CHAPTER – 3

THE DEMAND FOR PHARMACEUTICALS

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Chapter 3

THE DEMAND FOR PHARMACEUTICALS

3.1. Introduction

Having explained the historical perspective of pharmaceutical industry in last chapter we will now see the demand factors of pharmaceutical in this chapter. In the second section macro economic factors affecting demand for health are discussed. Moreover in the section three the Overview of demand related aspects of pharmaceutical industry and in section four market segmentation, product augmentation and pharmaceutical market (9 Ps) have been discussed. Lastly in section five we discuss how the markets for pharmaceutical products differ from other products.

3.2. Demand for health

The demands for drug have several special features: the physician, who is an agent of patient and consumer of drug who will decide to buy which drug and how much. Usually, information asymmetry on drug knowledge is huge between physicians and patients, thus agency problem between the two is a serious and important issue. Second, medical insurance pays for some patient. There exist another agency problem between insurance, physician and patient. Thus it is a very prevalent phenomena that physicians prescribe excessively high price drug to increase their revenue, not for the reduction of burden of patient. In developing economies, where coverage of social security system is limited, physicians depend on direct revenue from patient, this agency problem become more acute.
During the last few decades India has made notable progress in the field of health. The death rate was high 42.6 per thousand in 1901-11. It decreased sharply to 18.9 by 1961-71 and further 13.2 by 1981. Life expectancy has increased by over 30 yrs for male and 29 yrs for female. Infant mortality has also declined to appreciable extent. It fell from a level of 204 per 1000 live births to 129 by 1978-79. India’s progress in controlling widespread disease is equally impressive. Due to the availability of wide ranging drugs and medical facilities small pox and plague have been eradicated and several other diseases are being cured effectively. (Narayana P.L, 1984) Thus the demand for drugs has resulted into wonderful health results in India.

Thus, the low cost of domestically produced drugs together with government controlled prices, and the absence of patent regulations had made the market less attractive for foreign players. With the new patent laws in place the market scenario will change. Indian market will become attractive for foreign companies.

The Indian pharmaceuticals sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products, meeting almost 95% of the country’s pharmaceutical needs. With a growing population and increased demand for antibiotics and medicines to resist, reduce, and prevent disease, there is an ever-increasing demand for quality pharmaceuticals and new medicines. Currently, the Indian pharmaceutical industry is estimated to be nearly a USD 4.6 billion market; it is predicted to continue to grow at a rate of eight to nine percent over the course of the next several years, and double in nearly a decade. (Narayana P.L, 1984)
According to Dr. Richard Gerster, "The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent." The industry ranks very high amongst other countries in terms of technology, quality, and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex inhalers, almost every type of medicine is now made within this country. In the beginning of 2005, pharmaceutical companies were granted patent protection for their products in India, due to the establishment of Indian Patents Third Amendment Bill. This product patent regulation and a growing population will make the Indian market an appealing proposition for foreign companies (Narayana P.L., 1984)

Demand for drugs for treatment of lifestyle-related diseases such as diabetes, cardiovascular diseases, and central nervous system are on the increase. There are around 700,000 new cases of cancer each year and total of around 2.5 million cases. (Narayana P.L.1984) It is estimated that there are around 40 million people in India with diabetes and the number is rising, 5.1 million HIV/AIDS patients, and 14 million tuberculosis cases. According to industry reports, while the Indian pharmaceutical industry witnessed a growth of 7 percent, the cardio-vascular segment recorded 15 to 17 percent growth and anti-diabetes segment of over 10-12 percent growth. (Narayana P.L., 1984)

Indian Pharmaceutical Industry is playing a key role in promoting and sustaining development in the vital field of medicines. Around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets,
capsules, orals and vaccines is met by Indian pharmaceutical industry. A number of Indian pharmaceutical companies adhere to highest quality standards and are approved by regulatory authorities in USA and UK (Narayana P.L, 1984)

Pharmaceutical Industry in India has been de-licensed and industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are now free to produce any drug duly approved by the Drug Control Authority. Indian pharmaceutical industry got a major boost with the signing of General Agreement on Tariffs and Trade in January 2005 with which India began recognizing global patents. After recognizing the global patent regime the Indian pharmaceutical market became a sought after destination for foreign players (Narayana P.L, 1984)

The future of Indian pharmaceutical sector looks extremely positive. Indian pharmaceutical companies are vying for the branded generic drug space to register their global presence. Several Indian pharmaceutical companies have acquired companies in the US and Europe and many others are raising funds to do so. For example, Ranbaxy acquired Romania's Terapia, Ethimed NV of Belgium and GSK's generic business Allen SpA in Italy. Dr Reddy's acquired German generic drug maker Betapharm. Companies like Glenmark Pharma, Lupin, Aurobindo and Jubilant Organosys are on the lookout for lucrative acquisitions (Narayana P.L, 1984)
3.2.1. Macro economic factors affecting the demand for drugs and medicines

These macro economic factors affecting the demand for drugs and medicines from Krishnaphani Kesiraju report discusses the macro economic factors affecting this industry which are summarized as follows:

i.) Changing Disease Profile

The disease profile in India is changing. This is a result of factors like urbanization and improved economic status resulting in undesirable changes in lifestyle of people, in the form of diet rich in saturated fat, salt and excess calories, decreased physical activities, addiction like tobacco and alcohol and the augmentation of psychological stress. These have led to various health problems like increased stress levels, hypertension, insomnia, cardiovascular diseases, respiratory problems, etc. These new health problems and disorders throw an avenue for the pharmaceutical companies to cater to. These lifestyle related diseases/problems are in addition to an already existing pool of diseases like HIV, tuberculosis, malaria, hepatitis-B, etc. (Krishnaphani Kesiraju, 2003)

ii.) Increasing Health Consciousness

Health consciousness among the people is increasing due to increasing literacy rate, which has increased from 52.2 percent in 1991 to 65.38 percent in 2001 and increasing media reach. This has resulted in an increased awareness and the need for better and high quality drugs. (Krishnaphani Kesiraju, 2003)
iii.) Increased Life Expectancy and Female Literacy

In 1991, 17 percent of India’s population (145 million) was aged over 45 years (Census of India 1991 & 2001), and by 2005, the number is expected to grow to 310 million. This represents an attractive opportunity for segments that affect middle-aged people. Anecdotal evidence suggests that Indians are getting chronic diseases like diabetes, cardiovascular at an younger age, perhaps due to increased stress and strain. The female literacy level is rising faster than the male literacy level. From 1971 to 2001, female literacy increased from 22 percent to 54.16 percent, and this number is expected to increase further. Female life expectation has also increased from 45 years to 59 years over the 1971-91 period. This trend is likely to continue and is expected to result in increasing demand for feminine hygiene products for all ages, birth control measures as well as preventive medicines for children such as vaccines.

iv.) Legal Factors

The pharmaceutical industry has to comply with various parameters, namely:

- Manufacture and import;
- Patent;
- Animal testing, clinical trials and marketing, labeling and packing;
- Price;
- Quality;
- Advertisements.

Of the above the most significant are the patents and price control.
v.) Patent Related Factors

a.) The Indian Patent Act currently recognized only process patents until 2005. With the signing of WTO, India was required to change its then Intellectual Property Laws to recognize product patents. Further, the term of the patents now have to be extended from 5-7, to 20 years. India had time till the year 2004. Post-2004, WTO agreement requirements have come into force.

b.) India has, with an amendment to the Indian Patent Act in 1999, allowed acceptance of applications for product patents for drugs and medicines, except for chemical substances which are intermediates in the preparation or manufacture of medicines or drugs. Such applications were processed only after the year 2004.

c.) Though not an Indian regulation, but a regulation of the United States of America, this is relevant for the Indian Pharmaceutical Industry as, they would be bound by it, in case they export or supply generic drugs or medicines to US, which is a major market for the Indian pharmaceutical industry.

d.) The "Drug Price Competition and Patent Term Restoration Act of 1984," in United States, also known as the Waxman-Hatch Act, was enacted to streamline the approval process for the USFDA to use in approving generic versions of previously approved branded drugs without conducting costly and duplicative clinical trials. This poses a major opportunity for countries like India, who have the expertise to manufacture drugs at low costs. It is estimated that the size of the generics market would approximately reach $60 billion by year 2005, creating a huge market for generics drugs.
vi.) Price Related Factors

The Drug Price Control Order (DPCO) is an order issued by the Government of India under the Essential Commodities Act to regulate the prices of drugs. The Order *inter alia* provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by government, penalties for contravention of provisions etc. It is administered by the National Pharmaceutical Pricing Authority (NPPA).

Originally, DPCO brought about 350 bulk drugs under its purview. However, the number of drugs under the ambit of DPCO has been gradually reduced. At present about 38 bulk drugs and their formulations are covered by the DPCO. The criteria for including a bulk drug under DPCO are:

- The turnover of the bulk drug is more than Rs.25 crore and the market share, of any of the formulators is 50 percent or more.

- The turnover of the bulk drug less than Rs.25 crore but more than Rs.10 crore and the market share; of any of the formulators is 90 percent or more.

- All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control.

DPCO, 1995 limited the profitability of pharmaceutical companies, through its Third Schedule. However, the Pharma Policy 2002 has proposed to do away with this. The policy has also exempted drugs developed through indigenous R&D efforts from price controls.
vii) Other Economic Factors

- Low Accessibility to Drugs due to Low Income and Poor Infrastructure

The accessibility to drugs and medicines is attached a social aspect of human life, healthcare and welfare. Consequently accessibility to quality healthcare is an essential parameter for the growth and development of any economy. It is for this reason only that the WTO has recognized the supremacy of affordability of drugs over patents.

- Income of the people: This factor captures the affordability of the people to proper healthcare. The per capita Gross National Product (GNP) currently in India was Rs.19,592 (CMIE), around earlier years of new century which was significantly lower than that of many other developed and developing nations. India's per capita GNP is estimated at around USD450 compared to USD32230 of Japan and USD780 of China (World Development Report 2000/2001). The average annual per capita expenditure on drugs and medicines in India was only USD 3, around late nineties which is miserably less than that of other countries (OPPI).

- On the marketing side, since the pharmaceutical companies target doctors and chemists to sell, the latter were under no compulsion to sell the lowest selling drug to the consumer. Around 80 percent of drug sales are from the private rather than the public sector. Therefore, it comes as no surprise that medical care costs have been spiraling and medical costs have emerged as the second commonest cause of rural indebtedness (NCAER 1995)
i.) Infrastructure availability:

Another factor that influences the accessibility of drugs is the infrastructure facility in the economy. The infrastructure availability determines the distribution of the drugs, as only a small percentage of the total drugs available are Over the counter (OTC) drugs, others either being prescribed by the doctors or are to be administered under medical supervision.

Absence of an efficient healthcare infrastructure not only restricts the distribution or reach of medicines and drugs but also poses several risk and hazards. Sporadic supply, a lack of medical oversight, or inappropriate use of certain drugs not only harms the health of patients but may also encourage drug-resistant strains of certain diseases, posing a substantial public-health risk. In addition, the absence of a secure distribution system for these valuable drugs encourages theft, substitution, and parallel trade. (Mc Kinsey Quarterly, 2000)

Only 35 percent of the population had access to essential drugs. This depicts the pathetic situation prevalent in the country. (World Development Indicators, 2001)

Sufficient number of hospitals, clinics, doctors in every area, and good transportation facility are determinants of a sound healthcare infrastructure. This is very low in India, which in turn has constrained and restricted the full and complete growth of the Indian Pharmaceutical Industry.

The need to bridge the gap between number of hospital beds and the population in India, can be understood by the fact that, around 2000-2001 currently there was one hospital bed for every 1300 people at the national level as against the world standard of one bed for 250 people. (Dr Pratap Reddy, 2001)
ii.) Poor Availability of Finance to the Industry

Companies do not have access to sufficient amount of funds from the banking system, which in turn has stifled the growth opportunities of these companies. (Krishnaphani Kesiraju, 2003) The government has promised way back in year 2000 a budgetary allocation of Rs.150 crore to a Research and Development Fund, every year for 10 years, after which it was expected that the industry would become self-sustaining. The fund size is very small and moreover, going by this promise, Rs.300 crore should have already been made available by now to any company wanting to make investment in research and development. However, the industry has been crying foul over such false promises as not any amount is claimed to have been disbursed.

The government, to encourage investment in the industry, (in year 2001) permitted 100 percent Foreign Direct Investment (raised from 74 percent in March 2000) through automatic route in the pharmaceutical industry. However, slow progress on introducing Intellectual Property Rights in line with the WTO requirements, has impaired FDI in India.

Further, to create an investment friendly environment, the government has also done away with the industrial licensing for the manufacture of all drugs and Pharmaceuticals except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations. Reservation of 5 drugs for manufacture by the public sector was also abolished in 1999, thus opening them up for manufacture by the private sector.
iii.) Medical Insurance

Health insurance is a safeguard against rising medical costs. Hence health insurance has become a necessity in today’s world. The cost of medical care and treatment has soared to new heights in recent years and is expected to rise even further in the years to come. Health insurance can shield an individual from the risk of having to bear the enormous medical costs in case of a major injury or life-threatening illness.

Health insurance can be a good stimulant for the overall healthcare sector and certainly to the pharmaceutical industry. One step that could potentially drive down premiums was to make health cover mandatory. However, this is not possible in the current scenario (as the per capita income is quite low. If the health cover is made mandatory, the disposable income available with the people would be further reduced).

While 87 percent of the total expenditure on healthcare in India is private sector spending, 84.6 percent is out of pocket. Voluntary health insurance accounts for a meager 2.4 percent of the total expenditure on healthcare. (The World Health Report, 2000) This reflects the huge potential for health insurance.

The current insurance laws do not act as a deterrent for health insurance. In fact, the law clearly stipulates that the regulatory body should encourage health insurance. Thus, health insurance, needs to be encouraged which would give a boost to the healthcare sector and more so to the pharmaceutical industry.

viii.) Political Factors

**Threat of Bio-warfare:** The threat of bio-war looming over the world economy has brought the pharmaceutical industry in focus worldwide. The key to tackling such an attack is a sound healthcare system where primary healthcare centers are linked to
sound diagnostic laboratories and these share information across the world. This in turn has induced greater R&D activities by the pharmaceutical companies, so as to be able to meet such an attack, if any, within the least possible time. (Kaushesh Anshul, 2003) For instance, the anthrax scare has prompted a number of countries to stockpile this drug for possible treatment. While ciprofloxacin is not the only drug that can be used - penicillin and doxycycline are other medications - it is the preferred drug in the US. The German company said it would triple production. (Krishnapani Kesiraju, 2003)

ix.) Technology Related Factors

The Indian pharmaceutical industry has grown and thrived due to the process patents in force through the Indian Patents Act, 1970. Due to the process patents being in force, research in the Indian Pharmaceutical Industry was hitherto focused on process re-engineering and development of drug delivery systems. However, this is changing due to the inevitable introduction of the product patents in the country. The emphasis is shifting on research into the discovery of new chemical entities. Opportunities for Indian companies to participate in new product development lies in building the capability, to carry out comprehensive international R&D programs. But, this requires deep pockets. Though R&D expenditure by the Indian pharmaceutical companies has increased over time, it still is very low compared to their global counterparts. (Krishnapani Kesiraju, 2003)

While the Indian investment in R&D has been hovering around 1.5-2 percent of the sales, the MNCs invest around 15-20 percent of their sales in R&D. Thus, there is still a long way for the Indian pharma companies to go, to match up with the resources for R&D
available with their global counterparts. (Krishnaphani Kesiraju, 2003 and CP Chandrashekhar and Ghosh Jayanthi)

The Indian pharmaceutical companies are increasingly becoming technology savvy, i.e. more and more companies are having state-of-the-art manufacturing facilities. This is evident from the fact that more and more companies are obtaining USFDA and UKMCA certification. This is coupled with their strength of producing drugs at very low prices. (Krishnaphani Kesiraju, 2003 and Nair Satyan, 2001)

The manufacturing technology forms the backbone of not only the primary process involving the production of various bulk drugs from the raw materials and the intermediates, but also the secondary process involving the conversion of bulk drug into formulations. Formulations with a new delivery system or a highly specialized system like the multi-cell-multilayer, micro dialysis cell technology, timed release, HTS, combinatorial chemistry, micro-encapsulation, etc., are highly technology intensive. In the years to come, this technological component is certainly going to be the driving force in the pharmaceutical industry. Technology has always played a significant role in improving the patient's compliance and it is certainly expected to do so in future.

x.) Population Related Factors

In pharmaceutical markets, product demand is strongly influenced by the size of the country and the economic segmentation of the population. The affordability percentage of population is the primary measurable indicator of drug consumption.

For instance, in 1995, American consumers paid 52 percent of their pharmaceutical costs directly, constituting 30 percent of total out-of-pocket health expenditures. The situation in Europe and Japan is much worse, where the society faces even higher age averages,
combined with a shrinking population incapable of supporting growing expenditures. Thus the real consumption of drugs will grow manifold in the years to come. (Krishnaphani Kesiraju, 2003 and Datta Jyothi, 2002)

3.2. Demand faced by Indian Pharmaceutical Industry and Growth Prospects of the Industry

The industry has enormous growth potential. The factors below determine the rising demand for pharmaceutical:

- The growing population of over of a billion
- Increasing income
- Demand for quality healthcare service
- Changing lifestyle has led to change is disease patterns, and increased demand for new medicines to combat lifestyle related diseases.

More than 85% of the formulations produced in the country are sold in the domestic market. India is largely self-sufficient in case of formulations. Some life saving new generation under patent formulations continue to be imported, especially by MNCs, which then market them in India. Overall the size of the domestic formulations market is around Rs 160 billion and it is growing at 10% per annum. (Mickey Smith)

Export Demand

Over 60% of India’s bulk drug production is exported. India’s pharmaceutical exports are Rs 87 billion of which formulations contribute nearly 55% and the rest 45%
comes from bulk drugs. In the financial year 2005 exports grew by 21%. The India pharmaceutical market has been forecasted to grow to as much as USD 25 billion by 2010 as per Organization of Pharmaceutical Products of India (OPPI) estimates.

Domestic pharmaceutical exports growing at 30% per annum touched a new height of USD 4.8 billion in the financial year 2006-07.

3.3. Overview of the pharmaceutical market place

Fig 3.1 Forces driving industry competition

Source: The structural analysis of industries
3.3.1. Market structure Of Pharmaceutical Industry

Competition in an industry continually works to drive down the rate of return on invested capital toward the competitive return that would be earned by perfectly competitive industry. The presence of rates of return higher than the adjusted free market return serves to stimulate the inflow of capital into an industry either through new entry or through additional investment by existing competitors. The strength of the competitive forces in an industry determines the degree to which this inflow of investment occurs and drives the return to the free market level and thus the ability of firms to sustain above average returns. (Pharmaceuticals Industry Analysis Report, 2008)

The five competitive forces—entry threat of substitution, bargaining power of supplier and rivalry among current competitors—reflect the fact that competition in industry goes well beyond the established players. Customers, supplier's substitutes and potential entrants are all competitors to firms, in the industry and may be more or less prominent depending on the particular circumstances.

All five competitive forces jointly determine the intensity of industry competition and profitability and the strongest force or forces are governing and become crucial from the point of view of strategy formulation. The traditional structure - behavior performance approach ignores the question of how market structures are developed in the first place. It does not take account of product and market characteristics and in particular the nature prescribing decision. It also ignores the fact that in the pharmaceutical industry at least market share is a critical performance criterion: a
dominant position in a few market segments is a prerequisite for successful company. Market behavior has great impact on market structure as market structure has on behavior of companies in the market place.

Traditional theory suggests that product differentiation can give sellers some discretion in their pricing policies, but whether these results in profits over and above the normal rate of return on capital remain to be established. A priori reasoning however does not indicate whether the levels of advertising or profits are higher under monopoly/oligopoly.

The principal question raised by theory is that heavy advertising may lead to increased market concentration and possibility of excess profits. The mechanism by which this might begin is by economies of scale in advertising and erection of entry barriers.

Camanor and Wilson found a positive and statistically significant relationship between the advertising sales ratio and return on stockholders equity taking into capital goods, production scale economies and market concentration. Advertising is an important source of monopoly profit. In the context of pharmaceutical the dominant features are:

- Research expenditures lead to improved and new brands
- Very little price competition
- Intense rivalry in selling expenditures
- Highly oligopolistic structure in therapeutic classes
While no direct relationship appears to exist between concentration levels and sales/promotion ratio in the pharmaceutical industry, the nature of competition (level of concentration) in the individual therapeutic categories still has effect on most marketing decisions. Decisions relating to new products, product pricing and level of promotional expenditure can be made, particularly in an oligopolistic market without regard to the strengths, weakness and actions of competitors. High market shares can provide companies with definite marketing advantages due to economies of scale in marketing and brand loyalty. In turn firm's marketing decisions—which is marketing strategy— also affect the level of economic concentration depending on the extent to which they affect the market share.

The event that determines whether a company's product achieves a high or low market share is whether or not it obtains doctor acceptance an event which itself is a function of the level of promotional expenditure at the time of product introduction and the inherent therapeutic quality of the drug. The quality of drug vis a vis existing competitors is in turn a function of the quality and direction of the firms R and D efforts. The market share is in itself likely to be one of the factors that determines or at the very least acts as a constraint on marketing decisions.

3.4. Pharmaceutical market segmentation

Marketing depends upon what products or services you have to offer and to whom you want to offer them. The various dimensions of pharmaceutical market are:
• The demographic dimension i.e. geographical proximity of customers and some shared Socio-economic traits such as age, income, sex, educational level and family size.

• The generic dimension: this comprises the generic present in a number of formulation

• The therapeutic group: This comprises all the products aimed at relieving, treating and curing the same symptom diseases; eg: all products aimed at relieving, treating and curing "asthma" come under as"anti-asthmatic therapeutic group

• Competitive dimension: Apart from the size of the market the extents of competition i.e. number of competitors their share of the market; all these are important in determining the attractiveness and unattractiveness of market; eg: introducing yet another co-trimoxazole preparation.

This may not be an attractive proposal, though the market is large enough at Rs 96 cr and is growing at 5% (1992). Because there are over one hundred and one co-trimoxazole brands, competing with each other, it is worthwhile to enter the market if its distinctly superior dosage from greater safety margin; (Subba Rao Chaganti, 2007) Continuous monitoring of competitors activities is crucial for success in the market place. The feature of pharmaceutical marketing is that it reaches the end consumer (patient) through an intermediate consumer (physician who advices the end consumer through a prescription)
The two major potential target group that is patient (consumer) and doctors (customers). They have different needs. Segmentation is at consumer level (patient). The second logical step is at customer level (doctor) whether he is a general practitioner or a specialist or a hospital doctor, he is the influence!" when we define 'market" as individual and organizations with purchasing power desire and authority to buy products and services, the focus is clearly on the opportunity.

Source: Pharma Marketing in India -- Concepts Strategy Cases
To visualize a profile of market one views the market from all possible dimensions:

1. The size of geographical market - this information is needed both in terms of volume, value and the number of prescription generated.

2. The size of market by "therapeutic group" to the total pharmaceutical market by volume, value and the number of prescriptions in therapeutic category.

3. The size of the market by demographic both consumer i.e. the number of patient treated with demographic details with age groups, sex, location of treatment and income, education level etc and the customers.

4. The size of the prescription market the number of prescription written in each sub therapeutic group of the major therapeutic category.

5. The size of competition - the number of competition operating in each segment, region with their respective shares of the total market resources strength and weakness.

6. The size of the market by volume - dealer network i.e. distributors and retail chemists according to the volume of purchases like heavy, medium low and by location. The size of the institutional market - by nature, frequency, volume and type of purchases and by location. The most important way of segmenting the pharmaceutical market is by the various therapeutic groups. (Chaganti Subba Rao, 2007)
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<tr>
<th>Therapeutic Segments (%)</th>
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<td>1 Antiinfective</td>
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<td>2 Antipyretic analgesic</td>
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<td>2.7</td>
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<td>17 Others</td>
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Source: CMIE

In any given market there are different segments of the market, comprising groups of customers with varying needs: these customer groups select the competitive offerings that best suit their needs. This process creates market segments. Each competitor thus has some group of customers where he holds an absolute advantage over all other
competitors. He offers a benefit package of products and services that is best suited for his specific target customers.

Pharmaceutical market segmentation is a two step process. One is at the level of the customer (the doctor) and second level or base of segmentation being the consumer (the patient who is the end user). The pharmaceutical market can be segmented in number of ways such as therapeutic category, by severity of disease, by place of treatment, by type of practice etc. (Chaganti Subba Rao, 2007)

3.4.1. The pharmaceutical market (9 P's) promotion and place

A branded product therefore has the extra promise of customer satisfaction and customer satisfying. Brand has defined as, name, term symbol or design or combination of them which identifies the goods and services of one seller or group of sellers and to differentiate them from those of competitors.

Augmentation of the product is very essential in branding, particularly in the Pharmaceutical industry in India. In the Indian Pharmaceutical industry product augmentation is a must for survival and growth of brands. This is not because R and D activity is very high and therefore a number of newer and newer drugs are developed, making the existing products obsolete at faster rate. The main reason for the licensing policy of the government, which encourages the small scale sector even in a sophisticated, biotechnology industry like Pharmaceutical company which consider that branding means augmenting the product by creating and communicating the effectively are bound to succeed e.g.: there are umpteen number of brands of paracetamol in India products with different names only and not brands.
3.4.2. The product augmentation in the Indian pharmaceutical industry

A product is not what it is but what it does to the customer. They buy the benefits that the product offers. A person who buys some aspirin is not buying aspirin as such; he is buying relief from headache. Similarly when a doctor prescribes a recent antibiotic like ciprofloxacin, he is not prescribing it because it is the latest antibiotic. He is prescribing it because of its superior anti-bacterial power and its ability to control the infection.

While generic product is an undifferentiated product, a brand is the differentiated product e.g. ranitidine, the antiulcer drug is a generic product but then you call it Zantec a totally different image, the image of the world's largest selling prescription drugs a very effective antiulcer. The brand name gives a distinct identity to the product. Creating and building up a brand image is more complex. It is the communication that makes the brand and gives it the distinct personality. Communication includes all internal elements of marketing mix known as product, price in real sense but only crocin and metacin are very successful brands.

Branding by product augmentation in the Pharmaceutical industry is achieved by creating differentiation in the manufacturing process changes in the formulation, packaging communication and by giving an appropriate suggestive, memorable brand name. Branding strategy is very important because it is through a clear branding strategy alone that a marketer can communicate the extra of his products. Thus branding is mainly a means of product identification helping the consumer to know the differentiated, augmented product from me too maze of innumerable products.
The advantages of brand over the product are many particular in Pharmaceutical industry.

The divisions of product life cycle into four phases determine the marketing inputs that are required at various stages. (Chaganti Subba Rao, 2007) Marketing inputs also vary at different stages of product life cycle. The introductory phase the demand for product nor the capabilities of the product to fulfill the customers needs are proved. Here effort is to direct the customers to try the product. The duration of the introductory stage depends on the complexity of the product, degree of newness and fits into customer need. The growth phase is also growth phase of market. The demand for product accelerates, the market expands.

The maturity phase is market saturation in the sense that all the potential customers have taken the product except those who have decided not to adopt it. Competitors at this stage try to finer product differentiations and resort to price wars. Competitive strategies include product augmentation efforts in packing advertising communication. The decline phase is terminal point of product life cycle. The pharmaceutical industry has countless e.g. of products well past their life and which in theory should be either in maturity or decline stage, but are still selling at high volume and making acceptable profits. Today in the Pharmaceutical industry more than ever before, successful maintenance of mature products becomes a vital part of product planning and management. This is because the rate of new, absolutely new drug launches is declining. (Chaganti Subba Rao, 2007)
Customers satisfy their needs only through the use of products. Customers image of a product and decisions to buy products or not in the future is influenced only by their experiences with the product. The customers with rewarding experiences of products are likely to indulge in repeated purchase. Decisions relating to products are crucial to marketing strategy. There are two main reasons why a company adds a product or two to its existing product mix when it realizes that its existing products don't have the potential to attain the growth and profit objectives, the company has set for itself. The company spots new products opportunities that can be exploited since they are matching its resources or that the company is confident of mobilizing.

In Pharmaceutical industries there are several possible categories of new products:

a.) Innovative: These are products which are really innovative and truly unique like cancer cure. For these products there is real need and there is a number of existing satisfactory substitutes.

b.) Replacements: Products which are essentially of the same type, but with a significant differentiation from the existing product can be classified in this. Ibuprofen and ferrous sulphate and folic acid are some. The basic idea here is to create a product differentiation even if the drug is the same, by combining it with another drug (to achieve synergy) or using drug delivery system (to achieve a higher degree of safety and minimize the doze) and to achieve bigger share of the market.

c.) Imitative: Products in this category are new to the company but not to the market. The purpose of introducing products of this category is that company merely wants to
capture part of an existing maker with yet another brand of an existing type of product. The Pharmaceutical industry in India is flooded with imitative products and it is this category of products that have made Pharmaceutical market in India fiercely competitive.

Some firms pursue a policy of diversification. Others may prefer to concentrate and specialize in specific area and offer product mix e.g. Serum Institute of India specialize only in the area of immunological drugs. It is important to note that market opportunities for the firm's product mix serve to determine the upper limit for potential. Corporate profitability, while the quality of marketing programme tends to determine the extent to which this potential is achieved.

Marketing channel requires a minimum, of two parties in so far as the manufacturers of prescriptions drug is concerned the law requires that at least one intermediary stands between the manufacturer and the consumer-i.e. the doctor. It is illegal for the manufacturer to sell prescription drugs directly to the patient. The physician are not considered as a member of distribution channel. Instead he is considered influencer or intermediary customer. One can't overlook the role of the pharmacists and need of their services in the process of drug distribution. The pharmacist in the distribution channel could be either retail pharmacist who is a retail chemist or druggist or hospital pharmacist.(see Fig.3.3)

Another feature of pharmaceutical distribution in India is that only a licensed person can manufacture and sell allopathic drug. It is imperative that retail chemist or druggist should also be qualified and licensed to sell pharmaceutical preparations. The
minimum qualification for a registered pharmacist who can dispense medicine on the prescription of medical practitioner is Diploma in Pharmacy. Since pharmaceutical products are concerned with the health of the people it is essential that the persons who dispense the drugs on prescription of doctors, possess adequate technical knowledge. Only then, can they interact and communicate with consumers regarding matters related to the dosage, side effects and drug interaction.

Fig 3.3 Pharma distribution Channel

Source: Pharma Marketing in India; Subba Rao Chaganti, 2007
Currently there are a number of unqualified but experienced persons working in various pharmacies. If the 1979 amendment of the Pharmacy Act is strictly implemented there would be a severe shortage of qualified pharmacists in the country. Any company competing in the Indian pharmaceutical market has a relatively simple choice in so far as distribution channels are concerned. It has become mandatory for every manufacturer to distribute their product through stockist/wholesaler who in turn resells them to retailer and retailer finally sells to consumer (patient). In India pharmaceutical or manufacturer can never hope to reach the retailer directly. (Chaganti Subba Rao, 2007)

**Global pharmaceutical market place**

Factors that affect the pharmaceutical demand include economic demographic and sociopolitical factors. According to Madhu Agarwal factors affecting pharmaceutical competitiveness at the national and industry levels. The predefined factors on potentially related variables such as pharmaceutical market size, industry growth and R and D expenditure at the national level:

**TABLE 3.2: FACTORS ON POTENTIALLY RELATED VARIABLES OF PHARMACEUTICAL INDUSTRY**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Type of influence</th>
<th>Influence on</th>
</tr>
</thead>
<tbody>
<tr>
<td>GNP</td>
<td>positive</td>
<td>Industry growth</td>
</tr>
<tr>
<td>Price regulation</td>
<td>negative</td>
<td>Market size</td>
</tr>
<tr>
<td>Price regulation</td>
<td>negative</td>
<td>R and D expenditure</td>
</tr>
<tr>
<td>Population size</td>
<td>positive</td>
<td>Market sizes and industry</td>
</tr>
<tr>
<td>Approval time</td>
<td>negative</td>
<td>Market size</td>
</tr>
<tr>
<td>Approval time</td>
<td>negative</td>
<td>R and D expenditure</td>
</tr>
<tr>
<td>R and D expenditure</td>
<td>positive</td>
<td>Global sales</td>
</tr>
</tbody>
</table>
Patent expiration issues have put new pressure on the pharmaceutical industry. The economic value of an innovation is directly correlated with the length of its legal protection. Thus pharmaceutical companies must manage the legal framework to extend the exclusivity rights on a product. The trade related intellectual property right agreements requires WTO member countries to make patent available for any inventions—whether products or processes—in all the fields of technology without discrimination. During the term, a patented molecule is protected from the introduction of generics. (www.ibef.org, 2008)

However competitors can introduce modified molecules designated as me too drugs. The first mover advantage applies in the pharmaceutical industry as the first commercialized drug maintains leadership in term of market share, even it may face competition from me too drugs. Today the cost of developing a new drug is estimated at USD 500 million. Nearly two third of the medicines on the market today would not have been developed had there not been patent protection offering economic incentives for such enormous investments. According to Pharmaceutical Research and Manufacturer Association (PhRMA) countries like Argentina, India, Egypt South Africa, China, Israel, Canada and Turkey are infringing on international treaties that, is costing US $ 9 billion per year. (Kaushesh Anshul, 2003)

The main determinant of pharmaceutical price in a specific country is its per capita income level. With the demand for medication being inelastic, the demand is influenced by the level of income and increases with an individual’s wealth. The prices of pharmaceutical products vary widely among countries because of the differences in living standard income level, consumer preferences, disease pattern,
drug consumption patterns, product volume, exchange rates, product liability, regulatory requirement the degree of competition in market for healthcare and pharmaceutical and government interventions. Price regulation is common in a few European Union countries and price control policies are set according to each country's profile and reimbursement policies and regulate prices by modifying the amount paid out of pocket.

In pharmaceutical markets, product demand is strongly influenced by the size of the country and economic segmentation of the population. The affordability percentage of population is the primary measurable indicator of drug consumption. In 1995 American consumers paid 52% of their pharmaceutical costs directly, constituting 30% of total out of pocket health expenditure. Moreover, the US population of age 65 and over is expected to increase from 12.64% in 2000 to 13.3% by 2010 and this will lead to increased pharmaceutical consumption. The situation in Europe and Japan is much more worse. (Kaushesh Anshul, 2003)

Firms in the US are better placed, as the US market does not have price controls on pharmaceutical. This encourages pharmaceutical companies to bring innovative products to market. The development process from the new molecular entity takes nearly 15 yrs and cost as much as USD 650 million. Even though the approval time required by the US Food and Drug Administration (USFDA) is quite lengthy, it does not adversely affect innovation.

The size of a nation's economy or GDP and the size of its population generally determine the presence of a pharmaceutical market and govern the development of the nation's pharmaceutical industry.
### TABLE 3.3: LARGEST PHARMACEUTICAL MARKET

<table>
<thead>
<tr>
<th>Country</th>
<th>Drug Purchase (USD million) Sep-99</th>
<th>Population million Sep-00</th>
<th>2000</th>
<th>2000</th>
<th>1999</th>
<th>0-14</th>
<th>64</th>
<th>65+</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S</td>
<td>82023</td>
<td>94287</td>
<td>276</td>
<td>341.62</td>
<td>9265</td>
<td>41</td>
<td>66</td>
<td>13</td>
</tr>
<tr>
<td>Japan</td>
<td>54575</td>
<td>51774</td>
<td>126.5</td>
<td>409.28</td>
<td>2950</td>
<td>15</td>
<td>68</td>
<td>17</td>
</tr>
<tr>
<td>Germany</td>
<td>16204</td>
<td>14762</td>
<td>82.8</td>
<td>178.29</td>
<td>1864</td>
<td>16</td>
<td>68</td>
<td>16</td>
</tr>
<tr>
<td>France</td>
<td>14348</td>
<td>13689</td>
<td>59.3</td>
<td>23.84</td>
<td>1373</td>
<td>19</td>
<td>65</td>
<td>16</td>
</tr>
<tr>
<td>Italy</td>
<td>9544</td>
<td>9279</td>
<td>57.6</td>
<td>161.09</td>
<td>1212</td>
<td>14</td>
<td>68</td>
<td>18</td>
</tr>
<tr>
<td>U.K.</td>
<td>8791</td>
<td>9111</td>
<td>59.5</td>
<td>153.13</td>
<td>1290</td>
<td>19</td>
<td>65</td>
<td>16</td>
</tr>
<tr>
<td>Spain</td>
<td>5688</td>
<td>5392</td>
<td>40</td>
<td>134.8</td>
<td>677</td>
<td>15</td>
<td>68</td>
<td>17</td>
</tr>
<tr>
<td>Canada</td>
<td>4563</td>
<td>5375</td>
<td>31.3</td>
<td>171.73</td>
<td>722</td>
<td>19</td>
<td>68</td>
<td>13</td>
</tr>
<tr>
<td>Brazil</td>
<td>5255</td>
<td>5129</td>
<td>172.9</td>
<td>29.66</td>
<td>1057</td>
<td>29</td>
<td>66</td>
<td>5</td>
</tr>
<tr>
<td>Mexico</td>
<td>3758</td>
<td>4692</td>
<td>100.4</td>
<td>46.73</td>
<td>865</td>
<td>34</td>
<td>62</td>
<td>4</td>
</tr>
<tr>
<td>Argentina</td>
<td>3484</td>
<td>3414</td>
<td>37</td>
<td>92.27</td>
<td>367</td>
<td>27</td>
<td>63</td>
<td>10</td>
</tr>
<tr>
<td>Australia</td>
<td>2756</td>
<td>2896</td>
<td>23</td>
<td>125.91</td>
<td>480</td>
<td>21</td>
<td>67</td>
<td>12</td>
</tr>
</tbody>
</table>

Japan's Pharmaceutical Market

The Japanese pharmaceutical market is the second largest after the US. It grew 30 times between 1970 and 1980. The pharmaceutical sales in Japan represents 18% of the world market. The reasons for growth are prescribing habits of Japanese physicians, level of reimbursement of country's wealth and government regulation concerning intellectual property and foreign trade. The patent law was reformed in 1980's and Japan started recognizing product patents the protected Japanese industry was thrown open to competition which led to shake out in the country's pharmaceutical sector. Today only two Japanese companies, Takeda and Sankyo are listed among the world's top 20 producers of pharmaceuticals. (Kaushesh Anshul, 2003)

Pharmaceutical Market for European Union

An unstable regulatory framework, lack of clear policies for the industry and fragmented price levels and reimbursement policies characterize the European market. Each member state has its own price and reimbursement regulations for pharmaceutical products to control costs.

Some of the world's top 20 pharmaceutical companies Aventis, Glaxo Smith Kline, Novartis, Astra Zeneca Roche, Bayer and Sanofi Synthelabs are from Europe. European companies accounted for 40% of the world's pharmaceutical production in 1998 but more than half of sales of new medicines are generated from US while only a quarter of sales from the European counties. (Kaushesh Anshul 2003) There was sharp decline of new product filing by European companies in the decade of the 1990s while the American share increased by more than 20%. Although the pharmaceutical
expenditure to total share of the GDP is lower in countries with the highest levels of GDP. The Northern European countries have lowest expenditures per capita on drugs while the Mediterranean countries and Belgium have the highest drug expenditure per capita despite the overall growth in value terms.

**Pharmaceutical Market for Germany**

In the German pharmaceutical market, market shares for individual groups are relatively low as compared with the pharmaceutical markets of other major pharmaceutical producing countries. The German companies have 40% market share, followed by US firms with 22%, Swiss with 11%, and British and French with 9% each. The production capacities abroad, along with foreign demand, decide production in the German pharmaceutical industry. In 1999 total revenue from pharmaceutical exports was USD12.2 billion, major market being US, Switzerland, France, UK and Italy while Germany import largely from Ireland, UK, Switzerland and France.

France: ranks third in per capita consumption of pharmaceutical drugs after Japan and US and ranks 4th in terms of market size. France is the largest producer of drugs in Europe producing more than USD20 billion worth of drugs, French companies produce nearly 40% while foreign companies and their subsidiaries make up for the rest. Aventis and Sanofi Synthe laboratories are the major French companies. (Kaushesh Anshul, 2003)

**Pharmaceutical Market for United Kingdom:**

The pharmaceutical market in UK can be divided into two segments, prescription medicines (80%) and OTC medicines (20% and retail market drugs and
pharmaceutical were USD 9.1 billion in 2000. The UK is the fifth largest manufacturer of pharmaceuticals worldwide, with total production in 1998 reaching USD 16,552 million. World's pharmaceutical companies are from the UK including Glaxo Smith Kline and Astra Zeneca and D expenditures were approximately USD 4.1 billion in 1998 and UK is a net exporter of pharmaceuticals. In 1996 the major import market was the US with 15% share, Germany 15%, France with 12% and Switzerland 11. (Kaushesh Anshul 2003)

Mexico is expected to have the highest growth rates in Latin America by 2003 given its growing economy and population. The increased share of population is able to afford medication. In 1998 Mexico was net importer of medication while the main buyers were Panama, Columbia Venezuela and Brazil and main exporter Mexico and US.

**Emerging markets For Pharmaceuticals:**

The Asian pharmaceutical market is expected to grow at healthy rate over the next couple of years and the Eastern European market also has become attractive for investment. Hence the pharmaceutical market is of great importance in these emerging markets. The main markets are China, India and niche countries such as Singapore. China domestic market is growing at rate of 10%. China promotes non-branded generic production. Overproduction while only those products of foreign companies are listed for which there is no substitute. The lack of intellectual property rights enforcement and regulatory barriers are the concern of the global pharmaceutical industry.
India is considered as one of the biggest markets for pharmaceutical with a huge middle class population that is growing not only in number but economically. India's share is 8% of total drugs sold globally in volume terms while in value terms it is only 1% of global market. The low cost of production facilities are attractive as a way to outsource production of both bulk actives for export market. India can become the home for cheap generic to be exported to small countries that don't have the production capabilities for local manufacturing. As member of WTO, India is committed to adopt international patent standards by 2005. The local companies can partner with multinational companies to develop and produce world class products at low cost. (Kaushesh Anshul, 2003)

3.5. Indian pharmaceutical marketplace

India with global ambitions is just starting to grow up. Expanding overseas generic market, rapid change in the technology, an increasing domestic generic market and a restrictive patent regime are challenging many of the well established strategies in this field. Few big forces will power this transition.

First huge generic opportunity is pursuing India pharmaceutical companies to shift their focus to western countries for sustained profitability. Second, the overshooting drug development and lowering R and D productivity is shifting manufacturing bases of global pharmaceutical companies to countries like India that can produce quality products at low costs. Hence huge opportunities are opening up for domestic companies. Third rapid change in research and technology is shifting clinical testing to low cost countries to cut research expenses, provides scope to India. Fourth the
demand for pharmaceutical products in the domestic market is expected to witness healthy growth led mainly by the growth in lifestyle related segment as cardiovascular, central nervous system, diabetes. Finally India recognizing product patents post -2005, many of the patented drugs of multinational will be launched in the domestic market and IPR protection to consolidation.

Research is not only activity that India's pharmaceutical industry is focusing upon. Companies are acquiring other companies at home and abroad, they are also buying brands in India and chasing; foreign markets. They are increasing their R and D expenditure, setting up global marketing networks and acquiring production facilities in regulated market. MNCs are following a careful strategy of selecting products that have a long lifestyle, fetch good return. and are relevant to India.( Kaushesh Anshul, 2003)

The pharmaceutical industry in India is one of the largest and most advanced among the developing countries. It manufactures about 350 bulk drugs belonging to several major therapeutic areas and has developed excellent production facilities of all dosage forms such as tablets, capsules, liquids, orals and injectables. More than 30 manufacturing facilities for certain products have been approved by USFDA.

The USD$5.5 billion in 2001 Indian pharmaceutical industry ranks at the top in terms of the number of companies, 6th in terms of volume and among the top 15 in terms of value. And it is poised to grow to USD25 billion by 2010. The growth will come from R&D services, export of bulk drugs and generics, increased sales
in therapeutic areas relating to high specialty segments and better penetration into the market. The market is highly fragmented with more than 20,000 manufacturers. However, only 250 of them are in the organized sector representing 70 percent of the production. (Kaushesh Anshul, 2003)

The market is intensely competitive. Most of the Multinational Companies (MNCs) operate in India; but only 4 figure in the top 10. The top 10 pharma companies together cover around 31 percent of the total market. The pharmaceutical market in India is prescription-driven, branded generic market. Modern medicines reach only 26 percent of the total population in India, concentrated mostly in urban areas. The prescription market is around 80 percent, while rest of the market is covered by institutions/hospitals and dispensing doctors.

In India, antibiotics segment in the industry accounts for the largest market share followed by multi-vitamins and anti-inflammatory and anti-rheumatic segments. Antibiotics, vitamins, tonics, mineral supplements, anti-inflammatory, cough and cold preparations cover the top therapeutic groups. The greatest market potential exists in India's interior and rural markets, where the growth rate is estimated at 25 percent per annum. (Kaushesh Anshul, 2003)

3.5.1. How pharmaceutical market is different

The pharmaceutical market is unique in its reliance on person-to-person communication rather than mass media, as the main thrust of the marketing
effort. Thus the pharma salesperson, through whom most communications to the customer are channelized, can make or break the marketing strategy. A marketing program, in order to be successful must have a right mixture of marketing mix, not to mention market research, a quality product, an extensive distribution network, strong dose of promotion coupled with a right price.

3.5.2. Marketing Strategies in the Indian Pharma Market

The characteristic feature of the pharmaceutical marketing is that one reaches the end-customer (patient) through an intermediate customer (the physician who advises the end-customer through a prescription).

The US pharmaceutical industry spends something around USD 15.7 bn to promote its products through literature, journal advertising, sampling and DTC advertising i.e. around 14 percent of total revenues. Of the total expenditure, around 50 percent was spent on promotional activities through medical representatives. (Krishnaprani Kesiraju, 2003). This is the most traditional method of promoting drugs. But in India, marketing of prescription pharmaceuticals through mass media is not permissible, and in any case, would be inappropriate for many products. One-to-one communication to doctors is the norm. For this, a pharmaceutical company needs many field staff to regularly meet prospective and existing customers and promote the company's products. Thus the company's field representative becomes the chief link between the company and the doctor, often being described as the company's "ambassador" in the field.

The distribution network of pharmaceutical companies is organized either region-wise or product-wise. Generally, the entire market is segregated into different
territories with agents/dealers/distributors with dealers appointed region wise. But at times, companies as a precautionary measure appoint agents/distributors/dealers on a product-wise basis to cover more area. The second strategy would be ideal for the companies having a limited range of products. A distribution network supports the marketing network with depots/C&F agents covering the entire market.

Marketing of the pharma products includes marketing of both bulk drugs and formulations. Marketing of bulk drugs is totally different from that of formulations. In case of bulk drugs, the buyers are few in number and the manufacturer builds and maintains good relations with a few customers to whom he supplies regularly. As regards marketing of formulations, the company has to have a network of trained medical representatives to sell its products. Moreover, since the market for formulations is widely distributed, brand preferences need to be created. This makes selling of bulk drugs relatively simple when compared to selling of formulations. (Krishnaphani Kesiraju, 2003).

The traditional marketing approach of tailoring strategies to different physician and patient segments does provide a sound block for a product launch and marketing; its shortcoming, however, it relies on linear chain of events, i.e., a company targets specific audiences, develops its marketing mix and allocates resource-based on reaching these audiences and hopes that these audiences react as anticipated. The problem is that the outcome is often not as planned.

In today's complex marketing environment, astute business decisions require a comprehensive understanding of marketplace issues. Before launching any new product, it requires product concept evaluation, market potential analysis, product use profiling, and positioning strategies, while Indian firms need to evolve and
improve the competitive strength through innovation and strong marketing initiatives. Compared to innovative marketing approaches by western pharma companies, it is now high time for Indian pharmaceutical companies to gather better intelligence, predict the markets, including each segment's reaction to new drugs and develop, quantify and evaluate the impact of different marketing strategies. All these initiatives enable a company to identify before launch which marketing levers to pull and where to allocate the resources. (Krishnaprani Kesiraju, 2003).

**TABLE 3.4 INDIAN PHARMACEUTICAL INDUSTRIES:**

**TRENDS MARKET SHARE**

<table>
<thead>
<tr>
<th>Percentage Value</th>
<th>Annual Dec-00</th>
<th>Annual Dec-01</th>
<th>Annual Dec-02</th>
<th>Annual Dec-03</th>
<th>Annual Dec-04</th>
<th>Annual Dec-05</th>
<th>Annual Dec-06</th>
<th>Annual Dec-07</th>
<th>Annual Dec-08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs &amp; pharmaceuticals market shares: Ranbaxy Laboratories</td>
<td>5.89</td>
<td>5.7</td>
<td>5.77</td>
<td>8.07</td>
<td>9.02</td>
<td>9.02</td>
<td>7.63</td>
<td>6.96</td>
<td>6.41</td>
</tr>
<tr>
<td>Drugs &amp; pharmaceuticals market shares: Cipla</td>
<td>2.59</td>
<td>3.15</td>
<td>3.92</td>
<td>3.94</td>
<td>4.52</td>
<td>5.14</td>
<td>5.69</td>
<td>5.6</td>
<td>5.74</td>
</tr>
<tr>
<td>Drugs &amp; pharmaceuticals market shares: Dr. Reddy's Laboratories</td>
<td>1.64</td>
<td>2.95</td>
<td>4.68</td>
<td>4.32</td>
<td>4.21</td>
<td>3.83</td>
<td>4.11</td>
<td>5.94</td>
<td>4.92</td>
</tr>
<tr>
<td>Drugs &amp; pharmaceuticals market shares: Lupin</td>
<td>0.33</td>
<td>2.68</td>
<td>2.71</td>
<td>2.85</td>
<td>2.68</td>
<td>2.68</td>
<td>3.15</td>
<td>3.25</td>
<td>3.77</td>
</tr>
<tr>
<td>Drugs &amp; pharmaceuticals market shares: Sun Pharmaceutical</td>
<td>1.62</td>
<td>1.85</td>
<td>2.1</td>
<td>2.18</td>
<td>2.05</td>
<td>2.32</td>
<td>2.56</td>
<td>2.76</td>
<td>3.5</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
<td>Aurobindo Pharma</td>
<td>2.38</td>
<td>2.92</td>
<td>2.84</td>
<td>2.98</td>
<td>3.08</td>
<td>2.56</td>
<td>2.76</td>
<td>3.1</td>
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<tr>
<td>Drugs &amp; pharmaceuticals market shares:</td>
<td>Cadila Healthcare</td>
<td>1.56</td>
<td>1.45</td>
<td>1.6</td>
<td>2.5</td>
<td>2.49</td>
<td>2.45</td>
<td>2.42</td>
<td>2.35</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
<td>Glaxosmithkline Pharmaceuticals</td>
<td>3.26</td>
<td>2.83</td>
<td>2.97</td>
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<td>2.6</td>
<td>3.13</td>
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<td>2.56</td>
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<tr>
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<td>0.82</td>
<td>0.87</td>
<td>1.11</td>
<td>1.14</td>
<td>1.32</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
<td>Piramal Healthcare</td>
<td>1.14</td>
<td>1.18</td>
<td>1.65</td>
<td>1.76</td>
<td>1.93</td>
<td>1.76</td>
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<td>1.73</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
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<td>1.83</td>
<td>1.75</td>
<td>1.89</td>
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<td>Orchid Chemicals &amp; Pharmaceuticals</td>
<td>1.22</td>
<td>1.12</td>
<td>1.18</td>
<td>1.36</td>
<td>1.49</td>
<td>1.45</td>
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<tr>
<td>Drugs &amp; pharmaceuticals market shares:</td>
<td>Divi's Laboratories</td>
<td>0.52</td>
<td>0.57</td>
<td>0.59</td>
<td>0.63</td>
<td>0.71</td>
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<td>Ipca Laboratories</td>
<td>1.22</td>
<td>1.15</td>
<td>1.24</td>
<td>1.28</td>
<td>1.48</td>
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<tr>
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<td>Alembic</td>
<td>1.33</td>
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<td>1.4</td>
<td>1.26</td>
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<tr>
<td>Drugs &amp; pharmaceuticals</td>
<td>1.41</td>
<td>1.18</td>
<td>1.22</td>
<td>1.08</td>
<td>0.99</td>
<td>1.04</td>
<td>1.28</td>
<td>1.38</td>
<td>1.39</td>
</tr>
<tr>
<td>Drugs &amp; Pharmaceuticals market shares:</td>
<td>Aventis Pharma</td>
<td>Panacea Biotec</td>
<td>Biocon</td>
<td>Matrix Laboratories</td>
<td>Intas Pharmaceuticals</td>
<td>Nectar Lifesciences</td>
<td>U S V</td>
<td>Ankur Drugs &amp; Pharma</td>
<td>DSM Anti Infectives India</td>
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<tr>
<td>Market shares: Torrent Pharmaceuticals</td>
<td>1.76 1.63 1.62 1.67 1.54 1.66 1.55 1.42 1.27</td>
<td>0.66 0.69 0.8 0.29 0.62 0.75 1.04 1.35 1.21</td>
<td>0.37 0.46 0.65 1 1.23 1.11 1.21 1.17</td>
<td>0.14 0.12 0.29 1.06 1.28 1.42 1.26 1.2 1.14</td>
<td>0.47 0.55 0.63 0.75 0.87 1.01 1.18 1.25 1.13</td>
<td>0.38 0.38 0.36 0.43 0.49 0.49 0.54 0.68 1.06</td>
<td>0.81 0.88 1.03 0.97 1.23 1.09 1.07 1.02 0.98</td>
<td>0.01 0.01 0.05 0.09 0.16 0.26 0.44 0.97</td>
<td>1.1 1.13 0.99 0.96 1 1.07 0.96</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
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<tr>
<td>Cadila Pharmaceuticals</td>
<td>1.32</td>
<td>1.22</td>
<td>1.08</td>
<td>0.98</td>
<td>1</td>
<td>0.93</td>
<td>0.92</td>
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<td>0.83</td>
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<tr>
<td>Drugs &amp; pharmaceuticals market shares: J B Chemicals &amp; Pharmaceuticals</td>
<td>0.58</td>
<td>0.71</td>
<td>0.77</td>
<td>0.74</td>
<td>0.72</td>
<td>0.81</td>
<td>0.87</td>
<td>0.85</td>
<td>0.81</td>
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<td>Drugs &amp; pharmaceuticals market shares: Elder Pharmaceuticals</td>
<td>0.42</td>
<td>0.42</td>
<td>0.5</td>
<td>0.55</td>
<td>0.59</td>
<td>0.64</td>
<td>0.7</td>
<td>0.72</td>
<td>0.8</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
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<tr>
<td>Total for the above companies</td>
<td>34.73</td>
<td>40.97</td>
<td>46.74</td>
<td>51.16</td>
<td>53.56</td>
<td>55.2</td>
<td>55.52</td>
<td>58.02</td>
<td>59.9</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
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<tr>
<td>Total for the sample companies</td>
<td>87.82</td>
<td>93.17</td>
<td>93.42</td>
<td>92.65</td>
<td>92.72</td>
<td>92.52</td>
<td>91.23</td>
<td>90.02</td>
<td>90.2</td>
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<td>Drugs &amp; pharmaceuticals market shares:</td>
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<td></td>
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<tr>
<td>Import</td>
<td>5.51</td>
<td>5.19</td>
<td>5.75</td>
<td>7.31</td>
<td>6.81</td>
<td>7.06</td>
<td>8.63</td>
<td>9.38</td>
<td>9.66</td>
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<tr>
<td>Drugs &amp; pharmaceuticals:</td>
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<tr>
<td>Market Size (Value)</td>
<td>29316.2</td>
<td>33011.8</td>
<td>35226.6</td>
<td>39215.2</td>
<td>43458</td>
<td>44919.3</td>
<td>52750.9</td>
<td>62351.6</td>
<td>69179.9</td>
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Source: CMIE Prowess database

The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. There are about 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce 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. Regulatory measures have played important part in the competitive scenario of Indian pharma industry.

The WTO resolution on TRIPS will be implemented in phased manner in 2005 in developing countries and from 2015 in developed countries. The agreement gives Indian companies legitimate right to sell generic versions of patented drugs. The above table shows the Indian companies like Cipla, Ranbaxy, Lupin etc are the most cost efficient manufacturers and have found the opportunity being growth driver. Majority of the domestic players have started allocating large funds for Research & Development. It is likely that some of the Indian companies who have strong R and D capabilities may be able to introduce innovative products which will improve margin of profit.

Traditionally the critical success factors in the domestic pharmaceutical industry have been reverse engineering and low cost manufacturing. There are various forces changing the business dynamics of Indian Industry. The WTO resolution on TRIPS provides product patent regime and has been implemented in phased manner in 2005 in developing countries and 2015 in least developed countries. The second Patent Amendment Act was passed in 2002. The agreement gave Indian companies a legitimate right to sell generic version of patented drugs in poor countries post 2005. The diseases for which the license can be granted are spreading very rapidly in these countries and margins are expected to be very low. The volume will be high to
ensure huge revenues for Indian companies. Indian companies like Cipla, Aurobindo, Lupin etc who have USFDA approved plants and are the most cost efficient manufacturer. But majority of the domestic players have started allocating large funds for R and D continuously rising from Rs 2.2 billion (1997-98) to 7.5 billion (2002-2003). It is expected to rise Rs 15 billion. (Kaushesh Anshul 2003)

Indian companies have New Chemical Entities (NCEs) in various stages of clinical trials. Some prominent Indian companies are increasing focus on R and D for 1MCE Novel Drug Delivery System (NDDS). It is likely that some of the Indian companies who have strong R and D capabilities may be able to introduce innovative products, which will enable them to improve their margins and profitability. Indian companies have also made move in more tactical research. They are targeting niche area drugs.

While DPCO (1970) and IPA (1970) have proved to be a disincentive to MNCs and allowed domestic companies to thrive under the government protection, and new policy had recommended controlling prices of only those drugs that have a high level of market power concentration.

The government opened 100% foreign participation in drugs and pharmaceutical companies through the automatic approval route. The 100% foreign participation would increase chances of India getting access to technology transfer from pharmaceutical MNCs (Anshul Kaushesh, 2003). Another advantage is of automatic FDI approval for India. This policy may stimulate MNC investments to set up low cost research bases in the country.
Indian companies, in an effort to consolidate their position are increasingly looking at merger and acquisition options of either companies or products. This would help offset loss of new product options improve their R and D efforts, strengthen their product portfolio and improve distribution to penetrate markets with more geographical coverage.

India is not just a huge market for drugs for infectious diseases, vaccines but it is also becoming a market for lifestyle diseases. Growth in traditional therapeutic segments such as antibiotics is stagnation and competition is increasingly getting stiffer. The price war is so intense that companies have started promoting unbranded versions of formulations against their own branded formulations to generate growth. (Kaushesh Anshul 2003) Consequently the past few years have seen companies increasingly focusing on lifestyle segments such as cardiovascular, anti-diabetes, anti-ulcer etc. So rapid has the growth been in these sectors and so high is the potential that most companies have rushed to launch products in these segments.

Growth in domestic sales in the future will depend on the ability of companies to launch products in relatively fast growing therapeutic segments. The growing generic market and strong statistics are pulling several Indian pharmaceutical companies to US and European countries. For Indian generic companies though the US will remain the number one market in terms of growth opportunities, Europe is fast emerging as an equally important international market.
New concepts gaining momentum are contract research and contract manufacturing given the low cost high quality advantage, Indian companies are poised to benefit from contract research business on behalf of MNCs. There is immense potential for outsourcing research, clinical testing, and creating registers for drugs or to synthesize data in India. Outsourcing of patented drugs is a very lucrative market. Globally the trend for outsourcing pharmaceutical products like bulk drug intermediates and formulations by multinational drug giants have gained ground for the past decade. (Kaushesh Anshul 2003)

A large number of players who have their manufacturing facilities approved by regulatory authorities of developed countries are getting into contract manufacturing of bulk drugs and formulations on which patents have expired, many big Indian
companies have entered the contract manufacturing field like Ranbaxy-EliLilly and Lupin-Cynamid were the first major contract manufacturing agreements. Nicholas Piramal has taken aggressive steps for becoming an outsourcing base of choice for the MNC pharmaceutical companies. Wockhardt and Dr Reddy's have also built plants, which could be used as a contract manufacturing base in the future. (Kaushesh Anshul 2003)

High R and D costs made comparatively cheaper destination like India better alternatives. India share in the clinical trials business is increasing as the large patient population and a variety of ailment make it ideal for clinical testing, credibility and infrastructure also need to be considered. Indian hospitals and doctors had a good reputation in the international market. The large patient population, the presence of practically all kinds of illness, trained English speaking manpower and acceptance of ethical guidelines for clinical trials according to international code of harmonization have come together to make India an attractive destination for clinical trials. Elli Lilly India has undertaken about 50-55 clinical trials. Pfizer has conducted 20 trials. (Kaushesh Anshul 2003) Astra Zeneca also plans for clinical trials. Novartis, Glaxo and Roche are now getting their clinical research departments.

Despite liberalization in the air since 1990 and turbulence due to the new patent regime, the domestic pharmaceutical has advanced and is getting ready to compete in the changed environment. For companies in India, the major opportunity is enormous technical pool, which can participate in the development chain in both research but more in clinical development to help bring products to the market faster. It is said that Indian chemical research is of world standard and there is every prospect of global
pharmaceutical companies entering into research contract and licensing arrangements to develop that research into new and ultimately marketable drugs. (Kaushesh Anshul 2003) New concepts gaining momentum are contract research and contract manufacturing. Given the low cost high quality advantage, Indian companies are poised to benefit from contract research business on behalf of MNCs. There is immense potential for outsourcing research, clinical testing, creating registers for drugs or to synthesize data in India. Outsourcing of patented drugs is a very lucrative market. Globally the trend for outsourcing pharmaceutical products like bulk drugs, drug intermediates and formulations by multinational drugs giants have gained ground for the past decade.

Having talked about the demand and market structure of the pharmaceutical industry we now talk about pricing and other policies regarding this industry in the subsequent chapter.