyestuffs. It also provides specialty arylides, which include pharmaceutical, agrochemical, and pigment intermediaries. In addition, it offers active pharmaceutical ingredients, including salt of ephedrine and pseudoephedrine; active pharmaceutical ingredients, such as ephedrines and tannates; and formulation intermediates, which include pellets and granules.
Arch Phmalabs Ltd. offered to acquire a 20% stake in Avon Organics Limited (BSE: 531541) for INR 90 million in cash on November 7, 2007. Under the offer, it would acquire approximately 4.5 million shares at INR 20 per share. The Offer was subject to receiving the necessary approval from Reserve Bank of India under Foreign Exchange Management Act, 1999 and maximum tender. The offer will remain open from December 26, 2007 to January 14, 2008. As of November 21, 2008, the offer price was revised upward to INR 21.85 on account of payment of INR 1.85 per share towards the interest for delay in payment of consideration. Consequently, the total fund requirement for the offer was revised to approximately INR 98.3 million. As of November 21, 2008, the date of opening of the offer has been revised to December 3, 2008 and the date of closing of the offer was revised to December 22, 2008. XL Sofftech Systems Limited acted as registrar to the offer and Narendra Kumar Gamini and Niraj Atul Kothari of Ashika Capital Limited acted as financial advisors for Arch Pharmalabs Ltd.

4. SUVEN PHARMACEUTICALS

Suven Pharmaceuticals Limited was promoted in 1989 by Mr. Jasti Venkateswarlu and Mrs. Jasti Sudha Rani for the manufacture of bulk drugs and drug intermediates. The Company was incorporated as a Private Limited Company on 9th March, 1989 in the state of Andhra Pradesh. Subsequently on 4th January, 1995 it was converted into a Public Limited Company in terms of special resolution dated 25.11.94 U/s. 31(1)/44 of Companies Act. The Company develops and manufactures drug intermediates, under contract from the drug’s global patent holders.

Suven Life Sciences Limited operates as a bio-pharmaceutical company and is based in Hyderabad. It operates in four units: Contract Research and Manufacturing Services (CRAMS), Drug Discovery and Development Support Services (DDDSS), Asian Clinical Trials (ACT), and Suven Nishtaa. The CRAMS unit engages in process research and development, provision of supplies to clinical trials, rapid response pilot scale manufacture, and commercial manufacturing under co-operation and secrecy agreements. The DDDSS unit offers clinical trials, testing, and analysis services, as well as involves in collaborative research projects. The ACT unit provides solutions for pharmaceutical, biotechnology, and medical device
companies in the field of clinical research. It offers services, such as study design, investigator meeting support, protocol development, data management, regulatory consulting, bio-statistics, regulatory liaison, medical writing and clinical study reports, project management, study drug storage and logistics, and other clinical research operation services. The Suven Nishtaa unit engages in providing end-to-end drug product development services, including product development; multi manufacturing and packaging; new / novel drug delivery systems; analytical services, such as analytical development and validation, impurity profiling, stability studies, and management; regulatory management services; and pre-post submission and approval. Suven Life Sciences Limited principally serves customers in the United States and Europe, and sells bulk actives and other intermediates primarily to customers in India. The company was formerly known as Suven Pharmaceuticals Limited and changed its name to Suven Life Sciences Limited in 2003.

5. VENKAT PHARMA

Founded in 1989 and is based in Hyderabad, Venkat Pharma, Ltd. manufactures and exports pharmaceutical products in India. Its products include active pharmaceutical ingredients, such as omeprazole powder, omeprazole magnesium, lansoprazole powder, esomeprazole magnesium trihydrate, rabeprazole sodium, pantoprazole sodium sesiquihydrate, olanzapine, citalopram hydrobromide, celecoxib, itraconazole, guaiphenesin verapamil glibenclamide, ciprofloxacin HCL, and ofloxacin. The company also offers pharmaceutical formulation intermediates, including omeprazole pellets, lansoprazole pellets, itraconazole pellets, domperidone pellets, diltiazem pellets, guaiphenesin granules, guaiphenesin granules, dried ferrous sulphate pellets, zinc sulphate pellets, folic acid pellets, pantoprazole pellets, esomeprazole magnesium pellets, rabeprazole pellets, and venlafaxine hydrochloride pellets. In addition, Venkat Pharma provides finished dosages, such as anti bacterial products, antihypertensives, NSAIDS, cephalosporins, as well as anti-arthritis, anti-depressants, lipid lowering agent, anti-diabetic, anti-psychotics, anti-ptic, anti-malarial, anti-TB, and anti-arthritic products. Further, the company offers nutraceuticals, over-the-counter products for regulated markets, branded formulations, generic formulations, and dietary supplements.
Venkat Pharma Limited, manufactures pharma products, and constantly improvises existing product mix, thereby carving out a niche for itself, in the Global playing field of Pharma. It is a public company registered under the Indian Companies Act 1956 and its stock is listed in Bombay Stock Exchange (BSE) and is being actively traded. The company is solely in the manufacturing and export of Pharmaceutical Products since its inception.

6. VIVIMED LABS

The Company was originally promoted by Mr. A. M. Rao and incorporated as Emgi Pharmaceuticals & Chemicals Private Limited on September 22, 1988 with the Registrar of Companies of Karnataka, Bangalore. On Mr. Rao’s accidental death the Company was put for a sale. In 1989 Mr. Santosh Varalwar and Mr. Subhash Varalwar acquired it and commenced manufacturing Bulk Drugs in 1991. Both the present promoters are professionals and have long experience in the Chemicals and Pharmaceutical Industry. The Company was converted into a Public Limited Company on April 4, 1994. Its name was been changed to Vivimed Labs Limited on April 22, 1997. The Company’s manufacturing Unit is located at Bidar, Karnataka, where it was originally engaged in manufacturing Active Pharmaceutical Ingredients (APIs) and Bulk Drugs like Ibuprofen etc. However, due to downward price movement in the products of the Company during 1995, it gradually moved over to manufacturing Specialty Chemicals and cosmetic ingredients like Triclosan, Avis etc. catering to global and domestic markets.

The company started the production of Triclosan with a very small capacity of 5 MT p.a, in the year 1999 and increased its capacity to 225 MT p.a. over the next 5 years. The production capacity was doubled by adding one more production block in March 2004. The Company currently employs over 250 personnel including contract labourers.

Vivimed’s turnover has grown from Rs. 751.85 lakhs in FY1999 to Rs. 4,042.55 lacs in FY2004 and its Net profit grew from Rs. 15.26 lacs in FY1999 to Rs. 400.28 lacs in FY2004. The turnover of the company for 6 months period ending with September 30, 2004 was Rs. 2322.60 Lakhs and Net Profit was Rs.249.24 lacs. As on September 30, 2004, the Networth of the Company was Rs. 1850.15 lacs.
The Company has ISO 9001:2000 certifications for its Quality Management System related to manufacturing process and marketing aspects. Further, the Company is in the process of obtaining ISO 14001 certifications for Environmental Management System for which two Audits have already been completed.

7. PHAARMASIA LIMITED

The company which is based in Hyderabad was incorporated on February 6, 1981 as Phaarmasia Private Limited, and the company was converted into a public limited company, Phaarmasia Limited on February 15, 1992, manufacturing pharmaceutical formulations. The company's facilities are spread over in 3 acres of land with a built up area of 90,000 sq.ft. It engages in the manufacture and sale of pharmaceutical products in India and Nepal. The company offers pharmaceutical formulations, cosmetics, and creams. It also provides skin/face creams, tooth paste, and oral contraceptive pills.

PHAARMASIA LTD, is engaged in the processing and conversion of Liquid Orals and produces Tablets, creams and lotions. During the year 2000, the company became a Sick Industrial Company under the SICA and therefore is referred to BIFR.

As one of India's premier pharmaceutical contract (toll) manufacturing & marketing companies, the company claims to follow strict GMP (Good Manufacturing Practices) guidelines. The logo of Phaarmasia has been evolved on the basis of the Chinese symbol "Yin-Yang". According to Taoism, the universe is composed of two elementary forces—the active masculine/positive force and the passive/feminine force. Whoever can have these forces in equal quantities will achieve perfect harmony? Phaarmasia's facilities are spread over 3 acres of land with a built up area of 90,000 sq.ft. It is a diversified, multi-locational, multi-product group which has been promoted by professionals who have been associated with the pharmaceutical industry in India for the last 40 years. The company claims to quest for quality and dedicate itself to exceed expectations at all times. Its motto is to deliver to its customer's superior quality products which give consumers the fullest satisfaction. It claims to have an environment that encourages its employees, since "people make the difference", and also give special attention to quality consciousness.
Hindustan Bio Sciences is a limited company with a share capital of U.S $2.5 million and is based in Hyderabad, India. The people at the helm of affairs of the company have been associated with the Pharmaceutical and healthcare sector for over two decades and are claim to have penetrative knowledge of the needs of the sick.

This company is a new entrant in the field of Biopharmaceutical Industry and aims as providing quality healthcare for the treatment of life-threatening diseases at affordable cost even to the lower income segment of Indian Society.

The Company started its activities in the year 2001 and have been identifying potential Recombinant DNA-based Biopharmaceutical products for marketing in India. It has outsourced the manufacturing activity presently and its own manufacturing facilities will be established at a later stage. At present the company is setting up a research and development facility for developing the R DNA-based biopharmaceuticals for human consumption. The company has finalised a technical consultation tie-up with the CCMB (Centre for Cellular and Molecular Biology).

Marketing recombinant DNA products for the treatment of life-threatening diseases, establishment of research and development laboratory for conducting research on monoclonal antibodies, immune modulators and bio-pharmaceuticals using recombinant DNA techniques, establishment of manufacturing facilities to manufacture recombinant DNA engineered products, conducting clinical trials and post market surveys to establish the safety and efficacy of the DNA products being manufactured and marketed by them.

Products & services, Recombinant Human Erythropoietin:

The company has obtained the approval of Genetic Engineering Approval Committee (GEAC) for importing and marketing Recombinant Human Erythropoietin manufactured by M/s. Shandong Kexing Bioproducts Co., Ltd., Shandong, China.

The protocol submitted by the company to conduct clinical trials has been approved by the DCGI (Drug Controller General of India) and ethics committees of the Hospitals concerned. The company has been in the process of conducting phase III clinical trials, to prove the safety and efficacy of the product, from March 2005.
The company has entered into an MOU with M/s. Shenyang Sunshine Pharmaceutical Co., Ltd of Shenyang, China for custom manufacture of Interleukin-2 & Interferon alpha 2A for marketing in India. The company is in the process of getting the approval of the GEAC for these products.

Alliance

The company is looking for suitable alliances with manufacturers of recombinant DNA products for manufacturing and marketing in India. Granulocyte macrophage colony stimulating factor (GM-CSF), Granulocyte colony stimulating factor (G-CSF) and Streptokinase are their priority products for marketing in India.

9. GRANULES INDIA LTD

Granules India Ltd (GIL) a fully integrated pharmaceutical manufacture, with its head quarter in Hyderabad, was incorporated as a Private Limited Company on March 16, 1991 and was later converted into a Public Limited Company on February 8, 1993. The GIL commenced its operations in April 1991 as a merchant exporter of bulk drugs like Paracetamol, Guaifenesin and Chloro Pheniramaine Maleste. It has been exporting mainly to the developed markets such as U.S.A., Europe, Mexico and Hongkong. From 1992, GIL concentrated on the export of Paracetamol powder, which was procured from a Group Company, M/s.Triton Laboratories Pvt Ltd (TLPL), a smallscale unit. In 1993-94, the international prices of bulk drugs like Paracetamol were under pressure and the GIL decided to enter into value added areas.

In April 1993, the GIL also joined as a partner of M/s.Triton Laboratories (TL), a partnership firm promoted by the promoters in 1985. After the GIL became a partner. The TL crested facilities for the manufacture of DC blends of Paracetamol and directly entered into its export market. Later, the TL decided to diversify into manufacturing bulk drugs and implemented a project for the same. In August 1994, as part of consolidation and restructuring the Group's operations. The TL was dissolved and its assets and liabilities were taken over by the GIL at book value.

The GIL also purchased the assets of a sick unit from the Andhra Pradesh State Financial Corporation (APSFC) on March 30, 1994. This unit was manufacturing bulk drugs. The assets comprising land, buildings and plant and
machinery were purchased for Rs.35 lakhs, by availing itself of term loan from the APSFC (Rs.22.75 lakhs) and its own funds (Rs.12.25 lakhs). These assets are not presently used and are earmarked for future expansion needs of the company.

Granules India Ltd (GIL), has announced that its new plant at Gagillapur has successfully gone through first International Regulatory audit by the German Health Authority. The German approval enables it to export its products to Europe and significantly enhance its presence in these markets.

Granules India Ltd has informed that pursuant to the approval of the shareholders at the EGM held on September 25, 2004 to issue up to US $ 15 million Global Depository Receipts, each representing one equity share of Rs 10/- each in the share capital of the Company, the GDR issue was opened on January 13, 2005 and closed on January 19, 2005.

On October 12, 2006 Granules India Ltd has signed a Memorandum of Understanding (MoU) with Hubei Biocause Heilen Pharmaceutical Company (Biocause) of China. The company bagged the prestigious "Fastest Emerging Company from India" Award in the APIs & Intermediaries category at the inaugural Indo-Africa Pharma Business Meet hosted by Pharcxcel.

10. ROOPA INDUSTRIES

The Company based in Hyderabad, was incorporated on 17.06.1985 under the name Roopa Granites Private Limited, and subsequently the company converted as a Public Limited Company on 7-4-1992 in terms of Special Resolution dated 02.03.92 passed under section 31(1)/44 of the Companies Act 1956. The Company did not undertake any manufacturing or trading activity. Later the name of the Company has been changed to Roopa Industries Limited and obtained a fresh certificate of registration on 6-9-1994 from the Registrar of Companies, Andhra Pradesh.

Roopa Industries Ltd, has been a manufacturer of Neutraceuticals, Fine chemicals, Drug Intermediates and Bulk Drugs since 1998. Originally the Company proposed to set up a Granite Industry but due to the delay in obtaining Mining Lease from the State Government the company did not carry on any granite manufacturing activity and the project was shelved. Subsequently the Company proposed to set up
a Bulk Drug manufacturing unit and consequently changed the name as Roopa Industries Limited. The Company is setting up a Bulk Drug manufacturing unit to manufacture Ampicillin, Cloxacillin, Cephodroxil at Patancheru, Medak District, and Andhra Pradesh.

The board of the company has been broad based to include a good mix of experienced people in marketing, finance, technical and general administration areas.

Roopa Industries Limited engages in the manufacture and sale of bulk drugs, intermediates, and fine chemicals primarily in India. It offers triphenyl phosphine, liquid bromine, 1 bromo 3 chloro propane, glucosamine HCl, glucosamine sulphate sodium chloride, and glucosamine sulphate potassium chloride. The company also exports its products to Germany, the Netherlands, and Sri Lanka.

References:

1. www.smerating.com
2. http://en.wikipedia.org/wiki/Pharmaceuticals_in_India
3. www.bdmai.org/statistics
4. New trends in India's Pharmaceutical Market By Ames gross published by Pacific Bridge, Inc
6. www.google.com
10. Directorate General of Commercial Intelligence and Statistics - DGCIS, Kolkata