CHAPTER – 3
INDIAN PHARMACEUTICAL INDUSTRY -AN OVERVIEW
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3.1. OVERVIEW

The Indian pharmaceutical sector has emerged as a prominent provider for healthcare products catering to more than 95% pharmaceutical needs of the country with a population of 1.1 billion (FICCI Report 2005). There has been a paradigm shift in the policies and programs governing Indian pharmaceutical industry resulting in this industry, almost non existent till 1970, transforming to a 6 billion USD industry growing at a Compound Annual Growth Rate (CAGR) of 13.7% (ibid).

It currently ranks 4th and 13th in terms of global pharmaceutical business volume and value, respectively (ibid). The Indian pharmaceutical industry has progressed significantly by moving from traditional business models and exploring and adapting to emerging new business models including: Contract research (drug discovery & clinical trials), Contract manufacturing and Co-marketing alliances. The Indian pharmaceutical companies have gained the desired competence in their manufacturing capabilities and have also started fulfilling the Current Good Manufacturing Practices (cGMP) compliance requirements stipulated by International regulatory agencies like United States Food and Drug Administration (USFDA) and Medicine Control Council (MCC) (Report of the Technical Expert Group on Patent Law Issues 2006).

The Indian pharmaceutical industry is at the crossroads: on the one hand, opportunities are emerging in the developed markets, while on the other, the domestic market is becoming increasingly challenging following the introduction of the product patent regime. In developed markets, the focus on reducing healthcare costs has been increasing, with the result that there is pressure on the authorities to allow early introduction of low-cost generic drugs. This in turn points to large opportunities for Indian drug manufacturers with approved facilities and sound knowledge of patent/regulatory issues. Besides, the impending expiry of significant drug patents in the near term also offers opportunities for lower-cost Indian generic manufacturers in terms of greater market access. However, even as there are opportunities, the challenges are many: drawing up appropriate distribution strategies, selecting the right products, and anticipating competition, among others.
Historically, in the domestic market, the option to reverse engineer new molecules and come up with alternative drugs meant that investments in product development were generally low while at the same time competition was intense, given the low entry barriers. However, with the product patent regime having been introduced this calendar, domestic players, to augment their product baskets, would need to focus more on R&D and enter into alliances with innovator MNCs.

The pharmaceutical industry is one of the success stories of Indian manufacturing sector. Favourable Government policies along with industry/firm level initiatives have helped the industry to experience high growth rates over the years. Many Indian pharmaceutical companies have not only shown good performance domestically but have also been able to establish their foothold in overseas markets. Despite challenges posed by the WTO regime, the growth momentum has continued in this sector. The strategies being adopted by the industry are however to be strengthened along with an appropriate policy framework for shaping the future of the Indian pharmaceutical industry (EXIM Bank Report 2007).

Today, the industry 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, the Indian pharmaceutical industry is estimated to be worth 4.5 billion USD, growing at about 8 to 9% 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, Indian pharmaceutical industry boasts of quality producers and many units approved by regulatory authorities in 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 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 injectables. 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 the 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 talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market.

India currently represents just 6 billion USD of the 550 billion USD global pharmaceutical industry but its share is increasing at 10 %, compared to 7 % annual growth for the world market overall (360 Global Pharmaceutical Perspectives, 2004). Also, while the Indian sector represents just 8 % of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 % by value (Organisation of Pharmaceutical Producers of India, 2004), and its drug exports have been growing 30 % annually (Indian Government National Pharmaceuticals Policy, January 2006). The “organised” sector of the industry consists of 250 to 300 companies, which account for 70 % of products on the market, with the top 10 firms representing 30 %. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75% of India's demand for medicines is met by local manufacturing (Pharma Review 2005). The per capita consumption of drugs in India, stands at 3 USD, is amongst the lowest in the world, as compared to Japan- 412 USD, Germany- 222 USD and USA- 191 USD. India's 9.4 billion USD pharmaceutical industries are growing at the rate of 14 % per year. It is one of the largest and most advanced among the developing countries. The Indian pharmaceutical industry can reach a market size of 11.6 billion USD by end of 2009.
3.2. SIGNIFICANCE OF PHARMACEUTICAL INDUSTRY

India’s pharmaceutical sector is receiving a major boost from population growth. According to UN estimates, the population total looks set to rise from 1.1 bn at present to 1.4 bn in 2020. Up until 2020 India will see as many children being born as there are people living in Germany, France, the UK and Italy together. By 2025, India will probably have overtaken China as the world's most populous country. Its population growth results not least from higher life expectancy. This is attributable, among other things, to improved preventive healthcare. Of course, though, average life expectancy in India is still markedly lower than in western countries. While the figure is 64 years for men and 66 years for women in India, life expectancy in Germany is 76 years for men and 82 years for women.

The ageing of the population in India offers considerable market opportunities. According to a UN estimate, the share of people over the age of 65 in the total population will rise from 5% currently to 8% in 2025. This would mean roughly 55 million more people aged 65 and over than today. As a result, typical age-related illnesses such as cancer and cardio-vascular diseases will be more wide-spread. The pharmaceutical sector will also receive a boost from the gradual spreading of civilisation diseases such as obesity and diabetes. According to Price water house Coopers (PwC), the number of Indians with diabetes will reach approximately 74 mn in 2025 (currently 34 mn); this is roughly the population of Turkey today. In developing countries as a whole, there could be just fewer than 230 mn diabetes patients. This development should benefit India’s generics manufacturers.

For the next 15 years we expect average annual growth in India of 6-7% (Bergheim et al 2005). Strong income growth will broaden the middle class, an important group for foreign drugs manufacturers, as it has considerably higher incomes at its disposal than average Indians. Already today, nearly 60 m people in India’s middle class, with disposable incomes of EUR 3,500 to EUR 17,000 p.a., can afford western-produced medicines. Until 2025 their number looks set to rise to approximately 580 mn (+12% p.a.), according to McKinsey estimates. Over a space of ten years, a four-member middle-class family has seen spending on pharmaceuticals grow five times over, to approximately EUR 170 p.a. People’s improved income situation has also led to a growing desire to insure against illness.
At this juncture, only 4% of all Indians have health insurance, but this share should rise strongly over the medium term. This will have a positive impact on the demand for drugs as people with health insurance are usually more likely to obtain prescriptions than those without cover.

Globalisation has not caused traditional medicine to be abandoned but with higher education, rising income and a change in lifestyle, western medical treatment is gaining in importance. At present the population especially in rural areas still sees western medicine as a stop-gap cure which is unlikely, though, to provide a lasting solution to health problems. Today, about 70% of the population on the Indian subcontinent depend entirely or at least in part on traditional Indian medicine which is cheaper and more easily available than western drugs (Uwe Perlitz 2008).

Compared to the general price index, drug prices have risen much less in the last 15 years and remain far below average. Worldwide, India is a country of very low drug prices while producing high quality medicines. Self-sufficiency with regard to pharmaceutics exceeds 90% – in spite of the policy of a more open economy pursued by India since 1991.

The secret of this success is the Indian Patents Act 1970. India had entered independence with the patent system of the British colonial masters, enacted in 1911. This secured the Indian market for the British industry. Prior to 1970, multinational companies dominated the Indian market with a share of 85%; pharmaceutics were largely imported whereas local production remained minimal. Section 83 of the Patents Act 1970 states "that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent and not to enable patentees to enjoy a monopoly for the importation". At the turn of the century, the share of multinationals had declined to a share of 40% of India’s market, including a substantial share of local processing by multinationals. About 45 of the larger scale production units belong to multinational companies (Medicus Bulletin 2002).

Firms based in India and China could be among the first to bring biogenerics (generic versions of biological products) to the regulated markets and faster than expected. The first biogeneric product was approved by the European Medicines Agency (EMEA) which refers to these products as “biosimilars”, in April 2006.
3.3. EVOLUTION OF THE INDUSTRY

The Indian pharmaceutical industry has come a long way since the time of independence when multinational corporations dominated the industry. Over the years, under a favourable policy regime, the industry has grown phenomenally and has established itself as a major supplier of not only generic products but also new formulations. The industry, in addition to meeting domestic demand, is in a position to export significant volume of pharmaceutical products to various destinations, including the developed markets of USA, EU and Japan. Evolution of Indian pharmaceutical industry can be classified into the following four periods:

Pre-1970s: The first Indian pharmaceutical company, Bengal Chemicals and Pharmaceutical Works, which still exists today as one of 5 government-owned drug manufacturers, appeared in Calcutta in 1930. For the next 60 years, most of the drugs in India were imported by multinationals either in fully-formulated or bulk form. The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and with the Patents Act in 1970, enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out, Indian companies started to take their places. They carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present (EXIM Bank Report 2007).

During this period, the size of Indian pharmaceutical industry was small, both in terms of number of firms and volume of production. MNCs dominated the market, both in terms of volume of production and patent holdings, in India. The patent regime, based on Indian Patents and Designs Act, 1911, recognized both product and process patents. Due to monopoly status enjoyed by the MNCs, drug prices remained high during this period.
1970 – 1995: Up until the 1970s, India’s pharmaceuticals market was mainly supplied by large international corporations. Only cheap bulk drugs were produced domestically by state-owned companies founded in the 1950s and 60s with the help of the World Health Organisation (WHO). These state-run firms provided the foundation for the sector’s growth since the 1970s. Back then, India’s government aimed to reduce the country’s strong dependence on pharmaceutical imports by flexible patent legislation and to create a self-reliant sector. In addition, it introduced high tariffs and limits on imported medicines and demanded that foreign pharmaceutical companies reduce their shares in their Indian subsidiaries to two fifths. This made India a less attractive location for international companies, many of which left the country as a consequence. Especially India Drugs and Pharmaceutical Ltd. (IDPL) are credited with speeding up the development of a national pharmaceutical industry. Several IDPL staff has successfully founded their own firms, which now belong to the top group among India’s pharmaceutical companies. In the 1980s, however, the decline of state-run companies began – among other things because of increasing central government bureaucracy and insufficient corporate governance. Today, there are no (entirely) state-owned pharmaceutical companies left. By contrast, the weakening of the patent system and numerous protectionist measures sped up the development of a major national pharmaceutical industry on a private-sector basis, which made it possible to provide the population with a large number of drugs (Uwe Perlitz 2008).

Government of India introduced a new Patent Act, which came into effect in 1972, recognizing only process patent and not product patent. The Act enabled Indian firms to use ‘reverse engineering process’, to manufacture drugs, without paying royalty to the original patent holder. The Act, along with Drug Price Control Order, provided little incentive for MNCs to introduce new pharmaceutical products in India. During this period, the number of domestic pharmaceutical firms increased considerably, from around 2000 units in 1970 to 24,000 units in 1995. Production of bulk drugs increased from Rs. 18 crores in 1965-66 to Rs. 1518 crores in 1995, while that of formulations increased from Rs. 150 crores to Rs. 7935 crores during this period. The increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Low cost and high volume production has helped the Indian pharmaceutical industry in opening export channels to explore many developed and developing countries. Share of exports as a Percentage of total production has shown significant increase from 3.22% in 1980-81 to 24% in 1994-95.
1995-2005: As there was no efficient patent protection between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures. This proved more cost-efficient than the expensive development of original preparations as no funds were required for research, which contained the financial risks. This spending block may come to as much as EUR 600 mn for only one drug. This kind of money could previously only be raised by large corporations in the industrial countries. The competitiveness of generics producers is based on cost-efficient production. In this field, Indian companies are currently in top position. At one-fifth, India’s share in the global market for generic drugs is considerably higher than its share in the overall pharmaceuticals market (approximately 2%). At the same time, India’s pharmaceutical companies gained know-how in the manufacture of generic drugs. Hence, the name “pharmacy of the poor” is frequently applied to India. This is of significance not least for the domestic market as disposable income is as little as EUR 1,900 per year for roughly 140 million of the total of 192 million Indian households (Just et al 2006) which means the majority of Indians cannot afford expensive western preparations.

India’s pharmaceutical industry has been in transition for several years now. This is the result mainly of the changes to drug patent legislation in 2005. Prior to the Patent Amendment Bill, not the substance itself but merely the manufacturing process was protected for a period of seven years. India’s patent legislation had frequently been the reason for legal disputes with large western drug firms, especially from the US. In line with international standards, the sector is now subject to product and process patents valid for a period of 20 years. Indian companies seeking to copy drugs before the patent expires are forced to pay high licence fees. This became necessary following the signing by India's government of the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights). So Indian drug firms could no longer simply copy medicines with foreign patents by using alternative manufacturing processes and offer them on the domestic market. As a consequence of these major changes to India’s drug patent legislation, the country’s pharmaceutical industry is undergoing a process of re-orientation. Its new focus is increasingly on self-developed drugs and contract research and/or production for western drug companies.
Between 1996 and 2006, nominal sales of pharmaceuticals on the Indian subcontinent were up 9% per annum and thus expanded much faster than the global pharmaceutical market as a whole (+7% p.a.). Indian companies strongly expanded their capacities, making the country by and large self-sufficient. Nonetheless, with total sector sales of roughly EUR 10 bn, India commands a less than 2% share in the world’s pharmaceutical market (1966: 1.5%). This puts the country in twelfth place internationally, even behind Korea, Spain and Ireland and before Brazil, Belgium and Mexico. Among the Asian countries, India’s pharmaceuticals industry ranks fourth at 8%, but has lost market share to China, as sales growth there was nearly twice as high and sales volumes nearly four times higher than in India.

The year 1995 recorded another milestone for the Indian pharmaceutical industry. One of the Agreements under the World Trade Organisation was complying with the Trade Related Intellectual Property Rights (TRIPS) provisions. The TRIPS Agreement reintroduced product patent in India. Further, during this period, tariff and non-tariff measures have come down. Such developments have worked in favour of Indian pharmaceutical industry to undertake activities such as clinical research and new drug development. Indigenous producers dominated the market accounting for more than 70% of the market share. Exports also continued to increase during this period, due to strong R&D process and low manufacturing cost.

POST-2005: India's new product patent regime is the result of the WTO's Doha Round of negotiations in 2001. Final agreement was reached on TRIPs ground rules for patent protection among WTO member countries, stating that both processes and products should be protected. Subsequently, on March 22, 2005, India's parliament approved the Patents (Amendment) Act 2005, bringing in a system of product patents backdated to January 1, 2005. The new regime protects only products arriving on the market after January 1, 1995, abolishing the previous process patent system established by the 1970 Patent Act. Since the introduction of product patents the MNCs have largely returned, the most recent being Merck & Co, which inaugurated its wholly owned subsidiary MSD India Pvt Ltd in July 2005 after being absent for approximately 20 years. Assocham believes the new patent regime will enable the development of innovative new drugs, which will increase profitability for MNCs. It will also force domestic players to focus on R&D, which, for those who can afford to do so, will have long-term beneficial effects (Associated Chambers of Commerce and Industry of India Report to Government, 2005).
3.4. PORTER’S Competitive Forces

Porter’s five forces analysis is a framework for the industry analysis and business strategy development developed by Michael E Porter of Harvard Business School in 1979. It uses concepts developed in Industrial Organization (IO) economics to derive five forces which determine the competitive intensity and therefore attractiveness of a market. Attractiveness in this context refers to the overall industry profitability.

Porter referred to these forces as the micro environment, to contrast it with the more general term macro environment. They consist of those forces close to a company that affect its ability to serve its customers and make a profit. A change in any of the forces normally requires a company to re-assess the marketplace. The overall industry attractiveness does not imply that every firm in the industry will return the same profitability. Firms are able to apply their core competences, business model or network to achieve a profit above the industry average. By applying unique business models have been able to make a return in excess of the industry average.

Figure No.1: Porters Five Force analysis on Pharmaceutical Industry

3.4.1. **Industry competition**

Pharma industry is one of the most competitive industries in the country with as many as 10,000 different players fighting for the same pie. The rivalry in the industry can be gauged from the fact that the top player in the country has only 6% market share, and the top five players together have about 18% market share.

Thus, the concentration ratio for this industry is very low. High growth prospects make it attractive for new players to enter in the industry.

Another major factor that adds to the industry rivalry is the fact that the entry barriers to pharma industry are very low. The fixed cost requirement is low but the need for working capital is high.

The fixed asset turnover, which is one of the gauges of fixed cost requirements, tells us that in bigger companies this ratio is in the range of 3.5 to 4 times. For smaller companies, it would be even higher.

Many smaller players that are focused on a particular region have a better hang of the distribution channel, making it easier to succeed, albeit in a limited way.

An important fact is that pharma is a stable market and its growth rate generally tracks the economic growth of the country with some multiple. Though volume growth has been consistent over a period of time, value growth has not followed in tandem.

The product differentiation is one key factor, which gives competitive advantage to the firms in any industry. However, in pharma industry product differentiation is not possible since India has followed process patents, with laws favouring imitators. Consequently, product differentiation is not the driver, cost competitiveness is. However, companies like Pfizer and GlaxoSmithKlineBeecham have created big brands in over the years, which act as product differentiation tools. This will enhance over the long term, as product patents come into play from 2005.

3.4.2. **Bargaining power of buyers**

The unique feature of pharma industry is that the end user of the product is different from the influencer (read doctor). The consumer has no choice but to buy what the doctor says. However, when we look at the buyer's power, we look at the influence they have on the prices of the product.
In pharma industry, the buyers are scattered and they as such do not wield much power in the pricing of the products. However, government with its policies plays an important role in regulating pricing through the NPPA (National Pharmaceutical Pricing Authority).

3.4.3. Bargaining power of suppliers

The pharma industry depends upon several organic chemicals. The chemical industry is again very competitive and fragmented. The chemicals used in the pharma industry are largely a commodity.

The suppliers have very low bargaining power and the companies in the pharma industry can switch from their suppliers without incurring a very high cost. However, what can happen is that the supplier can go for forward integration to become a pharma company. Companies like Orchid Chemicals and Sashun Chemicals were basically chemical companies, who turned themselves into pharmaceutical companies.

3.4.4. Barriers to entry

Pharma industry is one of the most easily accessible industries for an entrepreneur in India. The capital requirement for the industry is very low; creating a regional distribution network is easy, since the point of sales is restricted in this industry in India.

However, creating brand awareness and franchisee amongst doctors is the key for long-term survival. Also, quality regulations by the government may put some hindrance for establishing new manufacturing operations. Going forward, the impending new patent regime will raise the barriers to entry. But it is unlikely to discourage new entrants, as market for generics will be as huge.

3.4.5. Threat of substitutes

This is one of the great advantages of the pharma industry. Whatever happens, demand for pharma products continues and the industry thrives. One of the key reasons for high competitiveness in the industry is that as an ongoing concern, pharma industry seems to have an infinite future.
However, in recent times, the advances made in the field of Biotechnology, can prove to be a threat to the synthetic pharma industry.

**3.5. SCENARIO OF PHARMACEUTICAL INDUSTRY**

The annual turnover of the Indian pharmaceutical industry is over 11 billion USD. Globally it ranks 4th in terms of volume with a share of 8% in the world pharmaceutical market. In terms of value, it ranks 14th. Key therapeutic segments of Indian pharmaceutical industry include anti-infective, gastrointestinal and cardiovascular. Acute therapies make up about 60% of the market. However, it is expected that with the changing lifestyle and aging population, sales of chronic therapies (i.e. diabetes, cardiovascular) are growing rapidly. The pharmaceutical industry is also showing good performance in terms of exports. It is one of the top export items from India accounting for more than 4% of India’s total exports in 2006-07. Exports, which constitute around 50% of the industry’s total production, have grown at a CAGR of 14% in the last decade. Major export markets include highly regulated markets such as USA, Germany, UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals accounting for more than 30% of the total exports, followed by the Americas region (25%). Government policies, viz., Drugs and Cosmetics Act (1940), Drugs Policy (1986), Indian Patents Act (1970), Drug Price Control Order (1995), Pharmaceutical Policy (2002), Indian Patents (Amendment) Act (2005), have played a major role in the growth of Indian pharmaceutical Industry. The Government has also formulated a Draft National Pharmaceutical Policy (2006), which will be finalised after consultation with the stakeholders. Besides, the Government has also facilitated the growth of the Indian pharmaceutical industry through institutional framework and encouraging investments in R&D (EXIM Bank Report 2007).

India’s pharmaceutical industry currently comprises about 20,000 licensed companies employing approximately 5,00,000 staff. Besides many very small firms these also include internationally well-known companies such as Ranbaxy, Cipla or Dr. Reddy’s. With sales of roughly EUR 1 bn, Ranbaxy is currently the world’s seventh largest generics manufacturer. Currently the most important segment on the domestic market is anti-infectives; they account for one-quarter of total turnover. Next in line, and accounting for one-tenth each, are cardio-vascular preparations, cold remedies and pain-killers. By contrast, medicines against civilisation diseases (such as
diabetes, asthma and obesity) or so-called lifestyle drugs (anti-depressants, drugs to help smokers to quit and anti-wrinkle formulations) are of little significance at present. All in all, the Indian pharmaceutical industry produces about 70,000 different drugs, which is higher than the number produced in Germany (60,000) (Uwe Perlitz 2008). India gained its foothold on the global scene with its innovatively-engineered generic drugs and active pharmaceutical ingredients (API), and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research.

3.6. PATENTS

As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India’s patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years. Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995 (The Economic Times 2005). Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose 650 million USD of the local generics market to rightful patent-holders (Singh et al 2004).

In the domestic market, this new patent legislation has resulted in fairly clear segmentation. The multinationals narrowed their focus onto high-end patients who make up only 12% of the market, taking advantage of their newly-bestowed patent protection. Meanwhile, Indian firms have chosen to take their existing product portfolios and target semi-urban and rural populations (Unnikrishnan 2005). The new patent regime to have taken effect at a time when Indian companies had recently started to aggressively pursue global opportunities, so it is not clear whether the flurry of international activity surrounding the enactment date is a result of the change in legislation. Mergers, acquisitions and alliances have been taking place on an unprecedented scale, most notably with companies in the U.S. and Europe. As stated in The Hindu Business Line, “In the last 10-odd months, the Indian pharmaceutical
industry has possibly seen the single largest number of global transactions in its 50-year history”. These transactions provide Indian companies with access to foreign markets and facilitate the process of seeking regulatory approval for new products, which can be quite daunting for a company that only has operations on Indian soil (Datta et al 2005).

3.7. PRODUCT DEVELOPMENT

Companies are also starting to adapt their product development processes to the new environment. For years, firms have made their ways into the global market by researching generic competitors to patented drugs and following up with litigation to challenge the patent. This approach remains untouched by the new patent regime and looks to increase in the future. However, those that can afford it have set their sights on an even higher goal new molecule discovery. Although the initial investment is huge, companies are lured by the promise of hefty profit margins and the recognition as a legitimate competitor in the global industry. Local firms have slowly been investing more money into their R&D programs or have formed alliances to tap into these opportunities.

3.8. SMALL AND MEDIUM ENTERPRISES

As promising as the future is for a whole, the outlook for small and medium enterprises (SME) is not as bright. The excise structure changed so that companies now have to pay a 16% tax on the maximum retail price (MRP) of their products, as opposed to on the ex-factory price. Consequently, larger companies are cutting back on outsourcing and what business is left is shifting to companies with facilities in the four tax-free states - Himachal Pradesh, Jammu & Kashmir, Uttaranchal and Jharkhand (D'Silva et al 2005). As SMEs wrestled with the tax structure, they were also scrambling to meet the July 1st deadline for compliance with the revised Schedule M Good Manufacturing Practices (GMP). While this should be beneficial to consumers and the industry at large, SMEs have been finding it difficult to find the funds to upgrade their manufacturing plants, resulting in the closure of many facilities. Others invested the money to bring their facilities to compliance, but these operations were located in non-tax-free states, making it difficult to compete in the wake of the new excise tax.
3.9. RESEARCH AND DEVELOPMENT

Both the Indian central and state governments have recognised R&D as an important driver in the growth of their pharmaceutical businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control. Government support is not the only thing in Indian pharma’s favour, though; companies also have access to a highly-developed IT industry that can partner with them in new molecule discovery.

3.10. MANUFACTURING

There are 74 U.S. FDA-approved manufacturing facilities in India, more than in any other country outside the U.S, and in 2005, almost 20% of all Abbreviated New Drug Applications (ANDA) to the FDA were filed by Indian companies. Growth in other fields’ notwithstanding, generics is still a large part of the picture. The focus of the Indian pharma companies is also shifting from process improvisation to drug discovery and R&D. the Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT, etc.

The Government policies, programs and initiatives enabled the industry a smooth transition from process patent to product patent regime and resulted in its emergence as a global leader in generic manufacturing field. Indian generic drug manufacturers have been manufacturing generic versions of branded drugs. The generic drug manufacturers who had made significant investment and were marketing the product prior to January 2005 are allowed to continue marketing the product in the new patent regime and the Act granted them immunity from infringement suits by patent holders. ‘Bolar’ exception in Indian patent law allows the generic manufacturers to carry out the mandatory tests necessary for regulatory approvals without having to wait till the expiry period of the patent. It also ensures Indian generic manufacturers to compete among themselves and provides continued availability of medicines at low costs for domestic and international, consumers. There is increased competition in the US and European generics market leading to considerable price reduction of pharmaceutical products. Generic players are also finding it difficult to obtain Para IV wins (India Packaging Show: Para IV Troopers 2007) to effectively compete in the market.
The Act has maintained a reasonable balance between stringent Intellectual Property measures while making use of some of the flexibilities that are inbuilt under TRIPS provisions. The Indian generic manufacturing industry is strong despite pricing pressure exerted on it from the generic markets of US and Europe. The Indian generic industry has a competitive advantage due to relatively cheaper generics whose market demand may also increase due to increase in ageing population in US and Europe and it is expected that such population of Europe is expected to increase from 20% to 26% by 2025 and that of US from 16% to 25% (Yahoo India Finance 2007).

3.11. PRODUCT CATEGORIES AND MARKET SHARE

The pharmaceutical industry can be divided on the basis of therapeutic application and on the basis of foam. On the basis of application, the industry can be divided into therapeutic segments, while on the basis of foam; the industry can be divided into bulk drugs and formulations. On the basis of application, the key segments in the pharmaceuticals Industry are as under, however some of the therapeutic segment are overlapping because of multiple applications (ICRA Report 2002).

1. **Anti-infective**: (penicilium, sulphonamides Aminoglycosides tetracyclines, macrolides, cepholsporins, aminolonesetc) anti –parasites (anti-protozoa, antimalarias, anti-fungals, anti-helmintic etc), anti-tuberculosis and vaccines.

2. **Antipyretics and analgesics**: pain killers, non steroidal anti inflammatory drugs (NSAIDs) and drugs for fevers.

3. **Cardivascular (CVS) drugs**: cardiac therapy, anti-hypertensives and anti-hypotensives.

4. **Central Nervous system (CNS) drugs**: analgesics, psycoleptics, anti-epilepsy, tranquillisers and sedatives and anti-Parkinson’s disease.

5. **Dermatological preparations**: topical corticosteroids, antiseptics and anti-fungals.


7. **Genitourinary and sex hormones**: corticosteroids, sex hormones and stimulants.

8. **Haematologicals**: anti-anaemic preparations.

9. **Muscular Drugs**: anti-inflammatory and anti-rheumatics.

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

11. **Other drugs**: General nutrients, minerals and vitamins.
Table No. 3: Market Share of Different Pharmaceutical Product Categories

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<th>Value (Rs. bn.)</th>
<th>Market Share (Percentage)</th>
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<tbody>
<tr>
<td>1.</td>
<td>Anti-infective</td>
<td>32.8</td>
<td>16.4</td>
</tr>
<tr>
<td>2.</td>
<td>Gastro-intestinal</td>
<td>21.8</td>
<td>10.9</td>
</tr>
<tr>
<td>3.</td>
<td>Cardiac</td>
<td>20.7</td>
<td>10.3</td>
</tr>
<tr>
<td>4.</td>
<td>Respiratory</td>
<td>20.4</td>
<td>10.2</td>
</tr>
<tr>
<td>5.</td>
<td>Vitamins / minerals / nutrients</td>
<td>19.3</td>
<td>9.6</td>
</tr>
<tr>
<td>7.</td>
<td>Dermatological</td>
<td>10.8</td>
<td>5.4</td>
</tr>
<tr>
<td>8.</td>
<td>Gynaecology</td>
<td>10.7</td>
<td>5.3</td>
</tr>
<tr>
<td>9.</td>
<td>Neuro psychiatry</td>
<td>10.6</td>
<td>5.3</td>
</tr>
<tr>
<td>10.</td>
<td>Anti-diabetics</td>
<td>8.8</td>
<td>4.4</td>
</tr>
<tr>
<td>11.</td>
<td>Opthologicals</td>
<td>3.5</td>
<td>1.7</td>
</tr>
<tr>
<td>12.</td>
<td>Others</td>
<td>22</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>200.5</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>


Figure No. 2: Market Share of Different Pharmaceutical Product Categories
3.12. ANTIBIOTICS

An antibiotic is a chemical produced by or derived from micro-organisms (i.e. germs such as bacteria and fungi) that kills bacteria or inhibits their growth (Dorlands Medical Dictionary: antibacterial, 2007). Antibiotics are among the most frequently prescribed medications in modern medicine. Antibiotics cure disease by killing the bacteria or by bacterial reproduction and growth inhibition. The term ‘antibiotic’ was coined by Selman Waksman in 1942 to describe any substance produced by a micro-organism that is antagonistic to the growth of other micro-organisms in high dilution (Waksman, 1947). Before bacteria can multiply and cause symptoms of diseases, our immune system can usually destroy them. Even if symptoms do occur, our immune system can usually cope and fight off the infection. There are occasions, however, when it is all too much and our bodies need some help - from antibiotics.

Although there are a number of different types of antibiotics, they all work in one of the following two ways:

- A bactericidal antibiotic kills the bacteria. Penicillin is a bactericidal. A bactericidal usually either interferes with the formation of the bacterium's cell wall or its cell contents.
- A bacteriostatic stops bacteria from multiplying.

Antibiotics target microorganisms such as bacteria, fungi and parasites. However, they are not effective against viruses. If an individual has an infection, it is important to know whether it is caused by a bacteria or a virus. Most upper respiratory tract infections, such as the common cold and sore throats are generally caused by viruses - antibiotics do not work against these viruses.

If antibiotics are overused or used incorrectly there is a chance that the bacteria will become resistant - the antibiotic becomes less effective against that type of bacterium.

3.12.1. CLASSIFICATION OF ANTIBIOTICS

Antibiotics are commonly classified based on their mechanism of action, chemical structure, or spectrum of activity. Most antibiotics target bacterial functions or growth processes (Calderon et al, 2007). Antibiotics that target the bacterial cell
wall (penicillin’s, cephalosporin’s), or cell membrane (polymixins), or interfere with essential bacterial enzymes (quinolones, sulfonamides) are usually bactericidal in nature. Those that target protein synthesis, such as the aminoglycosides, macrolides, and tetracyclines, are usually bacteriostatic (Finberg et al, 2004). Further categorization is based on their target specificity: "Narrow-spectrum" antibiotics target particular types of bacteria, such as Gram-negative or Gram-positive bacteria, whereas broad-spectrum antibiotics affect a wide range of bacteria. In the last few years, three new classes of antibiotics have been brought into clinical use. This follows a 40-year hiatus in discovering new classes of antibiotic compounds. These new antibiotics are of the following three classes: cyclic lipopeptides (daptomycin), glycycyclines (tigecycline), and oxazolidinones (linezolid) (Cunha, 2009). Tigecycline is a broad-spectrum antibiotic, whereas the two others are used for Gram-positive infections. These developments show promise as a means to counteract the bacterial resistance to existing antibiotics.

The main classes of antibiotics include:

- Macrolides
- Aminoglycosides
- Cephalosporins
- Fluoroquinolones
- Penicillins
- Tetracyclines
- Carbapenems

### 3.12.2. ANTIBIOTIC RESISTANCE

The emergence of antibiotic resistance is an evolutionary process that is based on selection of organisms that have enhanced ability to survive doses of antibiotics that would have previously been lethal (Levy SB, 1994). Antibiotics like Penicillin and Erythromycin, which used to be one-time miracle cures are now less effective because bacteria have become more resistant. Antibiotics themselves act as a selective pressure that allows the growth of resistant bacteria within a population and inhibits susceptible bacteria (Levy SB, 1994). Antibiotic selection of pre-existing antibiotic resistant mutants within bacterial populations was demonstrated in 1943 by the Luria–Delbrück experiment (Luria SE et al, 1943). Survival of bacteria often results from an inheritable
resistance (Witte W, 2003). Any antibiotic resistance may impose a biological cost. Spread of antibiotic-resistant bacteria may be hampered by reduced fitness associated with the resistance, which is disadvantageous for survival of the bacteria when antibiotic is not present. Additional mutations, however, may compensate for this fitness cost and aids the survival of these bacteria (Andersson DI, 2006).

The problem of resistance has been exacerbated by the use of antibiotics as prophylactics, intended to prevent infection before it occurs. Indiscriminate and inappropriate use of antibiotics for the treatment of the common cold and other common viral infections, against which they have no effect, removes antibiotic-sensitive bacteria and allows the development of antibiotic-resistant bacteria.

3.13. EMPLOYMENT GENERATION BY THE INDUSTRY

Most pharmaceutical companies operating in India, even the multinationals, employ Indians almost exclusively from the lowest ranks to high level management. Mirroring the social structure, firms are very hierarchical. Homegrown pharmaceuticals, like many other businesses in India, are often a mix of public and private enterprise. Although many of these companies are publicly owned, leadership passes from father to son and the founding family holds a majority share.

India’s greatest strengths lie in its people. India also boasts a cheap, well-educated, English-speaking labour force that is the base of its competitive advantage. Although molecular biologists are in short supply, there are a number of talented chemists who are equally as important in the discovery process. In addition, there has been a reverse brain-drain effect in which scientists are returning from abroad to accept positions at lower salaries at Indian companies. Once there, these foreign-trained scientists can transfer the benefits of their knowledge and experience to all of those who work with them (Joshi et al 2003). India’s wealth of people extends benefits to another part of the drug commercialisation process as well. With one of the largest and most genetically diverse populations in any single country, India can recruit for clinical trials more quickly and perform them more cheaply than countries in the West (Wilkie et al 2004). Indian firms have just recently started to leverage.
The fact that despite the low level of unit labour costs India boasts a highly skilled workforce has enabled the country’s pharmaceutical industry at a relatively early stage to offer quality products at competitive prices. Each year, roughly 1,15,000 chemists graduate from Indian universities with a master’s degree and roughly 12,000 with a Doctoral degree (Hajos et al). The corresponding figures for Germany – just fewer than 3,000 and 1,500, respectively – are considerably lower. After many chemists from India migrated to foreign countries over the last few years, they now consider their chances of employment in India to have improved. As a result, a smaller number is expected to go abroad in the coming years; some may even return.

3.14. PERFORMANCE INDICATORS OF THE INDUSTRY

The pharmaceutical industry is characterized by low fixed asset intensity and high working capital intensity (ICRA, 2002). The Material cost, Marketing and selling cost and Manpower Cost constitute the three major cost elements for the Indian pharmaceutical industry, accounting for close to 70% of the operating income. In the past 6-7 years, material costs, which account for almost 50% of the operating cost have declined owing to the decrease in prices of bulk drugs and intermediates, increase in exports which enabled procurement of raw materials in large quantities and hence at low prices and finally due to increase in production efficiencies. On the other hand, the marketing and selling expenses, comprising of promotional expenses, trade discounts, advertising and distributing costs; and freight and forwarding costs have increased in the past few years owing to the increase in emphasis on sales of formulations. This increased focus on marketing partly lead to the increase in the manpower costs of pharmaceutical companies during the last decade. The other factor for the increase in the manpower costs, at least in case of a few companies might be due to an increase in R&D efforts, which requires quality research personnel.

3.15. EXPORTS AND REVENUE THEREON

Indian drug manufacturers currently export their products to more than 65 countries worldwide (Organisation of Pharmaceutical Producers of India, 2004). Their largest customer is the U.S., the world's biggest pharmaceutical market. India’s pharmaceutical exports constitute almost 40% of total production of pharmaceuticals in India and valued at over USD 3.5 billions of which formulations and bulk drugs constitute 55% and 45% respectively (FICCI Report 2005). The export revenue now contributes almost half of the total revenue for the top 3-pharma majors: Dr Reddy’s, Ranbaxy and Cipla (ibid).
In 2006, India’s pharmaceutical industry exported products worth EUR 3 bn, up from only EUR 650 mn in 1996, which was due to the fact that demand for low-cost generic drugs is strongly on the rise, above all in the US, Europe and Japan. At 22%, export growth in 2006 was even twice as high as the global average and in Germany (roughly 11% each). Meanwhile, India’s export ratio has reached 32% – about double the figure registered ten years ago. For some time now, India has exported more pharmaceutical products than it imports. Over the last ten years, the export surplus has risen from about EUR 370 mn to currently just under EUR 2 bn. Slightly over 80% of the drugs are sold to the US and Europe, where India’s companies are benefitting from the population’s purchasing power as well as regulatory changes (greater cost-consciousness). By contrast, traditional sales markets such as Russia, Southeast Asia, Africa and Latin America have lost in importance. However, only 60 production locations of India’s pharma sector have been certified by the World Health Organisation, which implies they comply with the strict quality standards imposed by the US Food and Drug Administration (FDA). Compliance with FDA standards is the precondition for selling products on the important US market. High GDP growth rates, rising population numbers and, as a result, a growing middle class are the drivers of India’s pharmaceutical market.

Over 60 percent of India’s bulk drug production is exported. India’s pharmaceutical exports are to the tune of Rs. 87 billion, of which formulations contribute nearly 55 per cent and the rest 45 per cent comes from bulk drugs. In financial year 2005, exports grew by 21 per cent. The Indian pharmaceutical market has been forecasted to grow to as much as 25 billion USD by 2010 as per Organisation of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom’s market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at 11.6 billion USD by 2009. Domestic pharmaceutical exports, growing at 30 per cent per annum, touched a new height of 4.8 billion USD in the financial year 2006-07. The Year’s exports will push the drug sectors contribution to India’s Forex earnings to 7.75 per cent from the current 5 per cent. The growth in drug exports, despite the pressing generic competition in the global markets, is attributed to increased Abbreviated New Drug Applications (ANDAs) approvals in the US market and contribution from unconventional markets in Latin America, Australia and the emerging markets in the Middle East and African
Region. The export revenue now contributes almost half of the total revenue for the top three pharmaceutical majors Dr Reddy’s, Ranbaxy and Cipla. The other major exporters are Wockhardt Limited, Sun Pharmaceutical Industries Ltd. and Lupin Laboratories. The formulations and exports are largely to developing nations in CIS, South East Asia, Africa and Latin America. In the last 3 years generic exports to developed countries have picked up. In the coming years, opening up of US generics market and anti AIDS market in Africa will boost exports.

3.15.1. REVENUE FROM EXPORT

India accounts for less than two per cent of the world market for pharmaceuticals, with an estimated market value of 10.4 billion USD in 2007 at consumer prices, or around 9 USD per capita. India currently represents just 6 billion USD of the 550 billion USD global pharmaceutical industries but its share is increasing at 10 % a year, compared to 7 % annual growth for the world market overall. Also, while the Indian sector represents just 8 % of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 % by value, and its drug exports have been growing 30 % annually. Cipla, Nicholas Piramal, Ranbaxy, Zydus Cadila, Dr. Reddy’s are the few Indian pharmaceutical companies, which are known at the global level due to their quality products. The Indian market for over-the-counter medicines (OTCs) is worth about 940 million USD and is growing 20 % a year, or double the rate for prescription medicines. The industry's exports were worth more than 3.75 billion USD in 2004-05 and they have been growing at a compound annual rate of 22.7 % over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006. The Policy estimates that, by the year 2010, the industry has the potential to achieve 22.40 billion USD in formulations, with bulk drug production going up from 1.79 billion USD to 5.60 billion USD Indian exports are to more than 200 countries around the globe including highly regulate markets of US, Europe, Japan and Australia. More than 400 Bulk Drugs and about 60,000 Formulations (60 categories) are produced in India. Imports have registered a CAGR of only 2 % in the past 5 years. Import of bulk drugs have slowed down in the recent years.
3.15.2. EXPORT GROWTH

In the course of increasing contract production and low-cost manufacture of proprietary medicines, exports are expected to receive a major boost in future. However, Germany's very high export ratio of currently 55% will hardly be achieved by 2015, as this would imply more than a trebling of total exports. In this context, it should be considered that take-overs of foreign companies will lead to a strong increase in foreign production by Indian manufacturers, which will have a dampening effect on exports. A positive impact on exports is expected from foreign investment in India, though. Competition between Indian firms and western drug makers will probably be much fiercer as the companies from Asia are increasingly seeking to tap the global markets. The generics market will grow in both the developed countries and in the emerging markets. Most vital medicines are already exempt from patent protection today. The manufacture of generic drugs in that segment is growing strongly. In addition, patents for high-turnover drugs with a volume of EUR 100 bn will expire in the next few years. Of these drugs, roughly one-third will likely be produced by Indian companies.

3.16. MAJOR INDUSTRY PLAYERS

According to the German Chemicals Association, in 2005, India's top 10 pharmaceutical companies were Ranbaxy, Cipla, Dr. Reddy's Laboratories, Lupin, Nicolas Piramal, Aurobindo Pharma, Cadila Pharmaceuticals, Sun Pharma, Wockhardt Ltd. and Aventis Pharma (Country Report 2005). Indian-owned firms currently account for 70% of the domestic market, up from less than 20% in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994 (Indian Pharma Machinery Manufacturers Association, 2005).

3.17. CHALLENGES TO PHARMACEUTICAL INDUSTRY

All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy’s Laboratories spent only 5-10% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of
the entire Indian pharmaceutical industry. This disparity is too great to be explained by
cost differentials, and it comes when advances in genomics have made research
equipment more expensive than ever. The drug discovery process is further hindered by
a dearth of qualified molecular biologists. Due to the disconnect between curriculum
and industry, pharmas in India also lack the academic collaboration that is crucial to
drug development in the West (Dyer et al 2004).

It is expected to witness drugs sales rise by an annual 8% to nearly EUR 20 bn
between 2006 and 2015. To be sure, this growth rate is higher than that seen for
Germany (+5% p.a.) and the entire world (+6%). Nonetheless, India’s share in world
pharmaceutical sales will rise only marginally to a good 2%. Growth of India’s
pharmaceutical industry and thus its share in global drugs manufacturing could even
be slightly higher if the infrastructure problems could be remedied quickly. While the
pharmaceutical industries of China and Singapore will likely continue to show much
higher growth, India looks set to even lose market share in Asia. Mainly affected by
this development are smaller Indian companies with sales of up to EUR 10 mn which
focus on traditional Indian medicines. It is likely that many of these companies will
merge or disappear from the market altogether. By contrast, large pharmaceutical
companies with sales volumes of over EUR 50 m will be able to increase their sales as
they will be better equipped to adjust their product ranges to the demands of
international markets. These firms will expand their capacities in India – mostly in the
sector’s clusters surrounding Delhi and Mumbai – but will also take over firms in the
industrial countries. Medium-sized businesses will benefit from increasing contract
production for western firms.

Overall the share of pharmaceuticals in the total chemicals industry in India will
come to roughly 17% in 2015 (2006: 18%), compared with 28% in Germany (from
24% in 2006). For the world as a whole, the ratio will likely be only slightly lower than
the German level (25%). Although India’s pharmaceutical sector is growing strongly,
the population’s demand for drugs cannot be met by the country’s own production in all
segments. At EUR 1.5 bn, India’s total drugs imports are comparable in size to
Norway’s entire pharmaceuticals market. Imports look set to continue to rise strongly.
On a medium-term horizon, one-fifth of the world’s pharma sales will be accounted for
by the emerging markets. China will then be among the group of the five largest
manufacturers, while India will join the group of the ten largest suppliers.
3.18. FUTURE OF THE INDUSTRY

India’s pharmaceutical industry has the competitive advantage in improving its market share as prescription drugs worth more than USD 65 billion are to lose their patents in 2007-08 which shall enable India to become the regional hub in Research & Development (R&D), manufacturing and exporting activities (KPMG 2007). The new patent regime has provided for structural changes in the industry and encouraged innovation and greater investment in R&D. The Indian pharmaceutical industry is already on the concretized path of economic prosperity and is all set to benefit substantially through various developments arising out of impact due to TRIPS regime worldwide. It is expected that with the advent of a new patent regime in India, US is also required to provide special focus on modifying US legislation on matters relating to extension / evergreening of patents by US pharma majors which resulted in restricting the growth of the Indian generics manufacturing (US-India CEO Forum 2006).

3.19. ECONOMIC CONTRIBUTION OF PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry reported a compounded annual growth rate (CAGR) of 16% over last 10 years to attain a size of around Rs. 355 billion as of calendar 2004. Of these domestic formulation market accounted of an estimated Rs. 205 billion and exports of formulation and bulk drugs for the rest. In the domestic market approximately 20,000 registered pharmaceuticals manufacturers exist in the country, which contributes merely 1.3% of the global pharmaceutical sector. This low share is attributed to the relatively lower prices of drugs in India. Intense competition and pricing pressure contributed to a relatively modest CAGR of 8-10% over last years. Export growth during the same period albeit on a smaller base was significantly higher at 22% driven by India’s manufacturing cost advantages and the growing share of generics in the regulated market.

Until 1970, when recognition of product patent was abolished in India and the country moved towards acknowledging only process patents, the domestic drug market was dominated by MNCS, which together had a market share of around 80%. Since then, however, Indian generic companies have captured a major share (70%) of the domestic market. In the absence of product patent, there was also little interest among innovator MNCs to introduce patented products in the Indian market.
Over the last 35 years the established pharmaceutical brands in India have displayed strong longevity. This is reflected by the fact that all the 20 brands in the country have been in the market for at least 10 years from now. Also, among the top 300 pharmaceutical brands around 80% were launched before 1995 and 33% before 1980. This implies that large proportions of the current best selling pharmaceutical brands are based on old molecules. While there has been several success for product launches in the domestic market in more recent times, in most cases the same products have been launched by multiple companies under different brands thus resulting in the fragmentation of market share for the individual brands.

The Indian pharmaceutical market is one of the most price-sensitive markets in the world. While in volume terms, India is the forth-largest market globally, value wise it is ranked 13th. Low disposable incomes, besides low penetration of medical insurance among the Indian population, make Indian consumers highly price sensitive, and pricing a key parameter for the success of a new drug.

3.20. PROFILE OF SELECTED PHARMACEUTICAL FIRMS

3.20.1. ASTRA ZENECA(AZ)

AstraZeneca India is a multinational pharmaceutical firm in India that offers an integrated approach to the discovery, development and marketing of medicines. It also has the only dedicated research centre for TB in the world, located in India. It works together in partnership with several Indian firms to deliver high quality medicines to both international and Indian markets. With a strong pan-India presence, one of the fastest growing multinational company in India, with a fiscal turnover in 2009 of over Rs. 360 crore and growth rate was 12%, compared to 6% average growth among MNCs.

2001: AstraZeneca Pharma India is born, following global merger between Astra and Zeneca. Located in Bangalore, it operates through two companies. AstraZeneca Pharma India Limited (AZPIL) is involved in both the manufacturing and marketing of medicines. AstraZeneca India Private Limited (AZIPL) is responsible for R&D business.

The company focuses on providing medicines for following eight key areas of healthcare.
Table No. 4: AstraZeneca list of Products

<table>
<thead>
<tr>
<th>Key healthcare areas</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Betaloc, Seloken XL, Imdur, Ramace, Plendil, Zestril, Crestor, Seloram, Vigocil, Nitract SR, Xparin, Valfect</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Rhinocort, Mits Linctus, Bricarex &amp; Bricanyl, Symbicort, Clavatrol, Rhinofex</td>
</tr>
<tr>
<td>Maternal Healthcare</td>
<td>Prostodin, Cerviprime, Primiprost &amp; Partocin, Zoladex 3.6 mg, Gladis, Valenzia</td>
</tr>
<tr>
<td>Oncology</td>
<td>Arimidex, Nolvadex, Iressa, Casodex &amp; Faslodex</td>
</tr>
<tr>
<td>Infection</td>
<td>Meronem &amp; Vancocin CP, Actamace, Enclere, Naropin</td>
</tr>
<tr>
<td>Pain Control &amp; Anaesthesia</td>
<td>Xylocaine &amp; Sensorcaine, Diprivan</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Neksium</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Onglyza</td>
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</tbody>
</table>


**Pharmaceutical Development Bangalore**

Pharmaceutical Development Bangalore is a strategic part of Global Pharmaceutical Development with a vision of developing great medicines that will make the most meaningful difference to patient health.

The main mission of Pharmaceutical Development Bangalore (PDB) is to partner with discovery to identify opportunities & facilitate the nomination of high quality candidate drugs (CDs) along with efficient and timely supply of drug substance/API for toxicology (pre-clinical) and clinical studies.

In line with its mission PDB will innovate, develop and upscale safe and efficient processes towards candidate drugs received from AZ discovery sites situated worldwide and also to develop processes for tuberculosis (TB) drugs in coordination with RA, AstraZeneca Bangalore which is dedicated to discovering new treatments for TB.
Corporate Social Responsibility

Astrazeneca actively try to help improve the health and quality of life in local communities and promote the value of science among young people. Through sponsorships, charitable donations and various other initiatives, they hope to make a positive contribution to people’s lives in whatever way they can.

3.20.2. RANBAXY

Ranbaxy Laboratories Limited (Ranbaxy), India's largest pharmaceutical company, is an integrated, research based, international pharmaceutical company, producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies. Ranbaxy today has a presence in 23 of the top 25 pharmaceutical markets of the world. The company has a global footprint in 46 countries, world-class manufacturing facilities in 7 countries and serves customers in over 125 countries.

In June 2008, Ranbaxy entered into an alliance with one of the largest Japanese innovator companies, Daiichi Sankyo Company Ltd., to create an innovator and generic pharmaceutical powerhouse. The combined entity now ranks among the top 20 pharmaceutical companies, globally. The transformational deal will place Ranbaxy in a higher growth trajectory and it will emerge stronger in terms of its global reach and in its capabilities in drug development and manufacturing.

Mission

Ranbaxy's mission is ‘Enriching lives globally, with quality and affordable pharmaceuticals.

Financials

Ranbaxy was incorporated in 1961 and went public in 1973. For the year 2010, the Company recorded Global Sales of US $ 1868 Mn. The Company has a balanced mix of revenues from emerging and developed markets that contribute 50% and 44% respectively. In 2009, North America, the Company's largest market contributed sales of US $ 660 Mn, followed by Europe garnering US $ 272 Mn and Asia clocking sales of US $ 468 Mn.
Strategy

Ranbaxy is focused on increasing the momentum in the generics business in its key markets through organic and inorganic growth routes. Growth is well spread across geographies with focus on developed and emerging markets. It is the Company’s constant endeavor to provide a wide basket of generic and innovator products, leveraging the unique Hybrid Business Model with Daiichi Sankyo. The Company will also increasingly focus in high growth potential segments like Vaccines and Biogenerics. These new areas will add significant depth to the existing product pipeline.

R&D

Ranbaxy views its R&D capabilities as a vital component of its business strategy that will provide a sustainable, long-term competitive advantage. The company has a pool of over 1,200 R&D personnel engaged in path-breaking research.

Ranbaxy is among the few Indian pharmaceutical companies in India to have started its research program in the late 70's, in support of its global ambitions. A first-of-its-kind world class R&D centre was commissioned in 1994. Today, the company has multi-disciplinary R&D centers at Gurgaon, in India, with dedicated facilities for generics research and innovative research. Ranbaxy’s first significant international success using the NDDS technology platform came in September 1999, when the Company out-licensed its first once-a-day formulation to a multinational company.

Business Overview

Ranbaxy Pharmaceuticals Inc. (RPI), a wholly owned subsidiary of Ranbaxy Laboratories Limited. (RLL) was established in the U.S. in 1994. RPI began marketing FDA approved generic products in the U.S. in 1998 after receiving its first FDA approval for Cefaclor, a broad spectrum anti-infective agent.

Ranbaxy Laboratories Inc. (RLI), also a wholly owned subsidiary of Ranbaxy Laboratories Limited. (RLL) is the branded prescription division in the U.S. RLI has been expanding and growing on the strength of Ranbaxy’s R&D efforts, and continuing exploration of novel drug delivery systems (NDDS), licensing activities, mergers and acquisitions. RLI is expanding the visibility and presence of the Ranbaxy name by bringing value-added brand products to the market.
Ranbaxy Pharmaceuticals Inc. and RLI have built on RLL's years of successful pharmaceutical experience and expertise. Ranbaxy has positioned itself as a robust and capable player in the U.S. market through the combined commitment of RPI and RLI to developing new and innovative products and a rapidly expanding generic and brand product portfolio.

Manufacturing Facilities

An organisation’s capabilities and intent are strongly reflected in the product it manufactures. In other words, the manufacturing competencies and facilities echo truly, the R&D extent and the ability to implement it for the best of the market it targets.

Ranbaxy possesses the manufacturing strengths that have established it as a producer of world-class generics, branded generics and a major supplier of its range of Active Pharmaceutical Ingredients for pharmaceutical products of companies worldwide.

Ranbaxy has world-class manufacturing facilities in Seven countries namely Ireland, India, Malaysia, Nigeria, Romania, South Africa and USA. Its overseas facilities are designed to cater to the requirements of the local regulatory bodies of that country while the Indian facilities meet the requirements of all International Regulatory Agencies.

Products

Using the finest R&D and Manufacturing facilities, Ranbaxy Laboratories Limited manufacture and markets generic pharmaceuticals, value added generic pharmaceuticals, branded generics, active Pharmaceuticals Ingredients (API) and intermediates.

The company remains focused on ascending the value chain in the marketing of pharmaceutical substances and are determined to bring in increased revenues from dosage forms sales.
Ranbaxy's diverse product basket of over 5,000 products available in over 125 countries worldwide encompasses a wide therapeutic mix covering a majority of the chronic and acute segments. Healthcare trends project that the chronic treatment segments will outpace the acute treatment segments, primarily driven by a growing aging population and dominance of lifestyle diseases. Our robust performance in Cardiovasculars, Central Nervous System, Respiratory, Dermatology, Orthopedics, Nutritionals and Urology segments, clearly indicates that the Company has strengthened its presence in the fast-growing chronic and lifestyle disease segments.

Top 10 Molecules in 2010

Valacyclovir, Simvastatin, Donepezil, Atorvastatin & Combinations, Co-amoxyclov & Combinations, Ciprofloxacin & Combinations, Keterolac Tromethamine, Imipenem+Cilastatin, Ginseng+Vitamins, Loratadine & Combinations

3.20.3. GLAXO SMITHKLINE BEECHAM(GSK)

Established in the year 1924 in India GlaxoSmithKline Pharmaceuticals Ltd. (GSK Rx India) is one of the oldest pharmaceuticals company and employs over 3500 people. Globally, they are a £ 28.4 billion, leading, research-based healthcare and pharmaceutical company. GSK is One of the market leaders in India with a turnover of Rs. 2572 crore and a share of 4.3%. The GSK mission is to improve the quality of life by enabling people to do more, feel better and live longer. This mission drives to make a real difference to the lives of millions of people with commitment to effective healthcare solutions.

The GSK India product portfolio includes prescription medicines and vaccines. The prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, oncology, cardiovascular disease and respiratory diseases. The company is the market leader in most of the therapeutic categories in which it operates. GSK offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by H, influenzae, chickenpox, diphtheria, pertussis, tetanus, rotavirus, cervical cancer and others.

With opportunities in India opening up, GSK India is aligning itself with the parent company in areas such as clinical trials, clinical data management, global pack management, sourcing raw material and support for business processes including analytics.
GSK's best-in-class field force, backed by a nation-wide network of stockiest, ensures that the Company's products are readily available across the nation. GSK has two manufacturing units in India, located at Nashik and Thane as well as a clinical development centre in Bangalore. The state of art plant at Nashik makes formulations while bulk drugs and the active pharmaceutical ingredients are manufactured at Thane.

Being a leader brings responsibility towards the communities in which they operate. At GSK, they have a Corporate Social Responsibility program that works towards fulfilling basic healthcare, education and other developmental needs of the underserved population. With this dedication and commitment, they believe that the world will be better, healthier and happier.

GSK is committed to developing new and effective healthcare solutions. The values on which the group was founded have always inspired growth and will continue to do so in times to come.

GSK worldwide
- GSK is one of the world's leading research-based pharmaceutical and healthcare companies.
- They employ over 96,500 people in over 100 countries
- Around 13,000 people work in our research teams across the world to discover new medicines
- The vaccines are included in immunisation campaigns in 182 countries worldwide
- Every second, they distribute more than 35 doses of Vaccines.
- Every minute, more than 1100 prescriptions are written for GSK products.
- Every hour they spend more than £ 300,000 (US$562,000) to find new medicines
- January 2008 marked the tenth anniversary of our programme to help eliminate lymphatic filariasis (elephantiasis). Since the start of this programme they have donated more than 1.4 billion albendazole tablets to countries affected by LF
- GSK global community investment and charitable donations were £ 222 million in 2010
GSK India

- In India, GSK is one of the market leaders with a turnover of Rs. 2572 crore and a share of 4.3%.
- GSK leads in several therapeutic segments - dermatology, anti-helmentics, hormones.
- GSK has 7 products in the top 50 brands, and the top five GSK products are Augmentin, Calpol, Zinetac Ceftum, and Betnesol.
- GSK's vaccines division is ranked first in a fast-growing vaccines market. Some leading products in India are Havrix, Varilrix, Rotarix, Hiberix and Cervarix.
- GSK India's R&D centres at Thane and Nashik have been granted recognition by the Department of Scientific and Industrial Research, Government of India.
- The number of clinical studies conducted in India is rapidly growing across a range of therapy areas.
- GSK India's social responsibility program focuses on development of underdeveloped villages, women, children and aged, specifically in the areas of healthcare and education.

Products of Glaxosmith Kline

The GSK India product portfolio includes prescription medicines and vaccines. Prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, cardiovascular disease and respiratory diseases. The company is the market leader in most of the therapeutic categories in which it operates. GSK also offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by H, influenzae, chickenpox, diphtheria, pertussis, tetanus and others.

Analgesic, Anti-Infective, Anti-inflammatory, Anti-parasitic, CardioVascular, Dermatology, Diabetes, Endocrine, Intestinal, Gynaecology, Immunosuppressant, Nutritional, Respiratory, CNS, Oncology.
<table>
<thead>
<tr>
<th>Brand</th>
<th>Active ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentin (IV)</td>
<td>Amoxycillin Sodium, Potassium Clavulanate</td>
</tr>
<tr>
<td>Augmentin (ORAL)</td>
<td>Amoxycillin Trihydrate, Potassium Clavulanate</td>
</tr>
<tr>
<td>Cefizox</td>
<td>Cefizoxime Sodium</td>
</tr>
<tr>
<td>Cefspan</td>
<td>Cefixime</td>
</tr>
<tr>
<td>Ceftum</td>
<td>Cefuroxime Axetil</td>
</tr>
<tr>
<td>Dapsone</td>
<td>Diaminodiphenylsulphone</td>
</tr>
<tr>
<td>Esblanem</td>
<td>Meropenem</td>
</tr>
<tr>
<td>Fortum</td>
<td>Ceftazidime Pentahydrate</td>
</tr>
<tr>
<td>Hepitec</td>
<td>Lamivudine</td>
</tr>
<tr>
<td>Mycamine</td>
<td>Micafungin</td>
</tr>
<tr>
<td>Neosporin EYE Drop</td>
<td>Polymyxin B Sulphate, Neomycin Sulphate, Gramicidin</td>
</tr>
<tr>
<td>Polymyxin B Sulphate, Neomycin Sulphate, Hydrocortisone</td>
<td>Neosporin Antibiotic Ointment (Skin)</td>
</tr>
<tr>
<td>Polymyxin B Sulphate, Bacitracin Zinc, Neomycin Sulphate</td>
<td>Neosporin Antibiotic Powder</td>
</tr>
<tr>
<td>Polymyxin B Sulphate, Bacitracin Zinc, Neomycin Sulphate</td>
<td>Neosporin-H Ointment</td>
</tr>
<tr>
<td>Polymyxin B Sulphate, Bacitracin Zinc, Neomycin Sulphate</td>
<td>Phexin Hydrocortisone</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>Phexin BD</td>
</tr>
<tr>
<td>Cephalexin extended-release</td>
<td>Sepmax</td>
</tr>
<tr>
<td>Trimethoprim, Sulhamethoxazole</td>
<td>Septran</td>
</tr>
<tr>
<td>Trimethoprim, Sulhamethoxazole</td>
<td>Supacef</td>
</tr>
<tr>
<td>Cefuroxime Sodium</td>
<td>Timentin</td>
</tr>
<tr>
<td>Ticarcillin Disodium, Potassium Clavulanate</td>
<td>Zemetril</td>
</tr>
<tr>
<td>Cefprozil Monohydrate</td>
<td>Zobactin</td>
</tr>
<tr>
<td>Piperacillin Sodium, Tazobactam Sodium</td>
<td>Zovirax Aciclovir</td>
</tr>
</tbody>
</table>

Diversity

It is an equal opportunity employer employing people from diverse backgrounds while providing them an equal opportunity to grow and develop within the organisation.

3.20.4. PFIZER

Since Pfizer was founded by cousins Charles Pfizer and Charles Erhart in 1849, the pharmaceutical company has remained dedicated to discovering and developing new, and better, ways to prevent and treat disease and improve health and well being for people around the world. From the miracle of penicillin to Pfizer Helpful Answers, which helps people without prescription coverage maintain access to important medications, to medicine safety website, they focus on meeting the world's diverse health needs.

- Pfizer India Headquartered in Mumbai engaged more than 2300 employees and has state of art manufacturing facility at Thane, Maharastra.
- Pfizer Limited (India) has a turnover of US$ 165.86 million (November 2009)
- Pfizer is the highest spenders in pharmaceutical R&D globally, Pfizer has made clinical research investments of US$ 6.28 million (November 2009) in India
- The company was awarded the FICCI SEDF (Socio Economic Development Foundation) Certificate of Commendation for its social responsibility efforts
- Pfizer has won several awards including that for the multinational pharmaceutical company of the year and the most respected MNC

About our products

- Six Pfizer brands feature among the Top 100 pharmaceutical brands in India
- Two of Pfizer India's brands -- Corex (Cough Formulation) and Becosules (Multivitamin) -- continue to rank among the Top 10 pharmaceutical drug brands
- Pfizer has won the Golden Peacock Innovative Product for Magnex (Sulperazon)
- Becosules has won the Most Trusted Brand Award
Table No. 6 : Pfizer range of products

<table>
<thead>
<tr>
<th>Anti-infectives</th>
<th>Active Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloromycetin Capsule</td>
<td>Chloramphenicol and Chloramphenicol Palmitate</td>
</tr>
<tr>
<td>Chloromycetin Ointment</td>
<td>Chloramphenicol Eye Ointment 1%</td>
</tr>
<tr>
<td>Chloromycetin Palmitate</td>
<td>Chloramphenicol and Chloramphenicol Palmitate</td>
</tr>
<tr>
<td>CLARIBID</td>
<td>Clarithromycin</td>
</tr>
<tr>
<td>EquiO</td>
<td>Acelofenac and Paracetamol</td>
</tr>
<tr>
<td>ERYTHROCIN</td>
<td>Erythrocin</td>
</tr>
<tr>
<td>MAGNAMYCIN</td>
<td>Sterile Cefoperazone Sodium USP</td>
</tr>
<tr>
<td>MAGNEX Forte</td>
<td>Cefoperazone and Sulbactam</td>
</tr>
<tr>
<td>MAGNEX Injection</td>
<td>Sulbactam Sodium/Cefoperazone Sodium 1:1 and 1:2</td>
</tr>
<tr>
<td>NEBASULF</td>
<td>Neomycin, Bacitracin, Sulphacetamide</td>
</tr>
<tr>
<td>Neko Bouquet</td>
<td>Triclocarban [3, 4, 4’-Trichlorocarbanilide; TCC] and Total Fatty Matter [TFM] 76%</td>
</tr>
<tr>
<td>Oxytetracycline Capsules</td>
<td>Oxytetracycline</td>
</tr>
<tr>
<td>TERRAMYCIN SF Capsules</td>
<td>Oxytetracycline</td>
</tr>
<tr>
<td>TRULIMAX</td>
<td>Azithromycin</td>
</tr>
<tr>
<td>FASIGYN</td>
<td>Tinidazole</td>
</tr>
</tbody>
</table>


**Corporate Governance**

At Pfizer, management understand that good corporate governance and transparency is essential to ability to be a trusted member of society. In order to create and sustain value for the stakeholders, and for society as a whole, "In 1992, Pfizer became the first U.S. Company to establish a corporate governance department”

That is why, in 1992, Pfizer became the first U.S. Company to establish a corporate governance department. And, it’s why Pfizer’s Corporate Governance Committee considers the perspectives of stakeholders in the company’s decisions regarding current and emerging political, social and public policy issues.
To ensure that every employee throughout the organisation plays an active role in implementing our commitment to responsible business, Pfizer has developed Policies on Business Conduct. First written more than 20 years ago, the “Blue Book,” as it is known, is reviewed annually to ensure it meets or exceeds evolving societal expectations. The “Blue Book” has been translated into 36 languages and every employee, at every level of our organisation, is required to learn and abide by its rules.

**Pfizer Pipeline**

Pfizer is prioritizing its research and development efforts in areas with the greatest scientific and commercial promise: immunology and inflammation, oncology, cardiovascular and metabolic diseases, neuroscience and pain, and vaccines. Through major research efforts across multiple modalities — including small molecules, biologics and vaccines — Pfizer is developing the medical solutions that will matter most to the people they serve. Planned specialized efforts in biosimilars as well as orphan and genetic diseases also illustrate the dedication to develop and deliver innovative medicines and vaccines that will benefit patients around the world.

**3.20.5. MICROLABS**

Microlabs Ltd with its associate companies is a multi-faceted drug manufacturing organisation with 14 production sites that include 11 in and around Bangalore, 1 in Pondicherry, 1 in Goa and 1 in Baddi. Out of these are 9 oral formulation plants, an injectables unit and a bulk drug facility. Micro also has 4 overseas offices and more than 5800 employees across. Expansion plans include setting up of units in UK, Canada, South Africa, USA and Japan.

MicroLabs was established in the year 1973, with an objective of providing quality healthcare products at affordable prices by Late Mr. G.C. Surana. Now, under the leadership of Mr. Dilip Surana (Chairman & Managing Director) and Mr. Anand Surana (Director), it is a diversified pharmaceuticals manufacturing company with products ranging from oral solids, oral liquids, tropicales to injectables. With dedicated plants for penicillin and non-penicillin categories, Micro Labs has been ranked 21 on sales and 10th on Prescription by IMS in the Indian Pharmaceutical Industry.
With a constant aim to excel, the inspiration of the company is to exceed expectations globally, placing quality and efficiency at the top end of company values.

The Microlabs Group has been contributing significantly to the healthcare needs of the domestic market for more than three decades. Growing rapidly in Indian Pharmaceutical Market, it is well poised to achieve unparalleled status in the international market through business expansion plans.

Values
- Achieving customer satisfaction is core to their business
- Provide products and services of the best quality.
- Manage their operations with high concern for safety and environment
- Maintain self-esteem and dignity of each other by creating an open culture conducive for expression of views and ideas irrespective of hierarchy

Aspiration
MicroLabs will be a professionally oriented company delivering value through high quality products and building strong brands across therapy segments through scientifically supported segments and processes and strong implementation capabilities.

MicroLabs are well poised to achieve in the medium term status “BIG GENERIC COMPANY” in the global pharmaceutical space.

Strength
- Marketing of branded generics through own and outsourced distribution networks
- Marketing and distribution set up in more than 30 countries and exports to about 60 countries
- Subsidiaries / Representative offices in 10 countries including UK, Russia, Vietnam & Ukraine, Mexico, etc.
- MOH / Regulatory Approvals from USA, UK, Indonesia, Australia, New Zealand, Canada and South Africa
- Over 300 strong sales force exclusively promoting brands to doctors,
Business Model

- Focus on ethical promotion (brand building) – sale of branded Generic drugs
- Strategic marketing alliances with transnational companies
- Export of all major dosages in every therapeutic segment
- Contract manufacturing and collaborative research with supply of finished products
- Out-licensing projects from their development pipeline to various partners (Regulated Markets)
- Institutional business and NGO supplies

Manufacturing Facilities

Microlabs has well organized and technologically updated manufacturing units that are globally competitive. These manufacturing units are dedicated for various products, cost – effective solutions that boost healthcare & performance. These units maintain high standard of research studies, organisational case studies and individual testimonials that comprise strong body evidence and clearly demonstrate how the system is adding value to the lives of individuals and the organisation.

Micro Labs has State – of – the – art GMP compliant dedicated manufacturing facilities to accommodate the demands of domestic & export markets. The group has a total of 14 manufacturing facilities in India and 2 in South Africa and 1 under construction in Mexico

R&D Capabilities

The company is committed to developing Bio – equivalent Generics with the help of world class research and high quality standards

Focused effort in defined areas and lasting interest in new technology are the two key features of their efforts to develop NDDS & innovative combination products in the medium – long term.

Micro R&D centres are integrated set up with 2 Formulation R&D and 2 API centers.
Analytical facilities range from compound identification to bio – analytical capabilities consisting of all modern equipments. The research team consists of more than 200 scientists / Pharmacists / Analysts / Chemists / Microbiologists engaged in product & analytical development.

**Formulations**

Design and developed pharmaceutical products of International Standards include enteric coated tablets, Chewable tablets C apsules, Powders and Dry syrups for reconstitution

**3.20.6. CIPLA**

Cipla laid foundations for the Indian pharmaceutical industry back in 1935 with the vision to make India self-reliant in healthcare. Over the years Cipla has emerged as one of the most respected names not just in India but worldwide. Its state of the art R&D centre has given the country and the world many firsts. This includes the revolutionary AIDS cocktail for less than a dollar a day. With over 40 manufacturing units across the country, Cipla manufactures over 1200 products in 80 therapies.

With a turnover of over US $ 1 billion, Cipla serves doctors and patients in over 183 countries. It has earned a name for maintaining one global standard across all its products and services. Cipla continues to support, improve and save millions of lives with its high-quality drugs and innovative devices

Cipla is 2nd largest pharmaceutical company in India in terms of retail sales. Cipla manufactures an extensive range of pharmaceutical & personal care products and has presence in over 170 countries across the world. Cipla's product range includes Pharmaceuticals, Animal Health Care Products, OTC, Bulk Drugs, Flavours & Fragrances, and Agrochemicals. Cipla also provides a host of consulting services such as preparation of product and material specifications, evaluation of existing production facilities to meet GMP, definition of appropriate plant size and technologies etc.
Research & Development

Cipla's R&D division focuses on the development of new products and new drug delivery systems across a range of therapies. The company is spending over 4 per cent of its total turnover on R&D activities. It filed 55 ANDAs during 2004-05 and received approval for 11 products from US FDA. The company supplies drugs to treat over 2 lakh HIV-positive patients worldwide. The company has also been among the major suppliers of anti-malarial drugs and drugs for schistosomiasis to international markets.

It has a research alliance with a Bangalore-based biotech company Avesthagen, to develop biotherapeutic products. Cipla's manufacturing facilities have been approved by: Food and Drug Administration (FDA), USA; Medicines and Healthcare products Regulatory Agency (MHRA), UK; Therapeutic Goods Administration (TGA), Australia, Medicines Control Council (MCC), South Africa; National Institute of Pharmacy (NIP), Hungary; Pharmaceutical Inspection Convention (PIC), Germany; World Health Organisation (WHO); Department of Health, Canada.

Cipla's products include

**Pharmaceuticals**: Cipla manufactures anabolic steroids, analgesics / antipyretics, antacids, anthelmintics, anti-arthritis, anti-inflammatory drugs, anti-TB drugs, antiallergic drugs, anticancer drugs, antifungal, antimalarial, antispasmodics, antiulcerants, immunosuppressants etc.

**OTC**: These include: child care products, eye care products, food supplements, health drinks, life style products, nutraceuticals & tonics, skin care products, and oral hygiene products.

**Cipla's exports**

Cipla exports raw materials, intermediates, prescription drugs, OTC products and veterinary products rugs to more than 160 countries including the U.S., and a number of countries in Europe, Africa, Australia, Latin America and the Middle East. Cipla shipped products worth more than Rs. 10, 500 million last year. Exports amounted to more than Rs. 10, 500 million. Cipla exports. Cipla also offers technology for products and processes.