CHAPTER FOUR
PRESENT SCENARIO OF PHARMACEUTICAL SECTOR

Pharmaceuticals are medicinally effective chemicals, which are converted to doses forms suitable for patients to imbibe in the basic chemical form. Pharmaceuticals are called bulk drugs and final doses forms are known as formulations. Bulk drugs are derived from four types of intermediates i.e., raw materials viz., (i) plant derivatives or herbal products, (ii) animal derivatives e.g., insulin extracted from bovine pancreas, (iii) synthetic chemicals, and (iv) biogenetic or human derivatives e.g., human insulin. These are substances known as medicines and used in preventing and curing illness and diseases. Usage of pharmaceutical is governed by underlying science of illness and disease.

Branches of medical sciences have been divided into four categories, where allopathy system of medicine is known as modern medicine and world over pharmaceutical industry is focused upon it. Ayurvedic system of medicine is ancient Indian medicine science and mainly uses herbal remedies and gaining importance in pharmaceutical market particularly in United States of America. Unani system of medicine has its origin in China and is prevalent in South East Asia region. Homeopathy system of medicine is found by German physician and was fairly popular in 19th century and still prevalent in third world countries.

All the four systems of medicines have their own merits and demerits. Allopathic system of medicine is prevalent throughout the world and it has added advantage of surgery system to remove damaged portions from the body. Patient feels immediate relief with the prescribed medicines and this is the reason of its wide scale use. In addition, treatment of accidental cases is possible to keep the body in perfect condition to the possible extent. Allopathic system of medicine has most serious disadvantage of side effects of the medicines and in due course of time, body becomes medicated, where higher doses become necessary to cure disease.

Ayurvedic system of medicine takes long time in treatment and usually people avoid this system in serious diseases in view of long duration of treatment.
This system has no side effects and cure of disease is complete and perfect. There are various preventive medicines in Ayurvedic system, which people use for maintaining strength and stamina of the body. Most of the medicines are quite costly and quality control in many cases remains lacking. Ayurvedic system has treatment of various strategic diseases, but medicinal practitioners are not fully equipped to provide right medicine for identified disease.

Unani system of medicine was practiced in India before one century and doctors of this system had excellent knowledge of identification of disease and treatment system within prescribed time duration. Various haqims were famous for their treatment, but lack of patronage has declined use of this system through modern research and investigations. Similar situation exists for homeopathic system of medicine, where some doctors of this discipline have grip over treatment of various strategic diseases, which are not possible from other systems of medicines.

Usually pharmaceutical industry is used in allopathic system of medicine, for being most popular system world-wise and research and development work is carried out in this sector to great extent. For this reason the pharmaceutical industry is generally addressed and reported about the allopathy system. This sector is most competitive at the global level and various companies have their market in many countries of the world. Patents of allopathic medicines are maximum in each country and every industry remains effortful to introduce superb strategic medicine for global requirement.

4.1 PHARMACEUTICAL POLICY OF GOVERNMENT:

In February 2002, the Government of India announced pharmaceutical policy and its salient features are

(i) Industrial licensing for all bulk drugs cleared by Drug Controller General of India, all their intermediates and formulations have been abolished subject to stipulations laid down from time to time in the Industrial Policy except in cases of (a) bulk drugs produced by the use of recombinant DNA technology, (b) specific cell/ tissue targeted formulations,
(ii) Foreign investment up to 100 percent permitted subject to stipulations laid down from time to time in Industrial Policy, through the automatic route in the case of bulk drug cleared by Drug Controller General of India, all their intermediates and formulations, except those referred to in (i) above, kept under industrial licensing.

(iii) Automatic approval for foreign technology agreement be available in case of all bulk drugs cleared by Drug Controller General of India, all their intermediates and formulations except those referred to in (i) above kept under industrial licensing for which special procedure prescribed by the government need to be followed.

(iv) Measures to give impetus to research and development in the drug sector are (a) manufacturer producing new drug patented under the Indian Patent Act 1970 and not produced elsewhere, if developed through indigenous research and development, is eligible for exemption from price control in respect of that drug for a period of 15 years from the date of commencement of commercial production in the country. (b) A manufacturer producing drug in the country by a process developed through indigenous research and development patented under the Indian Patent Act 1970, is eligible for exemption from price control in respect of the drug till expiry of the patent from the date of commencement of its commercial production in the country through new patent process, (c) A formulation involving a new delivery system developed through indigenous research and development and patented under the Indian Patent Act 1970 for process patent for formulation involving new delivery system is eligible for exemption from price control in commercial production in the country till expiry of the patent.

(v) The system of price control is operated through a single list of price controlled drugs selected on the basis of criteria as laid down in the Pharmaceutical Policy 2002 and formulations based thereon with a MAPE of 100: percent for indigenous formulations and 50 percent for imported formulations. The 279 items appearing in alphabetical list of Essential Drugs in the National Essential Drug List of 1966 of the Ministry of Health of Family Welfare and 173 items, which are considered important by the
Ministry from the point of view of their use in various health programmes, in emergency care etc, with the exclusion, as in the past, of sera and vaccine drug products combinations etc are from total basket, out of which selection of drugs is to be made for price regulation.

(vi) Ceiling price can be fixed for any formulation, from time to time and it is obligatory for all, including small scale units or those marketing under generic name to follow the price so fixed.

(vii) An independent body of experts, called the National Pharmaceutical Pricing Authority has been entrusted with the task of price fixation or revision and other related matters.

(viii) Government has to keep close watch on the prices of medicines, which are taken out of price control, in case of prices of these medicines rise unreasonably, the government has to take appropriate measures including reclamping of price control.

(ix) The provision of limiting profitably, as per Schedule III of the present Drug Price Control Order, 1995 is to be done away with, however, to do so in public interest, prices of any formulation, including non-scheduled formulation is to be fixed or revised by the Government.

The Government constituted a Committee under the Chairmanship of Joint Secretary (Pharma) to examine the issue of span of price control, including trade margin subsequently a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was also constituted to explore options other than price control to make available life saving drugs at reasonable price. Based on the recommendations of the Committee under the Chairmanship of Joint Secretary Pharmaceutical and the recommendations of the Task Force and other extensive discussions with various stakeholders including drug industry, the Department prepared the Draft National Pharmaceutical Policy 2006 and in line with the declared objectives Government under the national Common Minimum Programme to make available life saving drugs at reasonable price to the poor. (1)
4.2 PUBLIC SECTOR PHARMA UNDERTAKINGS:

There are five Central Public Sector Undertakings and five Joint Sector Undertakings in the Pharmaceuticals Industry Sector under the administrative control of the Department of Chemicals and Petrochemicals, besides, there are two wholly owned subsidiaries. Details of these units are given hereunder:

4.2.1 Indian Drugs and Pharmaceuticals Limited (IDPL):

IDPL was incorporated on 5th April 1961 and the company has three manufacturing plants, one each at Rishikesh in Uttarakhand, Hyderabad in Andhra Pradesh and Gurgaon in Haryana. IDPL has two wholly owned subsidiaries, viz., IDPL Tamilnadu Ltd, Chennai in Tamilnadu and Bihar Drugs and Organic Chemicals Ltd at Muzaffarpur in Bihar. In addition, IDPL has two joint sector undertakings promoted in collaboration with the respective state governments. These are Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) Jaipur and Orissa Drugs and Chemicals Ltd (ODCL) Bhubneshwar.

In pursuance to Board of Industrial and Financial Reconstruction (BIFR) order dated 24th Match 2004, Uttar Pradesh Drugs and Pharmaceuticals Ltd, a joint sector undertaking of IDPL has been taken over by Uttar Pradesh Government with effect from First April 2004. BIFR recommended winding up of IDPL on 4-12-2004 and Department of Chemicals and Pharmaceuticals filed an appeal on opinion of BIFR in the Appellate Authority for Industrial and Financial Reconstruction (AAIFR) on 10-2-2004 and AAIFR at its hearing held on 13-9-2005 set aside the impugned order dated 4-12-2003 of BFIR and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL.

The Board for Reconstruction of Public Sector Enterprises (BRPSE) at its meeting held on 9-3-2007 having considered the rehabilitation scheme for revival of IDPL recommended for approval of Union Cabinet, which considered the proposal on 17-5-2007 and referred it to Group of Ministers (GoM) at the first instance and the issue was under active consideration.
4.2.2 Hindustan Antibiotics Ltd (HAL):

HAL Pimpri, Pune was incorporated on 30th March 1954 and was first Public Sector Company in drugs and pharmaceuticals. HAL has its plant located at Pimpri and there are three joint sector units promoted by HAL in collaboration with the respective state governments. These are Karnataka Antibiotics and Pharmaceuticals Ltd, Bangalore, Maharashtra Antibiotics and Pharmaceuticals Ltd, Nagpur and Manipur State Drugs and Pharmaceuticals Ltd at Imphal. MAPL and MSDPL have since been closed.

The main products of HAL are bulk drug Penicillin-G, various salts of Penicillin and Streptomycin. The company produces a wise range of pharmaceutical formulations including Agro-vet products. The company was referred to BIFR in January 1997 and was declared sick. In the year 2004-05, the government announced financial support for restructuring the company. In March 2006, government approved rehabilitation scheme for revival of the company with following package:

(a) Cash infusion by Government of India Rs. 137.59 crores
(b) Write off/ exemptions from Govt. of India Rs. 267.57 crores
(c) Sacrifices by banks, financial institutions and public sector undertakings Rs. 103.34 crores

The entire cash infusion of Rs. 137.59 crores was released to company, of which Rs. 56.96 crores was to be generated by HAL by selling land and fund of Government of India was to be treated as interest free loan and HAL was required to refund the amount within two years. The amount to be written of as part of package was approved by the Parliament. The BIFR had sanctioned rehabilitation package in its meeting held on 5-10-2006.

4.2.3 Bengal Chemicals and Pharmaceuticals Ltd (BCPL):

BCPL was incorporated on 17th March 1981 and the company has four manufacturing units one each at Maniktala in Kolkata, Panihati at North 24 Parganas district of West Bengal, one in Mumbai and fourth at Kanpur. The company manufactures and markets a wide range of industrial chemicals, large number of
drugs and pharmaceuticals besides cosmetics and home products. BIFR sanctioned a modified revised rehabilitation scheme on 14-1-2004 for its revival. In 2006, the Government approved rehabilitation scheme for revival of the company with following package:

(a) Cash infusion by Government of India Rs. 207.19 crores  
(b) Write off/ exemptions from Govt. of India Rs. 233.41 crores  
(c) Sacrifices by banks, financial institutions and public sector undertakings Not quantified

4.2.4 Bengal Immunity Ltd (BIL)

Bengal Immunity Ltd was incorporated on 1-10-1984 and BIFR issued winding orders for non-performance and recurring losses and the company was closed and appointment of liquidator in respect of BIL had stayed the writ petition filed by BIL. Employees union protest and the department of Chemicals considered the proposal and Committee was set up to into revival of the unit. The committee examined the feasibility aspect and submitted its report but the matter is still under examination.

4.2.5 Smith Stanistreet Pharmaceuticals Ltd. (SSPL):

The unit was established on 19th July 1978 but the BIFR has issued winding up orders for non-performance and recurring losses. The company has since been closed and High Court of Kolkata had appointed liquidator to examine into issues related to assets of the company.

The situation of Government of India undertakings in pharmaceutical sector is evident that all the undertaking could not manage functional level in the field of drug preparation. The main problem in all the undertakings remained the interference of political and administrative to run he units without understanding their structure and capability to manage preparation of drugs. The private companies of the country have managed well and earning profit with the government support, but its own units could not function smoothly. (2)
4.3 INDIAN PHARMACEUTICAL INDUSTRY:

Indian pharmaceutical sector has come a long way, almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95 percent of pharmaceutical needs of the country. In the present scenario, the industry is in front rank of science based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in third world, in terms of technology, quality and range of medicines manufactured. Range of medicines manufactured in India cover simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is made indigenously.

Playing a key role in promoting and sustaining development in the vital field of medicines, Indian pharma industry boasts of quality producers and many units approved by regulatory authorities in United States of America and United Kingdom. International companies associated with this sector have stimulated, assisted and spearheaded dynamic development in past 60 years and helped to put India on the pharmaceutical map of the world. Following the delicensing of pharmaceutical industry, industrial licensing for most of 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 research and development expenses, innovative scientific manpower, strength of national laboratories and increasing balance of trade. Total Indian production constitutes about 13 percent of the world market in value terms and eight percent in volume terms. The per capita consumption of drugs in India stands at US$ 3 is amongst the lowest in the world, as compared to US$ 412 of Japan, US$ 222 of Germany and US$ 191 of United States of America.

Indian pharmaceutical industry is on the way of transformation that could see it exerting for greater influence on the world. It is transformation of $ 5.5 billion industry; mostly build on copying drugs patented by other people, into a $ 25 billion
power house that is respected not just for its superb process skills, but also for its research process. Indian pharma companies are already in action setting up their own networks abroad, getting regulatory approvals for their manufacturing plants and generally learning to grow fast over global market. The transition process is also not easy, for being discounting for world wide pharma industry.

Old method of drug discovery based on chemistry is giving diminishing return, while new method of drug recovery based on biotechnology much like custom designing are get to mature so, even as global research and development spends too much, new drug discoveries are becoming rare. Drug recovery process is getting unbounded or big pharma turns to another company to acquire license new molecules. There is unbundling happening to contract research control manufacturing clinical trials. Advantages of pharmaceutical industry in India are as under:

(a) Competent Workforce: India has a pool of personnel with high management and technical competence as also skilled workforce. It has an educated workforce and English is commonly used professional service are easily available.

(b) Cost- effective Chemical Synthesis: Its track record of development particularly in the area of improvement cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

(c) Legal and Financial Framework: India has 65 years old democracy and has developed solid legal framework and strong financial markets. There is already an established international industry and business community. Foreign direct investment of 100 percent has helped in attracting foreign collaboration.

(d) Information Technology: Indian pharmaceutical industry has assured network of world-class education institutions and established strength in information technology.
(e) Globalization: The country is committed to free market economy and globalization. Above all, it has 90 million middle class markets, which is continuously growing.

(f) Consolidation: For the first time, the International pharmaceutical industry is finding great opportunities in India. The process of consolidation has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India. (3)

4.3.1 Retrospect of Indian Pharmaceutical Industry:

Quinine extracted from the cinchona tree bark was used to treat malaria way back in 1610, but Alexander Fleming discovery of penicillin in 1929 is considered real foundation of modern pharmaceutical research. Next major breakthrough came in 1932 with the synthetic sulphonamides in Germany by Klerer and Meitzsch. Fifteen year period between 1938 and 1953 became to be known as the age of antibiotics, due to unprecedented number of new anti-infecting agents introduced during the period. Antibiotics and vaccines have played major role in near eradication of following major debases viz.,

(a) Influenza/ pneumonia  
(b) Tuberculosis  
(c) Syphilis  
(d) Diphtheria  
(e) Whooping  
(f) Cough  
(g) Measles

Between 1920-1960, the death rate due to diseases in a year fell down from 12120 per million persons to 8000 per million persons. Every four years since 1965, one additional year has been added to life expectancy at birth due to advances in pharma research and development. As antibiotics enabled people to survive more advanced ages, researchers focused on cell biochemistry to find cure for more complex chronic diseases. Drug researchers are targeting to cure the underlying causes of diseases that are rooted in the human molecular structure.
Indian pharmaceutical industry has evolved significantly after independence and start of planned era, when infrastructure development was the priority of the national planning process. Initially the multi-national companies had a near monopoly, as they had technical know-how and talent, which helped such companies improve and marketing formulations in India, mainly low cost generics for the masses and also few specialties life saving high priced products with the government increasing pressure against imports of finished products, the multi-national companies set up formulating units and continued importing bulk drugs.

In 1960, Government of India laid down foundation of the domestic pharmaceutical industry by promoting Hindustan Antibiotics Ltd (HAL) and Indian Drugs and Pharmaceuticals Ltd (IDPL) for manufacturing bulk drugs. However, multi-national companies maintained lead due to backing of their global research and development, high cost for basic research deferred local players in the private sector. Year 1970 in known as revolutionary for Indian Pharmaceutical Industry for introduction of Indian Patent Act and Drugs Price Control Order (DPCO). The Indian Patent Act helped in reduction of local manufacturing cost, due to absence of royalty payment in reverse engineering drugs.

The Drugs Price Control Order effectively put ceiling on prices of certain mass usage bulk drugs and their formulations to prevent any undue profiteering, which further deterred the multi-national companies as selling the products at much lower prices in India, meant global repercussions and possible uproar in their home countries. As resultant impact, some multi-national companies curtailed the scope of their operations, which further strengthened the position of local pharmaceutical companies. Legal provisions of Indian Patent Act 1970 also helped in getting patent of new research based drugs.

Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units, which increased drastically after Indian Patent Act. Now 250 pharmaceutical companies control 70 percent of market with market leader having nearly seven percent of the market share. It has become most competitive industry mainly due to lower affordability, fragmented market with severe price competition
and government price control measures. Market share of multi-national companies has fallen from 75 percent in 1971 to around 35 percent.

Share of Indian companies increased from 20 percent to 65 percent in the same duration and domestic output exceeded Rs. 170 billion, accounting for 1.3 percent of global share. Indian pharmaceutical industry has been developed in all the systems of medicine i.e., allopathy, Ayurved, Unani and homeopathic, as the country people have faith in different systems of treatment. The position of allopathy sector grew considerably to meet country and outside requirements. Salient features of Indian pharmaceutical industry are as under:

(a) The pharmaceutical industry is lifeline industry, which plays very crucial role in building a strong human capital of the country and is very essential for economic growth and development. It is at the top of Indian science based industries, with wide ranging capabilities in the complex field of drug manufacture and technology. The contribution of the pharmaceutical industry towards national growth cannot be undermined.

(b) Pharmaceutical industry In India is one of the largest and most advanced among developing countries. In has wide ranging capabilities in complex field of drug manufacturing and technology. Pharma industry is highly fragmented and grew with government protection and low cost manufacturing structure.

(c) Output of Indian pharmaceutical industry ranks fourth in terms of volume and thirteen in terms of value. Now India accounts six percent of bulk drug exports. There are about 350 bulk drugs, active pharma molecule having therapeutic value and used for production of pharmaceuticals, accounting for majority of formulations produced in the county.

(d) Growth of Indian pharmaceuticals at around 15 percent per annum and the industry produces about 60,000 finished medicines and roughly 400 bulk drugs, used in formulations. The industry is highly fragmented with largest formulation players having market share of less than six percent.

(e) Top ten players of pharmaceutical industries account for 36 percent of global scenario, where top ten account for 49 percent of pharmaceutical market. The
product is required 74 percent in urban areas and sale of urban sector is increasing 15 percent per annum.

4.3.2 Present Status of Indian Pharmaceuticals:

Pharmaceutical industry of India is successfully meeting its inherent goals of providing employment to millions of the people and ensuring essential drugs at affordable price are available to vast population of the continent. The Indian pharmaceutical industry is still in the state of transition and companies are busy readying themselves for revolutionary change after favourable amendments made in 2005 in the Indian Patent Act 1970, where patent of product have become possible. The industry has witnessed several new trends and domestic industries have been churning new products to brand acquisition spree to strengthen their position.

The new situation has made it possible to merge the inactive and defunct industries and make alliance with other companies to expand business. Increased focus on generics and specialty segments are some of essential moves, where multinational companies have started their new appearance to regain their supremacy in the industry. Indian pharmaceutical industry is in front rank of science based industries with wide ranging capabilities in the complex fields of drug manufacturing and technology. Such changes in industrial environment have accelerated the growth rate of 8 to 9 percent annually.

The industry manufactures bulk drugs belonging to several major therapeutic groups requiring various manufacturing processes and has developed excellent facilities for production of all forms of doses e.g., tablets, capsules, liquids, ointment, orals and injectibles. The production of drugs and pharma industry is growing constantly, visible from the figures of 1992-93 with bulk drug production of Rs. 11.5 billion to Rs. 65 billion drug production and Rs. 241 billion for formulation production in 2002-03. The industry is playing vital role in promoting and sustaining development in the field of medicines.

Indian pharmaceutical industry boasts of quality producers and many of its units are approved by regulatory authorities in United States of America and United
Kingdom. International companies associated with this sector have stimulated, assisted and spearheaded the dynamic development. Licensing of drugs remained quite problematic and time consuming and delicensing of the pharma industry has significantly helped most of drugs and pharmaceutical products. Manufacturers felt significant relief to produce any drug with the approval of Drug Control Authority.

Technologically strong and totally self reliant pharmaceutical industry of India has been able to produce low cost production, low research and development costs, innovative scientific manpower, strength of national laboratories and increasing balance of trade have attained rich scientific talent and research capabilities, supported by Intellectual Property Protection Regime to have smooth entry in international market. There was bull run on multinational pharma companies stocks in India, but after April 2003, Indian pharma companies could manage over multinational peers through effective work performance.

Even the retail investors and fund managers have all of sudden become very bullish on pharma companies due to re-rating of pharma stocks. One of the important factors for surge in valuation of Indian pharma companies is their prospective entry into the United States and other developed countries markets, which offered huge potential after 2005. Traditionally, there are two types of stakeholders in Indian pharma market i.e., multinational companies and domestic pharma companies. The multi-national companies are brand focused and have developed molecules by adopting process re-engineering with sub-station lower prices than the original patented molecules.

Indian pharmaceutical companies have added advantages in comparison to multi-national companies, which helped to register comparative higher growth in their sales. India had signed World Trade Organization (WTO) agreement on pharmaceutical products patents and Indian pharma companies can no longer introduce molecule through process re-engineering after January 2005, but the same Agreement has thrown open doors for Indian companies to top the generic markets of the developed countries in the west. Generic medicines are considered as cheap bio-equivalent and copies of molecules for which patents have expired.
It is estimated that after 2005, large number of many block buster-patented drugs have gone off patent, having market size worth $40 billion. After 2010, the size of the off-patent drug market is estimated around $80 billion, which provides attractive opportunities to Indian companies to tap international market for these products. Most of large and medium sized pharma companies of India have started rolling up their sleeves to meet regulatory requirements of developed countries including food and drug authorities of United States.

As per World Trade Organization conditions from 2005, India has to grant product patent recognition to all new chemical entities. i.e., bulk drug developed onwards. The decision of the Government of India to allow 100 percent foreign direct investment into the research activities in the country was responded suitably. Technology transfer to 100 percent Indian subsidiaries of multi-national companies was expected only in 2005. Various International agreements can become favourable, if conditions creating obstacles are removed with insistence and conditions of the World Trade Organization became favourable to India, with similar sincere efforts.

4.3.3 Development Features of Pharmaceutical Industry:

Indian pharmaceutical industry is growing at the rate of 14 percent per year. Information given in figure 4.1 reveals that in the year 2004 the production of pharmaceutical products of India was US$ 8.2 billion, increased to US$ 11.6 billion in 2009. It is one of the largest and most advanced among the developing countries. Beginning was made with the signing of General Agreement on Tariffs and Trade in January 2005, with which India began recognizing global patents. Soon after, Indian pharmacy market became destination of foreign companies in view of 100 percent foreign direct investment policy of the Government of India. During the year 2005-06 foreign direct investments in pharmaceutical industry touched the figure of US$ 172 million.
During the period 2002-06 the cumulative annual growth rate of pharma industry remained 62.6 percent. Annual profits of pharma industries remained varied in the year 2005-06 from 473.9 percent of Nicolas Piramal, 313.7 percent of Torrent Pharma, 167.2 percent of Ranbaxy Laboratories, 74.5 percent of Glenmark, 66.4 percent of Cadila Healthcare, 65.8 percent of Dr. Reddy, 35.8 percent of Sun Pharma, 26.8 percent of Lupin Laboratories, 26.1 percent of Biocon and 5.2 percent of Cipla. Total annual profit of all the pharmaceutical companies of India was 57.2 percent, which was landmark of the industry in the country.

4.3.4 Changing Prescription:

As per World Trade Organization conditions from the year 2005, India granted product patent recognition to all new chemical entities in the form of bulk drug development. This introduction of product patent regime from January 2005, is leading into long-term growth for the future, which mandated patent protection on product and processes for a period of 20 years. Under new law, India is forced to recognize not only new patents, but also patents filed after first January 1995. Under the changed environment, the pharmaceutical industry is forced to adapt its business model to recent changes in the operating environment. The emerging model to capture outsourcing opportunity is given at Figure 4.2.
Indian pharmaceutical industry is mounting up the value chain from pure reverse engineering industry focused on domestic market, the industry is moving towards basic research driven, export oriented global presence, providing wide range of value added quality product and service, innovation, product life cycle management and enlarging their market reach. The old and mature categories like anti-infectives, vitamins, analgesics etc are de-growing, while new lifestyle categories like cardiovascular, central nervous system, anti-diabetic are expanding in double digit growth rate.
Indian companies are putting act together to top the generic drugs markets in the regulated high margin markets of the developed countries. United States remains the most lucrative market for Indian companies led by its market size and intensity of blockbuster drugs going off patent. An estimated US$ 45 billion have gone off patent in 2007 in United States alone. Indian pharmaceutical industry is getting increasingly United States foreign direct investment complaint to harness the growth opportunities in areas of contract manufacturing and research. Outsourcing in the field of research and development and manufacturing is the best event to pharma industry.

4.3.5 Research and Development:

Research and development is key to the future of pharmaceutical industry, which advances for considerable improvement in life expectancy and health all over the world are resultant impact of steady investment in research. There is considerable scope for collaborative research and development in India, which offers several strengths to international research and development community. These strengths relate to availability of excellent scientific talents, who are capable to develop combinatorial chemistry, new synthetic molecules and plant derived candidate drugs. Figure 4.3 reveals research environment in the country.

Research and development expenditure by pharmaceutical industry of India is around 1.9 percent of total annual turnover, which is little low as compared to foreign research based pharmaceutical companies. India is entering into patent protection area, which is helpful in high investment in research activities. India is providing strong base for clinical evaluation at the time of multi-centre trials, considering real availability of clinical materials in diverse therapeutic areas. According to Pharmaceutical Outsourcing Management Association and Biopharmaceutical Outsourcing Report, pharmaceutical companies are utilizing substantially the services of Contract Research Organization.
4.3.6 Domestic Demand Scenario:

Indian Pharmaceutical firms have made their ways into global market by researching generic competitors to patented drugs and following up with litigation to challenge the patents. This approach remains untouched by new patent regime and looks to increase in future. The excise structure has been changed, which has enabled the manufacturing companies to pay 16 percent tax on the maximum retain price of the product on ex-factory cost. This situation has compelled the large companies by cutting back on outsourcing and business has been concentrated in four states viz., Himachal Pradesh, Jammu and Kashmir, Uttarakhand and Jharkhand where state tax has been exempted on manufactured medicines.

Pharmaceutical industry has enough growth potential for consumption of drugs in domestic sector as well as outside India in view of quality product, low cost and world class technology. The domestic market has increased potential in view of population level of 1.21 billion, increasing income, demand for quality healthcare
service and changing lifestyle. More than 85 percent of formulations produced in the
country are sold in domestic market and country has largely become self sufficient
in medicines. Some life saving and new generation under-patent formulations
continue to be imported, especially by multi-national companies, for marketing in
India.

The size of domestic formulations marketed in the country account for Rs.
160 billion as per 2007 estimates and the demand is increasing at the rate of 10
percent per annum. Market share of different pharmaceutical product categories in
given in Figure 4.4, which also reveals the demand of type of medicines in the
country. This trend is helpful in assessment of the production and research in
specific field associated with the demand. The specific issue of domestic medicines
of low cost with world class quality has discouraged foreign companies to find
Indian market less attractive.

**Figure 4.4**

**Market Share of Different Pharmaceutical Product Categories**

4.4 **GROWTH DRIVERS OF INDIAN PHARMA INDUSTRY:**

Various policy measures of the Government of India and liberalization in
procedural issues have helped the Indian pharmaceutical industry to accelerate its
functioning in befitted manner. Patent process of various new formations processed
in the Indian Patent offices at Delhi, Chennai, Mumbai and Kolkata provided time
bound process and secrecy of the patent formula has helped the research institution to introduce various new drugs for country and international market has helped in production of cheap medicines, where material and labour cost remains reasonably low to float in international market. (4)

Laboratory facilities available in the country of international level and talent of persons engaged in the task has also helped in preparation of various strategic drugs for control and cure of serious diseases. Delicensing process has also helped in processing the task with Indian Drug Control Department having transparent and standard measures for approval of new drugs has helped in addition of variety of medicines for various diseases. The combined impact of all these measures have created favourable condition for growth of pharmaceutical industry, where following issues are worth reporting:

(a) Industrial Entrepreneurship and Scientific and Technological Skills: unique blend of these two key elements with innovation marketing strategies gave cutting edge to Indian companies strengthen in country and international market.

(b) Low Manufacturing Cost Base: Indian pharmaceutical industry have tried its best to maintain the quality of product and lower cost in view of lower labour and equipment cost. This issue is key factor for survival of Indian pharmaceutical industry in national and international market, as developed countries put various riders to restrict to free flow of product of developing countries.

(c) High Process Development Skills: Specialization of the companies by reverse engineering enables them to develop cost effective and non-infringing process for product going generic. India has developed requisite processes through prevalent patent system.

(d) Business Environment: Indian pharmaceutical companies have attained technical skills in patent and manufacturing of quality drugs and multinational companies were competing in Indian market are searching Indian companies for collaboration for research and patent for newly invented drugs. This has helped in creating conducive business environment.
(e) Innovative Scientific Manpower and Competent Workforce: India has pool of personnel with high managerial and technical competence as well as skilled workforce. There is sufficient availability of educated and talented workforce with proficiency in English in technical terminology and ingredients of the drugs. Such talented manpower is functional in India and abroad with pharma companies.

(f) Secret and Time Bound Patent System: Indian patents are accepted in all the convention countries as part of international agreement and before ascertaining the eligibility of any patent application, the content of application are made public for global information and claim of any person or institution with proof. This system has helped in maintaining the secrecy of patent and ensure global acceptance of the patent item.

4.5 EMERGENCE OF INDIAN PHARMA MNCs:

Global leaders of pharma industry dominate all components of business and industrial activities in drugs including research and development, production and marketing are designated as multi-national companies. Most of such companies are located in United States, Western Europe and Japan. Multi-national companies are defined as large business companies and these highly visible corporations are generally regarded as product of the capitalists and free trade societies of western world, gained their dominance during second half of last century.

These companies presently control global market as well as economics of the country of their base country and also have their access in most of the developed and developing countries. In pharma industry, the top twenty companies command over 60 percent of the global pharmaceutical market and various companies are growing in these countries in view of potential pharmaceutical sector market of most of the developing countries. Drugs are major requirement world over and most of the developing countries.

Global multi-national companies are getting more and more dominance through international trade agreements and adopt various tactics to get marketing facilities in most developing countries. Global multi-national companies have
special characteristics within themselves and there are wide disparities amongst these companies. Companies based in United Kingdom cover 60 percent of global sales coming from their domestic market, while multinational companies of smaller European countries comprising of Switzerland, Sweden and Denmark etc sell over 90 percent of their global production abroad.

Third categories of multi-national companies are from Japan, which have over last half century adopted policy of licensing their products to western multi-national companies and marketing in territories outside Japan. These multi-national companies get total requisite support from their country government through loans and assistance, where pre-conditions remain allowing their pharmaceutical companies to market their product without any interruption. These multi-national companies are running for capturing global market and pushing their products through business and country government support. (5)

4.5.1 Emerging Indian Pharma MNCs:

Indian pharmaceutical companies are emerging as multi-national companies with the support of international agreements and liberal trade practices on bilateral and multilateral basis. Though Indian pharma companies are developing their capabilities through better quality, technological support and cheaper products to be pushed in world market. The decision of the Government of India to allow foreign direct investment in pharmaceutical industries for preparation of drugs and research and development activities, various global companies are strengthening their position in Indian market.

Situation of India in global pharmaceutical market is of new entrant, where various terms and conditions of entry into various country market are challenging task, as other multi-national companies are creating most competitive conditions for India to sustain in drug sector and some sincere efforts of various pharmaceutical companies have remained successful in entering in developed countries, but Indian pharmaceutical companies need to satisfy following conditions to graduate the status of multi-national companies and keep their hold through competitive measures:
(a) A product range of relevance to major market abroad is pre-requisite, as Indian pharmaceutical products need to suffice the conditions imposed by country government to qualify the product in all requisite aspects.

(b) Access to international market with generic patent expired or non-patented products. International agreement allow Indian patent drugs in global market, except in cases, where the country government intends to protect its own manufactured drugs, but bilateral and multi-lateral agreements allow foreign companies to sell their product in Indian market and similar facilities are available to India.

(c) India has added advantage of talent personnel availability to manufacture quality product and cost of production remains comparatively lower to compete in global market. In addition, the specific pre-requisites need to be studied closely to suffice all the prevailing conditions are met with the product.

(d) Production as per regulatory requirement with adherence of laboratory, manufacturing and clinical practices to qualify the international requirements in general and country specific in particular.

(e) Research and development capabilities for discovery or partial development of drugs relevant to other markets. Such facilities remain helpful in inventing new medicines and cure of strategic diseases. Such efforts help in pushing unique product in global market.

(f) Marketing facilities through requisite subsidies in export and subsidiaries through tie-up with local companies. Unless local company takes interest to push Indian product in other countries, it is difficult to create network of Indian product.

(g) Abilities to get Abbreviated New Drugs Applications (ANDA) approvals to enable early marketing of generic versions of patented drugs.

There are various favourable conditions for India pharmaceutical products, but there is immense need to allow quality products of companies, as entry of sub-standard medicines in other country may create most humiliating situation to the company getting opportunities to outside market but return of total lot with sub-
standard product may disturb total export potential. There is need to hold low quality product by floating into external market. Other competing countries remain watchful to find some lacunae to defame the country and cautious approach can stop such situations.

4.5.2 Entering Global Generic Market:

The Indian Pharmaceutical Act 1970 enabled country companies to master the process technology for the production of most of bulk drugs used in formulation. Export of these products has been restricted to countries, where no valid patents for valid products were managed. New strategies the Indian companies could adopt include manufacturing and export of generic drugs, which have valid patents for global markets. Between 2002-05 drugs valued $ 40 billion are going off patents, in United States of America alone. Patents on several block busters such as Prilosec for ulcer of $ 4 billion, Claritine for allergy $ 3.4 billion and Neurotion for epilepsy $1.4 billion were expiring in 2002.

Depakote for CNS disorders $ 800 million, Accupril $ 650 million, Procirt for anemia $ 1.5 billion and Diflucan for vaginal candidasis $ 1 billion in 2004 and in 2005, Privacid for ulcer $ 3.7 billion, Zoloft for depression $ 3 billion and Pravachol for hyper choleseterolemin $ 1.7 billion were prestigious drugs. Indian pharmaceutical companies have capacity to produce all of these bulk drugs and offer those at competitive costs for the global generic market. Leading companies have made considerable progress in this sphere, which calls for early approval of abbreviated new drug applications (ANDA) to enable expires.

The market strategy involves direct selling and through subsidiaries, as well as through major generic companies e.g., Andrx, Ivax, Eva, Par, Warrick etc companies have been expediting their ANDAs to get benefit from the excluvity for 180 days provided for under the Hatch-Waxman Act is available to those ahead of other major products, which have targeted several block busters, e.g., Fluoxetine, Omeprazok, Cipofloxacin, Amlodipine, Steraline, Albendazol. Metaformin etc and some of biotechnology products such as erithropoietin, human insulin and hepatitis vaccines are of great value.
4.5.3 WTO and Indian Pharma Industry:

Prior to 1970, Indian pharmaceutical industry was largely dominated by foreign companies, which made the country exclusively dependent on import of bulk drugs and formulations. Prices of drugs were among highest in the world and burden to the society on account of exorbitant prices for medicines was explicit. With a view to bring down the burgeoning prices of drugs and to break the dominance of multi-national companies, Government of India introduced Indian Patent Act 1970, which allowed process patenting and fostering the self reliance of Indian pharmaceutical industry.

Process patenting helped significantly in availability of new drugs at significantly cheaper rates and promoted import substitution by encouraging local companies to introduce copies of drugs by developing their own processes, followed by bulk drug production. This process was largely helpful in protecting Indian pharmaceutical industry to facilitate self-sufficiency in availability of common drugs required for treatment of general diseases. Many efforts were made in post Second World War era to agglomerate world business through inter-governmental treaty like General Agreement of Trade and Tariff (GATT).

Uruguay round resolution of partner countries of GATT met in 1944 to establish new trade order through the ensconce of an international organization named World Trade Organization to materialize global efforts in the sphere of pharmaceutical industry. In practice, the World Trade Organization started multilateral trading system has become main vehicle of few industrialized developed countries for organizing and enforcing global economic governance. It is serving the purpose of developed countries, as a weapon to arm and twist their way into the markets of developing countries.

India has been amongst the first signatories to the World Trade Organization Charter, which facilitates recourse of cross relation for non-fulfillment of specific obligations. India has availed opportunity to export drugs, with the help of patent laws by complying the rules and provisions of trade. India has amended Patent Act
to allow product patent instead of process product. Provision of trade practices with regard to pharmaceutical products relevant to India are enumerated below:

(a) The minimum term of patented commodity or technology is twenty years from the date of filing of the patent.

(b) Patent production has been extended to pharmaceutical products.

(c) Importation has been accepted as one of the condition of working patent.

(d) Compulsory licensing has been deregulated but to be relegated to special circumstances.

(e) In case of infringement suits over process patents, the burden of proof has been reversed

(f) Provision of traditional arrangement in respect of deferment of the acceptance of pharmaceutical product patents by developing countries has been made valid for ten years.

(g) Limited exclusive rights have been granted to developing countries for pharmaceutical products, whose patent applications are filed after enforcement of trade practices agreement.

The exclusive marketing rights (EMRs) route is a backdoor method of granting monopoly rights. The World Trade Organization has granted ten years grace period for India to ensure smooth transition from process patent regime to product patent pattern. During the interim period, all patent applications received by it has been put in black box for future considerations. During the interim period, pharmaceutical companies can apply for exclusive marketing rights for products for the period of five years. Indian transition remained fully phased as pharmaceutical companies were fully facilitated to receive marketing rights for any of the member countries.

Grant of patent and exclusive marketing rights by any member country automatically qualify a company to avail exclusive marketing rights in India for that product for minimum period of five years. This clause has very serious implications as the company can experiment on lives of poor Indians, if their experiment fails, the drug can be withdrawn and in the process lives of poor Indians remains part of
experiment. If the drug proves successful, given the provision of validity of twenty years, the company can avail enormous monopoly profits.

These are about 23,000 pharmaceutical firms in India, engaged in production of 16,000 formulations and 700 drugs and about 28.60 lakh persons are engaged in these firms. The pharmaceutical sector started growing with India became signatory member of World Trade Organization. Individual companies like Ranbaxy, Dr. Reddy, Cipla, Dabur, Aurobindo Pharma and Orchid Chemicals have set their pace and defined industry standards. Ranbaxy with its presence in 30 countries with operations in 24 and manufacturing in 6 countries, with 7000 persons across the world are engaged in research and development activities, which meet double standards of such tasks for quality produce.

Modernization of plants and machinery remains primary objective of the companies and process of global marketing alliance, mergers and acquisition are the prime issues of success and expansion. Some Indian companies are engaged in examining their future role in path-breaking areas of research such as genetics, hoping to open up unexplored venues of global alliance for introduction of new therapeutically agents. Agronomy and scientific development of traditional medicines is one of the practiced modes of execution.

4.5.4 Impact of 2005 Agreement:

Indian entry into Trans National Concerns (TNCs) into post WTO has propped up pharmaceutical firms to follow the international challenges with united stand, as consolidation had become buzzword in the industry and smaller unites were unable to bear heavy competition individually. Year 2005 remained a turning point with implementation of TRIP agreement, which remained quite helping in defining Indian pharmaceutical trade and various business changes. Most transitional companies introduced new patented drugs to become fully operational. This also helped the patent holder to use its bargaining power, as foreign companies remained hesitant to set up their base in India.
Indian companies have unique cost advantage that facilitates production of drugs at 1/20\textsuperscript{th} of the cost incurred in other developed countries. Key ingredient is cost of manpower quite low enabling low cost manufacture of drugs. Such practices need to be applied in research function, which can be cost effective and research and development component is inevitable for pharmaceutical companies to remain in business. It is most essential factor for the pharma firms to get various new patents, which can expand Indian and world market.

If pharmaceutical companies of other countries are able to get new patents in view of their research activities, they can also get hold in India, as it is biggest market in the world and patent of one strategic disease can flourish a company over the world market in view of patent rights. The cost factor of medicine becomes immaterial if any medicine of strategic disease has monopoly and every patient has to use the medicine for treatment. There is immense need of continued research activities and avail patents of as many drugs as possible. This is the only way to survive in present situation.

4.6 INTRODUCTION OF ELYSIUM PHARMACEUTICAL Ltd.

Elysium Pharmaceutical Ltd. Began as small company in 1995 and became one of leading pharmaceutical company, due to strong foundation, expertise and resources. The company is engaged in manufacturing and marketing of pharmaceutical formulations finished products at Dabhasa, 17 km away from Vadodara city of Gujarat. The company new possesses uni-directional flow and World Health Organization and good manufacturing practices certificate, which has made the company unique among large number of pharma industries.

Elysium has ultra modern pharmaceutical formulation plant with multi-national company approved quality control and quality assurance departments with well-defined parameters. One of the unique feature of the company is the manufacturing department with highly advanced facilities for water system, air handling system, controlled man and material flow system to control particulate matter and streaming the product as per GMP guidelines of WHO, MCA, US FDA, EC with total quality assurance and model to watch one of the rarest well knitted plant.
The plant comprises of various departments positioned for unidirectional material flow pattern and segregated mind and material entries, equipped with fully automatic indigenous manufacturing machinery. The departments are designed for manufacturing various formulations. The product facility types are tablets, capsules, ointments and creams, liquid orals and injectibles including vials, ampoules etc. In manufacturing plant, facilities exist are central packing, warehouse, utility service block, service floor, administration, quality control and quality assessment and a separate B-lactum plant.

Pharmaceutical industry is growing at 8-10 percent per annum out of which formulations’ contribution is 85 percent. Drug Controller of India has imposed revised schedule ‘M’ policy to ensure international quality standards and to convert from non-GMP pharmaceutical unit to revised schedule ‘M’ or WHO GMP unit. Scope of WHO companies is unlimited due to regulatory measures of the Drug Controller of India to meet international standards, which is essential to qualify the product to be marketed in all the countries, as per feasibility and favorable conditions.

In the present, only one-third pharmaceutical concerns have their own plants and remaining are manufacturing their products either on third party or on loan license basis. Conditions imposed by Drug Controller of India would compel the remaining companies to get schedule M, which is only possible with establishment of manufacturing unit able to meet all the international conditions or close their business. For remaining in world market, Government of India has to implement TRIPS Agreement conditions and GATT Agreement conditions. Meeting all the international conditions may take some time, which is not restricted to India, as the situation of pharmaceutical companies is similar in other countries.

Elysium Pharmaceuticals Ltd has maintained its credibility in the global market, which has helped in contract manufacturing for different multinationals and transnational concerns e.g., Sanofi-Aventis, German Remedies Ltd, Cadila Laboratories Ltd, Bayer Pharmaceutical ltd, Torrent Pharmaceutical Ltd. In addition, Elysium Pharmaceuticals Ltd is actively engaged in ethical domestic marketing in
nine states viz., West Bengal, Orissa, Assam, Jharkhand, Uttar Pradesh, Andhra Pradesh, Kerala, Tamilnadu and Gujarat. EPL’s distribution channel is spread over all these states and flow of stock from the central warehouse at Vadodara is efficient and follows the norms of IDMA and OPPI with maintenance of cold chain.

The company logistic delivery system is prompt to far distant channel partners within minimum possible time in view of assured rail and road connectivity. Distribution channel associates in nine states are called as consignee sales agents. The part of company activity ensuring the growth of the company with its associated partners of 176 stockiest across the country are catering the requirement of about 5220 retail outlets. EPL have established their presence in the segment of life-saving drugs, nutraceitical, anti-ulcer ants, cough and cold, pain management, anti-histamine, anti-infective and anti-asthmatic.

Clientele of EPL consists of approximately 14,000 throughout the nation, of which specialty segment includes Cardiologist, Diabetologist, Gastro-enterologist, Gynecologist, Orthopedics and Physicians. Major share is contributed by corporate customers accounted to around 1700. Existing field force of the company is spread over the country, comprises of 105 professional sales representatives, 21 area managers, four regional sales managers, one senior divisional manager and one zonal sales manager. Products of company are of international excellence, which is evident of the sincere efforts of the management to reach the level.

With world-class quality product, dedicated field force supported by professional management, EPL is confident of capturing sizeable business from Employees State Insurance Corporation, government hospitals and research institutions through rate contract. The corporate team marketing division is headed by President, Marketing, assisted by Sales Manager and Product Executive in marketing. Strategic development and training, financial management and able support by highly qualified line managers is the theme of success of the company.

EPL is planning to introduce two unique molecules to establish their product in country and world market. The company has so far registered its products in 9
countries and effortful for opening new areas for its products. Achievements made by the company in short span have yielded success with well planning, strict quality control, meeting the international norms and low cost medicines to be floated in the world market. The developed countries are fully satisfied with the manufacturing quality and getting their product manufactured in view of cost and quality measures.

Since its foundation in 1995, the company emerged as modest pharmaceutical company with wide range of innovative products. Moving beyond pharmaceutical, the concept of total healthcare forms commercial heart of operations and activities. The company established its formulation unit in 1996 and commenced its manufacturing operations in 1997. The company is involved in manufacturing of sterile formulations like liquid and dry parenterals, non-sterile formulations like tablets, capsules, liquid orals, ointment, dry syrups and committed to maintain and improve the quality of manufactured products to meet customer satisfaction.

The company aims to becoming one of the ten units in Indian healthcare industry and leading Asian company in Asia by 2020 and effective global role by 2030. The aims and objectives of the company remained motto of success, which were further disaggregated by annual goals and trying to attain each mission well before time with zeal and hard work. It remained effortful to develop team of core competence in their resource to drive through continuous and constant efforts with upgrading the systems, technology and knowledge.

Business operations of the company include pharmaceuticals, positive responses to charge underline every aspect of group operations. It is multi-product company with multi-faceted group catering to wide spectrum of healthcare through drug manufacturing to drug administration. The company group has adopted the model of a performing organization, with self-reliant strategic business unit. The cohesive team individually and collectively contributes in overall performance. (6)

Organizational chart of Elysium Pharmaceuticals Ltd is given in Figure 4.5
**Distribution Networks**
The ultimate buyers are however the company goes to the doctors.
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